NQF

NATIONAL QUALITY FORUM

SAFE PRACTICES

Safe Practices for Better Healthcare–2010 Update

A CONSENSUS REPORT

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Foreword

IMPROVING THE SAFETY OF HEALTHCARE DELIVERY saves lives, helps avoid unnecessary complications, and increases the confidence that receiving medical care actually makes patients better, not worse. Unfortunately, 10 years after the Institute of Medicine report *To Err Is Human* issued a call to action, uniformly reliable safety in healthcare has not yet been achieved. Every day, patients are still harmed, or nearly harmed, in healthcare institutions across the country. This harm is not intentional; however, it usually can be avoided. The errors that create harm often stem back to organizational system failures, leadership shortfalls, and predictable human behavioral factors.

We can, and must, continue to do better.

Every healthcare stakeholder group should insist that provider organizations demonstrate their commitment to reducing healthcare error and improving safety by putting into place evidence-based safe practices. This includes promoting an environment of effective reporting and learning from errors or mistakes within a blame-free culture. Collective reporting and learning from the mistakes of others is also an essential component of this process to improve healthcare safety.

The original set of National Quality Forum (NQF)-endorsed® safe practices released in 2003, updated in 2006 and 2009, were defined to be universally applied in all clinical care settings in order to reduce the risk of error and harm for patients. The current 2010 updated report adds to the evolution of these practices and acknowledges their ongoing value to the healthcare community. This update of the NQF-endorsed safe practices was conducted as an abbreviated maintenance process, with few major changes to the safe practice statements or specifications. However, the practices have been updated with the most current evidence and expanded implementation approaches; additional measures for assessing the implementation of the practices have been included in each section as well. Each practice is specific and ready for implementation and has been shown to be effective in improving healthcare safety. Systematic, universal implementation of these practices can lead to appreciable and sustainable improvements for healthcare safety.

Every individual who seeks medical care should be able to expect and receive safe, reliable care, every time, under all conditions. We thank NQF Members and the NQF Safe Practices Consensus Committee for their stewardship of this important work.

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President and Chief Executive Officer

The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.

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Table of Contents

Executive Summary

NOW A DECADE AFTER the Institute of Medicine's report *To Err is Human,* some advances have been made in patient safety, yet the consensus is clear that there is still much to do. With the recognition that healthcare-associated infections are for the most part preventable, and that zero infections is the number we must chase, medical-related harm as the leading cause of death in America has not gone down, but gone up from the eighth leading cause in 1999 to the third leading cause.

The Safe Practices for Better Healthcare – 2010 Update presents 34 practices that have been demonstrated to be effective in reducing the occurrence of adverse healthcare events. The practices are organized into seven functional categories for improving patient safety:

- creating and sustaining a culture of safety (Chapter 2);
- informed consent, life-sustaining treatment, disclosure, and care of the caregiver (Chapter 3);
- matching healthcare needs with service delivery capability (Chapter 4);
- facilitating information transfer and clear communication (Chapter 5);
- medication management (Chapter 6);
- prevention of healthcare-associated infections (Chapter 7); and
- condition- and site-specific practices (Chapter 8).

Based on feedback from healthcare organizations, subject matter experts, and the NQF Safe Practices Consensus Committee, the 2010 update has made modest changes to the 2009 report.

In Chapters 2 through 8, the problem statements, implementation approach information, and other narrative elements that do not constitute the endorsed standards have been significantly updated. No substantive changes were made to the latest additional specifications. Chapter 9 describes selected contributions from patient advocate experts as examples of the themes that are believed to be important for patients and families to consider during their healthcare encounters. Specific recommendations regarding patients and families are embodied formally in each practice. This section has been modestly updated with input from patient advocates and organizations that have embraced the concept of involving patients and families in their safety and quality programs.

As with the previously endorsed practices, these 34 safe practices should be universally utilized in applicable healthcare settings to reduce the risk of harm resulting from processes, systems, and environments of care.

This set of safe practices is not intended to capture all activities that might reduce adverse healthcare events. Rather, this report continues the focus on practices that:

- have strong evidence that they are effective in reducing the likelihood of harming a patient;
- are generalizable (i.e., they may be applied in multiple clinical care settings and/or for multiple types of patients);
- are likely to have a significant benefit to patient safety if fully implemented; and
- have knowledge about them that consumers, purchasers, providers, and researchers can use.

The implementation of these practices will improve patient safety. Additionally, other important uses of the set are to help healthcare providers assess the degree to which safe practices already have been implemented in their settings and to assess the degree to which the practices provide tangible evidence of patient safety improvement and increased patient satisfaction and loyalty. And importantly, with this update, healthcare organization leaders and governance boards are explicitly called upon to proactively review the safety of their organizations and to take action to improve continually the safety and thus the quality of care they provide.

The safe practices are not prioritized or weighted within or across categories. This is because all are viewed as important in improving patient safety and because no objective, evidence-based method of prioritizing the practices could be identified that would equitably apply across the current heterogeneous universe of healthcare organizations that have variably implemented many—and in some cases all—of these practices. For any given healthcare provider, the choice of priority practices for implementation will depend on the provider's circumstances, including which of the practices already have been implemented, the degree of success the provider has had with implementation, the availability of resources, environmental constraints, and other factors.

This report does not represent the entire scope of NQF work pertinent to improving patient safety and healthcare quality; over the years since the publication of the original set of safe practices, NQF has completed and updated a number of projects of direct relevance to this report. In 2006, NQF endorsed 28 serious reportable events in healthcare that should be reported by all licensed healthcare facilities. In 2007, NQF completed a consensus project related to the assessment and prevention of healthcare-associated infections (HAIs). The HAI report specifically called for additional practices in HAI prevention, with a specific call for a new safe practice related to catheter-associated urinary tract infections. NQF also endorsed a set of Patient Safety Indicators developed by the Agency for Healthcare Research and Quality. Additional safety-related work included focused projects on perioperative care, the prevention of venous thromboembolism, a pressure ulcer prevention framework, and the endorsement of measures related to patient safety and medication management. Finally, the emerging priorities and goals from the National Priorities Partnership include a strong focus on avoidable harm, continuity of care, and patient safety.

Safe Practices for Better Healthcare–2010 Update

SAFE PRACTICE	PRACTICE STATEMENT
Safe Practice 1: Leadership Structures and Systems	Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served.
Safe Practice 2: Culture Measurement, Feedback, and Intervention	Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk.
Safe Practice 3: Teamwork Training and Skill Building	Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients.
Safe Practice 4: Identification and Mitigation of Risks and Hazards	Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.
Safe Practice 5: Informed Consent	Ask each patient or legal surrogate to "teach back," in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.
Safe Practice 6: Life-Sustaining Treatment	Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart.
Safe Practice 7: Disclosure	Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.
Safe Practice 8: Care of the Caregiver	Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events.

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Safe Practices for Better Healthcare–2010 Update

SAFE PRACTICE	PRACTICE STATEMENT
Safe Practice 9: Nursing Workforce	Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following: ■ A nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety. ■ Senior administrative nursing leaders, such as a Chief Nursing Officer, as part of the hospital senior management team. ■ Governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services. ■ Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills.
Safe Practice 10: Direct Caregivers	Ensure that non-nursing direct care staffing levels are adequate, that the staff are competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties.
Safe Practice 11: Intensive Care Unit Care	All patients in general intensive care units (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine ("critical care certified").
Safe Practice 12: Patient Care Information	Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and to all of the patient's healthcare providers/ professionals, within and between care settings, who need that information to provide continued care.
Safe Practice 13: Order Read-Back and Abbreviations	Incorporate within your organization a safe, effective communication strategy, structures, and systems to include the following: ■ For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and "read-back" the complete order or test result. ■ Standardize a list of "Do Not Use" abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.

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Safe Practices for Better Healthcare–2010 Update

SAFE PRACTICE	PRACTICE STATEMENT
Safe Practice 14: Labeling of Diagnostic Studies	Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time.
Safe Practice 15: Discharge Systems	A "discharge plan" must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for postdischarge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge.
Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry	Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure.
Safe Practice 17: Medication Reconciliation	The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care.
Safe Practice 18: Pharmacist Leadership Structures and Systems	Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.
Safe Practice 19: Hand Hygiene	Comply with current Centers for Disease Control and Prevention Hand Hygiene Guidelines.
Safe Practice 20: Influenza Prevention	Comply with current Centers for Disease Control and Prevention (CDC) recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control.
Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention	Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices.

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Safe Practices for Better Healthcare–2010 Update

SAFE PRACTICE	PRACTICE STATEMENT
Safe Practice 22: Surgical-Site Infection Prevention	Take actions to prevent surgical-site infections by implementing evidence-based intervention practices.
Safe Practice 23: Care of the Ventilated Patient	Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers.
Safe Practice 24: Multidrug-Resistant Organism Prevention	Implement a systematic multidrug-resistant organism (MDRO) eradication program built upon the fundamental elements of infection control, an evidence-based approach, assurance of the hospital staff and independent practitioner readiness, and a re-engineered identification and care process for those patients with or at risk for MDRO infections. Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *enterococci,* and *Clostridium difficile.* Multidrug-resistant gram-negative bacilli, such as *Enterobacter* species, *Klebsiella* species, *Pseudomonas* species, and *Escherichia coli,* and vancomycin-resistant *Staphylococcus aureus,* should be evaluated for inclusion on a local system level based on organizational risk assessments.
Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention	Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices.
Safe Practice 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention	Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ for all invasive procedures.
Safe Practice 27: Pressure Ulcer Prevention	Take actions to prevent pressure ulcers by implementing evidence-based intervention practices.
Safe Practice 28: Venous Thromboembolism Prevention	Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis.

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Safe Practices for Better Healthcare–2010 Update

SAFE PRACTICE	PRACTICE STATEMENT
Safe Practice 29: Anticoagulation Therapy	Organizations should implement practices to prevent patient harm due to anticoagulant therapy.
Safe Practice 30: Contrast Media-Induced Renal Failure Prevention	Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and gadolinium-associated nephrogenic systemic fibrosis, and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient's risk evaluations.
Safe Practice 31: Organ Donation	Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specify the roles and desired outcomes for every stage of the donation process.
Safe Practice 32: Glycemic Control	Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.
Safe Practice 33: Falls Prevention	Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices.
Safe Practice 34: Pediatric Imaging	When CT imaging studies are undertaken on children, "child-size" techniques should be used to reduce unnecessary exposure to ionizing radiation.

Chapter 1: Safe Practices for Better Healthcare–2010 Update

Introduction

IN 2003, THE NATIONAL QUALITY FORUM (NQF) published *Safe Practices for Better Healthcare: A Consensus Report,* which endorsed 30 practices that should be universally used in applicable clinical care settings to reduce the risk of harm to patients. This first report specifically noted the need to balance stability and consistency of program implementation with updated practices that reflect new evidence and innovation. In 2006, NQF updated the report using the then current evidence and harmonized the practices with standards, guidelines, and initiatives of other national other national bodies, including the Centers for Medicare & Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), The Joint Commission, the Institute for Healthcare Improvement, and The Leapfrog Group. The 2006 update provided additional information for each safe practice, including significantly expanded specifications, supporting literature, and guidance for implementation.

For the 2009 update, NQF conducted another update to review the evidence base for existing practices, strengthen implementation guidance, update research recommendations, and evaluate new practices to ensure that the set remains current and appropriate. There was also a continued effort to harmonize the practices with the evolving requirements or expectations of the national bodies mentioned above in addition to an even broader group of medical organizations and federal agencies. The opportunity for patient and family participation in implementation was also underscored for the practices.

This 2010 update of safe practices specifically included a review of the NQF-endorsed safe practices and supporting literature for continued currency and appropriateness and modification of practices as needed. Also, the example implementation approaches were expanded to further assist organizations with sustainable practice change. The evidence base for the 34 existing practices was extensively reviewed and updated. New practices were not added for the 2010 update to allow organizations to have continued focus on the current 34 practices for successful implementation.

Purpose

This set of 34 safe practices continues to be a critical part of the NQF effort to promote patient safety and reduce patient harm. An important use of the set is to help healthcare providers assess the degree to which safe practices already have been implemented in their settings and to assess the degree to which the practices provide tangible evidence of patient safety improvement in terms of the reduction of morbidity and mortality and avoidable harm. This update adds elements to assist with implementation and the measurement of success in implementation, while at the same time meeting many of the expectations of standards-setting organizations. Additionally, with this update, healthcare organization leaders and governance boards are explicitly called upon to proactively assess the safety of their organizations and to take action to continually improve the safety and thus the quality of the care they provide.

They include:

- harmonization of practices and specifications with accrediting and certifying organizations, as well as major national safety initiatives;
- expansion of the implementation examples to provide additional suggestions (and they are just suggestions—not requirements) to help either to implement the practices or to take them to another level;
- suggested outcome, process, structure, and patient-centered measures that can be used to gauge success in implementation and performance improvement;
- setting-specific comments and suggestions, where applicable;
- special attention to standardizing problem statements by addressing the frequency, severity, preventability, and cost impact of the adverse events being addressed by each of the practices;
- an explanded section and a dedicated chapter to "opportunities for patient and family involvement" to encourage active participation in their care;
- continued use of CMS care setting definitions and additions to the general glossary; and
- an extensive set of references for use during implementation or for framing future research questions.

The NQF-Endorsed Set of Safe Practices

This set of safe practices encompasses 34 practices that have been demonstrated to be effective in reducing the occurrence of adverse healthcare events. The practices are organized into seven broad categories for improving patient safety:

- creating and sustaining a culture of safety (Chapter 2);
- informed consent, life-sustaining treatment, disclosure, and care of the caregiver (Chapter 3);
- matching healthcare needs with service delivery capability (Chapter 4);
- facilitating information transfer and clear communication (Chapter 5);
- medication management (Chapter 6);
- prevention of healthcare-associated infections (Chapter 7); and

- condition- and site-specific practices (Chapter 8).

This chapter summarizes the rationale and criteria used to identify the safe practices included in this set. Chapters 2 through 8 are organized according to the seven categories presented above and provide additional background for each practice. For each of the 34 practices, the following are included:

- a summary of the problem the practice aims to improve;
- practice specifications;
- applicable clinical care settings;
- implementation examples;
- opportunities for patient and family involvement;
- measures of success;
- settings of care considerations;
- new horizons and areas for research;
- other relevant safe practices; and
- a set of references representing the body of work in the respective area.

Opportunities for Patient and Family Involvement was also updated for the 2010 update, recognizing the critical importance of patients and families in ensuring patient-centered care. Chapter 9 describes selected contributions from patient advocate experts as examples of the themes that are felt to be important for patients and families to consider during their healthcare encounters. Specific recommendations about patients and families are embodied formally in each practice.

Criteria

The new and updated practices were evaluated based on the same criteria used for the 2003, 2006, and 2009 sets (Box A): specificity, benefit, evidence of effectiveness, generalizability, and readiness.

Furthermore, recommendations to modify the endorsed practices were evaluated based on specific criteria for modifying a practice or for withdrawing the endorsement of a practice (Box B).

The safe practices are not prioritized or weighted within or across categories. This is because all of them are viewed as important in improving patient safety and because no objective, evidence-based method of prioritizing the practices could be identified that would equitably apply across the current heterogeneous universe of healthcare organizations that have variably implemented many—and in some cases all—of these practices. For any given healthcare provider, the choice of which practices receive priority for implementation will depend on the provider's circumstances, including which of the practices already have been implemented, the degree of success the provider has had with implementation, the availability of resources, environmental constraints, and other factors.

Table 1 is a summary of each practice, including the safe practice statement, additional specifications, and applicable clinical care settings.

Box A: Criteria for Inclusion in the Set

All practices, both new and updated, were evaluated based on the same criteria used for the previous safe practices:

- **Specificity.** The practice must be a clearly and precisely defined process or manner of providing a healthcare service. All candidate safe practices were screened according to this threshold criterion. Candidate safe practices that met the threshold criterion of specificity were then rated against four additional criteria relating to the likelihood of the practice improving patient safety.
- **Benefit.** If the practice were more widely utilized, it would save lives endangered by healthcare delivery, reduce disability or other morbidity, or reduce the likelihood of a serious reportable event (e.g., an effective practice already in near universal use would lead to little new benefit to patients by being designated a safe practice).
- **Evidence of Effectiveness.** There must be clear evidence that the practice would be effective in reducing patient safety events. Such evidence may take various forms, including the following:
  - research studies showing a direct connection between improved clinical outcomes (e.g., reduced mortality or morbidity) and the practice;
  - experiential data (including broad expert agreement, widespread opinion, or professional consensus) showing the practice is "obviously beneficial" or self-evident (i.e., the practice absolutely constrains a potential problem or forces an improvement to occur, reduces reliance on memory, standardizes equipment or process steps, or promotes teamwork); or
  - research findings or experiential data from nonhealthcare industries that should be substantially transferable to healthcare (e.g., repeat-back of verbal orders or standardizing abbreviations).
- **Generalizability.** The safe practice must be able to be utilized in multiple applicable clinical care settings (e.g., a variety of inpatient and/or outpatient settings) and/or for multiple types of patients.
- **Readiness.** The necessary technology and appropriately skilled staff must be available to most healthcare organizations.

Box B: Criteria for Changes to an NQF-Endorsed Safe Practice

Criteria for Modification of an NQF-Endorsed Safe Practice:

- Recommended modification(s) must be based upon and accompanied by the specific rationale for the recommended change (e.g., evidence supporting the practice has changed sufficiently that the practice warrants modification).
- The practice must continue to meet the criteria as outlined for new practices.
- To remain an endorsed practice, any recommended modification must make no material* change to the intent of the practice or the scope of the specifications.

Criteria for Withdrawing Endorsement of an NQF-Endorsed Safe Practice:

- The available evidence does not demonstrate the effectiveness of the practice in reducing the likelihood of a patient safety event.
- The practice has been overtaken or is subsumed by a recommended new or recommended modification to an endorsed safe practice.

*Recommendations involving material change are subject to NQF's Consensus Development Process. Material is defined as any modification that reasonably could be foreseen.

Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 1: Leadership Structures and Systems Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served. **Applicable Clinical Care Settings** This practice is applicable to Centers for Medicare & Medicaid (CMS) care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/ hospital, outpatient hospital, and skilled nursing facility.	**Awareness Structures and Systems:** Structures and systems should be in place to provide a continuous flow of information to leaders from multiple sources about the risks, hazards, and performance gaps that contribute to patient safety issues. [Botwinick, 2006] ▪ Identification of Risks and Hazards: Governance boards and senior administrative leaders should be regularly and thoroughly briefed on the results of activities undertaken as defined by the *Identification and Mitigation of Risks and Hazards* safe practice. [Botwinick, 2006; Reason, 1997; Morath, 2006; IHI, 2009i] ▪ Culture Measurement, Feedback, and Intervention: Governance boards and senior administrative leaders should be regularly and thoroughly briefed on the results of culture measurement and performance improvement initiatives addressed in the *Culture Measurement, Feedback, and Intervention* safe practice. [Botwinick, 2006; Conway, 2008] ▪ Direct Patient Input: A structure and system should be established to obtain direct feedback from patients about the performance of the organization. Information from satisfaction surveys is not enough—patients and/or patient families representing the population served should be included in the design of educational meetings or should participate on formal committees that provide input to the leadership on the management of safety and quality issues within the hospital. [Rider, 2002; IHI, 2009l] ▪ Governance Board and Senior Management Briefings/Meetings: Patient safety risks, hazards, and progress toward performance improvement objectives should be addressed at every board meeting and should be documented by meeting agendas and minutes. [IHI, 2009a] Such meetings and documentation systems should ensure that organizational leadership is kept knowledgeable about patient safety issues present within the organization and is continuously involved in processes to ensure that the issues are appropriately addressed and that patient safety is improved. [Conway, 2008] **Accountability Structures and Systems:** Structures and systems should be established to ensure that there is direct accountability of the governance board, senior administrative management, midlevel management, physician leaders (independent and employed by the organization), and frontline caregivers to close certain performance gaps and to adopt certain patient safety practices.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 1: Leadership Structures and Systems Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served. *(continued)*	■ Patient Safety Program: An integrated patient safety program should be implemented throughout the healthcare organization. [IHI, 2009j; TJC, 2009] This program should provide oversight, ensure the alignment of patient safety activities, and provide opportunities for all individuals who work in the organization to be educated and participate in safety and quality initiatives. Leaders should create an environment in which safety and quality issues are openly discussed. A just culture should be fostered in which frontline personnel feel comfortable disclosing errors—including their own—while maintaining professional accountability. [Botwinick, 2006] ■ Patient Safety Officer: The organization should appoint or employ a Patient Safety Officer who is the primary point of contact for questions about patient safety and who coordinates patient safety for education and the deployment of system changes. Governance boards and senior administrative leaders should support leaders in patient safety to ensure that there is compliance with the specifications of this safe practice. [Denham, 2009b; Denham, 2007b] ■ Direct Organization-Wide Leadership Accountability: Governance and senior management should have direct accountability for safety in the organization, including setting patient safety goals, ensuring that resources are provided to address those goals, and monitoring progress toward their achievement. [Botwinick, 2006; IHI, 2009h] ■ The Patient Safety Officer should have direct and regular communication with governance leaders and senior administrative management. [Denham, 2007b] Senior administrative leaders and leaders of clinical service lines and units should be held accountable for closing patient safety performance gaps. Performance should be documented using methods such as performance reviews and/or compensation incentives. [Botwinick, 2006] ■ Interdisciplinary Patient Safety Committee: Leaders should establish and support an interdisciplinary patient safety improvement committee(s) or equivalent structure(s) that is (are) responsible for creating, implementing, and administering mechanisms to oversee root cause analyses of every appropriate incident and provide feedback to frontline workers about lessons learned, disclose the organization's progress toward implementing safe practices, and provide professional training and practice in teamwork techniques (e.g., anesthesia crisis management, aviation-style crew resource management, medical team management). [TJC, 2009] See the *Identification and Mitigation of Risks and Hazards* and *Teamwork Training and Skill Building* safe practices for detailed specifications. [Botwinick, 2006]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 1: Leadership Structures and Systems Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served. *(continued)*	■ External Reporting Activities: Organizations should report adverse events to the appropriate external mandatory programs and voluntary programs as well as encourage voluntary practitioner reporting. Organizations should publicly disclose compliance with all National Quality Forum-endorsed® safe practices for public reporting that are applicable to the facility. [IOM, 2000] **Structures- and Systems-Driving Ability:** Capacity, resources, and competency are critical to the ability of organizations to implement changes in their culture and in patient safety performance. Systematic and regular assessment of resource allocations to key systems should be undertaken to ensure performance in patient safety. On a regular, periodic basis determined by the organization, governance boards and senior administrative leaders should assess each of the following areas for the adequacy of funding and should document the actions taken to adjust resource allocations to ensure that patient safety is adequately funded: [IHI, 2009f; TJC, 2009] ■ Patient Safety Budgets: Specific budget allocations for initiatives that drive patient safety should be evaluated by governance boards and senior administrative leaders. Such evaluations should include the detailed context of information from the activities defined in the *Identification and Mitigation of Risks and Hazards* safe practice. Designating a Patient Safety Officer or someone in charge of patient safety without providing the appropriate staffing infrastructure or budget is an example of inadequate resource allocation. ■ People Systems: Human resource issues should be addressed with direct input from the activities included in the *Identification and Mitigation of Risks and Hazards* safe practice, as well as those included in Safe Practices 9 and 10 relating to nurse staffing and direct caregiver staffing levels, competency, and training/orientation. [IHI, 2009c] ■ Quality Systems: Quality systems and structures such as performance improvement programs and quality departments should be adequately funded, actively managed, and regularly evaluated for effectiveness and resource needs. [IHI, 2009g] ■ Technology Systems: Budgets for technologies that can enable safe practices should be regularly evaluated to ensure that patient safety impact can be optimized. [IHI, 2009b]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 1: Leadership Structures and Systems Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served. *(continued)*	**Action Structures and Systems:** Structures and systems should be put in place to ensure that leaders take direct and specific actions, including those defined below. ■ Performance Improvement Programs: Leaders should document the actions taken to verify that the remedial activities that are identified through the analysis of reported patient safety events are implemented, are effective, and do not cause unintended adverse consequences. Leaders should establish patient safety priorities for performance improvement. The direct participation of governance board members and senior administrative leaders should be documented, as specified in the *Identification and Mitigation of Risks and Hazards* safe practice, to satisfy this requirement. [IHI, 2009k] ■ Regular Actions of Governance: • Confirmation of Values: Governance leaders should regularly confirm that senior administrative leadership is continuously ensuring that the values of the organization are mirrored by the behaviors of the staff and caregivers and that those values drive safety and performance improvement in the organization. At least annually, the board should document that it has confirmed that the behaviors of the organization related to quality and safety mirror its values with respect to patient safety. [TJC, 2009; IHI, 2009d; IHI, 2009e] • Basic Teamwork Training and Interventions Briefings: Governance board members should receive a dedicated period of basic training in teamwork, communication, and patient safety per board member per year as determined by the board and as documented by agendas and attendance records. • Governance Board Competency in Patient Safety: The governance board should take a systematic approach to ensuring that board members' command of patient safety knowledge is adequate to support the organization. At least annually, the board should discuss its own competency and document its strategy for ensuring that all existing and new board members are well versed in patient safety. [IHI, 2008] ■ Regular Actions of Senior Administrative Leadership: The actions of the CEO and senior leaders have a critical impact on the safety of every organization. Such actions should be informed, monitored, and directed by an engaged governance leadership on a regular basis. [IHI, 2008] • Time Commitment to Patient Safety: The CEO and senior administrative leaders should systematically designate a certain amount of time for patient safety activities (e.g., weekly walk-rounds and regular patient safety-related sessions at executive

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 1: Leadership Structures and Systems Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served. *(continued)*	staff and governance meetings). Leaders should establish structures and systems to ensure that they are personally reinforcing the principles of patient safety regularly and continuously to staff at all levels of the organization. They should provide feedback to frontline healthcare providers about lessons learned regarding patient safety from outside sources and from within the organization. • Culture Measurement, Feedback, and Interventions: The CEO and senior administrative leaders should be directly involved in the application of the knowledge that is generated by the measurement of culture as defined in the specifications of the *Culture Measurement, Feedback, and Intervention* safe practice. • Basic Teamwork Training and Team Interventions: The CEO and senior administrative leaders should be directly involved in ensuring that the organization implements the activities detailed in the specifications of the *Teamwork Training and Skill Building* safe practice. This includes participating in the defined basic training program. • Identification and Mitigation of Risks and Hazards: The CEO and senior administrative leaders should be continuously engaged in the activities addressed in the specifications of the *Identification and Mitigation of Risks and Hazards* safe practice. The actions taken to mitigate risks and hazards must be championed by senior administrative leaders with the support of the governance board. Such actions are vital to creating and sustaining a culture of patient safety. ▪ Regular Actions of Unit, Service Line, Departmental, and Midlevel Management Leaders: The entire leadership structure of an organization should be fully engaged in the patient safety activities addressed in *Safe Practice 1: Leadership Structures and Systems.* Leaders at all levels and in all clinical areas, including employed clinicians, should be continuously and actively engaged in the pursuit of patient safety. The CEO and senior administrative management should ensure that all leaders have the opportunity to lead and support patient safety activities. ▪ Regular Actions with Respect to Independent Medical Leaders: Governance and senior administrative leaders should establish the systems and structures needed to ensure that medical leaders in independent practice as well as those employed by the organization have regular and frequent opportunities to provide direct input to patient safety programs.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 2: Culture Measurement, Feedback, and Intervention Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ At least annually, leaders should assess the organization's safety and quality culture using a survey tool that is selected with consideration of validity, consistency, and reliability in the setting in which it will be applied and that is conceptualized around domains that are applicable to performance improvement (PI) initiatives/efforts such as teamwork, leadership, communication, and openness to reporting. [Deilkas, 2008; Relihan, 2009] • Survey a census of units or service areas that in aggregate deliver care to more than 50 percent of the patients receiving care. • Measure service lines or units where there is a high patient safety risk. • Identify and prioritize culture PI targets; provide adequate resources to address performance gaps over a specified period of time. [Fei, 2008; Smith, 2009] • Survey a valid sample to allow unit-level analysis and facilitate improvement. ■ Critical care areas and services and high-volume and high-risk areas should be surveyed (e.g., emergency department, outpatient surgical services, diagnostic centers) and should include, in the aggregate, ambulatory totals to determine which of these areas should be targeted initially. [Donnelly, 2009; Kaafarani, 2009; Pater, 2009] ■ The results of the culture survey process should be documented and disseminated widely across the enterprise in a systematic and frequent manner. [Audet, 2008; Chadwick, 2009; Hutchinson, 2009] The interventions component of this safe practice will be satisfied if the survey findings are documented and have been used to monitor and guide performance improvement interventions. [Pringle, 2009; Pronovost, 2005; Sexton, 2006; Sexton, 2007] ■ The organization should document that the results of the survey process, as defined in the *Leadership Structures and Systems* safe practice and by the activities defined in the *Teamwork Training and Skill Building* and the *Identification and Mitigation of Risks and Hazards* safe practices, have been provided to governance and senior medical leaders.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 3: Teamwork Training and Skill Building Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	**Effective Team Leadership:** Training programs should systematically address and apply the principles of effective team leadership and team formation. [Salas, 2008] Leadership at all levels of an organization should be fostered. **Effective Teamwork Training:** Every organization should provide teamwork and communication training through basic and detailed programs. [Salas, 2008; Clark, 2009] ▪ Basic Teamwork Training: Basic training should be provided annually to governance board members, senior administrative leaders, medical staff (both those who are independent and those who are employed by the organization), midlevel management, and frontline nurses. The subject matter should include sources of communication failures, hand-offs, and team failures that lead to patient harm. The length and modality of training should be established by the organization. Participation should be documented to verify compliance. [Salas, 2009] ▪ Detailed Teamwork Training: All clinical staff and licensed independent practitioners should receive detailed training consisting of the best available teamwork knowledge; however, staff of clinical areas that are deemed to be at high risk for patient safety issues should receive such training first. The clinical areas that are prioritized should focus on specific patient safety risks. The subject matter should include the principles of high reliability, human factors applied to real-world care processes, interpersonal team dynamics, hand-offs, and specific communication methods. [Frankel, 2006; McKeon, 2009] Focus should be placed on the development and application of structured tools. Detailed training should include a specified period of combined instruction and interactive dialogue regarding the application of the knowledge determined and documented by the organization. If all staff cannot be trained within one year, a goal should be set to train all clinical service area staff and caregivers over multiple years. ▪ Effective Teamwork Skill Building: To develop the characteristics of "team-ness," individuals should build their teamwork and communication skills by establishing a shared mental model, using structured and critical language, understanding communication hand-off methods, and using effective assertion behaviors such as "stop-the-line" methods. Individuals and teams also should develop the skills necessary to monitor team performance continuously over

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 3: Teamwork Training and Skill Building Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients. *(continued)*	time. Organizations should employ methods to verify the demonstration of teamwork skills. [Manser, 2009] A specified number of care units or service line areas and length of training should be set and documented by organization leadership each year with initiatives for building and measuring teamwork skills. **Effective Team-Centered Interventions:** In order to generate the greatest impact, team-centered performance improvement initiatives or projects should target the work "we do every day." The units and service lines selected should be prioritized based on the risk to patients, which in turn should be based on the prevalence and severity of targeted adverse events. The interventions should address the frequency, complexity, and nature of teamwork and communication failures that occur in those areas. Each year, every organization should identify a specific number of teamwork-centered intervention projects it will undertake, such as those cited below and in the Example Implementation Approaches section. Ideally, team-centered interventions should be undertaken in all areas of care. ■ Specific Team Performance Improvement Projects: Organizations should select high-risk areas for performance improvement projects; these include emergency departments, labor and delivery, intensive care units, operating rooms, ambulatory care, and other procedural care units. Performance targets and strategies to close known performance gaps should be identified. Such performance improvement initiatives should have the components of education, skill building, measurement, reporting, and process improvement. ■ Rapid Response Assessment: Annually, organizations should formally evaluate the opportunity for using rapid response systems to address the issues of deteriorating patients across the organization. [Kaplan, 2009; Bellomo, 2003; IHI, N.D.] ■ Internal and External Reporting: The performance improvement that is generated by team-centered interventions should be reported to governance boards and senior administrative management. Depending on the projects selected, the organization should submit the information to the appropriate external reporting organizations. [Drozda, 2008]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 3: Teamwork Training and Skill Building Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients. *(continued)*	**Minimum Requirements of Practice 3:** To meet the minimum requirements of this safe practice, an organization can satisfy the Detailed Teamwork Training, Effective Teamwork Skill Building, and Effective Team-Centered Interventions requirements, defined above, by targeting an organization-determined number of units or service lines initially and additional new units each year, if the Effective Team-Centered Interventions requirements are satisfied, because it is expected that those involved would receive the required training and skill-building experiences. The requirements of the interventions component of the *Culture Measurement, Feedback, and Intervention* safe practice also will be met if improvement of the culture survey scores is an aim of the specific performance improvement projects that are undertaken.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 4: Identification and Mitigation of Risks and Hazards Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	**Identification and Mitigation of Risks and Hazards** ■ Risk and Hazard Identification Activities: Risks and hazards should be identified on an ongoing basis from multiple sources, including independent retrospective, real-time and near real-time, and prospective views. The risk and hazard analysis should integrate the information gained from multiple sources to provide organization-wide context. [AHRQ, 2009a] The organizational culture should be framed by a focus on system (not individual) errors and blame-free reporting and should use data from risk assessment to create a just culture. [Nuckols, 2009; Pronovost, 2009b] • Retrospective Identification: Organizations should use a number of retrospective measures and indicators to identify risk and contributing factors from historical data. Specific steps should be taken to ensure that the lessons learned are communicated across the organization and that they are applied in other care settings, where applicable. Some retrospective identification and analysis activities are triggered by adverse events; events; [Nuckols, 2009] however, ideally the retrospective identification of risks and hazards should occur regularly, and progress reports should be generated as frequently as they are needed within each year. At least annually, a summary of progress based on an evaluation of the effectiveness of all of the relevant retrospective identification activities/tools listed below should be documented. 1. *Serious Reportable Events.* Processes for identifying, managing, and analysis of events should be defined and implemented to identify patterns and opportunities for improvement. [Levinson, 2008b; McDonald, 2009] 2. *Sentinel Event Reporting.* Processes for identifying, managing and analysis analysisof events should be defined and implemented to identify patterns and opportunities for improvement. 3. *Adverse Event Reporting.* Processes for identifying, managing, and analysis of events should be defined and implemented to identify patterns and opportunities for improvement. 4. *Root Cause Analysis.* The root cause analysis process for identifying the causal factors for events, including sentinel events, should be undertaken. [AHRQ, 2009b; Gupta, 2009] 5. *Closed Claims Analysis.* This analysis should be undertaken. [Richman, 2009]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 4: Identification and Mitigation of Risks and Hazards Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. *(continued)*	6. *Enterprise Systems Failures.* People systems, technology systems, and quality systems failures beyond those resulting in adverse outcomes should be evaluated. 7. *Skill Mix.* Because the proportion between highly trained and less-qualified staff can have an impact on patient safety, the organization must regularly review for, evaluate, and address any imbalance. [Rodriguez-Paz, 2009] 8. *Patient Safety Indicators.* Patient safety indicators should be used to generate hypotheses and guide deeper investigation. 9. *Retrospective Trigger Tools.* Such tools should be used retrospectively through chart review and real-time or near real-time reviews as mentioned below. 10. *External Reporting Source Input.* Such information should be an input to risk-assessment activities. [Reason, 2000] • Real-Time and Near Real-Time Identification: Organizations should evaluate real-time or near real-time tools at least annually for their value in risk identification for the areas identified as high risk for the organization. A concise, thorough assessment of tools such as those noted below and others that become available to the organization should be documented. – Trigger tools, manually or technology enabled. [Adler, 2008] – Observational tools, permitting direct observation of processes in high-risk areas. – Technology tools such as electronic health records. – Real-Time Risk Identification Behaviors. Organizations should support the frontline behaviors of real-time risk identification, including workflow design, that enable the early identification of patient risks and hazards and that inspire "stop-the-line" actions that can prevent patient harm. • Prospective Identification: A structured, proactive risk assessment should be undertaken by certain care units to identify risks and hazards in order to prevent harm and error. [Emily, 2009] At least annually, an organization should evaluate the prospective or proactive tools and methods, such as the two listed below, in order to identify risks. At a minimum, the organization should perform one prospective analysis per year using the tool or method deemed appropriate by the organization. Specific steps should be taken to ensure that lessons learned are communicated across the organization and that they are applied in other care settings, where applicable.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 4: Identification and Mitigation of Risks and Hazards Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. *(continued)*	– Failure Modes and Effects Analysis (FMEA). – Probabilistic Risk Assessment (PRA). [Alemi, 2007; Hovor, 2007] • Integrated Organization-Wide Risk Assessment: The continuous, systematic integration of the information about risks and hazards across the organization should be undertaken to optimally prevent systems failures. [Chiozza, 2009] Information about risks and hazards from multiple sources should be evaluated in an integrated way in order to identify patterns, systems failures, and contributing factors involving discrete service lines and units. The organization should integrate the information noted below, ensure that it is provided to those designing mitigation strategies and that it is documented and disseminated widely across the organization systematically and frequently, and ensure that the results of mitigation activities are made available to all who were involved in providing source information. Frequent progress reports should be generated on an ongoing basis, and a summary of such reports should be produced at least annually. – Risk management (claims management) services. [Boothman, 2009] – Complaints and customer services participation. – Disclosure support system. [McDonald, 2009] (See the *Disclosure* and *Care of the Caregiver* safe practices included in this report.) – Culture measurement, feedback, and intervention. (See the *Culture Measurement, Feedback, and Intervention* safe practice.) – Retrospective, real-time and near real-time, and prospective information. – Anticipated risks for surge in capacity, for example, flu pandemic and natural disaster emergency preparedness. [APIC, 2008] This organization-wide risk-assessment information should be provided to the governance board and senior administrative leadership continuously. The output of the activities of this element should be provided as an input to the activities articulated in the *Leadership Structures and Systems* safe practice.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 4: Identification and Mitigation of Risks and Hazards Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. *(continued)*	• Risk Mitigation Activities: Every organization has a unique risk profile and should carefully design performance improvement projects that target prioritized risk areas. An ongoing, proactive program for identifying and reducing unanticipated adverse events and safety risks to patients should be defined, documented, and implemented. [Damiani, 2009] • Performance Improvement Programs: The organization should provide documentation of performance improvement programs that bear evidence of the actions taken to close patient safety gaps identified in the *Identification and Mitigation of Risks and Hazards* safe practice. Such performance improvement programs should include education, skill building, measurement, reporting, and process improvement. [Denham, 2009a] 1. *Targeted Performance Improvement Projects:* Specific patient safety risks and hazards identified by the activities described above should be targeted through performance improvement projects. [Warye, 2009] Every organization should document the outcome, process, structure, and patient-centered measures of these projects. Organizations should document the projects' patient safety aims and regularly chart progress toward those aims. Such progress should be reported regularly to governance board members and senior administrative leaders as addressed in the *Leadership Structures and Systems* safe practice. 2. *Systems Solutions:* Products, services, and technologies that enable the use of best practices in people systems, technology systems, and quality/safety systems should be considered in order to reduce the potential for patient harm. Performance improvement projects targeting these systems should be documented, and the progress of such projects should be charted and regularly reported to and through senior administrative leaders to governance board members. 3. *Senior Leadership and Governance Engagement:* The direct participation of governance board and senior, midlevel, and line managers in monitoring the progress of all patient safety performance improvement programs should be documented. [Denham, 2005; Pronovost, 2009a] Tools such as summary reports, dashboards, or scorecards should be used to ensure that the most important messages are made as clear as possible and that information overload is minimized. Senior

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 4: Identification and Mitigation of Risks and Hazards Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. *(continued)*	administrative leaders and governance board members should be involved in the selection of these monitoring tools for the organization. [Denham, 2009a] • Specific Risk-Assessment and Mitigation Activities: The organization should provide documentation that bears evidence of high performance or of actions taken to close common patient safety gaps for the patient safety risk areas listed below. [Weingart, 2009] 1. *Falls:* The organization should monitor the effectiveness of fall reduction programs, including risk reduction strategies, in-services, patient/family education, and environment of care redesign. 2. *Malnutrition:* The organization should monitor its effectiveness in identifying malnutrition and in taking actions to reduce the potential adverse events that can result from malnutrition. For example, each patient should be evaluated upon admission, and periodically thereafter, for the risk of malnutrition. Clinically appropriate strategies should be employed to prevent malnutrition. 3. *Pneumatic Tourniquets:* The organization should monitor its effectiveness in reducing the harm that can accompany high-risk procedures, including the use of pneumatic tourniquets (if they are used in the organization). For example, whenever a pneumatic tourniquet is used, the patient should be evaluated for risk of ischemia and/or thrombotic complication, and the appropriate prophylactic measures should be utilized. 4. *Aspiration:* Upon admission and regularly thereafter, each patient should be screened for the risk of aspiration. An aspiration risk and prevention plan should be documented in the patient's record. 5. *Workforce Fatigue:* Because workforce fatigue can have a direct impact on patient safety, every organization should be cognizant of the issue and should include aspects of precursors and alleviation in an annual review of patient safety risk in the organization.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 5: Informed Consent Ask each patient or legal surrogate to "teach back," in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent. [Pizzi, 2001; IHI, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ At a minimum, patients should be able to explain, in their everyday words, [Shaw, 2009] the diagnosis/health problem for which they need care; the name/type/general nature of the treatment, service, or procedure, including what receiving it will entail; and the primary risks, benefits, and alternatives. This safe practice includes all of the following elements: • Informed consent documents for use with the patient should be written at or below the 5th-grade level and in the preferred language of the patient. [Garcia, 2008; Shaw, 2009] • The patient, and, as appropriate, the family and other decision-makers, should be engaged in a dialogue about the nature and scope of the procedure for which consent is being sought. • A qualified medical interpreter or reader should be provided to assist patients with limited English proficiency, limited health literacy, and visual or hearing impairments. • The risk that is associated with high-risk elective cardiac procedures and high-risk procedures with the strongest volume-outcomes relationship should be conveyed.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 6: Life-Sustaining Treatment Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart. [Cerminara, 2008] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ Organization policies, consistent with applicable law and regulation, should be in place and address patient preferences for life-sustaining treatment and withholding resuscitation.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 7: Disclosure Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event. [MCPME, 2006; UMich, 2009; IHI, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ The types of serious unanticipated outcomes addressed by this practice include, at a minimum: a) sentinel events; [TJC, 2009b] b) serious reportable events; and [NQF, 2002] c) any other unanticipated outcomes involving harm that require the provision of substantial additional care (such as diagnostic tests/therapeutic interventions or increased length of stay) or that cause the loss of limb or limb function lasting seven days or longer. [TJC, 2009a] ■ Organizations must have formal processes for disclosing unanticipated outcomes and for reporting events to those responsible for patient safety, including external organizations, where applicable, and for identifying and mitigating risks and hazards. [Kussman, 2008] ■ The governance and administrative leadership should ensure that such information is systematically used for performance improvement by the organization. Policies and procedures should incorporate continuous quality improvement techniques and provide for annual reviews and updates. [Sorensen, 2008] ■ Adherence to the practice and participation with the support system is expected and may be considered as part of credentialing. ■ Communication with patients, their families and caregivers, should include or be characterized by the following: • the "facts"—an explicit statement about what happened that includes an explanation of the implications of the unanticipated outcome for the patient's future health, an explanation of why the event occurred, and information about measures taken for its preventability; [Fein, 2007; Holden, 2009] • empathic communication of the "facts," a skill that should be developed and practiced in healthcare organizations; • an explicit and empathic expression of regret that the outcome was not as expected (e.g., "I am sorry that this has happened."); • a commitment to investigate and as possible prevent future occurrences by collecting the facts about the event and providing them to the organization's patient safety leaders, including those in governance positions; • feedback of results of the investigation, including whether or not it resulted from an error or systems failure, provided in sufficient detail to support informed decisionmaking by the patient; [O'Connell, 2009] • "timeliness"—the initial conversation with the patient and/or family should occur within 24 hours, whenever possible. Early and subsequent follow-up conversations should occur, both to maintain the relationship and to provide information as it becomes available;

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 7: Disclosure Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event. *(continued)*	• an apology from the patient's licensed independent practitioner (LIP) and/or an administrative leader should be offered if the investigation reveals that the adverse outcome clearly was caused by unambiguous errors or systems failures; • emotional support for patients and their families by trained caregivers should be provided; [HBQI, 2008; Iedema, 2008] and • a disclosure and improvement support system should be established and maintained to provide the following to caregivers and staff that includes: – emotional support for caregivers and administrators involved in such events by trained caregivers in the immediate postevent period that may extend for weeks afterward, – education and skill building regarding the concepts, tools, and resources that produce optimal results from this practice, centered on systems improvement rather than blame, and with a special emphasis on creating a just culture, [Frankel, 2006; Sorensen, 2008; Gallagher, 2009b] – 24-hour availability of advisory support to caregivers and staff to facilitate rapid responses to serious unanticipated outcomes, including "just-in-time" coaching and emotional support, and – education of caregivers regarding the importance and technique of disclosure to care teams of errors or adverse events when they happen. [Keller, 2009; Shannon, 2009] ▪ Healthcare organizations should implement a procedure to ensure and document that all LIPs are provided with a detailed description of the organization's program for responding to adverse events, including the full disclosure of error(s) that may have caused or contributed to patient harm. This is done with the expectation that the healthcare organizations and/or the LIPs will provide this information to their individual medical malpractice liability carriers in the event that they are provided liability coverage from entities outside of the organization. All new employees should also receive this information. ▪ A process should be in place to consider providing information to a Patient Safety Organization that would provide a patient safety evaluation program to protect privileged and confidential information. [AHRQ, 2008; Public Law 109-41] ▪ A process should be in place to consider early remediation and the waiving of billing for care services provided during the care episode and for subsequent treatment if the event was due to unambiguous systems failures or human error.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 8: Care of the Caregiver Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events. [Frankel, 2006] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ Indications • At a minimum, the types of serious unanticipated outcomes addressed by this practice include a) sentinel events; b) serious reportable events; or c) any other unanticipated outcomes that involve harm and require substantial additional care (such as diagnostic tests/therapeutic interventions or increased length of stay) or cause loss of limb or limb function lasting seven days or longer. (This definition of events triggering the implementation of this practice is identical to that in *Safe Practice 7: Disclosure*.) [NQF, 2003] • For the purposes of this practice, caregivers shall mean clinical providers, staff, and administrators "involved" in adverse events as defined above. Involvement is defined as being directly involved AND indirectly involved in the event. Those who were directly involved may be those whose activities had a direct bearing on the systems failures or error that led to patient harm. Those who were indirectly involved may be individuals who have been impacted by the event and who may be only tangentially involved in the error chain or systems failure that led to the event. ■ Formal structures, systems, and policies should be established so that administrative leaders have direct authority and accountability 24/7/365 to ensure that caregivers, staff, and administrators receive: [Denham, 2008d] • Treatment That Is Just: A well-organized, evidence-based process should be followed to assess the behavior of individuals directly involved in an adverse event to identify issues of substance abuse, intentional harm, illness, reckless violations of clear policies and procedures, and/or gross negligence, in order to avoid inappropriate blame. [Marx, 2007; Reason, 1997; Frankel, 2006; Wachter, 2009] Those who were involved in an incident that is the result of systems faults or predictable human performance factor failure should be clearly designated as free from direct personal blame by a senior administrative leader in a manner that is visible to the entire organization. This process should be undertaken within 24 hours of having enough factual information to support it. [Denham, 2007; Denham, 2008b; McDonald, 2009] If, after an event investigation, the organization is contemplating a corrective action that could result in a serious loss of livelihood of an individual, [Dunbar, 2009] that

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 8: Care of the Caregiver Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events. *(continued)*	individual should be notified of the potential action, and he or she should be advised that he or she may want to exercise the opportunity to seek the advice of legal counsel before providing a formal statement about the corrective action. • Respect: A formalized process should be followed by designated administrative senior leaders immediately after an incident to ensure that the individuals who are directly or indirectly involved are treated with respect and dignity. This process should outline who will interact with directly involved individuals and should recognize that these individuals may be undergoing extreme stress and discomfort. As those who interact with directly involved individuals address issues such as continued work, communication with co-workers, and follow-up investigations, they should treat the individuals as they themselves would wish to be treated had they unintentionally harmed a patient. Individuals should be treated as innocent of intentional or reckless harm until proven otherwise. By whatever means will best reach the organization, senior administrators should publicly request that all involved caregivers be treated with respect and dignity. [Marx, 2007; Reason, 1997; Denham, 2007; Denham, 2008b; Denham, 2008d; Denham, 2008a] (See Implementation Example Approach.) • Understanding and Compassion: A formalized process should be followed by a designated administrative leader to invite co-workers to express personal understanding and compassion to those directly and indirectly involved in such events as defined above. Designated administrative leaders should be trained in the critical importance of forgiveness and the provision of personal support to individuals involved in unintentionally and seriously harming others. [Denham, 2008b; Berlinger, 2007; Purtilo, 2005] • Supportive Care: Caregivers, staff, and administrators directly involved in serious unintentional harm as defined above must be considered "patients requiring immediate and ongoing care." A process must be established and regularly updated that must be led by a designated team or leader to ensure that all individuals directly involved and indirectly involved in the incident have the opportunity to receive appropriate professional care and are assessed for fitness for work to ensure their safety, that of their

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 8: Care of the Caregiver Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events. *(continued)*	co-workers, and that of the patients they will serve in the future. Such a process should include a structure and system for all who are directly and indirectly involved in an incident to voluntarily request such supportive care, and a structure, system, and accountability should be established for mandatory "fitness for work" assessments of individuals directly involved in events. Such assessments and supportive care should also be considered for "near misses" that are reported to the organization. • Transparency: Those individuals who are directly or indirectly involved in events should be invited to fully participate in the investigation and analysis of the incident unless, through the process defined above, they were found to have been engaged in substance abuse or gross negligence, or their behavior was found to have intentionally induced harm. [Denham, 2007; Denham, 2008b; Denham, 2008e; Denham, 2006b; McDonald, 2009] ▪ Formal structures, systems, and policies should be established to educate senior administrators, caregivers, and staff about the vulnerabilities of caregivers who have been involved in unintentional harm and to provide "just-in-time" coaching to administrative leaders who are accountable for executing the actions defined in this practice. [Boothman, 2009] ▪ The governance and administrative leadership should ensure that the information captured during the administration of this practice is systematically used for performance improvement by the healthcare organization. Policies and procedures should incorporate continuous quality improvement techniques and should provide for quarterly reviews and updates. ▪ A process should be in place to consider providing information to a Patient Safety Organization that would provide a patient safety evaluation program to protect privileged and confidential information. [AHRQ, 2008; Public Law 109-41]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 9: Nursing Workforce Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following: ■ A nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety. [IOM, 2004; Rother, 2009] ■ Senior administrative nursing leaders, such as a Chief Nursing Officer, as part of the hospital senior management team. [IOM, 2004; Laschinger, 2009; Simpson, 2009] ■ Governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services. ■ Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills. [IOM, 2004; Rafferty, 2009]	■ Implement explicit organizational policies and procedures, with input from nurses at the unit level, on effective staffing targets that specify the number, competency, and skill mix of nursing staff needed to provide safe, direct care services. [Smith, 2009] ■ Ensure that the governance board and senior, midlevel, and line managers are educated about the impact of nursing on patient safety. ■ Conduct ongoing organization-wide patient safety risk assessments to identify patient safety risks related to nurse staffing, nurse work hours, temporary nurse coverage, and other areas related to the prevention of patient harm. [Seago, 2001] This assessment must be reviewed by senior administrative management and the governance board at least annually to ensure that resources are allocated and performance improvement programs are implemented. ■ Use the data collected and analyzed from the daily monitoring of actual unit-specific nurse staffing levels to identify and address potential patient safety-related staffing issues. Such data should include, but not be limited to, nursing hours per patient day as defined in the NQF report, *National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set.* ■ Provide regular reports, at intervals determined by leadership, of unit-specific, potential patient safety-related staffing issues to senior nursing leadership, the governance board, and senior administrative leaders. ■ Put in place and document performance improvement programs that include the elements of education, skill building, measurement, reporting, and process improvement, and provide evidence of the actions taken to close patient safety gaps related to nursing services. [NWMH, 2003]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 9: Nursing Workforce **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility. *(continued)*	■ Provide reports at least annually to the public through the appropriate organizations. ■ Ensure, through ongoing assessments by managers/leaders in the practice environment, that all nurses are oriented and competent to provide safe care to the patients to whom they are assigned, including nurses who are new to the organization, temporary staff, float pool nurses, contract staff, and temporarily assigned nurses. [IHI, 2003] Ongoing education must be provided through in-services, training, and other activities to maintain and improve the competencies specific to the assigned duties [Duffield, 2008] and job responsibilities related to patient safety, infection control, and the population served.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 10: Direct Caregivers Ensure that non-nursing direct care staffing levels are adequate, that the staff are competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ Establish a staffing plan that is adequately resourced and actively managed, and the effectiveness of which is regularly evaluated with respect to patient safety. [NWMH, 2003; IHI, 2007] ▪ Conduct ongoing patient safety risk assessment to identify the patient safety risks related to non-nursing direct care worker staffing, work hours, temporary staff coverage, and other areas related to the prevention of patient harm. This assessment must be reviewed by senior administrative management and the governance board at least annually to ensure that resources are allocated and performance improvement programs are implemented. ▪ Senior administrative management and the governance board should ensure that resources are allocated and performance improvement programs are implemented based on their review of patient risk assessments related to non-nursing direct care worker staffing. Ideally all non-nursing direct care staff areas are assessed; however, at a minimum, the categories of direct care staff that in aggregate have direct contact with patients must be assessed. ▪ Establish and consistently implement explicit policies and procedures to ensure that effective staffing targets are met. These should specify the number, competency, and skill mix of staff related to safe care, with input from frontline staff at the unit level. ▪ Put in place and document performance improvement programs that include the elements of education, skill building, measurement, reporting, and process improvement, and provide evidence of the actions taken to close the patient safety gaps that are related to non-nursing direct caregiver services. ▪ Provide reports, at least annually, about the impact of non-nursing direct caregivers on patient safety to the governance board and senior administrative leaders. ▪ Ensure, through ongoing assessments by managers/leaders in the practice environment, that all staff are oriented and competent to provide safe care to the patients to whom they are assigned, including staff who are new to the organization, temporary staff, float pool staff, or contract staff, or those who are temporarily assigned. Ongoing education must be provided through in-services, training, and other activities to maintain and improve the competencies specific to the assigned duties and job responsibilities related to patient safety, infection control, and the populations served. [Clark, 2009; Regan, 2009]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 11: Intensive Care Unit Care All patients in general intensive care units (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine ("critical care certified"). **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include inpatient service/ hospital.	■ A "critical care certified" physician is one who has obtained critical care subspecialty certification by the American Board of Anesthesiology, the American Board of Internal Medicine, the American Board of Pediatrics, or the American Board of Surgery, or has completed training prior to the availability of subspecialty board certification in critical care in his or her specialty, and is board certified in one of these four specialties and has provided at least six weeks of full-time intensive care unit (ICU) care annually since 1987. [TJC, 2009] ■ Dedicated, critical care certified physicians shall be present in the ICU during daytime hours, a minimum of eight hours per day, seven days per week, and shall provide clinical care exclusively in the ICU during this time. ■ When a critical care certified physician is not present in the ICU, such a physician shall provide telephone coverage to the ICU and return more than 95 percent of ICU pages within five minutes (excluding low-urgency pages, if the paging system can designate them). When not in the hospital, the critical care certified physician should be able to rely on an appropriately trained onsite clinician to reach ICU patients within five minutes in more than 95 percent of cases. ■ If it is not possible to have a dedicated, critical care certified physician in the ICU eight hours daily, an acceptable alternative is to provide exclusively dedicated round-the-clock ICU telemonitoring by a critical care certified physician, if the system allows real-time access to patient information that is identical to onsite presence (except for manual physical examination). [Rosenfeld, 1999; Rosenfeld, 2000]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 12: Patient Care Information Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and appropriate family and caregivers, and to all of the patient's healthcare providers/professionals, within and between care settings, who need that information to provide continued care. [MCPME, N.D.] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ Identify communication gaps and/or failures about critical test results, implement performance improvement programs to ensure timely closure of information loops, and report the gaps and improvement progress to senior leadership and the board of governance. ■ Implement a standardized process to ensure that critical results are communicated quickly to a licensed healthcare provider so that action can be taken. [Valenstein, 2008; Rensburg, 2009] Values defined as critical by the laboratory must be reported to the responsible licensed practitioner within the timeframes established by the laboratory in cooperation with nursing and medical staff. [Valenstein, 2008; Huang, 2009] ■ Put in place intra- and intercare setting processes to ensure that, when the patient's responsible licensed practitioner is not available within the specified timeframes, there is a mechanism to report critical information to an alternate responsible practitioner. Also, include a process of how to communicate critical test results that are completed after the patient has been discharged from the organization. ■ Ensure that patients have access to their medical records, which should include, but not be limited to, medical histories and consultations, test results, including laboratory reports and imaging (including copies of imaging studies), medication lists, advance directives, and procedural reports, within 24 hours of a written request that includes the appropriate release documentation. Use technology to facilitate patient care information when possible. [Matheny, 2007; Reid, 2008; Piva, 2009]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 13: Order Read-Back and Abbreviations Incorporate within your organization a safe, effective communication strategy, structures, and systems to include the following: ■ For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and "read-back" the complete order or test result. ■ Standardize a list of "Do Not Use" abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ The process of verbal orders should be avoided except when it is impossible or impractical for the prescriber to write the order or enter it in the computer. [Baum, 2009] Explicit organizational policies and procedures on verbal and telephone orders should include, at a minimum: • strategies to minimize the use of verbal and telephone orders, and • the identification of items that cannot be ordered or reported verbally or by telephone. ■ The receiver of verbal information writes down the complete order or test result or enters it into a computer. ■ The receiver reads back the order or test result. ■ The receiver receives confirmation from the individual who gave the order or test result. ■ Rigorously prohibit the use of terms known to lead to misinterpretation including, at a minimum, *u, IU, qd, qod, trailing zero, absence of leading zero, MS, MSO4, MgSO4.* ■ At a minimum, prohibit terms known to lead to misinterpretation from all orders and other medication-related documentation when handwritten, entered as free text into a computer, or on preprinted forms. ■ Use the metric system to express all doses on prescription orders, except for therapies that use standard units, such as insulin and vitamins. ■ Trailing zeros may be used in nonmedication-related documentation when there is a clear need to demonstrate the level of precision, such as for laboratory values.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 14: Labeling of Diagnostic Studies Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ Label laboratory specimen containers at the time of use and in the presence of the patient. ▪ Take the critical steps of identifying the individual and matching the intended service or treatment, including read-back, to that individual to prevent miscommunication or inaccurate labeling. ▪ Use at least two patient identifiers (neither to be the patient's room number or physical location) when taking blood samples or other specimens for clinical testing, imaging, or providing any other treatments and procedures. ▪ Label x-ray imaging studies with the correct patient information while in the darkroom or close to the imaging device. ▪ Mark "left" or "right" on each radiographic image to prevent misinterpretation on the light box. ▪ Monitor and report errors and harm related to mislabeling to the organization-wide risk-assessment activity as part of a performance improvement program that addresses mislabeling of specimens or diagnostic studies.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 15: Discharge Systems A "discharge plan" must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for postdischarge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge. [Jack, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ Discharge policies and procedures should be established and resourced and should address: [Clancy, 2009] • explicit delineation of roles and responsibilities in the discharge process; • preparation for discharge occurring, with documentation, throughout the hospitalization; • reliable information flow from the primary care physician (PCP) or referring caregiver on admission, to the hospital caregivers, and back to the PCP, after discharge, using standardized communication methods; [Sherman, 2009] • completion of discharge plan and discharge summaries before discharge; [Jack, 2009] • patient or, as appropriate, family perception of coordination of discharge care; and • benchmarking, measurement, and continuous quality improvement of discharge processes. ■ A written discharge plan must be provided to each patient at the time of discharge that is understandable to the patient and/or his family or guardian and appropriate to each individual's health literacy and English language proficiency. [Chugh, 2009; Were, 2009] At a minimum, the discharge plan must include the following: • reason for hospitalization; • medications to be taken postdischarge, including, as appropriate, resumption of pre-admission medications, how to take them, and how to obtain them; • instructions for the patient on what to do if his or her condition changes; and • coordination and planning for follow-up appointments that the patient can keep and follow-up of tests and studies for which confirmed results are not available at the time of discharge. ■ A discharge summary must be provided to the ambulatory clinical provider who accepts the patient's care after hospital discharge. At a minimum, the discharge summary should include the following: • reason for hospitalization; • significant findings;

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 15: Discharge Systems A "discharge plan" must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for postdischarge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge. *(continued)*	• procedures performed and care, treatment, and services provided to the patient; • the patient's condition at discharge; • information provided to the patient and family; • a comprehensive and reconciled medication list; and • a list of acute medical issues, tests, and studies for which confirmed results are unavailable at the time of discharge and require follow-up. ▪ Original source documents (e.g., laboratory or radiology reports or medication administration records) should be in the transcriber's immediate possession and should be visible when it is necessary to transcribe information from one document to another. ▪ The organization should ensure and document receipt of discharge information by caregivers who assume responsibility for post-discharge care. This confirmation may occur through telephone, fax, e-mail response, or other electronic response using health information technologies. [Zsenits, 2009]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure. [Alfreds, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include inpatient service/ hospital.	■ Providers enter orders using an integrated, electronic information management system that is based on a documented implementation plan that includes or provides for the following: • Risks and hazards assessment to identify the performance gaps to be closed, including the lack of standardization of care; high-risk points in medication management systems such as at the point of order entry and upon the administration of medications; and the introduction of disruptive innovations. [Singh, 2009] • Prospective re-engineering of care processes and workflow. [Niazkhani, 2009] • Readiness of integrated clinical information systems that include, at a minimum, the following information and management systems: – Admit Discharge and Transfer (ADT). – Laboratory with Electronic Microbiology Output. – Pharmacy. – Orders. – Electronic Medication Administration Record (including patient, staff, and medication ID) (eMAR). – Clinical Data Repository with Clinical Decision Support Capability. – Scheduling. – Radiology. – Clinical Documentation. • Readiness of hospital governance, staff, and independent practitioners, including board governance, senior administrative management, frontline caregivers, and independent practitioners. • The following CPOE specifications, which: – facilitate the medication reconciliation process; – are part of an Electronic Health Record Information System or an existing clinical information system that is bi-directionally and tightly interfaced with, at a minimum, the pharmacy, the clinical documentation department (including medication administration record), and laboratory systems, to facilitate review of all orders by all providers;

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure. *(continued)*	– are linked to prescribing error-prevention software with effective clinical decision support capability; – require prescribers to document the reasons for any override of an error prevention notice; – enable and facilitate the timely display and review of all new orders by a pharmacist before the administration of the first dose of medication, except in cases when a delay would cause harm to a patient; – facilitate the review and/or display of all pertinent clinical information about the patient, including allergies, height and weight, medications, imaging, laboratory results, and a problem list, all in one place; – categorize medications into therapeutic classes or categories (e.g., penicillin and its derivatives) to facilitate the checking of medications within classes and retain this information over time; and – have the capability to check the medication ordered as part of effective clinical decision support for dose range, dosing, frequency, route of administration, allergies, drug-drug interactions, dose adjustment based on laboratory results, excessive cumulative dosing, and therapeutic duplication.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 17: Medication Reconciliation The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ Educate clinicians upon hire on the importance of medication reconciliation; frequency of ongoing education is based on the risk of noncompliance and adverse drug events as determined by the organization. ▪ Providers receiving the patient in a transition of care should check the medication reconciliation list to make sure it is accurate and in concert with any new medications that are ordered/prescribed. ▪ The list should include the full range of medications as defined by accrediting organizations such as The Joint Commission. At a minimum, the list should include the following: • prescription medications; • sample medications; • vitamins; • nutriceuticals; • over-the-counter drugs; • complementary and alternative medications; • radioactive medications; • respiratory therapy-related medications; • parenteral nutrition; • blood derivatives; • intravenous solutions (plain or with additives); • investigational agents; and • any product designated by the Food and Drug Administration (FDA) as a drug. ▪ At the time the patient enters the organization or is admitted, a complete list of medications the patient is taking at home (including dose, route, and frequency) is created and documented. The patient, and family, as needed, are involved in creating this list. ▪ The medications ordered for the patient while under the care of the organization are compared to those on the list created at the time of entry to the organization or admission. According to The Joint Commission's FAQ, organizations should keep two lists during the hospitalization. The "home medications" list should be maintained unchanged and available for subsequent use in the reconciliation process. The list of the patient's current medications while in the hospital is a dynamic document that will require

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 17: Medication Reconciliation The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care. *(continued)*	updating whenever changes are made to the patient's medication regimen. Both lists should be considered whenever reconciliation is carried out. The reason for referring to the "home" medication list is that some "home" medications may be held when a patient is admitted or goes to surgery. They may need to be resumed upon transfer to a different level of care, return from the operating room, or at discharge. ■ Any discrepancies (i.e., omissions, duplications, adjustments, deletions, additions) are reconciled and documented while the patient is under the care of the organization. ■ When the patient's care is transferred within the organization (e.g., from the ICU to a floor), the current provider(s) inform(s) the receiving provider(s) about the up-to-date reconciled medication list and documents the communication. ■ The patient's most current reconciled medication list is communicated to the next provider of service, either within or outside the organization. The communication between providers is documented. ■ At the time of transfer, the transferring organization informs the next provider of service of how to obtain clarification on the list of reconciled medications. ■ When the patient leaves the organization's care, the current list of reconciled medications is provided to the patient, and family, as needed, and is explained to the patient and/or family, and the interaction is documented. [Jack, 2009] ■ In settings where medications are used minimally, or are prescribed for a short duration, modified medication reconciliation processes are performed: • The organization obtains and documents an accurate list of the patient's current medications and known allergies in order to safely prescribe any setting-specific medications (e.g., IV contrast, local anesthesia, antibiotics) and to assess for potential allergic or adverse drug reactions. • If no changes are made to the patient's current medication list, or when only short-term medications (e.g., a preprocedure medication or a short-term course of an antibiotic) will be prescribed, the patient, and family, as needed, are provided with a list containing the short-term medication additions that the patient will continue after leaving the organization.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 17: Medication Reconciliation The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care. *(continued)*	• In these settings, there is a complete, documented medication reconciliation process when: – Any new long-term (chronic) medications are prescribed. – There is a prescription change for any of the patient's current known long-term medications. – The patient is required to be subsequently admitted to an organization from these settings for ongoing care. • When a complete, documented, medication reconciliation is required in any of these settings, the complete list of reconciled medications is provided to the patient and the patient's family, as needed, and to the patient's known primary care provider or original referring provider, or a known next provider of service.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 18: Pharmacist Leadership Structures and Systems Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	**Leadership and Culture of Safety** A structure should be established and maintained to ensure that pharmacy leaders engage in regular, direct communications with the administrative leaders and the board of directors about medication management systems performance. [NQF, 2006; ASHP, 2003] Pharmacists should actively participate in medication management processes, structures, and systems, by, at a minimum: ▪ Working with the interdisciplinary team to ensure safe and effective medication use across the continuum of care as patients move from one setting to another (e.g., from ambulatory care to inpatient to home care). [Chiquette, 1998; Dudas, 2002; Schnipper, 2006; Koshman, 2008; Jack, 2009] ▪ Establishing pharmacy leadership structures and systems to ensure organization awareness of medication safety gaps; that there is direct accountability of senior leadership for these gaps with adequate budget available for performance improvement; and that action is taken to ensure the safe medication use by every patient. [Manasse, 2000; Mark, 2007a; Mark, 2007b] ▪ Supporting an organizational culture of safe medication use; measuring pharmacy staff safety culture; providing feedback to leadership and staff; and undertaking interventions that will reduce medication safety risks. [Connor, 2007; Clarke, 2007; ISMP, 2007; Ashcroft, 2009] ▪ Establishing a proactive, systematic, and organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable patient harm. [Seghal, 2008; Clark, 2009] ▪ Systematically identifying and mitigating medication safety risks and hazards to reduce preventable patient harm. [Benjamin, 2003; Rath, 2008] ▪ Working with the interdisciplinary team to ensure evidence-based medication regimens for all patients. [Leape, 1999; Scarsi, 2002; Kucukarslan, 2003; Rodgers, 2007]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 18: Pharmacist Leadership Structures and Systems Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. *(continued)*	■ Establishing a medication safety committee to review medication errors, adverse drug events (ADEs), and medication near misses, and reporting data and prevention strategies to senior leadership, the Patient Safety Officer, and the interdisciplinary patient safety committee. [Piotrowski, 2002; Kowiatek, 2004; Odwazny, 2005; Denham, 2007; Abramson, 2009] ■ Performing medication safety walk-rounds to evaluate medication processes and frontline staff input about medication safe practices. [Frankel, 2005; Thomas, 2005] ■ Ensuring that pharmacy staff engage in teamwork and communication, leadership, and safety culture training, at least annually. [Seghal, 2008; Clark, 2009] ■ Establishing a central role in readiness planning for the implementation of CPOE, medication and patient barcoding, and other health information technologies that have an impact on medication management systems and medication use. [McGregor, 2006; Kilbridge, 2006; ASHP, 2003] ■ Engaging in public health initiatives on behalf of the pharmacy community, including best practice immunization and vaccination initiatives, smoking cessation, and emergency preparedness. [ASHP, 2003; Hogue, 2006; Terriff, 2008; Dent, 2009] **Selection and Procurement** ■ Pharmacists work with physicians and other health professionals to select and maintain a formulary of medications chosen for safety, effectiveness, and cost, as well as medication-associated products or devices, medication use policies, important ancillary drug information, decision support tools, and organizational guidelines. The formulary system should have a process for which the medical staff has oversight and approval of the formulary. [Pedersen, 2001; Pedersen, 2008] ■ Medication selection should be informed by the best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. [NQF, 2006] The prescriber should document the specific reason, clinical indications, and/or patient preferences, and why a patient is not receiving a recommended medication, based on readily available, current guidelines. [Meyer, 2000]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 18: Pharmacist Leadership Structures and Systems Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. *(continued)*	■ Pharmacists are actively involved in the development and implementation of evidence-based drug therapy protocols and/or order sets. [ASHP, 2003; Magee, 2007] **Storage** ■ Identify and, at least annually, review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs. [AHA, 2005; McCoy, 2005; TJC, 2009a] ■ Ensure that the written medication storage policy is implemented. The policy includes safe storage, safe handling, security, and disposition of these medications. [Rich, 2004; TJC, 2009a] ■ Ensure that all medications, including pediatric doses, parenteral, and those used during emergencies, are available in unit-dose (single unit), age- and/or weight-appropriate, and ready-to-administer forms, whenever possible. [Rich, 2004; TJC, 2009b] **Ordering and Transcribing** ■ Ensure with the healthcare team that only the medications needed to treat the patient's condition are ordered, provided, and administered. [TJC, 2005; Gardner, 2009] **Preparing and Dispensing** ■ Pharmacists should review all medication orders and the patient medication profile for appropriateness and completeness, address any problems and ensure needed change, and document actions taken before medications are dispensed or made available for administration, except in those instances when review would cause a medically unacceptable delay or when a licensed independent practitioner controls the ordering, preparation, and administration of the medication. [TJC, 2009b; Westerlund, 2009] ■ Pharmacists should oversee the preparation of medications, including sterile products, and ensure that they are safely prepared. [Kastango, 2005; TJC, 2009b] ■ Medications should be labeled in a standardized manner according to hospital policy, applicable law and regulation, and standards of practice. [ISMP, 2008b; Jennings, 2007; Shrank, 2007; Momtahan, 2008; TJC, 2009a]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 18: Pharmacist Leadership Structures and Systems Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. *(continued)*	■ Every unit-dose package label should contain a machine-readable code identifying the product name, strength, and manufacturer. Machine-readable coding should be considered in compounding, stocking, and dispensing procedures to facilitate accuracy. [VHA, 2006; ASHP, 2009] ■ When a full-time pharmacist is not available onsite, a pharmacist should be available by telephone or accessible at another location that has 24-hour pharmacy services. [Woodall, 2004; Pedersen, 2008; TJC, 2009a] **Medication Administration** ■ Organizations should prepare for the use of medication administration technologies such as barcode-enabled medication administration (BCMA) and "Smart Pump" infusion devices as part of their medication safety strategy. [Johnson, 2002; Wilson, 2004; Larsen, 2005; Rothschild, 2005; Poon, 2006; Cohen, 2007b; Fanikos, 2007; Paoletti, 2007] ■ The five rights for medication administration (right patient, right medication, right dose, right time and frequency, and right route of administration) have historically been a guideline for nurses and caregivers; however, this framework is not all inclusive of domains relating to medication adverse events. It does not address all pertinent organizational systems, human factors performance, and human-technology interface issues. The practitioner's duty is to follow the procedural rules designed by the organization to produce optimal outcomes. If system issues negatively affect the adherence to procedural rules and their intended impact, the practitioner also has the duty to report the hindrance so that it can be remedied. [Bechtel, 1993; ISMP, 2007] **Monitoring** ■ Pharmacists should monitor patient medication therapy regularly, based on patient needs and best evidence, for effectiveness, adherence, persistence, and avoidance of adverse events. Monitoring information should be communicated to providers, caregivers, and patients. [Bond, 2006; Bond, 2007] ■ Medication errors and near miss internal reports should be shared with organizational safety, risk, and senior leadership through the pharmacy leader. A performance improvement and risk mitigation

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 18: Pharmacist Leadership Structures and Systems Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. *(continued)*	plan should be created, integrated into the organization's improvement strategy, implemented, and documented annually. This plan should be updated as frequently as necessary based on internal data. [Cohen, 2000; Lehmann, 2007; Montesi, 2009] ■ Medication error and near miss information is reported through external sources such as Patient Safety Organizations, the Food and Drug Administration (FDA), the United States Pharmacopeia, or the Institute for Safe Medicine Practices (ISMP), as appropriate, in an effort to trend data to prevent future patient harm. [Cohen, 2000; MCPME, 2006] ■ Proactive risk mitigation strategies should be demonstrated to prevent errors in the organization. Example: On an ongoing basis*, utilize external sources for review (such as ISMP, FDA) of reported near miss/medication errors. [ISMP, 2009] *The NQF Maintenance Committee recommends quarterly review of published literature and internal organizational data to identify potential harm to patients and implementation of risk mitigation strategies. **High Alert Medications** ■ Identify high alert medications within the organization. [ISMP, 2008b] ■ Implement institutional processes for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and monitoring high alert medications. [Runy, 2004; Cohen, 2007a; Federico, 2007; TJC, 2009b] **Evaluation** ■ Perform medication safety self-assessments to identify organizational structure, system, and communication opportunities to proactively target harm reduction and risk mitigation strategies. [ISMP, N.D.a; Smetzer, 2003; TJC, 2009b] ■ Evaluate the ability of the patient to understand and adhere to medication regimens when in the community setting. Consider patient health literacy, feasible dosing schedules, and affordability, as well as cultural, physical, and environmental barriers. [NQF, 2006; Davis, 2006a; Davis, 2006b]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 19: Hand Hygiene Comply with current Centers for Disease Control and Prevention Hand Hygiene Guidelines. and/or World Health Organization (WHO) Guidelines on Hand Hygiene in Health Care. [CDC, 2002; WHO, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility. [Aiello, 2008]	At a minimum, this practice should include all of the following elements: ▪ Implement all Centers for Disease Control and Prevention (CDC) guidelines with category IA, IB, or IC evidence and/or WHO Guidelines on Hand Hygiene in Health Care. [CDC, 2002; Braun, 2009; Stevenson, 2009; WHO, 2009] ▪ Encourage compliance with CDC guidelines with category II evidence. ▪ Ensure that all staff know what is expected of them with regard to hand hygiene, and ensure compliance. [Boyce, 2008; Creedon, 2008; Kohli, 2009; McGuckin, 2009]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 20: Influenza Prevention Comply with current Centers for Disease Control and Prevention (CDC) recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control. [Pearson, 2006; Fiore, 2008] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ *Healthcare workers* are individuals currently employed in a healthcare occupation or in a healthcare-industry setting who come in direct contact with patients. Healthcare workers with contraindications to immunization or who refuse immunization are exempted. ■ Patients who should be immunized are specified by current CDC recommendations. ■ Explicit organizational policies and procedures, as well as a robust voluntary healthcare worker and patient influenza immunization program, should be in place. ■ Document the immunization status of all employees, subject to collective bargaining, labor law, and privacy law. ■ At a minimum, this practice should include all of the following elements: [Pearson, 2006; Fiore, 2008; Fiore, 2009]: • Implement the CDC Advisory Committee on Immunization Practices annual recommendations for influenza prevention and control. • Implement all CDC guidelines with category IA, IB, or IC evidence. – Educate healthcare personnel (HCP) on the benefits of influenza vaccination and the potential health consequences of influenza illness for themselves and their patients, the epidemiology and modes of transmission, diagnosis, treatment, and nonvaccine infection control strategies, in accordance with their level of responsibility in preventing healthcare-associated influenza (category IB). – Offer influenza vaccine annually to all eligible HCP to protect staff, patients, and family members, and to decrease HCP absenteeism. Use of either available vaccine (inactivated or live, attenuated influenza vaccine [LAIV]) is recommended for eligible persons. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged, when feasible, for eligible HCP (category IA). – Provide influenza vaccination to HCP at the work site and at no cost as one component of employee health programs. Use strategies that have been demonstrated to increase influenza vaccine acceptance, including vaccination clinics, mobile carts, vaccination access during all work shifts, and modeling and support by institutional leaders (category IB).

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 20: Influenza Prevention Comply with current Centers for Disease Control and Prevention (CDC) recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control. *(continued)*	– Monitor HCP influenza vaccination coverage and declination at regular intervals during the influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration (category IB). • Encourage compliance with CDC guidelines with category II evidence. – Use the level of HCP influenza vaccination coverage as one measure of a patient safety quality program (category II).

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices. [CDC MMWR, 2002; Marschall, 2008a; Mermel, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	**Before insertion:** ▪ Educate healthcare personnel involved in the insertion, care, and maintenance of central venous catheters (CVCs) about central line-associated bloodstream infection (CLABSI) prevention. [Sherertz, 2000; Eggimann, 2000; Coopersmith, 2002; Warren, 2003; Warren, 2004; Marschall, 2008a] **At insertion:** ▪ Use a catheter checklist to ensure adherence with infection prevention practices at the time of CVC insertion. [Berenholtz, 2004; Tsuchida, 2007] ▪ Perform hand hygiene prior to catheter insertion or manipulation. [Boyce, 2002; Rosenthal, 2005; Yilmaz, 2007; Smith, 2008; OSHA, N.D.] ▪ Avoid using the femoral vein for central venous access in adult patients. [Goetz, 1998; Merrer, 2001] (Subclavian or internal jugular are the preferred sites, unless contraindicated.) ▪ Make available and easily accessible for use a catheter cart or kit that contains all necessary components for aseptic catheter insertion. [Berenholtz, 2004] ▪ Use maximal sterile barrier precautions during CVC insertion to include a mask, cap, sterile gown, and sterile gloves worn by all healthcare personnel involved in the procedure. The patient is to be covered with a large sterile drape during catheter insertion. [Mermel, 1991; Raad, 1994; Hu, 2004; Young, 2006; Smith, 2008] ▪ Use chlorhexidine-gluconate 2% and isopropyl alcohol solution as skin antiseptic preparation in patients over two months of ageand allow appropriate drying time per product guidelines. [Maki, 1991; Garland, 1995; Humar, 2000; Chaiyakunapruk, 2002; CDC MMWR, 2002; Darouiche, 2008; Pronovost, 2008] **After insertion:** ▪ Use a standardized protocol to disinfect catheter hubs, needleless connectors, and injection ports before accessing the ports. [Salzman, 1993; Luebke, 1998; Casey, 2003; Shapey, 2009] ▪ Remove nonessential catheters. [Lederle, 1992; Parenti, 1994; Garnacho-Montero, 2008]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices. *(continued)*	■ Use a standardized protocol for nontunneled CVCs in adults and adolescents for dressing care, such as changing transparent dressings and performing site care with a chlorhexidine-based antiseptic every five to seven days, or earlier if the dressing is soiled, loose, or damp; change gauze dressings every two days, or earlier if the dressing is soiled, loose, or damp. [Maki, 1994; Rasero, 2000; Ruschulte, 2009] ■ Perform surveillance for CLABSI and report the data on a regular basis to the units, physician and nursing leadership, and hospital administrators overseeing the units. [Marschall, 2008a; Marschall, 2008b; Rosenthal, 2008a] **Pediatric Specificity:** Chlorhexidine may be contraindicated for use in very low birthweight (VLBW) infants. Optimal catheter site selection is specific to the size and condition of the infant or child and accessibility factors.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 22: Surgical-Site Infection Prevention Take actions to prevent surgical-site infections by implementing evidence-based intervention practices. **Applicable Clinical Care Settings** This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory surgical center and inpatient service/ hospital.	■ Document the education of healthcare professionals, including nurses and physicians, involved in surgical procedures about healthcare-acquired infections, surgical-site infections (SSIs), and the importance of prevention. Education occurs upon hire and annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities. ■ Prior to all surgical procedures, educate the patient and his or her family as appropriate about SSI prevention. ■ Implement policies and practices that are aimed at reducing the risk of SSI that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). ■ Conduct periodic risk assessments for SSI, select SSI measures using best practices or evidence-based guidelines, monitor compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts. ■ Ensure that measurement strategies follow evidence-based guidelines, and that SSI rates are measured for the first 30 days following procedures that do not involve the insertion of implantable devices, and for the first year following procedures that involve the insertion of implantable devices. ■ Provide SSI rate data and prevention outcome measures to key stakeholders, including senior leadership, licensed independent practitioners, nursing staff, and other clinicians. ■ Administer antimicrobial agents for prophylaxis with a particular procedure or disease according to evidence-based standards and guidelines for best practices. • Administer intravenous antimicrobial prophylaxis within one hour before incision to maximize tissue concentration (two hours are allowed for the administration of vancomycin and fluoroquinolones). • Discontinue the prophylactic antimicrobial agent within 24 hours after surgery (within 48 hours is allowable for cardiothoracic procedures). ■ When hair removal is necessary, use clippers or depilatories. *Note: Shaving is an inappropriate hair removal method.* ■ Maintain normothermia (temperature >36.0°C) immediately following colorectal surgery. ■ Control blood glucose during the immediate postoperative period for cardiac surgery patients. ■ Preoperatively, use solutions that contain isopropyl alcohol as skin antiseptic preparation until other alternatives have been proven as safe and effective, and allow appropriate drying time per product guidelines.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 23: Care of the Ventilated Patient Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers. [Coffin, 2008] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include emergency room, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ Educate healthcare workers about the daily care of ventilated patients and the necessity for the prevention of associated complications such as ventilator-associated pneumonia (VAP), venous thromboembolism (VTE), peptic ulcer disease (PUD), dental complications, and pressure ulcers. [Bloos, 2009] ▪ Implement policies and practices for disinfection, sterilization, and maintenance of respiratory equipment that are aligned with evidence-based standards (e.g., CDC and professional organization guidelines). [Tablan, 2004; Brito, 2009] ▪ Conduct active surveillance for VAP and associated process measures in units that care for ventilated patients that are known or suspected to be at high risk for VAP based on risk assessment. [Erhart, 2004; Tablan, 2004; Hortal, 2009a; Hortal, 2009b] ▪ Provide ventilated patient data on VAP, VAP-related process measures, and general care process measures to key stakeholders, including senior leadership, LIPs, nursing staff, and other clinicians. ▪ Educate patients, as appropriate, and their families about prevention measures involved in the care of ventilated patients. ▪ For adult patients, institute a ventilated patient checklist and a standardized protocol for the following prevention measures: • Adhere to hand hygiene guidelines. [Erhart, 2004; Tablan, 2004] • Perform regular antiseptic oral care according to product guidelines. [Panchabhai, 2009; Prendergast, 2009] • Maintain patients in semi-recumbent position: 30-45° elevation of head of bed (unless medically contraindicated). [Torres, 1992; Kollef, 1993; Orozco-Levi, 1995; Drakulovic, 1999; Collard, 2003; Helman, 2003; Erhart, 2004; Tablan, 2004; Kollef, 2004; Dellinger, 2005; Resar, 2005] • Perform daily assessment of readiness to wean and sedation interruption. [ATS/ IDSA, 2005; Resar, 2005; Girard, 2008] • Use weaning protocols. [Thorens, 1995; Brook, 1999; Kress, 2000; Marelich, 2002; Needleman, 2002; Burns, 2003; Kollef, 2004; Dellinger, 2005; Girard, 2008; Burns, 2009] • Implement PUD prophylaxis based on patient risk assessment. (PUD prophylaxis data remain controversial. Clinical judgment should be used based on individual patient needs.) [Prod'hom, 1994; Bonten, 1997]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 23: Care of the Ventilated Patient Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers. *(continued)*	• Provide VTE prophylaxis unless contraindicated (refer to Safe Practice 28). • Implement a pressure ulcer prevention program based on patient risk assessment (refer to Safe Practice 27). For pediatric patients (less than 18 years of age), institute a ventilated patient checklist and a standardized protocol for the following prevention measures: • Elevate airway opening between 15-30° for neonates and 30-45° for infants through pediatric ages, unless clinically inappropriate for the patient. • Assess readiness to extubate daily.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 24: Multidrug-Resistant Organism Prevention Implement a systematic multidrug-resistant organism (MDRO) eradication program built upon the fundamental elements of infection control, an evidence-based approach, assurance of the hospital staff and independent practitioner readiness, and a re-engineered identification and care process for those patients with or at risk for MDRO infections. [Siegel, 2006; Calfee 2008; Dubberke, 2008] Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *enterococci,* and *Clostridium difficile.* Multidrug-resistant gram-negative bacilli, such as *Enterobacter* species, *Klebsiella* species, *Pseudomonas* species, and *Escherichia coli,* and vancomycin-resistant *Staphylococcus aureus,* should be evaluated for inclusion on a local system level based on organizational risk assessments. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ The organization's leadership has assigned responsibility for oversight and coordination of the development, testing, and implementation of a multidrug-resistant organism (MDRO) prevention program. ■ Conduct a risk assessment for MDRO acquisition and transmission. ■ Upon hire and annually thereafter, educate staff and licensed independent practitioners about MDROs, including risk factors, routes of transmission, outcomes associated with infection, prevention measures, and local epidemiology. [Seto, 1995] ■ Educate patients who are infected with methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *enterococci,* or *Clostridium difficile,* or who are colonized with MRSA, and their families, as needed, about healthcare-associated infections and infection prevention strategies. [Lewis, 1999] ■ Implement a surveillance program for MDROs based on risk assessment. ■ Measure and monitor MDRO prevention processes and outcomes, including: • Infection rates using evidence-based metrics. • Compliance with evidence-based guidelines or best practices. [Calfee, 2008] • Evaluation of the education program provided to staff and licensed independent practitioners. ■ Provide MDRO surveillance data, prevention processes, and outcome measures to key stakeholders, including senior hospital leadership, physicians, nursing staff, and other clinicians. [Calfee, 2008] ■ Implement a laboratory-based alert system to provide immediate notification to infection control and clinical personnel about newly diagnosed MDRO-colonized or -infected patients. ■ Implement an alert system that identifies readmitted or transferred MRSA-colonized or -infected patients. ■ Promote compliance with hand hygiene recommendations. [Boyce, 2002; GopalRao, 2002; Johnson, 2005; D'Agata, 2009; Lederer, 2009] ■ Use contact precautions for MDRO-colonized or -infected patients. [Siegel, 2006; CDC, 2007; Siegel, 2007; Salgado, 2009] ■ Ensure cleaning and disinfection of equipment and environment. [Rampling, 2001; de Gialluly, 2006; Hardy, 2006; Huang, 2006; Salgado, 2009; Boyce, 2009]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices. [Gould, 2008; CDC, 2009; Lo, 2008] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ Document the education of healthcare personnel involved in the insertion, care, and maintenance of urinary catheters about catheter-associated urinary tract infection (CAUTI) prevention, including alternatives to indwelling catheters and procedures for catheter insertion, management, and removal. [Willson, 2009] Education should occur upon hire and annually thereafter, and when involvement in these procedures is added to an individual's job responsibilities. [Kanouff, 2009] ▪ Prior to insertion of a urinary catheter, educate the patient, and his or her family, as appropriate, about CAUTI prevention. ▪ Identify the patient groups or units on which surveillance should be conducted, using risk assessments that consider frequency of catheter use and potential risk. ▪ Implement policies and practices that are aimed at reducing the risk of CAUTI, that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). [Smith, 2008] Evidence-based practices include, but are not limited to, the following: • Perform hand hygiene immediately before and after catheter insertion and any manipulation of the catheter site or apparatus. [Barford, 2009] • Ensure that the supplies necessary for aseptic technique for catheter insertion are readily available. • Insert catheters following an aseptic technique and using sterile equipment. • Insert urinary catheters only for appropriate indications, and leave them in place only as long as indications remain. • Obtain a urine culture before initiating antimicrobial therapy for urinary tract infection in a patient with a urinary catheter. ▪ Measure compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts for internal performance improvement. ▪ Provide CAUTI surveillance data, including process and outcome measures, to key stakeholders within the organization, including senior hospital leadership, physicians, nursing staff, and other clinicians.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ for all invasive procedures. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory surgical center, emergency room, inpatient service/hospital, and outpatient hospital.	**Specifications of Universal Protocol:** [Angle, 2008; TJC, 2008b] ■ Create and use a preoperative verification process to ensure that relevant preoperative tasks are completed and that information is available and correct. [Haynes, 2009; Henrickson, 2009; HPR, 2009] ■ Mark the surgical site and involve the patient in the marking process, at a minimum, for cases involving right/left distinction, multiple structures (e.g., fingers, toes) or multiple levels (e.g., spinal procedures). [Robinson, 2009] ■ Immediately before the start of any invasive procedure, conduct a "time out" to confirm the correct patient, procedure, site, and any required implants or special equipment. [Dillon, 2008]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 27: Pressure Ulcer Prevention Take actions to prevent pressure ulcers by implementing evidence-based intervention practices. [NQF, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	■ Explicit organizational policies and procedures should be in place about the prevention of pressure ulcers. [IHI, 2009; NPUAP, 2009] ■ Plans are in place for the risk assessment, prevention, and early treatment of pressure ulcers, which address the following: • During patient admission, identify individuals at risk of requiring pressure ulcer prevention using a pressure ulcer risk assessment plan/guide, including a comprehensive skin assessment, to identify the specific risks. [Braden, N.D.; Norton, N.D.] • Document the pressure ulcer risk-assessment and prevention plan as indicated in the patient's record. • Assess and periodically reassess each patient's skin and risk for developing a pressure ulcer, and take action to address any identified risks. [AHRQ, 2009a] • Maintain and improve tissue tolerance to pressure in order to prevent injury. • Protect against the adverse effects of external mechanical forces. • Reduce the incidence of pressure ulcers through staff educational programs. • Perform quarterly prevalence studies to evaluate the effectiveness of the pressure ulcer prevention program, and implement a performance improvement initiative as indicated, including the following elements: – education about the pertinent pressure ulcer frequency and severity; – skill building in the use of pressure ulcer prevention interventions; – implementation of process improvement interventions; – measurement of process or outcomes indicators; and – internal reporting of performance outcomes.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 28: Venous Thromboembolism Prevention Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory surgical center, emergency room, home care, home health services/ agency, inpatient service/ hospital, outpatient hospital, and skilled nursing facility.	▪ Ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established, evidence-based protocols. [NQF, 2006; Geerts, 2008] ▪ Have in place a system for ongoing quality improvement that demonstrates that evidence-based guidelines/practices are acted upon (rationale for departing from guidelines should be documented unless documentation itself is for some reason contraindicated). ▪ Include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment. [Hairon, 2008] ▪ Include appropriate quality improvement activity/monitoring for all phases of care with periodic (as defined by institutional policy) assessment of compliance with policies and measures. ▪ Provide for a system of provider education that encompasses all aspects of venous thromboembolism (VTE) prevention and care, including primary and secondary prevention, risk assessment and stratification, prophylaxis, diagnosis, and treatment. ▪ Provide for the risk assessment of all patients based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified). [Caprini, 2009; Patel, 2009] ▪ Document in the patient's health record that VTE risk assessment/stratification was completed. ▪ Provide and explain to VTE patients or their caregivers, at the patient-appropriate reading and health literacy level, written discharge instructions, or other educational material, addressing all of the following: 1) follow-up/monitoring; 2) compliance issues; 3) dietary restrictions; 4) potential for adverse drug reactions/ interactions; and 5) VTE prophylaxis issues related to that patient.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 29: Anticoagulation Therapy Organizations should implement practices to prevent patient harm due to anticoagulant therapy. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ The organization implements a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulant therapy, and the patient's medication plan is documented in the medication record. [Robert-Ebadi, 2009] ▪ Clinical pharmacy medication review is conducted to ensure safe anticoagulant selection and avoidance of drug-drug interactions. ▪ To reduce compounding and labeling errors, the organization uses only oral unit-dose products, prefilled syringes, or premixed infusion bags, when these types of products are available. ▪ The organization uses approved, standardized protocols for the initiation and maintenance of anticoagulation therapy that is appropriate to the medication used, the condition being treated, and the potential for medication interactions. [Airee, 2009] ▪ For patients starting on warfarin, a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust therapy. [Merli, 2009] ▪ When dietary services are provided by the hospital, the service is notified of all patients receiving warfarin and responds according to its established food/medication interaction program. ▪ When heparin is administered intravenously and continuously, the hospital uses programmable infusion pumps in order to provide consistent and accurate dosing. ▪ The organization has a written policy that addresses baseline and ongoing laboratory tests that are required for heparin and low molecular weight heparin therapies. ▪ The organization provides education on anticoagulation therapy to prescribers, staff, patients, and families. ▪ The organization evaluates its anticoagulation safety practices, takes appropriate action to improve its practices, and measures the effectiveness of those actions on a regular basis. [Zhan, 2008]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 30: Contrast Media-Induced Renal Failure Prevention Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and gadolinium-associated nephrogenic systemic fibrosis, and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient's risk evaluations. [Ellis, 2009] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory surgical center, inpatient service/hospital, and outpatient hospital.	▪ Use evidence-based protocols, developed by a multidisciplinary team that includes a pharmacist and that are approved by the medical staff, for the prevention of contrast media-induced nephropathy (ensure frequent updates based on the rapid evolution of contrast agents and forthcoming national guidelines). [Reddan, 2009] ▪ Monitor and document the use of evidence-based protocols (include variance and rationale for departing from protocol). ▪ Document provider education that encompasses all aspects of contrast media-induced nephropathy prevention and care. ▪ Specify the qualifications for staff who are authorized to initiate protocols for imaging that include contrast media, and screen patients at risk for contrast media-induced nephropathy. ▪ Perform risk assessments on all patients that are based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified). ▪ Ensure that there is documentation by a licensed clinician placed in the patient's health record that risk assessment/stratification was completed.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 31: Organ Donation Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specify the roles and desired outcomes for every stage of the donation process. [DHHS, 2005] **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include inpatient service/ hospital.	**Key organ donation effective practice strategies:** ■ Hospitals and organ procurement organizations (OPOs) maintain a focus on joint accountability and intent for implementing highly effective organ donation programs on behalf of donors, donor families, and patients with end-stage organ failure in need of transplantation. [Antommaria, 2009] ■ Key hospital and OPO donation staff are linked rapidly and early to support and assist potential donor families and to implement donor evaluation, organ optimization, organ placement, and organ procurement procedures. [Rudow, 2009] ■ Hospitals and OPOs establish and manage an integrated donation process that clearly defines roles and responsibilities; focuses on the needs of donors, donor families, and transplant candidates; and provides feedback about results. ■ Hospitals and OPOs build and sustain a network of quick response and collaborative relationships among the donor family, the hospital staff, the OPO staff, medical examiners/coroners, transplant physicians and surgeons, and the transplant program staff. ■ Every organ donation opportunity is highly valued and is routinely evaluated through death record reviews, quick deployment, re-approaches, and organ optimization to ensure that every suitable organ can be transplanted and that the end-of-life intentions of the donor and donor family have been honored. [Iltis, 2009] ■ Hospital-specific organ donation performance outcomes are published by the Scientific Registry of Transplant Recipients at www.ustransplant.org. [Scientific Registry, 2008] ■ The hospital addresses the wishes of the patient, or surrogate decisionmaker, regarding donation by incorporating processes and staff education that focus on the following: • Donor identification and referral are implemented using processes jointly developed by hospital and OPO experts. [Shafer, 2006] • Donation consent discussions are informed by previously registered donation intentions and conducted by experienced healthcare team members that are jointly identified by hospital and OPO representatives. [DHHS, 2005]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 31: Organ Donation Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specify the roles and desired outcomes for every stage of the donation process. *(continued)*	• Organ function optimization protocols are developed and jointly implemented by hospital and OPO experts and are evidence based. [Wood, 2004; DHHS, 2005] • The donation process is documented by the hospital, beginning with donor identification and concluding with the operative procedure to retrieve donated organs. • Continuous quality improvement methods are utilized to evaluate the effectiveness of donation protocols. Outcomes are benchmarked against national goals and those of other similar organizations. [IOM, 2006]

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 32: Glycemic Control Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include inpatient service/hospital.	**Essential elements of improving glycemic control:** [ADA, 2008; Moghissi, 2009; TJC, N.D.] ■ A multidisciplinary team is established that is empowered to develop and guide processes for improving glycemic control for patients. This team should be charged with assessing and monitoring the quality of glycemic management within the organization. Members of this team should include all key stakeholders. ■ Organizations systematically track glucose data and medication error or near miss reports to assess the quality of care delivered and share this data with senior leadership and frontline clinicians. ■ Evidence-based protocols and order sets are developed to guide the management of hyperglycemia and hypoglycemia throughout the organization. Specifically, written protocols are developed for the management of patients on intravenous insulin infusions. ■ Patient medications are reconciled appropriately, including, upon discharge, restarting prehospital antiglycemic agents when appropriate. ■ Patients with newly diagnosed diabetes or educational deficits have at least the following educational components reflected in their plan of care: • Medication management, including how to administer insulin (when appropriate) and potential medication interactions. • Nutritional management, including the role of carbohydrate intake in blood glucose management. • Exercise. • Signs, symptoms, and treatment of hyperglycemia and hypoglycemia. • Importance of blood glucose monitoring and how to obtain a blood glucose meter. • Instruction on the use of a blood glucose meter if available. • Sick-day guidelines. • Information for whom to contact in case of emergency or for more information. • A plan for postdischarge education or self-management support.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 33: Falls Prevention Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	▪ The hospital or healthcare organization must establish a fall reduction program. ▪ The fall reduction program includes an evaluation appropriate to the patient population, settings, and services provided. ▪ An organization may consider individual patient assessments for what the organization deems to be the high-risk groups in its patient population. ▪ The fall reduction program includes interventions to reduce the patient's fall risk factors. ▪ Staff receive education and training about the fall reduction program. Education occurs upon hire and annually thereafter. [Dempsey, 2009] ▪ The patient, and family as needed, is educated about the fall reduction program and any individualized fall reduction strategies. ▪ The organization evaluates the fall reduction program to determine its effectiveness.

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Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 34: Pediatric Imaging When CT imaging studies are undertaken on children, "child-size" techniques should be used to reduce unnecessary exposure to ionizing radiation. **Applicable Clinical Care Settings** This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, inpatient service/ hospital, and outpatient hospital.	Organizations should establish a systematic approach to regularly updating protocols for computed tomography (CT) imaging of children. Four simple steps should be undertaken by imaging team members to improve patient care in the everyday practice of radiology: [Goske, 2008] ▪ Scan only when necessary. This provides an opportunity to discuss the benefits of the CT exam as well as the potential risks with the child's pediatrician or other healthcare provider, who has unique medical knowledge critical to the care of the patient. Commit to making a change in daily practice by working as a team with technologists, medical physicists, referring doctors, and parents to decrease the radiation dose. ▪ Reduce or "child-size" the amount of radiation used. This can be accomplished by contacting a medical physicist to determine the baseline radiation dose for an adult for CT equipment and comparing that dose with the maximum recommended by the American College of Radiology's (ACR's) CT Accreditation Program. If the doses are higher than those suggested, reduce the technique for adult patients. Use evidence-based protocols for children. Refer to the Image Gently™ website (www.image gently.org), and view the protocols provided for children. [Strauss, 2009] These protocols are independent of equipment manufacturer, age of machine, or number of detectors. Although an institution or site may wish to lower scan technique even more, these protocols provide a starting point for making this important change. Work with radiologic technologists to implement the protocols. These professionals control the critical "last step" before a scan is obtained. [Singh, 2009] ▪ Scan only the indicated area required to obtain the necessary information. Protocols in children should be individualized. Be involved with patients. Ask the questions required to ensure that the scan is "child-sized." Decisions about shielding those radiosensitive areas (such as reproductive organs) outside of the scan range or those within the scan field (in-plane shielding) should be based on discussion with a qualified physicist and should incorporate local and national standards of practice. ▪ Scan once; single-phase scans are usually adequate in children. Pre- and postcontrast and delayed CT scans rarely add additional information in children, yet can double or triple the radiation dose to the child. Consider removing multiphase protocols from routine practice.

Practices Recommended for Further Research

A number of practices, both those endorsed in the 2006 and 2009 sets and among those evaluated with this set, met the threshold criterion of specificity but failed to meet one or more of the additional criteria. The list of practices recommended for further research centers on the acute-care setting and is not all-inclusive (see Table 2), but it does include items that could improve patient safety in the near term. Therefore, they should be given high priority for additional research before they are recommended for universal implementation.

Patient safety research should include, in addition to the specific items recommended in Table 2, investigation of the following:

- methods to ascertain the success of implementation of the safe practices; and
- new, unintended concerns that may arise from the use of safe practices.

Because many strategies and performance measures for evaluating and auditing the degree of use of a practice in a healthcare institution are available and included in this report, the practice titled "the development of tools to evaluate the success of implementation" was removed from the research list; however, such research is always useful both in refining measures currently available and promulgating others.

Table 2: Practices Recommended for Further Research

Research to Demonstrate Effectiveness

A. The implementation of a falls reduction program and the effectiveness of such a program.
B. The use of machine-readable patient identification systems to replace conventional wristbands in order to reduce patient identification errors.*
C. The use of hand-held electronic prescribing devices to reduce medication errors.
D. The application of strategies to inform patients of clinically significant abnormal or questionably abnormal test results.*
E. The use of computerized reminders to improve primary care provider compliance with patient notification of abnormal results.*
F. The use of computerized prescriber order entry (CPOE) compared with verbal orders to reduce transcription errors.
G. The use of training programs to reduce fatigue-related preventable adverse events.*
H. The use of simulator-based training to reduce errors.*
I. The encouragement of each adult to designate a healthcare advocate; this is a person who 1) knows the patient's medical history and treatment preferences; 2) can speak for the patient when he or she is not able to speak for himself; and 3) can otherwise help ensure that the patient understands his or her treatment and thus receives appropriate treatment.
J. The use of Rapid Response Teams/Systems for critical events, such as the early recognition of shock in nontrauma patients, and the rapid resuscitation of those patients.

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Table 2: Practices Recommended for Further Research

K. The development of safeguards to prevent adverse events associated with organ donation.

L. The provision of appropriately sized equipment/furniture for the care of all patients.

M. The use of standardized protocols to prevent infection in flexible endoscopy.

Research to Demonstrate the Likely Benefit of Implementing the Safe Practice
(how much the practice would reduce morbidity and mortality if universally implemented)

N. The use of antibiotic-impregnated catheters (e.g., coated with minocycline and rifampin) instead of standard, noncoated catheters.*

O. The use of multidisciplinary teams (i.e., geriatrician, clinical nurse specialist, social worker, and specialists from such fields as occupational and physical therapy, nutrition, pharmacy, audiology, and psychology) in a dedicated geriatric unit.*

P. The use of specially designed endotracheal tubes for the continuous aspiration of subglottic secretions.*

Q. Safe care of the surgical patient: The use of perioperative oxygen supplementation and normothermia to reduce infection rates. The use of standardized protocols to prevent surgical fires.

R. The implementation of comprehensive pain management to prevent medication errors and unnecessary patient suffering.

Research to Improve Existing Safe Practices

S. The utilization of high-volume referrals in rural settings for patients scheduled for high-risk, elective procedures or treatments.

T. The readiness of utilizing intensivists (who have specific training caring for the critically ill and who are board certified in critical care medicine) in rural settings to manage all patients in adult general medical and surgical intensive care units.

U. The identification and application of practices to improve patient safety for vulnerable populations.

V. The best practices that lead to the absolute preventability of healthcare-associated infections.

Research to Develop Strategies for Implementation, Assess Their Effectiveness, and Evaluate the Degree of Utilization

W. The development of institutional incentives to implement the safe practices.

X. The development of strategies to involve consumers in the implementation of safe practices.

Y. The development of tools to determine which implementation strategy is most effective in achieving the universal implementation of a practice.

Z. The implementation of a reliable continuum of care for patients.

*Practices recommended for further research that are included in NQF's 2010 publication *Safe Practices for Better Healthcare* were derived from a report commissioned by the Agency for Healthcare Research and Quality and conducted by the Evidence-based Practice Center at the University of California San Francisco-Stanford University, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. The report is available at http://www.ahrq.gov/clinic/tp/ptsaftp.htm. Last accessed December 17, 2009.

Additional Recommendations

NQF recommends that specific action should be undertaken in three areas: dissemination and implementation, measuring implementation, and updating and improving the set.

- **Dissemination and Implementation**
  NQF Members should continue to be lead agents for disseminating and implementing these practices. The impact of the safe practices will depend on the broad array of NQF Members and others who build upon, coordinate, and systematically implement the practices within the context of their many quality improvement activities.
- **Measuring Implementation**
  Successfully understanding and expanding the implementation of the safe practices rests on appreciating their value in the process of improving quality and safety in healthcare. A number of organizations have set goals to implement all of the practices, and a few have accomplished this goal. This set provides an array of strategies and tools to measure both implementation and its success. Nonetheless, it remains imperative that measures continue to be developed and refined to help in assessing practice implementation and the related improvements in quality and safety. Although a provider may be using some or all of the practices and may be seeing tangible improvement, this may not be apparent to other stakeholders, such as consumers, purchasers, and other providers whose patients could benefit from the practices. To assist providers with internal quality improvement and to facilitate consumer and purchaser choice, measures should continue to be developed, refined, and used for assessing and reporting the use of these safe practices.
- **Updating and Improving the Set**
  As biomedical knowledge, diagnostic and treatment technology, and healthcare practices change, patient safety concerns and safe practices change as well. To promote stability and consistency in implementation, the 2003 set of safe practices remained unchanged for more than two years. The 2006 update marked the beginning of on ongoing cycle of review and updating that should reflect the changes that are occurring in the larger arena of quality and safety improvement. Future efforts will continue to focus on the state of the evidence; practices identified for further research that meet the criteria for inclusion in the set; and the evolution of new technologies that both enable and endanger the safety and quality of healthcare. This 2010 update contains changes to the 2009 new practices to further clarify their intent and to reflect the rapidly evolving research and increased national priority of patient safety. All healthcare organizations should continue to monitor the evolving literature regarding the safe practices and new standards established by federal and regulatory agencies. Products, services, and technologies used in conjunction with the safe practices should be in compliance with approved product indications for use.

Chapter 2: Improving Patient Safety by Creating and Sustaining a Culture of Safety

Background

AS THE DECADE CLOSES, there is universal agreement that dramatic transformation will be required to make healthcare safe and financially sustainable in the United States. There is also the uniform belief that the responsibility for such transformation lies squarely on the shoulders of healthcare leaders. Leaders from suppliers of technologies and services, to providers of care, and purchasers of care across the healthcare value chain must all move to priorities. A move from a revenue-centered focus to a patient-centered focus with responsible stewardship of resources is important. Blind cost-cutting will only make healthcare increasingly unsafe. Proper and thoughtful investment of financial and talent resources will be required to maintain the sacred trust of patients and communities served. Governance, administrative, and clinical leaders must all act independently and collectively on teams in their local communities.

The practice of modern healthcare encompasses an exceedingly complex set of activities, one that is highly dependent on the actions of human beings and that combines a variety of sophisticated technologies that are capable of both healing and causing significant harm. This combination of complex processes, dependence on human performance, and powerful technologies makes healthcare a high-risk and error-prone enterprise fraught with the potential for multisystems failures. Yet although the serious problem of healthcare errors has been increasingly recognized over the past 50 years, healthcare as an industry has been slow to address safety improvement as a priority. Indeed, compared to other high-risk industries, healthcare's approach to safety can be described as lackluster, at best. In fact, only modest progress has been made since the Institute of Medicine's (IOM's) report *To Err Is Human* was published in 2000.

A number of barriers impede the improvement of the safety of healthcare, including both the medical and larger societal culture that perpetuate the myth that "good" healthcare professionals will perform perfectly and, conversely, that adverse events are caused by

carelessness, negligence, or incompetence. Other barriers include medical-legal and liability concerns that stifle open communication about safety problems and data sharing; a lack of awareness of the prevalence of healthcare errors and adverse events; a lack of effective reporting systems; a lack of systems thinking and knowledge about the systemic nature of healthcare errors; and a lack of leadership with respect to safety.

In most settings today, the high-risk, error-prone nature of modern healthcare and the shared responsibility for risk reduction are not widely recognized. Free and open communication and nonpunitive reporting of adverse events and patient safety concerns are not the norm, and organizational objectives and rewards are not clearly aligned with the goal of improving patient safety. To address these issues, there is a need to promote a culture of safety in all healthcare settings—a safety-conscious culture demonstrating the values, attitudes, competencies, and behaviors that determine the commitment to health and safety management. Additionally, such a culture overtly encourages and supports the reporting of any situation or circumstance that threatens, or potentially threatens, the safety of patients, caregivers, healthcare personnel, or visitors and views the occurrence of errors and adverse events as opportunities to make the healthcare system better.

Dispelling any magical thinking that safety is an easy fix through technology acquisition is critical to recognize. Without reorganization of workflow to adopt technologies safely, these new technologies can be even more dangerous than existing care delivery.

This chapter describes the four safe practices involved in creating and sustaining a patient safety culture, which involve leadership structures and systems; culture measurement, feedback, and intervention; teamwork training and skill building; and the identification and mitigation of risks and hazards.

Leaders drive values, values drive behaviors, and the collective behaviors of the individuals in an organization define its culture. Leaders must be involved in creating the transformational change that is required to develop and sustain a culture of safety, and leadership structures and systems should be established and maintained to ensure that engagement. In the end, results are all about meshing strategies with execution of tactics targeting line-of-sight objectives that, in sequence, can achieve the preferred destination. This requires a cadence of accountability and a continuous rhythm of leadership engagement —from the top down. Midlevel managers and front-line leaders are a vital link.

Although the manifestations of culture can be measured, measurement by itself is not enough. It must be coupled with feedback systems and performance improvement activities that can inspire the entire organization. Culture measurement is vital to front-line clinicians and staff when the results are provided with specificity to the unit level. Likewise, although teamwork is central to transformational culture change, more than teamwork training is needed. Skill building, team-centered interventions, and projects that have finite patient safety aims are required.

Finally, the identification of risks and hazards should be undertaken with an integrated, systematic, and regular reporting approach to historical events, near real-time assessment of risks, and prospective evaluation of risk in order to prevent future systems failures. Although the focus of these and subsequent safe practices is patient safety, the safety of others in the healthcare setting is also important and should be addressed within an organization's overall safety program. These four safe practices were originally elements of one practice in the 2006 update, were enhanced for the 2009 update, and references as well as implementation information have been updated for 2010. They continue to be enhanced to emphasize accountability and ease of implementation for leaders within healthcare organizations.

SAFE PRACTICE 1: CULTURE OF SAFETY LEADERSHIP STRUCTURES AND SYSTEMS

The Objective

Ensure that healthcare organizations establish and nurture the leadership structures and systems that drive the values, behaviors, and performance necessary to create and sustain a healthcare culture of safety.

The Problem

Leadership by trustees, chief executive officers (CEOs), physicians, and other personnel across all departments and services is the single most important factor in turning the barriers to *awareness, accountability, ability,* and *action* into accelerators of performance improvement and transformation. [Govier, 2009; Gowen, 2009] This "4A framework" is embedded in prior National Quality Forum (NQF)-endorsed® safe practices and now in pay-for-performance systems used by healthcare purchasers. [Weiner, 1997; Denham, 2005; NQF, 2007; LFG, 2008]

According to The Joint Commission, leadership failure is one of the most frequent causes of sentinel events. Failure of execution of governance and administrative leadership strategies by midlevel managers is a major component of the problem. [Denham, 2008] Engagement of governance boards in quality and safety directly affects their organizations' performance. Interestingly, a survey of more than 1,000 governance board chairman by Jha and Epstein revealed that 58 percent of those from hospitals in the bottom decile of quality believed that they were above average, and no respondent reported that their performance was worse than that of the typical U.S. hospital. [Jha, 2009] Another survey of hospital and system leaders found that 80 percent of the 562 responding CEOs indicated that their governance boards establish strategic goals for quality improvement [Jiang, 2008] or use quality dashboards to track performance and follow up on corrective actions related to adverse events. [Levinson, 2008] Despite this progress, only 61 percent of responding CEOs indicated that their governance boards have a quality committee. Studies of organizations from all industry sectors reveal that failure in reliability and systems performance stems from inconsistent execution more than from failure of strategy. [Bossidy, 2002] Quality, value, cost, speed, and trust are intrinsically interdependent and tightly coupled. [Covey, 2006; Denham, 2007; Denham, 2009] These business laws must be respected and leveraged by leaders. Successful centers that have been studied are more likely to have a shared sense of purpose, leaders with a hands-on leadership style, and clear accountability structures. [Keroack, 2007; Frankel, 2006]

While the severity of harm resulting from inadequate performance of leadership structures and systems that are driven by a commitment to quality cannot be definitively quantified, chronic failure of consistent execution plagues all industries. Severe shortfalls in performance are seen across organizations throughout the entire healthcare industry. [Denham, 2009c]

Preventability of harm to patients and sustainable transformation to a higher state of reliability is directly related to governance board engagement and administrative execution. [Govier, 2009; Gowen, 2009] For instance, having a governance board quality committee was associated with lower mortality rates for six common medical conditions measured by the Agency for Healthcare Research and Quality's (AHRQ's) Inpatient Quality Indicators and State Inpatient Data-bases.

[Jiang, 2008] Quality leaders have found that hospital boards are more successful when they set specific aims to reduce harm and make a public commitment to measurable quality improvement. [Wang, 2006; Conway, 2008; Jha, 2009]

Successful boards and administrators use actionable information to drive performance. Successful organizations have used performance improvement models that make the status quo uncomfortable and the future attractive by leveraging will, ideas, and execution. [Reinertsen, 2008] They encourage organizational learning by studying and translating best practices from top performers within and outside of healthcare and become skilled at systematic problem-solving, experimenting with new approaches, learning from best practices of others, and transferring knowledge quickly and efficiently throughout the organization. [Garvin, 1993; Garvin, 2008] They leverage financial and quality crises to galvanize the will to improve. [George, 2009]

Costs associated with leadership structures and systems failures and the impact of improvement are difficult to delineate. When adverse events occur, there is significant cost impact on an organization, and costs can be direct, indirect, tangible, and intangible. Costs most frequently cited are those direct costs generated by event management, including malpractice. Intangible and indirect costs can be huge, such as brand erosion, which is expensive and sometimes impossible to reverse. Leaders must insist on investing in infrastructure, and the infrastructure of the healthcare system must be capable of supporting the measurement of progress and the translation of practices into action. [Alexander, 2006; Pronovost, 2008; Denham, 2009d] Measurement is critical. In the words of Don Berwick, leader of one of the most successful patient safety campaigns in the history of U.S. healthcare: "Some is not a number, soon is not a time." [IHI, 2009m]

In 2008, NQF convened the National Priorities Partnership, a diverse group of 28 national organizations representing those who receive, pay for, deliver, and evaluate healthcare. This group expanded to 32 stakeholders in 2009. The Partnership identified six National Priorities that target reform in ways that will eliminate waste, harm, and disparities to create and expand world-class, patient-centered, affordable healthcare. The six National Priorities are:

- patient and family engagement, to provide patient-centered, effective care;
- population health, to bring greater focus on wellness and prevention starting in our communities;
- safety, to improve reliability and eliminate errors wherever and whenever possible;
- care coordination, to provide patient-centered, high-value care;
- palliative and end-of-life care, to guarantee appropriate and compassionate care for patients with advanced illnesses; and
- overuse, to remove waste, encourage appropriate use, and achieve effective, affordable care. [NPP, 2009]

Without the engagement of governance and administrative leaders, these Priorities cannot be tackled.

Leaders must first know about performance gaps before they can commit to adopting an innovative idea or process that will address them. Unfortunately, few leaders are fully *aware* of the magnitude of the problems that are common to organizations like their own. Fewer still are completely aware of the performance gaps at their specific organization, as found by Jha et al. described above.

[Jha, 2009] These gaps can be identified only by directly measuring them and by communicating the results of such measurement to the appropriate leadership teams. Although initiatives such as pay for performance are causing many to focus on quality as a strategic priority, few leaders are held directly and personally *accountable* for closing specific and measurable patient safety performance gaps. [Conway, 2008; Wang, 2006] However, in order to spur the adoption of needed innovations, leaders must be held accountable for closing these gaps. In addition, organizations should be held accountable to their patients, to their communities, and to the national community through public reporting. Evenleaders who are aware of performance gaps and who are held accountable for those gaps will fail to close them if their organizations do not have the *ability* to adopt new practices and technologies. The dimension of ability may be measured as capacity and competency, and it requires an investment in knowledge, skills, staff time, and line-item budget allocations. Finally, to accelerate the adoption of innovative practices, organizations need to take explicit *actions* toward line-of-sight targets that close performance gaps that can be easily measured.

Leaders drive values, values drive behaviors, and behaviors drive performance. The collective behaviors of an organization define its culture. [Denham, 2007b] Great cultures embody talent, passion, and hard work. [Gladwell, 2008] The adoption of all of the safe practices presented in this report hinges on our leadership. Fear is an enemy that never sleeps: fear of failure, fear of malpractice, and even fear of admitting that organizations can do better. Through faith in core values, leaders can use the safe practices as a blueprint for their road ahead.

Safe Practice Statement

Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served.

Additional Specifications

Awareness Structures and Systems: Structures and systems should be in place to provide a continuous flow of information to leaders from multiple sources about the risks, hazards, and performance gaps that contribute to patient safety issues. [Botwinick, 2006]

- Identification of Risks and Hazards: Governance boards and senior administrative leaders should be regularly and thoroughly briefed on the results of activities undertaken as defined by the *Identification and Mitigation of Risks and Hazards* safe practice. [Reason, 1997; Botwinick, 2006; Morath, 2006; IHI, 2009i]
- Culture Measurement, Feedback, and Intervention: Governance boards and senior administrative leaders should be regularly and thoroughly briefed on the results of culture measurement and performance improvement initiatives addressed in the *Culture Measurement, Feedback, and Intervention* safe practice. [Botwinick, 2006; Conway, 2008]
- Direct Patient Input: A structure and system should be established to obtain direct feedback from patients about the performance of the organization. Information from

satisfaction surveys is not enough—patients and/or patient families representing the population served should be included in the design of educational meetings or should participate on formal committees that provide input to the leadership on the management of safety and quality issues within the hospital. [Rider, 2002; IHI, 2009]

- Governance Board and Senior Management Briefings/Meetings: Patient safety risks, hazards, and progress toward performance improvement objectives should be addressed at every board meeting and should be documented by meeting agendas and minutes. [IHI, 2009a] Such meetings and documentation systems should ensure that organizational leadership is kept knowledgeable about patient safety issues present within the organization and is continuously involved in processes to ensure that the issues are appropriately addressed and that patient safety is improved. [Conway, 2008]

Accountability Structures and Systems: Structures and systems should be established to ensure that there is direct accountability of the governance board, senior administrative management, midlevel management, physician leaders (independent and employed by the organization), and frontline caregivers to close certain performance gaps and to adopt certain patient safety practices.

- Patient Safety Program: An integrated patient safety program should be implemented throughout the healthcare organization. This program should provide oversight, ensure the alignment of patient safety activities, and provide opportunities for all individuals who work in the organi-zation to be educated and participate in safety and quality initiatives. Leaders should create an environment in which safety and quality issues are openly discussed. A just culture should be fostered in which frontline personnel feel comfortable disclosing errors—including their own—while maintaining professional accountability. [Botwinick, 2006]
- Patient Safety Officer: The organization should appoint or employ a Patient Safety Officer who is the primary point of contact for questions about patient safety and who coordinates patient safety for education and the deployment of system changes. Governance boards and senior administrative leaders should support leaders in patient safety to ensure that there is compliance with the specifications of this safe practice. [Denham, 2007b; Denham, 2009d]
- Direct Organization-Wide Leadership Accountability: Governance and senior management should have direct accountability for safety in the organization, including setting patient safety goals, ensuring that resources are provided to address those goals, and monitoring progress toward their achievement. [Botwinick, 2006; IHI, 2009h]
- The Patient Safety Officer: Should have direct and regular communication with governance leaders and senior administrative management. [Denham, 2007b; Denham, 2009d] Senior administrative leaders and leaders of clinical service lines and units should be held accountable for closing patient safety performance gaps. Performance should be documented using methods such as performance reviews and/or compensation incentives. [Botwinick, 2006]
- Interdisciplinary Patient Safety Committee: Leaders should establish and support an interdisciplinary patient safety improvement committee(s) or equivalent structure(s) that is (are) responsible for creating, implementing, and administering mechanisms to oversee root cause analyses of every appropriate incident and provide feedback to frontline

workers about lessons learned, disclose the organization's progress toward implementing safe practices, and provide professional training and practice in teamwork techniques (e.g., anesthesia crisis management, aviation-style crew resource management, medical team management). [TJC, 2009; JCR, 2010] See the *Identification and Mitigation of Risks and Hazards* and *Teamwork Training and Skill Building* safe practices for detailed specifications. [Botwinick, 2006]

- External Reporting Activities: Organizations should report adverse events to the appropriate external mandatory programs and voluntary programs as well as encourage voluntary practitioner reporting. Organizations should publicly disclose compliance with all National Quality Forum-endorsed® safe practices for public reporting that are applicable to the facility. [Kohn, 2000]

Structures- and Systems-Driving Ability: Capacity, resources, and competency are critical to the ability of organizations to implement changes in their culture and in patient safety performance. Systematic and regular assessment of resource allocations to key systems should be undertaken to ensure performance in patient safety. On a regular, periodic basis determined by the organization, governance boards and senior administrative leaders should assess each of the following areas for the adequacy of funding and should document the actions taken to adjust resource allocations to ensure that patient safety is adequately funded: [IHI, 2009f; TJC, 2009; JCR, 2010]

- Patient Safety Budgets: Specific budget allocations for initiatives that drive patient safety should be evaluated by governance boards and senior administrative leaders. Such evaluations should include the detailed context of information from the activities defined in the *Identification and Mitigation of Risks and Hazards* safe practice. Designating a Patient Safety Officer or someone in charge of patient safety without providing the appropriate staffing infrastructure or budget is an example of inadequate resource allocation.
- People Systems: Human resource issues should be addressed with direct input from the activities included in the *Identification and Mitigation of Risks and Hazards* safe practice, as well as those included in Safe Practices 9 and 10 relating to nurse staffing and direct caregiver staffing levels, competency, and training/orientation. [Denham, 2009d; IHI, 2009c]
- Quality Systems: Quality systems and structures such as performance improvement programs and quality departments should be adequately funded, actively managed, and regularly evaluated for effectiveness and resource needs. [IHI, 2009g]
- Technology Systems: Budgets for technologies that can enable safe practices should be regularly evaluated to ensure that patient safety impact can be optimized. [IHI, 2009g]

Action Structures and Systems: Structures and systems should be put in place to ensure that leaders take direct and specific actions, including those defined below.

- Performance Improvement Programs: Leaders should document the actions taken to verify that the remedial activities that are identified through the analysis of reported patient safety events are implemented, are effective, and do not cause unintended adverse consequences. Leaders should

establish patient safety priorities for performance improvement. The direct participation of governance board members and senior administrative leaders should be documented, as specified in the *Identification and Mitigation of Risks and Hazards* safe practice, to satisfy this requirement. [IHI, 2009k]

- Regular Actions of Governance:
  - Confirmation of Values: Governance leaders should regularly confirm that senior administrative leadership is continuously ensuring that the values of the organization are mirrored by the behaviors of the staff and caregivers and that those values drive safety and performance improvement in the organization. At least annually, the board should document that it has confirmed that the behaviors of the organization related to quality and safety mirror its values with respect to patient safety. [IHI, 2009d; IHI, 2009e; TJC, 2009; JCR, 2010]
  - Basic Teamwork Training and Interventions Briefings: Governance board members should receive a dedicated period of basic training in teamwork, communication, and patient safety per board member per year as determined by the board and as documented by agendas and attendance records.
  - Governance Board Competency in Patient Safety: The governance board should take a systematic approach to ensuring that board members' command of patient safety knowledge is adequate to support the organization. At least annually, the board should discuss its own competency and document its strategy for ensuring that all existing and new board members are well versed in patient safety. [IHI, 2008]
- Regular Actions of Senior Administrative Leadership: The actions of the CEO and senior leaders have a critical impact on the safety of every organization. Such actions should be informed, monitored, and directed by an engaged governance leadership on a regular basis. [IHI, 2008]
  - Time Commitment to Patient Safety: The CEO and senior administrative leaders should systematically designate a certain amount of time for patient safety activities (e.g., weekly walk-rounds and regular patient safety-related sessions at executive staff and governance meetings). Leaders should establish structures and systems to ensure that they are personally reinforcing the principles of patient safety regularly and continuously to staff at all levels of the organization. They should provide feedback to frontline healthcare providers about lessons learned regarding patient safety from outside sources and from within the organization.
  - Culture Measurement, Feedback, and Interventions: The CEO and senior administrative leaders should be directly involved in the application of the knowledge that is generated by the measurement of culture as defined in the specifications of the *Culture Measurement, Feedback, and Intervention* safe practice.
  - Basic Teamwork Training and Team Interventions: The CEO and senior administrative leaders should be directly involved in ensuring that the organization implements the activities detailed in the specifications of the *Teamwork Training and Skill Building* safe practice. This includes participating in the defined basic training program.

- Identification and Mitigation of Risks and Hazards: The CEO and senior administrative leaders should be continuously engaged in the activities addressed in the specifications of the *Identification and Mitigation of Risks and Hazards* safe practice. The actions taken to mitigate risks and hazards must be championed by senior administrative leaders with the support of the governance board. Such actions are vital to creating and sustaining a culture of patient safety.

- Regular Actions of Unit, Service Line, Departmental, and Midlevel Management Leaders: The entire leadership structure of an organization should be fully engaged in the patient safety activities addressed in *Safe Practice 1: Leadership Structures and Systems.* Leaders at all levels and in all clinical areas, including employed clinicians, should be continuously and actively engaged in the pursuit of patient safety. The CEO and senior administrative management should ensure that all leaders have the opportunity to lead and support patient safety activities.
- Regular Actions with Respect to Independent Medical Leaders: Governance and senior administrative leaders should establish the systems and structures needed to ensure that medical leaders in independent practice as well as those employed by the organization have regular and frequent opportunities to provide direct input to patient safety programs.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

Governance boards and senior administrative leaders should be briefed on all practice elements of Chapter 2, which includes Safe Practices 1 through 4, to understand how tightly linked they are and how many of the activities overlap. Then a systematic strategy should be employed to establish the systems, structures, and resource requirements for implementation. Governance boards and senior administrative leaders should become personally involved in patient safety to comply with the practices that will constitute the first step in transforming the culture of the organization. [Denham, 2009c; Denham, 2009d; Kanter, 2009]

- There is consensus among leaders from quality, certifying, and purchasing organizations that traditional infection control departments and structures are failing to deliver the prevention of infections we know is possible. Governance and administrative leaders should consider a "chasing zero" approach and can use the framework of this practice to integrate performance improvement infection control and management of real risk beyond malpractice claims. This will require new structures and systems. [Denham, 2009a; Denham, 2009b] They not only include restructuring how people work together, but also by using evolving health information technologies. [Denham, 2009b; Denham, 2009e]
- The power of stories can be used as a vehicle to communicate the critical concepts of medical errors and harm data. Stories bring life to cold statistics of harm that can ignite passion and prompt action. [Denham, 2009e, Denning, 2005] Great leaders can use storytelling to engage the heart and the

mind, so that they can put the hands to work. Leading organizations use stories of their own patients who have been harmed in their care. Safety leaders have used stories that embed safety principles with great utility [Nance, 2008], and even videos of stories from other hospitals have been found to galvanize resolve of leaders to pursue major objectives that have led to their success. [Pryor, 2007; Pryor, 2008; TMIT, N.D.] Success stories sustain missions and refresh resolve. [George, 2003]

Strategies of Progressive Organizations

- Some organizations have declared that governance board members will spend equal time on financial issues and quality/safety issues in their meetings and activities. Others have established an external multi-disciplinary committee that includes external experts and patients and that reviews all incidents. Certain organizations have taken entire leadership teams and much of their staff through training in other industries and in other countries to learn leadership and performance improvement methods.
- High-performing organizations understand three critical issues, described in the literature, that impact execution:
  - Execution is integral to strategy, it is a major responsibility of the leader, and it is core to the organization's culture, behavior, and reward system. If the strategy is not achievable—that is, not mapped to skills, resources, and assets of the organization—success is unlikely. [Kanter, 1983]
  - The leader must be engaged in the execution of the strategy to adjust goals and priorities or make available additional resources to overcome barriers in a timely manner. [Nance, 2008]
  - The leader has a direct impact on the behaviors of the employees, by joining in the execution of the strategy and clarifying the expected results and aligning the rewards system. The leader must ensure the right person for the right role, and with execution as part of the expected behavior, it becomes part the culture. [Collins, 2001; Bossidy, 2002; Covey, 2006; Gladwell, 2008; IHI, 2009]

Opportunities for Patient and Family Involvement

- Create an environment that supports patient safety by listening to patients and families.
- Include patients and/or family members on boards of governance and on executive walk-rounds. [NPP, 2009]
- Some organizations may even consider including patients and families in root cause analyses, both for cases they are directly involved in and for cases of other patients, to ensure that there is accountability to the community.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts, and may not necessarily address all external reporting needs. This safe practice will affect systems across the organization; thus, the list of impact metrics is long and will grow over time. Some of the metrics for this safe practice are listed below as examples. The force of transparency will drive public reporting of many of them.

- **Outcome Measures** include improved discrete clinical practices and processes, as well as the absence of systems failures; improved operational and financial outcomes; and improved workforce-related benefits.
- **Process Measures** include compliance with the defined specifications of this safe practice, including documentation of activities such as meetings, assessments, and actions taken.
- **Structure Measures** include actions such as the appointment of a patient safety officer or other designated person for such responsibilities, and the creation of multidisciplinary committees, standing meetings, and frameworks that ensure that the activities defined in the safe practice specifications are accomplished.
- **Patient-Centered Measures** include (but are not limited to) feedback from patients through satisfaction surveys, and direct input from patients and families to senior administrative management about the dimensions of patient-centered care, such as how well the organization:
  - respects patients' values, preferences, and expressed needs;
  - succeeds at fostering continual collaboration, coordination, and integration of care among providers and across conditions and settings;
  - makes care information accessible and customized to the patient;
  - fosters good communication and education, including self-efficacy and self-management skills for patients and families, and provides easy access to decision support tools;
  - prioritizes the physical comfort of patients;
  - provides emotional support and the relief of fear and anxiety for patients;
  - involves family and friends in care; and
  - ensures access to care.

Settings of Care Considerations

- **Rural Healthcare Settings:** All rural healthcare settings should comply with the relevant specifications of this safe practice. Although small, rural organizations may have more resource constraints than larger urban or suburban organizations, great efficiencies can be realized by participating in the national safety and quality collaborative initiatives of similar organizations. Alliances with these organizations in noncompetitive service areas provide significant opportunities for sharing information and identifying resources.
- **Children's Healthcare Settings:** All children's healthcare settings should comply with the relevant specifications of this safe practice. Some of the most progressive work in patient safety, leadership structures and systems, and disclosure can be found in these settings.
- **Specialty Healthcare Settings:** All specialty healthcare settings should comply with the relevant specifications of this practice. National alliances and collaborative initiatives provide rich opportunities to realize efficiencies in information and resource sharing.

New Horizons and Areas for Research

That leadership is critical to patient safety is clear to academics, frontline caregivers, and patients. Leaders should become aware of the performance gaps that can harm patients;

should be held accountable for taking actions that will close those gaps; should invest in the ability of their organizations to improve in these areas; and should clearly understand how they can create an environment in which explicit actions affecting patient safety will become a priority. More research is needed to help design the structures and systems that must be established to support leaders. Research in the development of the necessary concepts, tools, and resources should be undertaken, including efforts that focus on the application of concepts in high reliability, [Hines; 2008] tools such as performance dashboards, and resources such as educational programs for governance board members and leadership teams, and near-real-time risk management support. The World Health Organization's (WHO) 19-item checklist for surgical patient safety has been estimated to save one in 144 surgical patients' lives. [Haynes, 2009] Although further research is needed to validate other system checklists and composite activities that reduce harm to patients, it is critical that even non-clinical governance and administrative leaders become aware of such powerful tools. [Gawande, 2009] Finally, governance, administrative, and clinical leaders must recognize the critical need for investment in midlevel and upper administrative management who are in desperate need of skills and knowledge in order to fulfill their roles in translating vision and strategy into action and results. They need training in people skills of talent recruitment and management, applied leadership skills to practically move their troops to new destinations, healthcare systems knowledge to know how their silo activities help or hurt organizational performance, and performance improvement know-how. The future will be owned by those who improve at improving.

Other Relevant Safe Practices

All NQF safe practices are influenced by the safe practice of Leadership Structures and Systems.

Notes

Alexander, 2006: Alexander JA, Weiner BJ, Shortell SM, et al. The role of organizational infrastructure in implementation of hospitals' quality improvement. Hosp Top 2006 Winter;84(1):11-20.

Bossidy, 2002: Bossidy L, Charan R. Execution: The Discipline of Getting Things Done. New York (NY): Crown Business; 2002.

Botwinick, 2006: Botwinick L, Bisognano M, Haraden C. Leadership Guide to Patient Safety. IHI Innovation Series white paper. Cambridge (MA): Institute for Healthcare Improvement; 2006. Available at www.ihi.org/NR/rdonlyres/69FB6E98-B3C8-470D-80C3-8E8038560AB4/0/IHILeadershipGuidetoPtSafetyWhitePaper2006.pdf. Last accessed October 15, 2009.

Collins, 2001: Collins J. Level 5 Leadership: The Triumph of Humility and Fierce Resolve. Harv Bus Rev 2001 Jan;79(1):66-76, 175.

Conway, 2008: Conway J. Getting boards on board: engaging governing boards in quality and safety. Jt Comm J Qual Patient Saf 2008 Apr;34(4):214-20.

Covey, 2006: Covey SMR, Merrill RR. The SPEED of Trust: The One Thing That Changes Everything. New York (NY): Free Press; 2006.

Denham, 2005: Denham CR. Patient safety practices: leaders can turn barriers into accelerators. J Patient Saf 2005 Mar;1(1):41-55.

Denham, 2007a: Denham CR. TRUST: The five rights of the second victim. J Patient Saf 2007 Jun;3(2):107-19.

Denham, 2007b: Denham CR. Values genetics: who are the real smartest guys in the room? J Patient Saf 2007 Dec;3(4):214-26.

Denham, 2008: Denham CR. CEOs: May I have the envelope please? J Patient Saf 2008 June ;4(2):119-23.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: Can Reality Meet the Rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: Making Idealized Design a Reality. J Patient Saf 2009 Dec;5(4):210-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Denham, 2009d: Denham CR. The no outcome no income tsunami is here. Are you a surfer, swimmer or sinker? J Patient Saf 2009 Mar;5(1):42-52.

Denham, 2009e: Denham CR. Are you infected? J Patient Saf 2009 Sept;5(3):188-196.

Denning, 2005: Denning S. The Leader's Guide to Storytelling: Mastering the Art and Discipline of Business Narrative. San Francisco (CA): Jossey-Bass; 2005.

DFCI, 2009: Dana-Farber Cancer Institute. Patient- and Family-Centered Care. Available at http://www.dana-farber.org/pat/pfac/establishing-patient-centered-care.html. Last accessed December 10, 2009.

Frankel, 2006: Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. Health Serv Res 2006 Aug;41(4 Pt 2):1690-709.

Garvin, 1993: Garvin DA. Building a learning organization. Harv Bus Rev 1993 Jul-Aug;71(4):78-91.

Garvin, 2008: Garvin DA, Edmondson AC, Gino F. Is yours a learning organization? Harv Bus Rev 2008 Mar;86(3):109-16, 134.

Gawande, 2009: Gawande A. The Checklist Manifesto: How To Get Things Right. New York (NY): Metropolitan Books; 2009.

George, 2003: George B. Authentic Leadership: Rediscovering the Secrets to Creating Lasting Value. San Francisco (CA): Jossey-Bass; 2003.

George, 2009: George B. 7 Lessons for Leading in Crisis. San Francisco (CA): Jossey-Bass; 2009.

Gladwell, 2008: Gladwell M. Outliers: The Story of Success. Boston (MA): Little, Brown and Company; 2008.

Govier, 2009: Govier I, Nash S. Examining transformational approaches to effective leadership in healthcare settings. Nurs Times 2009 May 12-18;105(18):24-7.

Gowen, 2009: Gowen CR 3rd, Henagan SC, McFadden KL. Knowledge management as a mediator for the efficacy of transformational leadership and quality management initiatives in U.S. health care. Health Care Manage Rev 2009 Apr-Jun;34(3):129-40.

Haynes, 2009: Haynes HR, Weiser TG, Berry WR, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med 2009;360:491-9. Epub 2009 Jan 14. Available at http://content.nejm.org/cgi/reprint/360/5/491.pdf. Last accessed September 28, 2009.

Hines, 2008: Hines S, Luna K, Lofthus J, et al. Becoming a High Reliability Organization: Operational Advice for Hospital Leaders. (Prepared by the Lewin Group under Contract No. 290-04-0011.) AHRQ Publication No. 08-0022. Rockville (MD): Agency for Healthcare Research and Quality [AHRQ]; 2008 Apr. Available at http://www.ahrq.gov/qual/hroadvice/hroadvice.pdf. Last accessed September 3, 2009.

IHI, 2008: Institute for Healthcare Improvement. Getting Started Kit. Governance Leadership "Boards on Board" How to guide. V3. March 1, 2008. Available at http://www.ihi.org/nr/rdonlyres/95eadb8f-3ad6-4e09-8734-fb7149cfdf14/0/boardhowtoguide.doc. Last accessed September 15, 2009.

IHI, 2009a: [No authors listed.] Execution: Portfolio of Projects. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=3ae157f8-7769-431e-b975-512e4211eaed. Last accessed October 14, 2009.

IHI, 2009b: [No authors listed.] Execution: Reliable Processes. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=7df7152c-e51f-4d25-ab63-6afeaa6b49cf. Last accessed October 14, 2009.

IHI, 2009c: [No authors listed.] Foundation: Build Capability for Execution & Improvement. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=eeec4d58-0c9d-48f8-ba37-9588f5140362. Last accessed October 14, 2009.

IHI, 2009d: [No authors listed.] Foundation: Governance & Improvement. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=a3e67c0e-cdc9-423b-8be1-c2d390de773c. Last accessed October 14, 2009.

IHI, 2009e: [No authors listed.] Foundation: Operating Values. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=12462e64-8045-42cb-a679-2418b10e706c. Last accessed October 14, 2009.

IHI, 2009f: [No authors listed.] Ideas: Innovation & Knowledge Management. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=c8bbf468-fe17-469f-83d3-54001026941b. Last accessed October 14, 2009.

IHI, 2009g: [No authors listed.] Ideas: Scanning. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=fcdb03ca-a268-49f7-9860-b07049ee832c. Last accessed October 14, 2009.

IHI, 2009h: [No authors listed.] Set Direction: Aims. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=df22d619-fd64-45dc-8b6f-97a211427acf. Last accessed October 14, 2009.

IHI, 2009i: [No authors listed.] Set Direction: Alignment and Coordination. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=096a9494-93e3-4708-b575-de26d77b3eb6. Last accessed October 14, 2009.

IHI, 2009j: [No authors listed.] Will: Connect Leaders to the Front Line. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=c5f81ee9-fd82-44b0-aedf-0632e151175b. Last accessed October 14, 2009.

IHI, 2009k: [No authors listed.] Will: Measure, Oversee, & Communicate Transparency. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=77b22769-0a57-4c53-82b0-55c6ce7a85a1. Last accessed October 14, 2009.

IHI, 2009l: [No authors listed.] Will: Patients & Families. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=13ffd8f7-9e9b-4ad0-b2af-dfe192ec66c9. Last accessed October 14, 2009.

IHI, 2009m: Institute for Healthcare Improvement. Protecting 5 Million Lives from Harm. Soon is not a number. Soon is not a time. Available at http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=1. N.D. Last accessed October 15, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards LD.03.03.01; LD.03.02.01; LD.03.01.01; LD.04.04.05; and PI.01.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

Jha, 2009: Jha AK, Epstein AM. Hospital governance and the quality of care. Health Aff (Millwood) 2010 Jan-Feb;29(1):182-7. Epub 2009 Nov 6.

Jiang, 2008: Jiang HJ, Lockee C, Bass K, et al. Board engagement in quality: findings of a survey of hospital and system leaders. J Healthc Manag 2008 Mar-Apr;53(2):121-34; discussion 135.

Kanter, 1983: Kanter RM. Change Masters. New York (NY): Simon & Schuster; 1983.

Kanter, 2009: Kanter RM. SuperCorp: How Vanguard Companies Create Innovation, Profits, Growth, and Social Good. New York (NY): Random House; 2009.

Keroack, 2007: Keroack MA, Youngberg BJ, Cerese JL, et al. Organizational factors associated with high performance in quality and safety in academic medical centers. Acad Med 2007 Dec;82(12):1178-86.

Kohn, 2000: Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000. Available at http://www.nap.edu/catalog.php?record_id=9728. Last accessed November 11, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed October 15, 2009.

LFG, 2008: The Leapfrog Group (LFG). Leapfrog Hospital Survey. 2008. Available at https://leapfrog.medstat.com/(S(zfquka55n0jhe055p2t3xy45))/index.aspx. Last accessed October 15, 2009.

Morath, 2006: Morath JM. Patient safety: a view from the top. Pediatr Clin North Am 2006 Dec;53(6):1053-65.

Nance, 2008: Nance JJ. Why Hospitals Should Fly: The Ultimate Flight Plan to Patient Safety and Quality Care. Bozeman (MT): Second River Healthcare Press; 2008.

NPP, 2009: National Priorities Partnership. National Quality Forum. Available at http://www.nationalprioritiespartnership.org/Home.aspx. Last accessed October 15, 2009.

NQF, 2007: National Quality Forum (NQF). Safe Practices for Better Healthcare – 2006 Update: A Consensus Report. Washington, DC: The National Quality Forum; 2007.

Pronovost, 2008: Pronovost PJ, Rosenstein BJ, Paine L, et al. Paying the piper: investing in infrastructure for patient safety. Jt Comm J Qual Patient Saf 2008 Jun;34(6):342-8.

Pryor, 2007: Pryor D. Stories from the front lines: The clinical Transformation of Ascension Health. TMIT High Performer Workshop Presentation. 2007 Dec 8. Available at http://www.safetyleaders.org/workshop120807/Presentations/davidPryor.pdf. Last accessed Jan. 15, 2010.

Pryor, 2008: Pryor D. The Clinical Transformation of Ascension Health. Presentation at the Institute of Medicine. Meeting 6: Engineering a Learning Healthcare System – A Look at the Future. 2008 Apr 29. Available at http://www.iom.edu/Activities/Quality/EBM/2008-APR-29.aspx. Last accessed December 12, 2009. Direct Link to Presentation available at http://www.iom.edu/~/media/Files/Activity%20Files/Quality/EBM/S3_4PryorPresentation.ashx. Last accessed December 12, 2009.

Reason, 1997: Reason JT. Managing the Risks of Organizational Accidents. Farnham, Surrey (UK): Ashgate Publishing; 1997.

Reinertsen, 2008: Reinertsen JL, Bisognano M, Pugh MD. Seven Leadership Leverage Points for Organization-Level Improvement in Health Care (Second Edition). IHI Innovation Series white paper. Cambridge (MA): Institute for Healthcare Improvement; 2008. Available at http://www.ihi.org/IHI/Results/WhitePapers/SevenLeadershipLeveragePointsWhitePaper.htm. Last accessed October 15, 2009.

Rider, 2002: Rider EA, Perrin JM. Performance profiles: the influence of patient satisfaction data on physicians' practice. Pediatrics 2002 May;109(5):752-7. Available at http://pediatrics.aappublications.org/cgi/reprint/109/5/752. Last accessed October 14, 2009.

TJC, 2009: [No authors listed.] Issue 43: Leadership committed to safety. Sentinel Event Alert. Oakbrook Terrace (IL): The Joint Commission; 2009 Aug 27. Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_43. Last accessed September 3, 2009.

TMIT, N.D.: TMIT. Dr. Sandy Tolchin interview. No date. TMIT website. Available at www.safetyleaders.org. Last accessed December 12, 2009.

Wang, 2006: Wang MC, Hyun JK, Harrison M, et al. Redesigning health systems for quality: Lessons from emerging practices. Jt Comm J Qual Patient Saf 2006 Nov;32(11):599-611.

Weiner, 1997: Weiner BJ, Shortell SM, Alexander J. Promoting clinical involvement in hospital quality improvement efforts: the effects of top management, board, and physician leadership. Health Serv Res 1997 Oct;32(4):491-510. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1070207&blobtype=pdf. Last accessed October 15, 2009.

SAFE PRACTICE 2: CULTURE MEASUREMENT, FEEDBACK, AND INTERVENTION

The Objective

Ensure that organizations are measuring their patient safety culture, providing feedback to all levels of the organization, and, most importantly, undertaking interventions that generate improvements that reduce patient harm.

The Problem

Since achieving its own high-risk designation from the Institute of Medicine (IOM) a decade ago, healthcare has intensified its activities to measure safety culture and to develop interventions to improve it. [Kohn, 2000] While a universal definition or model of safety culture has not emerged, several definitions have gained popularity. One such definition of safety culture is "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to and style and proficiency of an organization's health and safety management." [Health and Safety Commission, 1993] Another definition more succinctly describes safety culture as "the way we do things around here." [Helmreich, 1998] Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures. [Health and Safety Commission, 1993; Denham, 2007] There are no estimates on the frequency of medical errors or adverse events resulting from deficient or suboptimal safety culture, but it is known to be a contributing factor to their occurrences. [Pizzi, 2001] An organization's safety culture determines the degree of personal risk an individual provider will take to protect the safety of his or her patients, thereby maximizing the safety of the unit and hospital. Its contribution to medical errors and adverse outcomes becomes elevated in relation to other factors when the perceived risk of being blamed or punished for mistakes is high. [Denham, 2007]

The severity of harm resulting directly from the effects of poor safety culture is unknown and possibly immeasurable. [Pizzi, 2001] However, history shows us that the consequences of poor safety culture can range from no harm (i.e., safe operations) to death. Safety improvements in aviation and steel production illustrate the positive effects of a strong safety culture on organizational performance. [Clark 1991; Spears, 1999; Helmreich, 1999]

Safety culture and the preventability of medical errors or adverse events are difficult to measure because they change continually over time. Survey instruments may be used to measure safety climate, which has been described as a "snapshot" of an organization's safety culture. Safety climate is the measurement of the workforces' attitudes and perceptions of the current environment or prevailing conditions at a point in time. [Flin, 2000] There are numerous surveys that measure patient safety climate. [Colla, 2007] While many hospitals are actively using or implementing safety improvement strategies based on culture measurement, the effectiveness of such strategies has not been proven. [Ginsburg, 2005; Nakajima, 2005; Thomas, 2005; Fleming, 2008; McKeon, 2008; Pronovost, 2008; Zimmerman, 2008] The need persists for systematic quantitative and qualitative analyses of interventions to create a safe culture. [Pizzi, 2001]

Currently, there is no standard to estimate the cost of poor safety culture to a clinical unit, a hospital, or a hospital system. However,

IOM firmly established that the safety culture of the U.S. healthcare system is deeply flawed and is the root cause of substandard care delivery.

Safe Practice Statement

Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk. [AHRQ, 2009; AHRQ, N.D.; JCR, 2010]

Additional Specifications

- At least annually, leaders should assess the organization's safety and quality culture using a survey tool that is selected with consideration of validity, consistency, and reliability in the setting in which it will be applied and that is conceptualized around domains that are applicable to performance improvement (PI) initiatives/efforts such as teamwork, leadership, communication, and openness to reporting. [Deilkås, 2008; IHI, 2009; Relihan, 2009]
  - Survey a census of units or service areas that in aggregate deliver care to more than 50 percent of the patients receiving care.
  - Measure service lines or units where there is a high patient safety risk.
  - Identify and prioritize culture PI targets; provide adequate resources to address performance gaps over a specified period of time.
  - Survey a valid sample to allow unit-level analysis and facilitate improvement.
- Critical care areas and services and high-volume and high-risk areas should be surveyed (e.g., emergency department, outpatient surgical services, diagnostic centers) and should include, in the aggregate, ambulatory totals to determine which of these areas should be targeted initially. [Donnelly, 2009; Kaafarani, 2009; Pater, 2009]
- The results of the culture survey process should be documented and disseminated widely across the enterprise in a systematic and frequent manner. [Audet, 2008; Chadwick, 2009; Hutchinson, 2009] The interventions component of this safe practice will be satisfied if the survey findings are documented and have been used to monitor and guide performance improvement interventions. [Pronovost, 2005a; Sexton, 2006; Sexton, 2007; Pringle, 2009]
- The organization should document that the results of the survey process, as defined in the Leadership Structures and Systems safe practice and by the activities defined in the *Teamwork Training and Skill Building and the Identification and Mitigation of Risks and Hazards* safe practices, have been provided to governance and senior medical leaders. [IHI, N.D.]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Organizations measure culture by using proprietary surveys and/or those found in the public domain. What is important is that the leadership and those implementing

these surveys understand their aims and their limits, and ensure that they are building feedback processes and interventions into their designs.

- Some organizations are undertaking cultural measurement in certain subsets of the workforce against performance improvement goals to reduce specific adverse events. Although not enterprise wide, such subset assessments of culture tied to safety outcomes are valuable, and due to the narrower scope may be more easily done on a quarterly basis to inform performance improvement activities.
- Using validated surveys to assess culture should be done at the unit or care area level across the entire organization. The unit level needs assessment, then guides leadership for resource needs and quality improvement. [Pronovost, 2005b; Sexton, 2005; Rose, 2006; Huang, 2007]

Strategies of Progressive Organizations

- Some organizations have embraced culture measurement, feedback, and interventions with vigor. They are measuring culture in an organization-wide fashion, linking broad performance improvement programs to patient safety performance gaps, and correlating the outcomes to culture measurement. Staff turnover, retention, and other operational metrics are also being tracked. Many are exploring new survey instruments and customizing them to suit their strategic objectives.

Opportunities for Patient and Family Involvement

- Include patient and family members in culture of safety survey measurement. [NPP, N.D.]
- Encourage patients to share their stories/experiences with staff at staff meetings or grand rounds.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts, and may not necessarily address all external reporting needs.

- **Outcome Measures** should be correlated with other patient safety measures that are related to clinical care. Staff turnover, staff retention, job satisfaction, and teamwork can be correlated with operations and financial impact.
- **Process Measures** include survey response rates, the percentage of total staff surveyed, reliability, consistency, representation, and other measures pertinent to the survey tools used. These metrics relate to the domains assessed and other considerations pertinent to the survey groups.
- **Structure Measures** pertain to the structural elements put into place to ensure that the information gained from the survey is used to reduce patient harm.
- **Patient-Centered Measures** are in their infancy and would not be used directly in the measurement of culture through surveying staff; however, any correlations that can be made between an organization's culture and patient-centered care should be made with a consideration of the following dimensions drawn from IOM's report *Crossing the Quality Chasm: A New Health System for the 21st Century.*

1. respect for patients' values, preferences, and expressed needs;
2. continuous collaboration, coordination, and integration of care among providers and across conditions and settings;
3. accessible and customized information;
4. communication, education (including self-efficacy and self-management skills for patients and families), and easy access to decision support tools;
5. the provision of physical comfort to patients;
6. the offering to patients of emotional support and relief from fear and anxiety;
7. the involvement of family and friends in care; and
8. access to care.

Settings of Care Considerations

- **Rural Healthcare Settings:** All rural healthcare settings should comply with the relevant specifications of this safe practice. Although small and rural organizations may have more resource constraints than larger urban or suburban organizations, great efficiencies can be realized by participating in the national safety and quality collaborative initiatives of similar organizations. Alliances with these organizations in noncompetitive service areas provide significant opportunities for sharing information and identifying resources.
- **Children's Healthcare Settings:** All children's healthcare settings should comply with the relevant specifications of this safe practice. National alliances and collaborative initiatives provide rich opportunities for efficiencies in information and resource-sharing about culture measurement and transformation.
- **Specialty Healthcare Settings:** All specialty healthcare settings should comply with the relevant specifications of this safe practice. National alliances and collaborative initiatives with similar specialty facilities offer special opportunities to compare performance in culture measurement and improvement.

New Horizons and Areas for Research

One of the most important new horizons in culture measurement and improvement is the dimension of leadership. Although a growing number of studies tie systems failures in healthcare organizations to an overemphasis on financial performance, many administrative leaders are uncomfortable managing a highly clinical business and continue to neglect opportunities for performance improvement. As culture measurement continues to be refined and correlated with workforce performance—and, in turn, safety and quality—new dimensions and opportunities for improvement will be identified. Researchers are investigating direct correlations between an organization's unit- or area-specific teamwork climate and overall nurse retention, for example.

Other Relevant Safe Practices

Safe Practice 1: Leadership Structures and Systems; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards, are directly relevant. All practices involving performance improvement projects, and those projects in which teamwork is important, are also relevant.

Notes

AHRQ, 2009: [No authors listed.] Patient Safety Culture Surveys. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2009 Apr. Available at http://www.ahrq.gov/qual/patientsafetyculture/. Last accessed October 15, 2009.

AHRQ, N.D.: [No authors listed.] Patient Safety Primer: Safety Culture. AHRQ PSNet Patient Safety Network. Rockville (MD):Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=5. Last accessed October 15, 2009.

Audet, 2008: Audet AM, Raju R, Jacobs CM, et al. Transparency as a pillar of a quality and safety culture: the experience of the New York City Health and Hospitals Corporation. Jt Comm J Qual Patient Saf 2008 Dec;34(12):707-12.

Chadwick, 2009: Chadwick DP. Developing your safety culture. Occup Health Saf 2009 Apr;78(4):14.

Clark, 1991: Clark KB, Margolis JD. Workplace Safety at Alcoa (A). Boston (MA): Harvard Business Publishing; 1991 Oct 31.

Colla, 2007: Colla JB, Bracken AC, Kinney LM, et al. Measuring patient safety climate: a review of surveys. Qual Saf Health Care 2005 Oct;14(5):364-6. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=16195571. Last accessed November 2, 2009.

Deilkås, 2008: Deilkås ET, Hofoss D. Psychometric properties of the Norwegian version of the Safety Attitudes Questionnaire (SAQ), Generic version (Short Form 2006). BMC Health Serv Res. 2008 Sep 22;8:191. Available at http://www.biomedcentral.com/content/pdf/1472-6963-8-191.pdf. Last accessed July 9, 2009.

Denham, 2007: Denham CR. Values Genetics: Who are the real smartest guys in the room? J Patient Saf 2007 Dec;3(4):214-26.

Donnelly, 2009: Donnelly LF, Dickerson JM, Goodfriend MA, et al. Improving patient safety: effects of a safety program on performance and culture in a department of radiology. AJR Am J Roentgenol 2009 Jul;193(1):165-71.

Fei, 2008: Fei K, Vlasses FR. Creating a safety culture through the application of reliability science. J Healthc Qual 2008 Nov-Dec;30(6):37-43.

Fleming, 2008: Fleming M, Wentzell N. Patient safety culture improvement tool: development and guidelines for use. Healthc Q 2008;11(3 Spec No.):10-5.

Flin, 2000: Flin R, Mearns K, O'Connor P, et al. Measuring safety climate: identifying the common features. Safety Science 34 (2000), pp. 177-92. Available at http://www.abdn.ac.uk/iprc/documents/Measuring%20Safety%20Climate...%20FLIN.MEARNS.OCONNOR%20220205.pdf. Last accessed November 2, 2009.

Ginsburg, 2005: Ginsburg L, Norton PG, Casebeer A, Lewis S. An educational intervention to enhance nurse leaders' perceptions of patient safety culture. Health Serv Res 2005 Aug;40(4):997-1020. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=16033489. Last accessed November 2, 2009.

Health and Safety Commission, 1993: Health and Safety Commission (of Great Britain), Study Group on Human Factors. ACSNI (Advisory Committee on the Safety of Nuclear Installations) study group on human factors. Third report. Organising for safety. Sudbury (UK): HSE Books; 1993.

Helmreich, 1998: Helmreich RL, Merritt AC. Culture at Work in Aviation and Medicine: National, Organizational and Professional Influences. Aldershot (UK): Ashgate Publishing; 1998 Sep.

Helmreich, 1999: Helmreich RL, Merritt AC, Wilhelm JA. The evolution of crew resource management training in commercial aviation. International Journal of Aviation Psychology 1999;9(1):19-32.

Huang, 2007: Huang DT, Clermont G, Sexton JB, et al. Perceptions of safety culture vary across the intensive care units of a single institution. Crit Care Med 2007 Jan;35(1):165-76.

Hutchinson, 2009: Hutchinson A, Young TA, Cooper KL, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. Qual Saf Health Care 2009 Feb;18(1):5-10.

IHI, 2009: [No authors listed.] Foundation: Operating Values. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=12462e64-8045-42cb-a679-2418b10e706c. Last accessed October 14, 2009.

IHI, N.D.: [No authors listed.] Wentworth-Douglass Hospital. Policy on a Culture of Safety. Cambridge (MA): Institute for Healthcare Improvement (IHI); No Date. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Policy+on+a+Culture+of+Safety.htm. Last accessed October 15, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Oak Brook (IL): Joint Commission Resources; 2010.

Kaafarani, 2009: Kaafarani HM, Itani KM, Rosen AK, et al. How does patient safety culture in the operating room and post-anesthesia care unit compare to the rest of the hospital? Am J Surg. 2009 Jul;198(1):70-5. Epub 2009 Mar 6.

Kohn, 2000: Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000. Available at http://www.nap.edu/catalog.php?record_id=9728. Last accessed December 30, 2008.

McKeon, 2008: McKeon LM, Cunningham PD, Detty Oswaks JS. Improving patient safety: patient-focused, high-reliability team training. J Nurs Care Qual 2008 Aug 25.

Nakajima, 2005: Nakajima K, Kurata Y, Takeda H. A web-based incident reporting system and multidisciplinary collaborative projects for patient safety in a Japanese hospital. Qual Saf Health Care 2005 Apr;14(2):123-9. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15805458. Last accessed November 2, 2009.

NPP, N.D.: National Priorities Partnership. National Quality Forum. No Date. Available at http://www.nationalprioritiespartnership.org/Home.aspx. Last accessed November 2, 2009.

NQF, N.D.: National Quality Forum Website. Endorsing a Framework and Preferred Practices for Measuring and Reporting Cultural Competency. Available at http://www.qualityforum.org/projects/cultural_competency.aspx. Last accessed November 2, 2009.

Pater, 2009: Pater R. Stepping up your safety culture. Occup Health Saf 2009 Jan;78(1):24.

Pizzi, 2001: Pizzi LT, Goldfarb NI, Nash DB. Promoting a culture of safety. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality [AHRQ]; 2001 Jul: Chapter 40. Available at http://www.ahrq.gov/clinic/ptsafety/pdf/chap40.pdf. Last accessed November 2, 2009.

Pringle, 2009: Pringle J, Weber RJ, Rice K, et al. Examination of how a survey can spur culture changes using a quality improvement approach: a region-wide approach to determining a patient safety culture. Am J Med Qual 2009 Jun 15. [Epub ahead of print]

Pronovost, 2005a: Pronovost P, Sexton B. Assessing safety culture: guidelines and recommendations. Qual Saf Health Care 2005 Aug;14(4):231-3. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1744052/pdf/v014p00231.pdf. Last accessed October 23, 2009.

Pronovost, 2005b: Pronovost P, Weast B, Rosenstein B, et al. Implementing and validating a comprehensive unit-based safety program. J Patient Saf 2005 Mar;1(1):33-40.

Pronovost, 2008: Pronovost PJ, Rosenstein BJ, Paine L, et al. Paying the piper: investing in infrastructure for patient safety. Jt Comm J Qual Patient Saf 2008 Jun;34(6):342-8.

Relihan, 2009: Relihan E, Glynn S, Daly D, et al. Measuring and benchmarking safety culture: application of the safety attitudes questionnaire to an acute medical admissions unit. Ir J Med Sci 2009 May 13. [Epub ahead of print]

Rose, 2006: Rose JS, Thomas CS, Tersigni A, et al. A leadership framework for culture change in health care. Jt Comm J Qual Patient Saf 2006 Aug;32(8):433-42.

Sexton, 2005: Sexton JB, Thomas EJ, Pronovost P. The Context of Care and the Patient Care Team: The Safety Attitudes Questionnaire. IN: Building a Better Delivery System: A New Engineering/Health Care Partnership. Reid PP, Compton WD, Grossman JH, et al, eds. Washington, DC: The National Academies Press; 2005. Available at http://books.nap.edu/openbook.php?record_id=11378&page=119. Last accessed October 23, 2009.

Sexton, 2006: Sexton JB, Helmreich RL, Neilands TB, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res 2006;6:44. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1481614/pdf/1472-6963-6-44.pdf. Last accessed October 23, 2009.

Sexton, 2007: Sexton JB, Paine LA, Manfuso J, et al. A check-up for safety culture in "my patient care area". Jt Comm J Qual Patient Saf 2007 Nov;33(11):699-703, 645.

Smith, 2009: Smith P, Pearson PH, Ross F. Emotions at work: what is the link to patient and staff safety? Implications for nurse managers in the NHS. J Nurs Manag 2009 Mar;17(2):230-7.

Spears, 1999: Spear SJ. Workplace Safety at Alcoa (B). Boston (MA): Harvard Business Publishing; 1999 Dec 22.

Thomas, 2005: Thomas EJ, Sexton JB, Neilands TB, et al. The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical units. BMC Health Serv Res 2005 Apr 11;5(1):28. Erratum in: BMC Health Serv Res 2005 Jun 8;5(1):4. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15823204. Last accessed December 22, 2008.

Zimmerman, 2008: Zimmerman R, Ip I, Daniels C, et al. An evaluation of patient safety leadership walkarounds. Healthc Q 2008;11(3 Spec No.):16-20.

SAFE PRACTICE 3: TEAMWORK TRAINING AND SKILL BUILDING

The Objective

Establish a proactive and systematic approach to developing team-based care through teamwork training and team-led performance improvement interventions that reduce preventable harm to patients.

The Problem

Team error is defined as human error made in group processes. [Sasou, 1999] Team errors are individual or shared errors that are not detected, indicated, or corrected by the team. [Sasou, 1999] Care has become fragmented and requires successful team communication to prevent system failures. Organizations are treating sicker patients at ever faster rates with treatments that are becoming increasingly complex. The aviation industry has determined that between 50 and 80 percent of all incidents and accidents can be directly attributed to human error involving poor group decision-making, ineffective communication, inadequate leadership, and poor task or resource management. [Freeman, 1991; US GAO, 1997] Comparable findings are now being reported in healthcare.

The frequency of medication errors, delays in treatment, and wrong-site surgeries is due primarily to communication failure, [Denham, 2008] with this being the primary root cause of approximately 70 percent of sentinel events reported to The Joint Commission from 1995 to 2004. Breakdowns in team communication are also the second most frequently cited root cause of operative and postoperative events and fatal falls. [Smith, 2005] A systematic review of emergency department closed claims determined that fundamental teamwork behaviors would have prevented or mitigated the adverse event in 43 percent of reviewed cases. [Risser, 1999]

The severity of harm resulting from teamwork failures can range from no harm to patient death. Common patient care errors resulting from such breakdowns include incorrect treatment, delays in treatment, and missed treatment. [Smith, 2005] Seventy-five percent of communication-related sentinel events reported to The Joint Commission between 1995 and 2004 resulted in patient death. [Smith, 2005] Poor team communication has been found to be a root cause in 80 percent of perinatal deaths and injuries, [TJC, 2004] and in 40 percent of maternal deaths and 45 percent of near miss morbidities. [Geller, 2004]

The preventability of team errors is not yet known; more evidence is needed to quantify the effectiveness of team training and skill building to improve patient safety. The aviation industry has demonstrated that Crew Resource Management (CRM) training has a positive impact on participants' reactions and attitudes about its importance and perceived value, and it improves individual aviator knowledge and behaviors. [Salas, 2001] While it is suspected that CRM training has played a major role in this improvement in air safety, sufficient research has not been conducted to demonstrate its specific impact. [Salas, 2001] The importance of teamwork in promoting high-quality healthcare and preventing medical errors has been described in the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) [AHRQ, N.D.c] training resources, [TEAMWISE, N.D.a] which are sponsored jointly by the Agency for Healthcare Research and Quality and the Department of Defense. [Clancy, 2007; AHRQ, 2009]

The cost of communication failures to the healthcare industry is unknown and difficult to determine. A study of international risk managers agrees that up to 80 percent of malpractice claims are attributed to failures in communication and/or a lack of interpersonal skills, usually on the part of the physician. [Woods, 2006]

Safe Practice Statement

Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients. [AHRQ, N.D.b; IHI, 2009; JCR, 2010]

Additional Specifications

Effective Team Leadership: Training programs should systematically address and apply the principles of effective team leadership and team formation. [Salas, 2008] Leadership at all levels of an organization should be fostered.

Effective Teamwork Training: Every organization should provide teamwork and communication training through basic and detailed programs. [Salas, 2008; Clark, 2009]

- Basic Teamwork Training: Basic training should be provided annually to governance board members, senior administrative leaders, medical staff (both those who are independent and those who are employed by the organization), midlevel management, and frontline nurses. [Denham, 2006a; Denham, 2006b] The subject matter should include sources of communication failures, hand-offs, and team failures that lead to patient harm. The length and modality of training should be established by the organization. Participation should be documented to verify compliance. [Salas, 2008]
- Detailed Teamwork Training: All clinical staff and licensed independent practitioners should receive detailed training consisting of the best available teamwork knowledge; however, staff of clinical areas that are deemed to be at high risk for patient safety issues should receive such training first. The clinical areas that are prioritized should focus on specific patient safety risks. The subject matter should include the principles of high reliability, human factors applied to real-world care processes, interpersonal team dynamics, hand-offs, and specific communication methods. [Frankel, 2006; McKeon, 2009] Focus should be placed on the development and application of structured tools. Detailed training should include a specified period of combined instruction and interactive dialogue regarding the application of the knowledge determined and documented by the organization. If all staff cannot be trained within one year, a goal should be set to train all clinical service area staff and caregivers over multiple years.
- Effective Teamwork Skill Building: To develop the characteristics of "team-ness," [TEAMWISE, N.D.b] individuals should build their teamwork and communication skills by establishing a shared mental model, using structured and critical language, understanding communication hand-off methods, and using effective assertion behaviors such as "stop-the-line" methods. Individuals and teams also should develop the skills necessary to monitor team performance continuously over time. Organizations should employ methods to verify the demonstration of teamwork skills. [Manser, 2009] A specified number of care units or service line areas and length of training should be set and documented by organization leadership each year with initiatives for building and measuring teamwork skills.

Effective Team-Centered Interventions: In order to generate the greatest impact, team-centered performance improvement initiatives or projects should target the work "we do every day." The units and service lines selected should be prioritized based on the risk to patients, which in turn should be based on the prevalence and severity of targeted adverse events. The interventions should address the frequency, complexity, and nature of teamwork and communication failures that occur in those areas. Each year, every organization should identify a specific number of teamwork-centered intervention projects it will undertake, such as those cited below and in the Example Implementation Approaches section. Ideally, team-centered interventions should be undertaken in all areas of care. [Baker, 2005]

Specific Team Performance Improvement Projects: Organizations should select high-risk areas for performance improvement projects; these include emergency departments, labor and delivery, intensive care units, operating rooms, ambulatory care, and other procedural care units. Performance targets and strategies to close known performance gaps should be identified. Such performance improvement initiatives should have the components of education, skill building, measurement, reporting, and process improvement. [IHI, 2004]

- Rapid Response Assessment: Annually, organizations should formally evaluate the opportunity for using rapid response systems to address the issues of deteriorating patients across the organization. [AHRQ, N.D.a; IHI, N.D.; Bellomo, 2003; Kaplan, 2009]
- Internal and External Reporting: The performance improvement that is generated by team-centered interventions should be reported to governance boards and senior administrative management. Depending on the projects selected, the organization should submit the information to the appropriate external reporting organizations. [Drozda, 2008]

Minimum Requirements of Practice 3: To meet the minimum requirements of this safe practice, an organization can satisfy the Detailed Teamwork Training, Effective Teamwork Skill Building, and Effective Team-Centered Interventions requirements, defined above, by targeting an organization-determined number of units or service lines initially and additional new units each year, if the Effective Team-Centered Interventions requirements are satisfied, because it is expected that those involved would receive the required training and skill-building experiences. The requirements of the interventions component of the *Culture Measurement, Feedback, and Intervention* safe practice also will be met if improvement of the culture survey scores is an aim of the specific performance improvement projects that are undertaken.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Organizations should take a systematic approach and should provide clear leadership (governance boards and senior administrative management), including visible physician leadership and commitment. Teamwork should be a fundamental behavior of the organization, and it should be recognized that systematic and regular reinforcement of the principles of team

performance should occur across the organization. [Salas, 2008] Such fundamentals should be applied through performance improvement projects that target specific patient safety goals.

- Organizations that are making a fresh start in establishing the activities required by this safe practice, but are constrained by resources, could consider combining the requirements of the Detailed Teamwork Training and Effective Teamwork Skill Building specifications of Effective Teamwork Training, thus targeting two areas of high risk. Early wins with such projects will help build momentum and reduce resistance, easing the development of additional broader programs.
- The didactic elements of training may be delivered through multimedia or distance learning strategies that can be updated with the latest evidence. Documentation of participation can be maintained to verify compliance and to ensure that new and temporary staff receives such training.
- Intensive Care Unit (ICU) Team Example Projects: [Reader, 2009] Projects employed by interdisciplinary teams in ICU are creating daily goals to help guide therapy. Nurses are using checklists to ensure that patients who have central catheters receive evidence-based interventions (see the *Nursing Workforce* safe practice).
- Labor and Delivery Team Example Projects: Applying fundamental teamwork skills, common definitions of fetal well-being, and standardized approaches to fetal and maternal monitoring interpretation, as well as practicing for emergencies, is reported to have a dramatic impact on preventable newborn adverse events. A dominant theme in root cause analyses of perinatal deaths and injuries is a breakdown in team function.
- Emergency Department Team Example Projects: [Fernandez, 2008a] The emergency department provides fertile ground for opportunities to undertake team training projects, because there are many failures in performance that are preventable in certain high-risk conditions. [Rosen, 2008b] Such projects could implement the principles of high reliability, communication, and communication hand-offs. They could also involve initiatives that confirm the closure of information loops with physicians who are managing patients after an emergency department discharge.
- Operating Room Team Example Projects: The operating room is an environment that is conducive to the application of principles of communication, such as briefing, structured language, critical language, and team leadership. [Salas, 2008]
- Rapid Response Systems Examples: Many organizations have embraced team-based approaches to early intervention for deteriorating patients. Whether they are intensivist-led, hospitalist-led, or nurse-led programs, many anecdotally report a reduction in codes, in improved mortality rates, and in unplanned ICU admissions. All such programs require critical teamwork skills. For the purposes of compliance with this practice, the establishment of a rapid response team could be considered one of the hospital patient care units' team-centered intervention projects.
- Team Simulation Examples: [Fernandez, 2008b; Rosen, 2008a] Many organizations use simulation for knowledge transfer and skill-building. Low-fidelity simulations, such as scenario-based techniques and the use of standardized patients, may address low-frequency, high-impact scenarios that will allow staff and physicians to practice

teamwork skills. Simulations also may be used to assess teams in action. High-fidelity simulation offers the benefits of procedural competency and risk identification.

- Tactical Team Techniques: Certain techniques that are effective in sustaining gains and accelerating the adoption of teamwork practices and skills include using internally developed coaches and clinical champions, taking advantage of external performance improvement collaborative initiatives, and collaborating with outside experts. Early and clear gains from projects that are led by internal clinical champions provide evidence to the rest of the organization that supports the investment made in teamwork training and team interventions.

Strategies of Progressive Organizations

- Many organizations have embedded the development of team-based methods very broadly and systematically across clinical, operational, and financial activities. Some have extensively adopted simulation techniques. Some organizations are exploring the use of virtual teams using telephony and Internet-based tools. Certain progressive organizations have established a "Patient Safety College" that provides Internet-based training for all staff and leaders, allowing them access to training according to their own schedules. Many organizations have participated in the 100,000 Lives Campaign developed and launched by the Institute for Healthcare Improvement and have made team-centered rapid response teams a major feature of their performance improvement programs. Early findings show that these teams are having a dramatic impact. Clearly, this area will be a focus of further research.

Opportunities for Patient and Family Involvement

- Include patient and/or family members in teamwork training and planning committees. [NPP, 2009]
- Provide education and support to patients, families, and staff on patient- and family-centered care and on how to collaborate effectively in quality improvement and healthcare redesign. For example, provide opportunities for administrators and clinical staff to hear patients and family members share stories of their healthcare experiences during orientation and continuing education programs.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include patient harm (death, disability, or harm causing unanticipated treatment or increased length of stay), as well as operational and financial outcomes.
- **Process Measures** include the correlation of culture survey measurement with team performance and team domains; the use of observational markers for team behaviors; and the use of other measures based on the performance improvement projects undertaken.

- **Structure Measures** include the verification of basic and detailed training programs; the existence of documentation of attendance at those programs; the existence of performance improvement programs with stated performance goals; and the existence of structures for reporting to senior administrative leaders and governance board leaders.
- **Patient-Centered Measures** include the verification of the involvement of patients and their families in the team approach to their care, as well as satisfaction with the communication between patients and their caregivers.

Settings of Care Considerations

- **Rural Healthcare Settings:** Teamwork is as important in small and rural hospitals as it is in larger urban or suburban hospitals. In fact, a smaller environment may lend itself more readily to team-based approaches to care. High-impact events that occur infrequently offer valuable opportunities to apply team-based methods, and are particularly important patient safety occurrences in settings where the infrequency of the events can cause mitigating diagnostic and treatment opportunities to be missed. Regional alliances with other hospitals offer teamwork opportunities as patients move between care settings.
- **Children's Healthcare Settings:** All relevant requirements of the practice apply to children's healthcare settings.
- **Specialty Healthcare Settings:** All relevant requirements of the practice apply to specialty healthcare settings.

New Horizons and Areas for Research

Research on the linkage between teamwork behavior and clinical outcomes should provide even more evidence to support investing in team performance improvement. Rapid response systems design and early warning assessment approaches will likely hold promise for the development of improved rapid response practices, as will work in the area of simulation, as noted previously. The WHO 19-item checklist for surgical patient safety has been estimated to save 1 in 144 surgical patients' lives. [Haynes, 2009] Further research is needed to validate other system checklists and composite activities that reduce harm to patients.

Other Relevant Safe Practices

All elements of this safe practice are directly relevant. All practices involving performance improvement projects, and those for which teamwork is important, are relevant.

Notes

AHRQ, 2009: [No authors listed.] National Healthcare Quality Report 2008. AHRQ Publication No. 09-0001. Rockville (MD): Agency for Healthcare Research and Quality; 2009 Mar. Available at http://www.psnet.ahrq.gov/resource.aspx?resourceID=10079. Last accessed October 19, 2009.

AHRQ, N.D.a: [No authors listed.] Patient Safety Primer: Rapid Response Systems. AHRQ PSNEt Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality; No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=4. Last accessed October 19, 2009.

AHRQ, N.D.b: [No authors listed.] Patient Safety Primer: Teamwork Training. AHRQ PSNEt Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality; No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=8. Last accessed October 19, 2009.

AHRQ, N.D.c: [No authors listed.] TeamSTEPPS™: National Implementation. Rockville (MD): Agency for Healthcare Research and Quality; No Date. Available at http://teamstepps.ahrq.gov/. Last accessed October 19, 2009.

Baker, 2005: Baker DP, Gustafson S, Beaubien J, et al. Medical Teamwork and Patient Safety: The Evidence-based Relation. Literature Review. AHRQ Publication No. 05-0053. Rockville (MD): Agency for Healthcare Research and Quality; 2005 Apr. Available at http://www.ahrq.gov/qual/medteam/. Last accessed October 19, 2009.

Bellomo, 2003: Bellomo R, Goldsmith D, Uchino S, et al. A prospective before-and-after trial of a medical emergency team. Med J Aust 2003 Sep 15;179(6):283-7. Available at http://www.mja.com.au/public/issues/179_06_150903/bel10089_fm.pdf. Last accessed October 23, 2009.

Clancy, 2007: Clancy CM, Tornberg DN. TeamSTEPPS: assuring optimal teamwork in clinical settings. Am J Med Qual 2007 May-Jun;22(3):214-7. Available at http://ajm.sagepub.com/cgi/reprint/22/3/214. Last accessed January 9, 2009.

Clark, 2009: Clark PR. Teamwork: building healthier workplaces and providing safer patient care. Crit Care Nurs Q 2009 Jul-Sep;32(3):221-31.

Denham, 2006a: Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3):162-70.

Denham, 2006b: Denham CR. The patient safety battles: put on your armor. J Patient Saf 2006 Jun;2(2):97-101.

Denham, 2008: Denham CR. Are you listening … are you really listening? J Patient Saf Sept 4(3)148-161

Drozda, 2008: Drozda JP Jr, Libby D, Keiserman W, et al. Case management decision support tools: predictive risk report or health risk assessment? Popul Health Manag 2008 Aug;11(4):193-6.

Fernandez, 2008a: Fernandez R, Kozlowski SW, Shapiro MJ, et al. Toward a definition of teamwork in emergency medicine. Acad Emerg Med 2008 Nov;15(11):1104-12. Epub 2008 Oct 1.

Fernandez, 2008b: Fernandez R, Vozenilek JA, Hegarty CB, et al. Developing expert medical teams: toward an evidence-based approach. Acad Emerg Med 2008 Nov;15(11):1025-36.

Frankel, 2006: Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. Health Serv Res 2006 Aug;41(4 Pt 2):1690-709.

Freeman, 1991: Freeman C, Simmon DA. Taxonomy of crew resource management: Information processing domain. IN: Proceedings of the 6th Annual International Symposium on Aviation Psychology. Jensen RS, ed. Columbus (OH): Ohio State University; 1991: pgs. 391-7.

Geller, 2004: Geller S, Rosenberg B, Cox S. The continuum of maternal morbidity and mortality: factors associated with severity. Am J Obstet Gynecol 2004 Sep;191(3:)939-44.

Haynes, 2009: Haynes HR, Weiser TG, Berry WR, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med 2009;360:491-9. Epub 2009 Jan 14. Available at http://content.nejm.org/cgi/reprint/360/5/491.pdf. Last accessed September 28, 2009.

IHI, 2004: [No authors listed.] Kaiser Permanente. SBAR Toolkit. Cambridge (MA): Institute for Healthcare Improvement; 2004. Available at http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARToolkit.htm. Last accessed October 19, 2009.

IHI, 2009: [No authors listed.] Communication & Teamwork. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=54d111e7-9bef-437b-b3c2-27f775b9eb53. Last accessed October 19, 2009.

IHI, N.D.: [No authors listed.] Establish a Rapid Response Team. Cambridge (MA): Institute for Healthcare Improvement; No Date. Available at http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Changes/EstablishaRapidResponseTeam.htm. Last accessed October 19, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standard LD.02.04.01. Oak Brook (IL): Joint Commission Resources; 2010.

Kaplan, 2009: Kaplan LJ, Maerz LL, Schuster K, et al. Uncovering system errors using a rapid response team: cross-coverage caught in the crossfire. J Trauma 2009 Jul;67(1):173-8; discussion 178-9.

Manser, 2009: Manser T. Teamwork and patient safety in dynamic domains of healthcare: a review of the literature. Acta Anaesthesiol Scand 2009 Feb;53(2):143-51. Review.

McKeon, 2009: McKeon LM, Cunningham PD, Oswaks JS. Improving patient safety: patient-focused, high-reliability team training. J Nurs Care Qual 2009 Jan-Mar;24(1):76-82.

NPP, 2009: National Priorities Partnership. National Quality Forum. Available at http://www.nationalpriorities partnership.org/Home.aspx. Last accessed October 15, 2009.

Reader, 2009: Reader TW, Flin R, Mearns K, et al. Developing a team performance framework for the intensive care unit. Crit Care Med 2009 May;37(5):1787-93. Review.

Risser, 1999: Risser DT, Rice MM, Salisbury ML, et al. The potential for improved teamwork to reduce medical errors in the emergency department. The MedTeams Research Consortium. Ann Emerg Med 1999 Sep;34(3):373-83.

Rosen, 2008a: Rosen MA, Salas E, Wilson KA, et al. Measuring team performance in simulation-based training: adopting best practices for healthcare. Simul Healthc 2008 Spring;3(1):33-41.

Rosen, 2008b: Rosen MA, Salas E, Wu TS, et al. Promoting teamwork: an event-based approach to simulation-based teamwork training for emergency medicine residents. Acad Emerg Med 2008 Nov;15(11):1190-8. Epub 2008 Jul 14.

Salas, 2001: Salas E, Burke CS, Bowers CA, et al. Team training in the skies: Does crew resource management (CRM) training work? Hum Factors 2001 Winter;43(4):641-74.

Salas, 2008: Salas E, DiazGranados D, Weaver SJ, et al. Does team training work? Principles for health care. Acad Emerg Med 2008 Nov;15(11):1002-9. Epub 2008 Oct 1.

Sasou, 1999: Sasou K, Reason J. Team errors: definition and taxonomy. Reliability Engineering & System Safety 1999 June;65(1):1-9.

Smith, 2005: Smith IJ, ed. The Joint Commission [TJC] Guide to Improving Staff Communication. Oak Brook (IL): Joint Commission Resources; 2005 Aug.

TEAMWISE, N.D.a: [No authors listed.] TEAMWISE Tools: Teamwise 7 Overview. Melbourne (Australia): TEAMWISE Tools; No Date. Available at http://www.teamwisetools.com/page7.htm. Last accessed October 19, 2009.

TEAMWISE, N.D.b: [No authors listed.] TEAMWISE Tools: WorkSafe 7 Overview. Melbourne (Australia): TEAMWISE Tools; No Date. Available at http://www.teamwisetools.com/page14.htm. Last accessed October 19, 2009.

TJC, 2004: The Joint Commission. Sentinel Event Alert #30: Preventing infant death and injury during delivery. 2004 Jul 21. Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_30.htm. Last accessed November 2, 2009.

US GAO, 1997: United States General Accounting Office. Human Factors: FAA's guidance and oversight of pilot crew resource management training can be improved. Washington, DC: United States General Accounting Office; 1997 Nov. GAO/RCED-98-7. Available at http://www.gao.gov/archive/1998/rc98007.pdf. Last accessed November 2, 2009.

Woods, 2006: Woods MS. The DUN factor: how communication complicates the patient safety movement. PSQH 2006 May-Jun. Available at http://www.psqh.com/mayjun06/dun.html. Last accessed November 2, 2009.

SAFE PRACTICE 4: RISKS AND HAZARDS

The Objective

Ensure that patient safety risks and hazards are continually identified and communicated to all levels of the organization, that mitigation activities are aggressively undertaken to minimize harm to patients, and that patient safety information is communicated to the appropriate external organizations. [IHI, N.D.b; Pizzi, 2001]

The Problem

Healthcare organizations are fraught with systems failures that compromise care by making it more fragmented and complex. [Denham, 2006] Opportunities for these organizations to learn from their failures are often impeded by their own structures and cultures. [Reason, 2001]

The frequency with which healthcare systems blame frontline individuals, deny the existence of systemic errors, and fixate on production and financial indicators of performance makes them more vulnerable to adverse events. [Reason, 2001; Denham, 2007] Medical errors have been associated with substantial subsequent personal distress, decreased empathy, and increased probability of making another medical error. [West, 2006] System-related harm to patients is much more frequent than previously thought—especially in older patients. [Levinson, 2008a] Tools are available, [Griffin, 2009] such as the Institute for Healthcare Improvement- recommended Global Trigger Tool, which can be the basis not only for identifying risk and estimating the frequency of adverse events in an organization but also for determining the impact of interventions that focus on reducing adverse events in surgical patients. [Griffin, 2008] The activities of identifying and mitigating risks and hazards are typically not systematically integrated across an organization. Even in hospitals where these systems are in place, clinicians significantly underreport medical errors. [Kaldjian, 2007; Kaldjian, 2008] The numbers of medical errors and adverse events that go unreported are not known. Recent focus on episodes of care and re-hospitalizations reveals that significant harm occurs after discharge from acute-care hospitals, be the discharge to the ambulatory space or to nursing homes. [Jencks, 2009] Reporting activities are mainly retrospective and are not fully communicated to governance boards and senior leadership. Rarely is risk identification fully linked to mitigation activities or performance improvement programs, nor is it routinely tied to the impact of disclosure or non-disclosure of medical errors causing harm. [Denham, 2009a] Rich opportunities for risk identification and mitigation can be harvested from risk management and complaints services, yet these information sources are rarely tapped to prevent patient harm. [Hogan, 2008; Murff, 2006] Traditionally, risk management departments and internal reporting processes have prioritized capital protection and have shielded governance boards and senior administrative management from the details of patient harm and risk. A culture of name, blame, and shame behaviors and the fear of malpractice liability have been major barriers to performance improvement. [TJC, 2008] Consumers, certifying organizations, regulators, and purchasing organizations have responded by driving transparency through the use of public reporting initiatives, thus making transparency a requirement for healthcare organizations. [Apold, 2006; Conway, 2008] Certifying, quality, and purchasing organizations have also declared that zero must be the goal for adverse events such as infections that had

historically not been recognized as the patient safety issues that they are now. [Denham, 2009d; Denham, 2009e]

The severity of harm resulting from the absence of coordinated patient safety programs cannot be accurately estimated. However, recent studies, including one by the Office of the Inspector General, have shown that as many as 15 percent of Medicare beneficiaries experience serious harm in hospitals. [Levinson, 2008a; Levinson, 2008c] It has been reported that the readmission and mortality rates of seniors after acute care hospital admissions may be much higher than previously presumed. [Boutwell, 2008; Denham, 2009c; Jencks, 2009] Organizations that fail to establish error reporting programs are inherently ill-equipped to predict, prevent, and mitigate risks and hazards. They are more susceptible to latent errors that undermine frontline workers and propagate active errors at the sharp end.

The preventability of harm by performing risk mitigation strategies has been studied, and healthcare organizations can identify and mitigate patient safety risks and hazards by using a number of internal methods, including retrospective, real-time, and near real-time and prospective risk analysis. [Bagian, 2002; Battles, 2006; Tuttle, 2002; Milch, 2006; Marx, 2003; Wreathall, 2004] Analysis of risk across an organization should be integrated and complemented by the use of information from outside sources. The mitigation of risk should include effective performance improvement activities and the adoption of systems solutions that will close gaps in organization performance and that will correct conditions that put patients at risk. Risks and mitigation opportunities should be communicated internally across the entire organization and externally to the appropriate organizations. The broadening role of patient safety organizations that provide federal protection of information should increase the sharing of adverse event information and lessons learned within an organization. [CMS, 2008b] The identification and mitigation of risks and hazards should be backed by adequate resources to cover the cost of such strategies and should be actively managed and regularly evaluated for effectiveness. [Helmreich, 2000; Carthey, 2001]

The scope of an organization-wide patient safety program includes a focus on the full range of safety issues, including areas of specific risks and hazardous conditions, potential errors and no-harm errors (sometimes referred to as "near misses," "close calls," or "good catches"), adverse events requiring unanticipated care, and sentinel events with serious adverse outcomes. [IHI, N.D.a; Reason, 2000; Denham, 2008; JCR, 2010] The risk and hazard identification and mitigation activities are presented in categories; however, these activities should be integrated throughout the organization. [Boothman, 2009; McDonald, 2009] The expanding role of health information technology (HIT) solutions will both create and reduce risk to patients and caregivers. HIT leaders suggest that information is the lifeblood of healthcare and that HIT is the circulatory system. [Blumenthal, 2010] Third-party verification of performance, such as that used to implement measurement of CPOE performance, as defined in the CPOE Safe Practice, using a CPOE "flight simulator" will become more common. [Kilbridge, 2006] Finally, it is the governance, administrative, and clinical leaders who must make sure that risks and hazards are identified and mitigated by their own direct engagement in the process. [Denham, 2009b]

Safe Practice Statement

Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.

Additional Specifications

Identification and Mitigation of Risks and Hazards

- Risk and Hazard Identification Activities: Risks and hazards should be identified on an ongoing basis from multiple sources, including independent retrospective, real-time and near real-time, and prospective views. The risk and hazard analysis should integrate the information gained from multiple sources to provide organization-wide context. [AHRQ, 2009a] The organizational culture should be framed by a focus on system (not individual) errors and blame-free reporting and should use data from risk assessment to create a just culture. [IOM, 2004; Nuckols, 2009; Pronovost, 2009b]
  - Retrospective Identification: Organizations should use a number of retrospective measures and indicators to identify risk and contributing factors from historical data. Specific steps should be taken to ensure that the lessons learned are communicated across the organization and that they are applied in other care settings, where applicable. Some retrospective identification and analysis activities are triggered by adverse events; [Nuckols, 2009] however, ideally the retrospective identification of risks and hazards should occur regularly, and progress reports should be generated as frequently as they are needed within each year. At least annually, a summary of progress based on an evaluation of the effectiveness of all of the relevant retrospective identification activities/tools listed below should be documented.
    1. *Serious Reportable Events.* Processes for identifying, managing, and analyzing events should be defined and implemented to identify patterns and opportunities for improvement. [AHRQ, N.D.a; AHRQ, N.D.c; Levinson, 2008b; McDonald, 2009]
    2. *Sentinel Event Reporting.* Processes for identifying, managing, and analyzing events should be defined and implemented to identify patterns and opportunities for improvement. [AHRQ, N.D.a; AHRQ, N.D.c; JCR, 2010]
    3. *Adverse Event Reporting.* Processes for identifying, managing, and analyzing events should be defined and implemented to identify patterns and opportunities for improvement. [AHRQ, N.D.a; AHRQ, N.D.c]
    4. *Root Cause Analysis.* The root cause analysis process for identifying the causal factors for events, including sentinel events, should be undertaken. [AHRQ, N.D.b; AHRQ, 2009b; Gupta, 2009]
    5. *Closed Claims Analysis.* This analysis should be undertaken. [Richman, 2009]
    6. *Enterprise Systems Failures.* People systems, technology systems, and quality systems failures beyond those resulting in adverse outcomes should be evaluated.
    7. *Skill Mix.* Because the proportion between highly trained and less-qualified staff can have an impact on patient safety, the organization must regularly review for, evaluate, and address any imbalance. [Rodriguez-Paz, 2009]

8. *Patient Safety Indicators.* Patient safety indicators should be used to generate hypotheses and guide deeper investigation. [AHRQ, 2006]
9. *Retrospective Trigger Tools.* Such tools should be used retrospectively through chart review and real-time or near real-time reviews as mentioned below. [IHI, N.D.c]
10. *External Reporting Source Input.* Such information should be an input to risk-assessment activities. [Reason, 2000]

- Real-Time and Near Real-Time Identification: Organizations should evaluate real-time or near real-time tools at least annually for their value in risk identification for the areas identified as high risk for the organization. A concise, thorough assessment of tools such as those noted below and others that become available to the organization should be documented.
  - Trigger tools, manually or technology enabled. [Adler, 2008]
  - Observational tools, permitting direct observation of processes in high-risk areas.
  - Technology tools such as electronic health records.
  - Real-Time Risk Identification Behaviors. Organizations should support the frontline behaviors of real-time risk identification, including workflow design, that enable the early identification of patient risks and hazards and that inspire "stop-the-line" actions that can prevent patient harm.
- Prospective Identification: A structured, proactive risk assessment should be undertaken by certain care units to identify risks and hazards in order to prevent harm and error. [Emily, 2009] At least annually, an organization should evaluate the prospective or proactive tools and methods, such as the two listed below, in order to identify risks. At a minimum, the organization should perform one prospective analysis per year using the tool or method deemed appropriate by the organization. Specific steps should be taken to ensure that lessons learned are communicated across the organization and that they are applied in other care settings, where applicable. [JCR, 2010]
  - Failure Modes and Effects Analysis (FMEA).
  - Probabilistic Risk Assessment (PRA). [IOM, 2004; Alemi, 2007; Hovor, 2007]
- Integrated Organization-Wide Risk Assessment: The continuous, systematic integration of the information about risks and hazards across the organization should be undertaken to optimally prevent systems failures. [Chiozza, 2009] Information about risks and hazards from multiple sources should be evaluated in an integrated way in order to identify patterns, systems failures, and contributing factors involving discrete service lines and units. The organization should integrate the information noted below, ensure that it is provided to those designing mitigation strategies and that it is documented and disseminated widely across the organization systematically and frequently, and ensure that the results of mitigation activities are made available to all who were involved in providing source information.

Frequent progress reports should be generated on an ongoing basis, and a summary of such reports should be produced at least annually.

- Risk management (claims management) services. [Boothman, 2009]
- Complaints and customer services participation.
- Disclosure support system. [McDonald, 2009] (See the *Disclosure* and *Care of the Caregiver* safe practices included in this report.)
- Culture measurement, feedback, and intervention. (See the *Culture Measurement, Feedback, and Intervention* safe practice.)
- Retrospective, real-time and near real-time, and prospective information.
- Anticipated risks for surge in capacity, for example, flu pandemic and natural disaster emergency preparedness. [CDC, N.D.b; CDC, N.D.c; APIC, 2008]

This organization-wide risk-assessment information should be provided to the governance board and senior administrative leadership continuously. The output of the activities of this element should be provided as an input to the activities articulated in the *Leadership Structures and Systems* safe practice.

- Risk Mitigation Activities: Every organization has a unique risk profile and should carefully design performance improvement projects that target prioritized risk areas. An ongoing, proactive program for identifying and reducing unanticipated adverse events and safety risks to patients should be defined, documented, and implemented. [Damiani, 2009]
- Performance Improvement Programs: The organization should provide documentation of performance improvement programs that bear evidence of the actions taken to close patient safety gaps identified in the *Identification and Mitigation of Risks and Hazards* safe practice. Such performance improvement programs should include education, skill building, measurement, reporting, and process improvement. [Denham, 2009b]

  1. *Targeted Performance Improvement Projects:* Specific patient safety risks and hazards identified by the activities described above should be targeted through performance improvement projects. [Warye, 2009] Every organization should document the outcome, process, structure, and patient-centered measures of these projects. Organizations should document the projects' patient safety aims and regularly chart progress toward those aims. Such progress should be reported regularly to governance board members and senior administrative leaders as addressed in the *Leadership Structures and Systems* safe practice.
  2. *Systems Solutions:* Products, services, and technologies that enable the use of best practices in people systems, technology systems, and quality/safety systems should be considered in order to reduce the potential for patient harm. Performance improvement projects targeting these systems should be documented, and the progress of such projects should be charted and regularly reported to and through senior administrative leaders to governance board members.

3. *Senior Leadership and Governance Engagement:* The direct participation of governance board and senior, mid-level, and line managers in monitoring the progress of all patient safety performance improvement programs should be documented. [Denham, 2005; Pronovost, 2009a; JCR, 2010] Tools such as summary reports, dashboards, or scorecards should be used to ensure that the most important messages are made as clear as possible and that information overload is minimized. Senior administrative leaders and governance board members should be involved in the selection of these monitoring tools for the organization. [Denham, 2009b]

- Specific Risk-Assessment and Mitigation Activities: The organization should provide documentation that bears evidence of high performance or of actions taken to close common patient safety gaps for the patient safety risk areas listed below. [Weingart, 2009]

  1. *Falls:* The organization should monitor the effectiveness of fall reduction programs, including risk reduction strategies, in-services, patient/family education, and environment of care redesign. [JCR, 2010]
  2. *Malnutrition:* The organization should monitor its effectiveness in identifying malnutrition and in taking actions to reduce the potential adverse events that can result from malnutrition. For example, each patient should be evaluated upon admission, and periodically thereafter, for the risk of malnutrition. Clinically appropriate strategies should be employed to prevent malnutrition.
  3. *Pneumatic Tourniquets:* The organization should monitor its effectiveness in reducing the harm that can accompany high-risk procedures, including the use of pneumatic tourniquets (if they are used in the organization). For example, whenever a pneumatic tourniquet is used, the patient should be evaluated for risk of ischemia and/or thrombotic complication, and the appropriate prophylactic measures should be utilized.
  4. *Aspiration:* Upon admission and regularly thereafter, each patient should be screened for the risk of aspiration. An aspiration risk and prevention plan should be documented in the patient's record.
  5. *Workforce Fatigue:* Because workforce fatigue can have a direct impact on patient safety, every organization should be cognizant of the issue and should include aspects of precursors and alleviation in an annual review of patient safety risk in the organization. [Yeo, 2009]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- The best way to begin is to have the organization's leaders partner with frontline caregivers to design the migration path for the adoption of the activities of this safe

practice and to ensure the appropriate links to leadership structures and systems so that information, actions, and resources can flow freely to make patients safer. [NQF, 2010]

- Healthcare organizations should consider periodic assessment of the tools used for prospective, near real-time, and retrospective risk identification and mitigation. For instance, organizations may consider annual assessment of such tools, [Griffin, 2009] which are evolving through the innovation of many organizations. Organizations should be aware that the value of the tools used may become clearer with the contribution of ongoing research. [Wu, 2008; Mills 2008; Percarpio 2008]
- Additional Interest Areas: New risk identification opportunities are presented through the use of evolving trigger tools, such as the Global Trigger Tool, [Griffin, 2009] which was developed through collaboration among many hospitals and the Institute for Healthcare Improvement. Other areas of additional interest include the use of PRA tools and the evaluation of the impact of disruptive behaviors among caregivers on patient safety. [In the future, organizations may require guidelines for identifying, reporting, and managing behaviors that disrupt patient safety.]
- Healthcare organizations should consider exploring new information sources and the use of pattern recognition methods to provide caregiver support as patients transit from care settings and between organizations.
- Healthcare organizations may consider evaluating the risk areas identified by purchasers to be high priority to them. Such conditions may include iatrogenic pneumothorax, delirium, and Legionnaires' disease. [CDC, N.D.a; CMS, 2008a; CMS, 2008c]

Strategies of Progressive Organizations

- Some organizations have declared that governance board members must spend equal time in their meetings and activities on financial issues and quality/safety issues, recognizing that governance leaders are often ill-informed about the quality and safety of care delivered by their organizations. [Jha, 2009] In addition, many organizations have embraced patient safety and risk reduction as their primary competitive initiatives, while others are exploring new opportunities for real-time risk and mitigation strategies to create early warning systems that can prevent incipient systems failures. [Nance, 2008] Some are recognizing that risk reduction can be a reconciling principle to pull together their teams and surf the wave of new forces in a dramatically different environment. [Denham, 2009c] Some are taking lessons from other industries and realizing that denial of risk and peril is a path to enterprise failure. [Collins, 2009] Certain organizations use risk assessment indexing to prioritize no-harm and near miss events by measuring the severity of an outcome against the likelihood of the incident occurring. Some academic organizations have created processes whereby frontline care providers and trainees are encouraged and rewarded for regularly submitting near miss and adverse event reporting as a requirement and mandatory component of their training. This has been shown to substantially increase near miss and adverse event data, leading to more robust performance improvement activities to reduce systems harm. [McDonald, 2008]

- An example of an effective risk mitigation activity is use of the WHO 19-item checklist for surgical patient safety, which has been estimated to save 1 in 144 surgical patients' lives. [Haynes, 2009]
- High-performing organizations provide feedback to staff on improvements and enhanced performance that resulted from adverse event reporting. [Gallagher, 2009; McDonald, 2009]

Opportunities for Patient and Family Involvement

- Listening and open communication, along with an early admission assessment with the patient, and the family when appropriate, is a fundamental first step in reducing risk of harm to the patient.
- Healthcare organizations should consider formally encouraging patients and their families to report concerns about safety. Example: mechanisms in place to provide input to trigger a rapid response; that is, global call-in or hotline numbers, online reporting systems, contact person during patient care encounters. [NPP, 2009]

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** range from mortality and disability to the occurrence of harm that requires additional treatment. NQF has endorsed a set of serious reportable events that are grouped into six categories: surgical, product or device, patient protection, care management, environmental, and criminal events. The Joint Commission has identified as reportable those serious adverse outcomes that are proximally related to treatment or therapy. Operational and financial outcomes include re-work, efficiencies, malpractice costs, and the indirect costs of preventable patient harm.
- **Process Measures** include assessments, briefings, and evidence of identification and mitigation activities; compliance with organizational policies and procedures, including assessment for falls, malnutrition, and the specific monitoring that is required when a pneumatic tourniquet is used; and changes that are implemented as a result of root cause analysis, FMEA, or other risk identification tools.
- **Structure Measures** include the numerous structural elements presented in the specifications of this safe practice. The dynamic sharing of information between risk management and performance improvement staff and near-real-time reporting to administrative and governance leaders is the ultimate measure of successful adoption of this practice. Accountability is vital—personal, financial, and public accountability must be structurally reinforced. Leaders and staff must be accountable for the flow of information and action—they must own processes. Financial accountability means resource allocation must be made to risk mitigation. Public accountability means public reporting of performance.
- **Patient-Centered Measures** should fall along the following dimensions:
  - respect for patients' values, preferences, and expressed needs;

- continuous collaboration, coordination, and integration of care among providers and across conditions and settings;
- accessible and customized information;
- communication and education, including self-efficacy and self-management skills for patients and families, and easy access to decision support tools;
- the provision of physical comfort to patients;
- the offering to patients of emotional support and relief from fear and anxiety;
- the involvement of family and friends in care; and
- access to care.

Settings of Care Considerations

- **Rural Healthcare Settings:** All rural healthcare settings should comply with the specifications of this safe practice. Although small and rural hospitals may be more resource-constrained than larger urban or suburban hospitals, great efficiencies can be gained through participation in the national safety and quality collaborative initiatives of similar organizations. Alliances with similar organizations in noncompetitive service areas provide opportunities for information sharing and resource access. Collaboration with external reporting organizations provides an excellent opportunity for rural and small organizations to identify and mitigate risks proactively.
- **Children's Healthcare Settings:** All children's healthcare settings should comply with the relevant specifications of this safe practice. Progressive work in risk identification and mitigation is occurring in such settings.
- **Specialty Healthcare Settings:** All specialty hospitals should comply with the relevant specifications of this safe practice. National alliances and collaborative initiatives provide rich opportunities for efficiencies in information sharing and resource sharing.

New Horizons and Areas for Research

That leadership is critical to patient safety is clear to academics, frontline caregivers, and patients. Leaders should become aware of the performance gaps that can harm patients; should be held accountable to take actions that will close those gaps; should invest in the ability of their organizations to improve in these areas; and should clearly understand how they can create an environment in which explicit actions affecting patient safety will become a priority. More research is needed to help design the structures and systems that must be established to support leaders. Research in the development of the necessary concepts, tools, and resources should be undertaken, including efforts that focus on the application of concepts in high reliability, tools such as performance dashboards, and resources such as educational programs for governance board members and leadership teams; and near-real-time risk management support. Leadership decision-support systems need to be developed and optimized to balance risk reduction and investment in safety. Risk reduction and mitigation must be factored into clinical, operational, and financial performance for representative hospital situations, allowing healthcare leaders to then customize their decisions to their unique scenarios. Organizations must manage risk and performance information in a manner that will allow them to give finance teams enough confidence to vote "yes" to greenlight

investment in patient safety initiatives—even in an environment where financial resources are in short supply. [Denham, 2009d]

Other Relevant Safe Practices

All of the NQF-endorsed® safe practices are pertinent to Safe Practice 4: Identification and Mitigation of Risks and Hazards.

Notes

Adler, 2008: Adler L, Denham CR, McKeever M, et al. Global Trigger Tool: Implementation Basics. J Patient Saf 2008 Dec;4(4):245-9.

AHRQ, 2006: [No authors listed.] AHRQ Quality Indicators. Fact Sheet. Patient Safety Indicators. Rockville (MD): Agency for Healthcare Research and Quality; 2006 Feb. Available at http://www.qualityindicators.ahrq.gov/downloads/psi/2006-Feb-PatientSafetyIndicators.pdf. Last accessed October 20, 2009.

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

AHRQ, N.D.a: [No authors listed.] Patient Safety Primer: Never Events. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=3. Last accessed October 20, 2009.

AHRQ, N.D.b: [No authors listed.] Patient Safety Primer: Root Cause Analysis. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=10. Last accessed October 14, 2009.

AHRQ, N.D.c: [No authors listed.] Patient Safety Primer: Voluntary Patient Safety Event Reporting (Incident Reporting). AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=13. Last accessed October 20, 2009.

Alemi, 2007: Alemi F. Probabilistic risk analysis is practical. Qual Manag Health Care 2007 Oct-Dec;16(4):300-10.

APIC, 2008: Association for Professionals in Infection Control and Epidemiology (APIC). Pandemics. 2008. Available at http://www.apic.org/AM/Template.cfm?Section=Pandemics&Template=/CM/HTMLDisplay.cfm&ContentID=12080. Last accessed January 11, 2009.

Apold, 2006: Apold J, Daniels T, Sonneborn M. Promoting collaboration and transparency in patient safety. Jt Comm J Qual Patient Saf 2006 Dec;32(12):672-5.

Bagian, 2002: Bagian JP, Gosbee J, Lee CZ, et al. The Veterans Affairs root cause analysis system in action. Jt Comm J Qual Improv 2002 Oct;28(10):531-45.

Battles, 2006: Battles JB, Dixon NM, Borotkanics RJ, et al. Sensemaking of patient safety risks and hazards. Health Serv Res 2006 Aug;41(4 Pt 2):1555-75.

Blumenthal, 2010: Blumenthal D. Launching HITECH. N Engl J Med 2010 Jan 4. [Epub ahead of print]

Boothman, 2009: Boothman RC, Blackwell AC, Campbell DA Jr, et al. A better approach to medical malpractice claims? The University of Michigan experience. Journal of Health & Life Sciences Law 2009 Jan;2(2):125-59.

Boutwell, 2008: Boutwell A, Jencks S, Nielsen G, et al. Reducing Re-hospitalizations in a State or Region. Minicourse M1. Presented at the Institute for Healthcare Improvement's 20th Annual National Forum on Quality Improvement in Health Care; November 19, 2008; Nashville, TN. Available at http://www.ihi.org/ihi/files/Forum/2008/Handouts/M1_ReducReHosp_Boutwell.pdf. Last accessed October 29, 2009.

Carthey, 2001: Carthey J, de Leval MR, Reason JT. Institutional resilience in healthcare systems. Qual Health Care 2001 Mar;10(1):29-32.

CDC, N.D.a: Centers for Disease Control and Prevention. Legionellosis Resource Site (Legionnaires' Disease and Pontiac Fever). No Date. Available at http://www.cdc.gov/legionella/index.htm. Last accessed November 3, 2009.

CDC, N.D.b: [No authors listed.] Emergency Preparedness and Response. Atlanta (GA): Centers for Disease Control and Prevention; No Date. Available at http://emergency.cdc.gov/. Last accessed October 20, 2009.

CDC, N.D.c: [No authors listed.] Pandemic Influenza Resources. Pandemic Influenza Information for Health Professionals. Atlanta (GA): Centers for Disease Control and Prevention; No Date. Available at http://www.cdc.gov/flu/pandemic/healthprofessional.htm. Last accessed October 20, 2009.

Chiozza, 2009: Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. Clin Chim Acta 2009 Jun;404(1):75-8. Epub 2009 Mar 17.

CMS, 2008a: Centers for Medicare & Medicaid (CMS) Press Release. CMS Proposes to Expand Quality Program for Hospital Inpatient Services in FY 2009. Available at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3041&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=true&cboOrder=date. Last accessed November 3, 2008.

CMS, 2008b: Centers for Medicare & Medicaid Services (CMS). Department of Health and Human Services. Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights; Final Rule. Fed Regist 42 CFR Part 482. 2006 Dec 8. Available at http://www.cms.hhs.gov/CFCsAndCoPs/downloads/finalpatientrightsrule.pdf. Last accessed October 14, 2009.

CMS, 2008c: CMS. Hospital-Acquired Conditions Overview. Centers for Medicare & Medicaid Services. Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed November 3, 2008.

Collins, 2009: Collins J. How the Mighty Fall: And Why Some Companies Never Give In. New York (NY): HarperCollins Publishers Inc.; 2009.

Conway, 2008: Conway J. Getting boards on board: engaging governing boards in quality and safety. Jt Comm J Qual Patient Saf 2008 Apr;34(4):214-20.

Damiani, 2009: Damiani G, Pinnarelli L, Scopelliti L, et al. A review on the impact of systematic safety processes for the control of error in medicine. Med Sci Monit 2009 Jul;15(7):RA157-66.

Denham, 2005: Denham CR. Patient safety practices: leaders can turn barriers into accelerators. J Patient Saf 2005 Mar;1(1):41-55.

Denham, 2006: Denham CR. From harmony to healing: join the quality choir. J Patient Saf 2006 Dec;2(4):225-32.

Denham, 2007: Denham CR. TRUST: the five rights of the second victim. J Patient Saf 2007June;3(2):107-19.

Denham, 2008: Denham CR. May I have the envelope please? J Patient Saf 2008 Jun;4(2):119-23.

Denham, 2009a: Denham CR. Is your hospital as safe as your bank? ... time to ask your board. J Patient Saf 2009 Jun;5(2):122-6.

Denham, 2009b: Denham CR. Are you infected? J Patient Saf 2009 Sep;5(3):188-96.

Denham, 2009c: Denham CR. The no outcome no income tsunami is here. Are you a surfer, swimmer or sinker? J Patient Saf 2009 Mar;5(1):42-52.

Denham, 2009d: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2009 Dec;5(4):Pending.

Denham, 2009e: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4):210-5.

Emily, 2009: Emily M, Casez P, François O. Risk assessment for hospital-acquired diseases: a risk-theory approach. Risk Anal 2009 Apr;29(4):565-75. Epub 2008 Dec 23.

Gallagher, 2009: Gallagher T. A 62-year-old woman with skin cancer who experienced wrong-site surgery: review of medical error. JAMA 2009;302(6):669-677.

Griffin, 2008: Griffin FA, Classen DC. Detection of adverse events in surgical patients using the Trigger Tool approach. Qual Saf Health Care 2008 Aug;17(4):253-8.

Griffin, 2009: Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). White Papers: 13. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/IHI/Results/WhitePapers/IHIGlobalTriggerToolWhitePaper.htm. Last accessed October 20, 2009.

Gupta, 2009: Gupta P, Varkey P. Developing a tool for assessing competency in root cause analysis. Jt Comm J Qual Patient Saf 2009 Jan;35(1):36-42.

Haynes, 2009: Haynes HR, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 2009;360:491-9. Epub 2009 Jan 14. Available at http://content.nejm.org/cgi/reprint/360/5/491.pdf. Last accessed December 14, 2009.

Helmreich, 2000: Helmreich RL. On error management: lessons from aviation. BMJ 2000 Mar 18;320(7237):781-5. Available at http://www.bmj.com/cgi/content/full/320/7237/781. Last accessed November 3, 2008.

Hogan, 2008: Hogan H, Olsen S, Scobie S, et al. What can we learn about patient safety from information sources within an acute hospital: a step on the ladder of integrated risk management? Qual Saf Health Care 2008 Jun;17(3):209-15.

Hovor, 2007: Hovor C, O'Donnell LT. Probabilistic risk analysis of medication error. Qual Manag Health Care 2007 Oct-Dec;16(4):349-53.

IHI, N.D.a: [No authors listed.] How to Improve: Medication Systems. Cambridge (MA): Institute for Healthcare Improvement (IHI); No Date. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/HowToImprove/. Last accessed October 20, 2009.

IHI, N.D.b: [No authors listed.] How to Improve: Medication Systems. Rockville (MD): Institute for Healthcare Improvement (IHI); No Date. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/HowToImprove/. Last accessed October 19, 2009.

IHI, N.D.c: IHI (in partnership with Premier, Inc., San Diego, CA). Trigger Tool for Measuring Adverse Drug Events (IHI Tool). Cambridge (MA): Institute for Healthcare Improvement (IHI); No Date. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Trigger%20Tool%20for%20Measuring%20Adverse%20Drug%20Events%20%28IHI%20Tool%29. Last accessed October 20, 2009.

IOM, 2004: Committee on Data Standards for Patient Safety; Aspden P, Corrigan JM, Wolcott J, et al., eds. Patient Safety: Achieving a New Standard for Care. Quality Chasm Series: Institute of Medicine. Washington, DC: The National Academies Press; 2004. Available at http://www.nap.edu/catalog.php?record_id=10863#toc. Last accessed October 20, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Oak Brook (IL): Joint Commission Resources; 2010.

Jencks, 2009: Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med 2009 Apr 2; 360(14):1418-28. Available at http://content.nejm.org/cgi/reprint/360/14/1418.pdf. Last accessed October 14, 2009.

Jha, 2009: Jha AK, Epstein AM. Hospital governance and the quality of care. Health Aff (Millwood) 2010 Jan-Feb;29(1):182-7. Epub 2009 Nov 6.

Kaldjian, 2007: Kaldjian LC, Jones EW, Wu BJ, et al. Disclosing medical errors to patients: attitudes and practices of physicians and trainees. J Gen Intern Med 2007 Jul;22(7):988-96. Epub 2007 May 1. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=17473944. Last accessed November 3, 2008.

Kaldjian, 2008: Kaldjian LC, Jones EW, Wu BJ, et al. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. Arch Intern Med 2008 Jan 14;168(1):40-6.

Kilbridge, 2006: Kilbridge, PM. Classen D, Bates DW, Denham CR. The National Quality Forum Safe Practice Standard for Computerized Physician Order Entry: Updating a Critical Patient Safety Practice. J Patient Saf 2006 Dec;(2)4:183-90.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed January 6, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed January 6, 2009.

Levinson, 2008c: Levinson DR. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: case study of incidence among Medicare beneficiaries in two selected counties. OEI-06-08-00220. Available at http://oig.hhs.gov/oei/reports/oei-06-08-00220.pdf. Last accessed January 5, 2009.

Marx, 2003: Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. Qual Saf Health Care 2003 Dec;12 Suppl 2:ii33-8. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=14645893. Last accessed November 3, 2008.

McDonald, 2008: McDonald T, Smith KM, Mayer D. Full Disclosure and Residency Education. ACGME Bulletin. 2008 May;5-9. Available at http://www.acgme.org/acWebsite/bulletin/bulletin5_08.pdf. Last accessed November 3, 2008.

McDonald, 2009: McDonald TB, Helmchen L, Smith KM, et al. Responding to Patient Safety Incidents: The Seven Pillars. Qual Saf Health Care [accepted]

Milch, 2006: Milch CE, Salem DN, Pauker SG, et al. Voluntary electronic reporting of medical errors and adverse events. An analysis of 92,547 reports from 26 acute care hospitals. J Gen Intern Med 2006 Feb;21(2):165-70. Epub 2005 Dec 22. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=16390502. Last accessed November 3, 2008.

Mills, 2008: Mills PD, Neily J, Kinney LM, et al. Effective interventions and implementation strategies to reduce adverse drug events in the Veterans Affairs (VA) system. Qual Saf Health Care 2008 Feb;17(1):37-46.

Murff, 2006: Murff HJ, France DJ, Blackford J, et al. Relationship between patient complaints and surgical complications. Qual Saf Health Care 2006 Feb;15(1):13-6.

Nance, 2008: Nance JJ. Why Hospitals Should Fly: The Ultimate Flight Plan to Patient Safety and Quality Care. Bozeman (MT): Second River Healthcare Press; 2008.

NPP, 2009: National Priorities Partnership. National Quality Forum. No Date. Available at http://www.nationalprioritiespartnership.org/Home.aspx. Last accessed November 2, 2009.

NQF, 2010: National Quality Forum (NQF). Safe Practice 1: Culture of Safety: Leadership Structures and Systems. Safe Practices for Better Healthcare – 2010 Update: A Consensus Report. Washington, DC: The National Quality Forum; 2010.

Nuckols, 2009: Nuckols TK, Bell DS, Paddock SM, et al. Comparing process- and outcome-oriented approaches to voluntary incident reporting in two hospitals. Jt Comm J Qual Patient Saf 2009 Mar;35(3):139-45.

Percarpio, 2008: Percarpio KB, Watts BV, Weeks WB. The effectiveness of root cause analysis: what does the literature tell us? Jt Comm J Qual Patient Saf 2008 Jul;34(7):391-8.

Pizzi, 2001: Pizzi LT, Goldfarb NI, Nash DB. Promoting a culture of safety. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality [AHRQ]; 2001 Jul: Chapter 40. Available at http://www.ahrq.gov/clinic/ptsafety/pdf/chap40.pdf. Last accessed October 19, 2009.

Pronovost, 2009a: Pronovost PJ, Goeschel CA, Olsen KL, et al. Reducing health care hazards: lessons from the commercial aviation safety team. Health Aff (Millwood) 2009 May-Jun;28(3):w479-89. Epub 2009 Apr 7.

Pronovost, 2009b: Pronovost PJ, Sexton JB, Pham JC, et al. Measurement of quality and assurance of safety in the critically ill. Clin Chest Med 2009 Mar;30(1):169-79, x. Review.

Reason, 2000: Reason J. Human error: models and management. BMJ Mar 18;320(7237):768-70. Available at http://www.bmj.com/cgi/content/full/320/7237/768. Last accessed October 12, 2009.

Reason, 2001: Reason JT, Carthey J, de Leval MR. Diagnosing "vulnerable system syndrome": an essential prerequisite to effective risk management. Qual Health Care 2001 Dec;10 Suppl 2:ii21-5. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=11700375. Last accessed November 2, 2009.

Richman, 2009: Richman J, Mason T, Mason-Whitehead E, et al. Social aspects of clinical errors. Int J Nurs Stud 2009 Aug;46(8):1148-55. Epub 2009 Feb 8.

Rodriguez-Paz, 2009: Rodriguez-Paz JM, Kennedy M, Salas E, et al. Beyond "see one, do one, teach one": toward a different training paradigm. Qual Saf Health Care 2009 Feb;18(1):63-8.

TJC, 2008: The Joint Commission (TJC). 2009 Accreditation Requirements Chapters. Accreditation Program: Hospital. Pre-publication Version. 2008. Available at http://www.jointcommission.org/NR/rdonlyres/8CCED568-76C9-4B3A-AC9C-B99FF0A2ED04/0/HAP_AllChapters.pdf. Last accessed October 20, 2009.

Tuttle, 2002: Tuttle D, Panzer RJ, Baird T. Using administrative data to improve compliance with mandatory state event reporting. Jt Comm J Qual Improv 2002 Jun;28(6):349-58.

Warye, 2009: Warye K, Granato J. Target: zero hospital-acquired infections. Healthc Financ Manage 2009 Jan;63(1):86-91.

Weingart, 2009: Weingart SN, Morway L, Brouillard D, et al. Rating recommendations for consumers about patient safety: sense, common sense, or nonsense? Jt Comm J Qual Patient Saf 2009 Apr;35(4):206-15.

West, 2006: West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006 Sep 6;296(9):1071-8. Available at http://jama.ama-assn.org/cgi/content/full/296/9/1071. Last accessed January 11, 2009.

Wreathall, 2004: Wreathall J, Nemeth C. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. Qual Saf Health Care 2004 Jun;13(3):206-12. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15175492. Last accessed November 2, 2009.

Wu, 2008: Wu AW, Lipshutz AK, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. JAMA 2008 Feb 13;299(6):685-7. Available at http://jama.ama-assn.org/cgi/content/full/299/6/685. Last accessed November 2, 2009.

Yeo, 2009: Yeo H, Viola K, Berg D, et al. Attitudes, training experiences, and professional expectations of US general surgery residents: a national survey. JAMA 2009 Sep 23;302(12):1301-8. Available at http://jama.ama-assn.org/cgi/reprint/302/12/1301. Last accessed December 15, 2009.

Chapter 3: Improving Patient Safety Through Informed Consent, Life-Sustaining Treatment, Disclosure, and Care of the Caregiver

Background

IMPROVED TRANSPARENCY IN HEALTHCARE provides opportunities to reduce preventable pain, suffering, and stress for the patients treated and the caregivers who have their trust. Trust is a critical theme to this chapter of practices. Improved communication of information to patients and families helps caregivers earn patients' trust in healthcare and also helps to provide a buffer for caregivers who have unwillingly harmed patients through system failures and predictable human error. Trust in healthcare leadership and justice of the various systems that swing into action after adverse events occur is vital to a cultural transformation to truly safe care.

This chapter provides guidance about practices that require conveying important but often difficult information to patients and an administrative practice to care for caregivers after an adverse event causing harm to patients. The practices addressing transfer of information to patients include asking each patient or legal surrogate to "teach back," in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent; providing written documentation of the patient's preferences for life-sustaining treatments; and disclosing unanticipated outcomes when they occur. A fourth safe practice discusses the provision of care to the caregivers (clinical providers, staff, and administrators) involved in serious unintentional and preventable harm to patients.

Although many patients have the capacity to make good choices about their care, they do not always do so. This happens for many reasons, including a lack of energy, a desire to please the healthcare provider by doing what he or she thinks is best, a sense of discomfort or intimidation associated with the healthcare setting, or a low level of health literacy or limited English language proficiency. For providers, the challenge of communicating in a

way that meets the needs of each patient means that providers must be trained and practiced in communication skills and empathic listening. Explaining care options in appropriate and objective ways and accepting each patient's choices are hallmarks of professional behavior.

In the case of informed consent, patients receive information about both expected and unanticipated outcomes; in discussions about end-of-life care, all parties to the conversation must acknowledge the fact that death can and does occur in healthcare settings. Disclosure of untoward outcomes of care is a painful acknowledgment that the healthcare system and those within it do not always function perfectly. In such circumstances, healthcare providers may experience feelings of guilt and may fear that patients and families will not understand that the event was unintended. The *Care of the Caregiver* practice encourages systems to have a process in place so that when a harmful event occurs, involved caregivers will receive timely and systematic care as they become patients who have sustained a traumatic psychological emergency. This practice also encourages the organization to foster transparency and implement performance improvement efforts that may reduce future harmful events.

As difficult as these disclosures and acknowledgments may be, caregivers and organizations that are committed to patients as part of the healthcare team must take the steps that are needed to involve them in decisions that affect their care and in discussions about unanticipated outcomes. They also must understand that it is only when patients are treated with respect that a sincere effort to ensure their full participation in all decisions affecting their healthcare can occur.

SAFE PRACTICE 5: INFORMED CONSENT

The Objective

Ensure that patients, and, when appropriate, families and legal guardians, understand the proposed treatment and its potential complications.

The Problem

Obtaining informed consent is an essential part of the healthcare process and is, in fact, a process rather than a single act or event. It is a process of communication between the patient and healthcare provider that results in the patient's agreement to undergo a specific medical intervention. Informed consent can be plainly described as the *learned* choice made by a patient. [Plawecki, 2009] The process may result in the execution of a written informed consent document. Informed consent is imperative before the undertaking of any major procedure, including, but not limited to, surgery and other invasive procedures. The primary purpose of the informed consent process is to ensure that the patient makes an informed decision about whether to undergo a proposed treatment or procedure. The process involves the patient as a collaborator with the healthcare provider in developing and evaluating treatment options. A properly executed informed consent process includes, and documents, shared decision-making. In recent years, the forms that have been used to document informed consent have become mainly legal documents that protect institutions rather than provide information for shared decisionmaking.

The frequency with which patients do not receive the appropriate informed consent documents is of great concern. Studies have shown that more than two-thirds of patients in the United States do not receive any written information about their condition from their physicians. Other studies have shown that up to 75 percent of written consent forms are incomplete. [Shojania, 2001] Because an estimated 90 million adults in the United States have limited health literacy, [IOM, 2004] policies should be implemented to ensure the use of clear informed consent documents that most patients and their families can easily understand. [Denham, 2008a; Shaw, 2009]

Communication failures between patients and healthcare providers are at the root of systems failures and human errors that lead to harm, [Denham, 2008b; Levinson, 2008] but the severity of these failures is not known. Applicants may understand only 30 to 81 percent of information in standard consent forms. [Kripalani, 2008] Informed consent is a critical healthcare process, both clinically, to provide patients with vital information, and ethically, to preserve patient autonomy. A study in the *Archives of Surgery* examined 540 consent forms in 157 hospitals. Only 26 percent of them addressed the four key elements of informed consent: benefits of treatment, risks, alternatives, and educational information. [Bottrell, 2000]

Communication is the key to preventing harm related to the lack of informed consent. [Schyve, 2007; Shaw, 2009] Informed consent should be an interactive process between healthcare providers and patients, not simply a form for which a signature must be obtained. [Balfour, 2009; Childers, 2009] Asking patients to recount, or "teach back," the proposed treatment or procedure is one method that providers can use to determine how well patients understand the information they receive. Effective communication must take into account language, cultural differences, and health literacy of the population serviced

to ensure safe healthcare. Communication issues are the most frequent root cause of serious adverse events reported to The Joint Commission's Sentinel Event Database. A Joint Commission study indicated that adverse outcomes due to medical errors are more serious in patients with limited English proficiency than in English-speaking patients. [O'Leary, 2007; Schyve, 2007]. Teach-back requires that patients translate the information into words and concepts they understand and demonstrates their comprehension and the degree to which their consent is truly informed. During the communication process, it is essential that the healthcare provider disclose and discuss the patient's diagnosis and the nature and purpose of the treatment/procedure. The risks and benefits of both the treatment and alternatives to treatment should be thoroughly reviewed. The patient should have the opportunity to ask questions and openly communicate with the healthcare provider.

Informed consent has been used to promote cost-effective care. Improving missed, incomplete, or poorly understood informed consent provides a significant opportunity to improve patient safety opportunity, and it has the potential for significantly affecting cost. Better-informed patients, by acting as another layer of protection, are less likely to experience medical errors. [Shojania, 2001] Ensuring that informed consent is provided is an ethical, professional, and legal requirement of physicians, but one that is often overlooked. [Balfour, 2009; Pattinson, 2009] A doctor-patient relationship with open communication and active listening is a critical element in the practice of good medicine. [Childers, 2009] Patients who are well informed are more satisfied with their care, more likely to have a good outcome, more trusting of their providers, and more able to make decisions that reflect their personal preferences and values.

Safe Practice Statement

Ask each patient or legal surrogate to "teach back," in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent. [Pizzi, 2001; IHI, 2009]

Additional Specifications

- At a minimum, patients should be able to explain, in their everyday words, [Shaw, 2009] the diagnosis/health problem for which they need care; the name/type/general nature of the treatment, service, or procedure, including what receiving it will entail; and the primary risks, benefits, and alternatives. This safe practice includes all of the following elements: [Johnson, 2008; UMich, 2008]
  - Informed consent documents for use with the patient should be written at or below the fifth grade level and in the primary language of the patient. [Garcia, 2008; Shaw, 2009]
  - The patient, and, as appropriate, the family and other decisionmakers, should be engaged in a dialogue about the nature and scope of the procedure for which consent is being sought.
  - A qualified medical interpreter or reader should be provided to assist patients with limited English proficiency, limited health literacy, and visual or hearing impairments.
  - The risk that is associated with high-risk elective cardiac procedures and high-risk procedures with the strongest volume-outcomes relationship should be conveyed. [NQF, 2006]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- "Teach-back" should begin early in the process of patient care decisionmaking to ensure that patients have time to understand and think about the options.
- Questions that begin with phrases such as "I want to be sure we have the same understanding...." "Please tell me in your own words...." "This is important for your safety...." asked by healthcare professionals or interpreters will allow patients to relay or "teach back" what they understand they have been told.
- Consider use of a visual presentation through pictures and illustrations in addition to written and verbal instructions. [Yates, 2009]
- Consider the utilization of a computerized electronic consent system or an electronic information module, both of which are gaining popularity as educational tools that can assist providers in fully informing patients about the treatment, benefits, alternative therapies, and risks associated with specific situations. [Nwomeh, 2009; Patel, 2009; Rigatelli, 2009]
- As an example, healthcare organizations could disclose information about where the evidence is the strongest for the volume-outcome relationship for specific procedures to patients. Such information would include mortality/survival rates and annual procedures or treatment volumes. [Kazmers 1996; Jollis 1994; Glasgow 1996; Begg 1998a; Patti 1998; Begg, 1998b; Phibbs 2007]
- Conceptual differences in thinking about Health Literacy [Garcia, 2008; Reeves, 2008]
  - Risk – the impact of low health literacy is recognized, and healthcare workers are expected to aid those with low literacy to minimize disadvantages/inequity that may result. Currently, this is the model in use and has the largest amount of research to support it.
  - Asset – build up health literacy through patient education to enable patients to take a more active role in disease management, discussions with healthcare providers, and navigation of the health-care system. This is a newer concept and there is little evidence to support or refute it. [Nutbeam, 2008; Nutbeam, 2009]
- To be complete, institutional policies on informed consent should document the following elements:
  - which type of procedures or care, treatment, or services require informed consent; [JCR, 2010b]
  - the process used to obtain informed consent; [JCR, 2010b]
  - how informed consent is to be documented in the record; [JCR, 2010b]
  - when a surrogate decisionmaker, rather than the patient, may give informed consent; [JCR, 2010b] and
  - when procedures or care, treatment, and services normally requiring informed consent may be given without informed consent. [JCR, 2010b]

Strategies of Progressive Organizations

- [Wu, 2005a; Wu, 2005b] Some organizations have a standardized approach to educating providers, using a strategy that promotes adequate communication and informed consent and one that appreciates the implications of limited health literacy. [AHRQ, 2009] They use new employee orientations and ongoing educational and peer reinforcement events to teach the process of obtaining informed consent, which includes the following:
- specifically telling the patient that to help ensure safety he or she needs to state in his or her own words what the procedure is, its risks and benefits, and what part of his or her body will be involved;
- having the patient write that information directly onto consent forms or having staff write the patient's specific response on the form or into his or her healthcare record; and
- requiring evidence of "teach-back" on the consent form or in the patient's healthcare record before the procedure can be performed.

Opportunities for Patient and Family Involvement

- Healthcare providers can formally encourage active patient involvement of patients in their own care as a patient safety strategy. [Johnson, 2008; DFCI, 2009; Jack, 2009; TJC, 2009; JCR, 2010a]
- Providers should systematically encourage patients and family members to ask questions during the informed consent process. [Balfour, 2009]
- Healthcare organizations should include patients and/or family members on internal committees for informed consent protocol/policy development.
- Healthcare providers should give full details of all treatment procedures and medication side effects, and risks and benefits, in language that is easy for the patient and his or her family to understand.
- Healthcare organizations should consider formally encouraging patients and their families to report concerns about safety regarding the organization's informed consent process. An example would be to have mechanisms in place to provide input that may trigger a rapid response (e.g., global call-in numbers, contact person during patient care encounters). [JCR, 2010a]
- When completing the instruction, ask the patient to restate what he or she has just learned in order to determine whether comprehension took place as intended.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include the monitoring and trending of patients' concerns about how they were informed and perceived gaps in information.
- **Process Measures** include evidence of compliance with all elements of the organization's informed consent policy and procedures.

- NQF-endorsed® process measures:
  1. #0310: LBP: Shared Decision Making [Ambulatory Care (office/clinic)]: Percentage of patients with whom a physician or other clinician reviewed the range of treatment options, including alternatives to surgery prior to surgery. To demonstrate shared decisionmaking, there must be documentation in the patient record of a discussion between the physician and the patient that includes all of the following:
     - treatment choices, including alternatives to surgery;
     - risks and benefits; and
     - evidence of effectiveness.

     Note: This measure is applicable only for physicians who perform surgery.
  2. #0324: Patient Education Awareness – Facilities: [Ambulatory Care (office/clinic)]: Percentage of all ESRD patients 18 years and older with documentation regarding a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no treatment). Measured once a year.

- **Structure Measures** include the presence of an informed consent policy and procedures that meet accreditation requirements and measure staff awareness based on orientation and training.
- **Patient-Centered Measures** include evidence of results from the "teach-back" process, patient satisfaction with the informed consent process, and overall confidence in the transparency of the healthcare setting.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** The informed consent process for pediatrics involves the family and the patient (appropriate to his or her age and developmental milestones).
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Areas in which research could be valuable include the following:

- evaluation of patient understanding when consent forms are in the patient's primary language; [The White House, 2000]
- evaluation of patient understanding when consent forms are simplified in terms of reading levels; and
- assessment of patient and provider attitudes about informed consent.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards.

Notes

AHRQ, 2009: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

Balfour, 2009: Balfour D. Frequent questions on informed consent. OR Manager 2009 Apr;25(4):23-5.

Begg, 1998a: Esophagectomy: Begg CB, Cramer LD, Hoskins WJ, et al. Impact of hospital volume on operative mortality for major cancer surgery. JAMA 1998 Nov 25;280(20):1747-51. Available at http://jama.ama-assn.org/cgi/content/full/280/20/1747. Last accessed October 13, 2009.

Begg, 1998b: Pancreatectomy: Begg CB, Cramer LD, Hoskins WJ, et al. Impact of hospital volume on operative mortality for major cancer surgery. JAMA 1998 Nov 25;280(20):1747-51. Available at http://jama.ama-assn.org/cgi/content/full/280/20/1747. Last accessed October 13, 2009.

Bottrell, 2000: Bottrell MM, Alpert H, Fischbach RL, et al. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. Arch Surg 2000 Jan;135(1):26-33.

Childers, 2009: Childers R, Lipsett PA, Pawlik TM. Informed consent and the surgeon. J Am Coll Surg 2009 Apr;208(4):627-34. Epub 2009 Jan 21.

Denham, 2008a: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Denham, 2008b: Denham CR, Dingman J, Foley ME, et al. Are you listening … Are you really listening? J Patient Saf 2008 Sep;4(3):148-61.

DFCI, 2009: Dana-Farber Cancer Institute. Patient- and Family-Centered Care. Available at http://www.dana-farber.org/pat/pfac/establishing-patient-centered-care.html. Last accessed December 10, 2009.

Garcia, 2008: Garcia CH, Hanley J, Souffrant G. A single question may be useful for detecting patients with inadequate health literacy. J Gen Intern Med 2008 Sep;23(9):1545.

Glasgow, 1996: Pancreatectomy: Glasgow RE, Mulvihill SJ. Hospital volume influences outcome in patients undergoing pancreatic resection for cancer. West J Med 1996 Nov;165(5):294-300. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1303846&blobtype=pdf. Last accessed October 13, 2009.

IHI, 2009: [No authors listed.] Shared Decision Making. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=dd91f497-7eaa-433f-928c-838818fdf1f5. Last accessed October 13, 2009.

IOM, 2004: Nielsen-Bohlman L, Panzer AM, Kindig DA, eds.; Committee on Health Literacy. Institute of Medicine (IOM). Health Literacy: A Prescription to End Confusion. Washington, DC: The National Academies Press; 2004. Available at http://www.nap.edu/catalog.php?record_id=10883. Last accessed October 13, 2009.

Jack, 2009: Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009 Feb 3;150(3):178-87.

JCR, 2010a: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.13.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

JCR, 2010b: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standard RI.01.03.01. Oak Brook (IL): Joint Commission Resources; 2010.

Johnson, 2008: Johnson B, Abraham M, Conway J, et al. Partnering with patients and families to design a patient- and family-centered health care system: recommendations and promising practices. Bethesda (MD) and Cambridge (MA): Institute for Family-Centered Care and Institute for Healthcare Improvement; 2008 April. Available at http://www.familycenteredcare.org/pdf/PartneringwithPatientsandFamilies.pdf. Last accessed January 13, 2010.

Jollis, 1994: PCI: Jollis JG, Peterson ED, DeLong ER, et al. The relation between the volume of coronary angioplasty procedures at hospitals treating Medicare beneficiaries and short-term mortality. N Engl J Med 1994 Dec 15;331(24):1625-9. Available at http://content.nejm.org/cgi/content/full/331/24/1625. Last accessed October 13, 2009.

Kazmers, 1996: AAA: Kazmers A, Jacobs L, Perkins A, et al. Abdominal aortic aneurysm repair in Veterans Affairs medical centers. J Vasc Surg 1996 Feb;23(2):191-200.

Kripalani, 2008: Kripalani S, Bengtzen R, Henderson LE, et al. Clinical research in low-literacy populations: using teach-back to assess comprehension of informed consent and privacy information. IRB 2008 Mar-Apr;30(2):13-9.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 13, 2009.

NQF, 2006: NQF. Safe Practices for Better Healthcare: 2006 Update. A Consensus Report. Washington, DC: National Quality Forum (NQF); 2006. Available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1246. Last accessed October 30, 2009.

Nutbeam, 2008: Nutbeam D. The evolving concept of health literacy. Soc Sci Med 2008 Dec;67(12):2072-8. Epub 2008 Oct 25.

Nutbeam, 2009: Nutbeam D. Defining and measuring health literacy: what can we learn from literacy studies? Int J Public Health 2009;54(5):303-5.

Nwomeh, 2009: Nwomeh BC, Hayes J, Caniano DA, et al. A parental educational intervention to facilitate informed consent for emergency operations in children. J Surg Res 2009 Apr;152(2):258-63. Epub 2008 Feb 4.

O'Leary, 2007: O'Leary DS, Davis RM, Cordell T. Low health literacy puts patients at risk: The Joint Commission sets forth solutions to national problem. Director 2007 Summer;15(3):44, 59.

Patel, 2009: Patel V, Aggarwal R, Kinross J, et al. Improving informed consent of surgical patients using a multimedia-based program?: results of a prospective randomized multicenter study of patients before cholecystectomy. Ann Surg 2009 Mar;249(3):546-7; author reply 547-8.

Patti, 1998: Esophagectomy: Patti MG, Corvera CU, Glasgow RE, et al. A hospital's annual rate of esophagectomy influences the operative mortality rate. J Gastrointest Surg 1998 Mar-Apr;2(2):186-92.

Pattinson, 2009: Pattinson SD. Consent and informational responsibility. J Med Ethics 2009 Mar;35(3):176-9.

Phibbs, 2007: High-Risk Deliveries: Phibbs CS, Baker LC, Caughey AB, et al. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. N Engl J Med 2007 May 24;356(21):2165-75. Available at http://content.nejm.org/cgi/reprint/356/21/2165.pdf. Last accessed October 13, 2009.

Pizzi, 2001: Pizzi LT, Goldfarb NI, Nash DB. Role of the Patient: Procedures For Obtaining Informed Consent. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Section H, Ch. 48. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2001. Available at http://www.ahrq.gov/clinic/ptsafety/chap48.htm. Last accessed October 13, 2009.

Plawecki, 2009: Plawecki LH, Plawecki HM. Obtaining informed consent can be a very complex task. J Gerontol Nurs 2009 Feb;35(2):3-4.

Reeves, 2008: Reeves K. Health literacy: the newest vital sign. Medsurg Nurs 2008 Oct;17(5):288, 296.

Rigatelli, 2009: Rigatelli G, Magro B, Ferro S, et al. Education, and obtaining of informed consent, using multimedia before adults with congenitally malformed hearts are submitted to transcatheter interventions. Cardiol Young 2009 Feb;19(1):60-3. Epub 2008 Dec 23.

Schyve, 2007: Schyve PM. Language differences as a barrier to quality and safety in health care: the Joint Commission perspective. J Gen Intern Med 2007 Nov;22 Suppl 2:360-1. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2078554&blobtype=pdf. Last accessed October 13, 2009.

Shaw, 2009: Shaw A, Ibrahim S, Reid F, et al. Patients' perspectives of the doctor-patient relationship and information giving across a range of literacy levels. Patient Educ Couns 2009 Apr;75(1):114-20. Epub 2008 Nov 28.

Shojania, 2001: Shojania K, Duncan BW, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality; 2001 Jul.

The White House, 2000: Clinton WJ. The White House. Executive Order 13166: Improving Access to Services for Persons with Limited English Proficiency; 2000 Aug 11. Available at http://www.usdoj.gov/crt/cor/Pubs/eolep.php. Last accessed October 13, 2009.

TJC, 2009: The Joint Commission. Speak Up Initiatives. 2009 Dec 08. Available at http://www.jointcommission.org/PatientSafety/SpeakUp/. Last accessed December 10, 2009.

UMich, 2008: UMHS Compliance Office, Informed Consent Committee, Office of Clinical Affairs. Policy 62-10-001: Informed Consent for Invasive Procedures and Treatments Involving Substantial Risk of an Adverse Outcome. Ann Arbor (MI): University of Michigan Hospitals and Health Centers; 2008 May. Available at http://www.med.umich.edu/patientsafetytoolkit/disclosure/consent.doc. Last accessed October 13, 2009.

Wu, 2005a: Wu HW, Nishimi RY, Page-Lopez CM, et al. Improving patient safety through informed consent for patients with limited health literacy. An Implementation Report. Washington, DC: National Quality Forum (NQF); 2005. Available at http://www.qualityforum.org/Publications/2005/09/Improving_Patient_Safety_Through_Informed_Consent_for_Patients_with_Limited_Health_Literacy_.aspx. Last accessed October 30, 2009.

Wu, 2005b: Wu HW, Nishimi RY, Page-Lopez CM. Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals. Washington, DC: National Quality Forum (NQF); 2005. Available at http://input.qualityforum.org/pdf/reports/informed_consent_guide.pdf. Last accessed October 30, 2009.

Yates, 2009: Yates BC, Dodendorf D, Lane J, et al. Testing an alternate informed consent process. Nurs Res 2009 Mar-Apr;58(2):135-9.

SAFE PRACTICE 6: LIFE-SUSTAINING TREATMENT

The Objective

Ensure that the patient receives only the life-sustaining treatment that he or she desires.

The Problem

A patient's preference for life-sustaining treatment often is not known by his or her caregivers. According to the published literature, there are significant problems in all areas relevant to advance planning (e.g., determining a patient's preferences, transmitting this information to the care setting, and respecting the patient's preferences when life-sustaining treatment decisions are made and carried out). [Denham, 2008]

In 2001, Luce and colleagues found the frequency of deaths occurring in or after intensive care unit admissions to be 22 percent. [Luce, 2001] In the prospective cohort study within a university hospital respiratory care unit, only 33 of the 209 (16.2 percent) patients studied had advance directives. Limitation of life-sustaining treatment was rare (19 percent) and occurred later in the hospital course (median, 39 days). Renal replacement therapies and vasopressors limited more than mechanical ventilation, nutrition, and hydration. [Camhi, 2009]. In 1995, the findings of the landmark SUPPORT (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment) study were published. [SUPPORT Principal Investigators, 1995] The results of more than 9,000 patients showed that communication about end-of-life issues between physicians and patients is limited. Forty-six percent of patients received mechanical ventilation within three days of death. Another study was designed to evaluate the use of advance directives, and the effect of the documents on the care decisions made by healthcare providers. [Fins, 1999] It was reported that 28 percent of all terminally ill patients possessed a Durable Power of Attorney for Healthcare. Forty-six percent of the patients were placed on a ventilator at some time during their hospitalization. Both studies highlighted the lack of regard for the patient's preferences when life-sustaining treatment decisions are carried out.

The severity of the issue was further emphasized by Pieracci and colleagues, who developed a study to analyze life-sustaining treatment decisions that occurred between house staff and either patients or their surrogates. The study showed that despite patients' wishes, the indiscriminate use of technology and the lack of communication between patients and healthcare providers have been shown to result in unnecessary pain and suffering for patients. [Pieracci, 2008] The results of these studies reinforce the subjectivity involved in the decision for life-sustaining treatment. [Meeker, 2009] The presence of end-of-life documents does not appear to influence healthcare providers' decisions about the hospital unit in which patients are treated, the use of life-sustaining treatments, or the initiation of comfort care plans. The presence of a living will does appear to influence healthcare providers' decisions to write do-not-resuscitate orders more often and to use cardiopulmonary resuscitation less often, for patients possessing the document. [Dobbins, 2007] For patients with family caregivers making decisions, the knowledge of family members should be made visible and considered complementary to the care of professionals. [James, 2009]

The preventability of disregarding patients' end-of-life wishes is dependent on open communication between physicians and patients

or their surrogates. [AHRQ, 2009a; AHRQ, 2009b; Camhi, 2009] The American College of Critical Care Medicine has made recommendations for end-of-life care in the intensive care unit. The purpose of the recommendations is to improve the care of patients throughout the dying process. The establishment of objective acuity thresholds for house staff to initiate life-sustaining treatment decisions may eliminate the disparities that are seen among care decisions. [Fins, 1999]

Depending upon geographical location, the cost of providing life-sustaining treatment has been reported to range between $11,000 and nearly $36,000. In a study of 603 patients with advanced cancer, patients who reported having an end-of-life conversation with their physicians had significantly lower healthcare costs in their final week of life, as compared to patients who did not, or $1,876 versus $2,917, a difference of $1,041. [Zhang, 2009] The provision of unwanted end-of-life care is an adverse event that can be avoided by effective patient/provider collaboration. The patient has the right to participate in the development and implementation of his or her plan of care; this includes the right to formulate advance directives and to have hospital staff and practitioners provide care that complies with them. [CMS, N.D.] Documentation of patient preferences should indicate that the patient and his or her family, if appropriate, have given thought to this important issue and have stated preferences in a written advance directive.

Safe Practice Statement

Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart. [Cerminara, 2008]

Additional Specifications

- Organization policies, consistent with applicable law and regulation, should be in place and address patient preferences for life-sustaining treatment and withholding resuscitation. [TJC, 2008; IHI, 2009; JCR, 2010]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, Inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- The organization addresses the wishes of the patient about end-of-life decisions by incorporating processes and staff education efforts that are focused on the specifications and on the following: [Garas, 2001; Loomis, 2009; IHI, N.D]
  - Adults are given written information about their right to accept or refuse medical or surgical treatment, which includes foregoing or withdrawing life-sustaining treatment or withholding resuscitative services. [JCR, 2010]
  - The existence or lack of an advance directive does not determine an individual's access to care, treatment, and services. [JCR, 2010]
  - Documentation indicates whether the patient has signed an advance directive. [JCR, 2010]
  - The patient has the option to review and revise advance directives. [JCR, 2010]

- Appropriate staff members are aware of the advance directive, if one exists. [JCR, 2010]
- The healthcare facility helps or refers patients for assistance in formulating advance directives upon request. [JCR, 2010]
- The healthcare facility documents and honors the patient's wishes concerning organ donation within the limits of the law or its capacity. [JCR, 2010]

- Physicians and caregivers providing end-of-life care need education about compassion fatigue and self-awareness in order to minimize burnout. [Chaplin, 2009; Kearney, 2009]
- Physicians and caregivers should be cognizant of how particular cultural and spiritual beliefs of the patients affect their own view of end-of-life care. [Browning, 2009]

Strategies of Progressive Organizations

- For outpatient hospital settings, the hospital policies address advance directives and specify the extent to which the hospital will honor them. These policies are communicated to patients and families as appropriate to the care, treatment, and services that are provided. The hospital helps patients formulate medical advance directives or refers them for assistance. [JCR, 2010]

Opportunities for Patient and Family Involvement

- Healthcare organizations should include patients and/or family members on internal committees for advance directive protocol/policy development.
- Health providers formally encourage active patients' development of their end-of-life plans of care. [Hansen, 2009]
- Providers should systematically encourage patients and family members to ask questions about end-of-life treatment.
- Fully honest, complete, transparent, and early disclosure to patients and to family members is made that includes the clear and realistic risks, benefits, expectations, and potential for improvement of all possible life-sustaining treatments. [DFCI, 2009; Foong, 2009; Meeker, 2009; Tucker, 2009]

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures** include evidence of compliance with standards of accrediting organizations and evidence that patients' wishes, expressed in their advance directives, mirror the actions taken.
- **Process Measures** include adherence to organizational policy, including the use of ethics committees to address end-of-life issues that arise in the institution.
  - NQF-endorsed® process measure:
    1. #0326: Advance Care Plan: [Ambulatory Care (office/clinic)]: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decisionmaker documented in the medical record or documentation in the medical record that an advance care plan was

discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.

- **Structure Measures** include the presence of an organizational policy.
- **Patient-Centered Measures** include evidence that patients' values and preferences are respected; that accessible and customized information for patients and families is provided; that emotional support and the relief of fear and anxiety is offered; and that patients' satisfaction with the process and their overall confidence in the transparency of the healthcare setting are assessed.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice apply to rural hospitals.
- **Children's Healthcare Settings:** Pediatric care involves unique challenges, because the withholding of resuscitative services is based on the wishes of the parent or legal guardian for children who are legally minors and/or not-yet-emancipated adults. In these instances, the desires of the parent or legal guardian are documented and followed.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

There is some evidence that many patients do not want to use the current standard approach to advance care planning, which includes providing specific instructions and having control over end-of-life medical decisions. Research is needed that explores issues such as the use of advance planning models that involve surrogate decisionmaking based on goal-oriented advance directives versus specific medical treatments; what aspects of care patients want to influence in their end-of-life care; and patient surrogate communication about end-of-life decisionmaking. [Camhi, 2009] With respect to nursing staff, effective nursing education about end-of-life treatments and family counseling should be provided to nurses so they understand the challenges the patient and family members face through end-of-life decisions. [Hansen, 2009]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Browning, 2009: Browning AM. Incorporating spiritual beliefs into end-of-life care. J Christ Nurs 2009 Jan-Mar;26(1):10-7; quiz 18-9.

Camhi, 2009: Camhi SL, Mercado AF, Morrison RS, et al. Deciding in the dark: advance directives and continuation of treatment in chronic critical illness. Crit Care Med 2009 Mar;37(3):919-25.

Cerminara, 2008: Cerminara KL, Bogin SM. A paper about a piece of paper. Regulatory action as the most effective way to promote use of physician orders for life-sustaining treatment. J Leg Med 2008 Oct-Dec;29(4):479-503.

Chaplin, 2009: Chaplin D. Developing an end-of-life care pathway to improve nurses' bereavement care. Nurs Times 2009 Jan 13-19;105(1):20-1.

CMS, N.D.: CMS. Overview: Conditions for Coverage (CfCs) & Conditions of Participations (CoPs). 42 CFR §482.13. Baltimore (MD): Centers for Medicare & Medicaid Services; No Date. Available at http://www.cms.hhs.gov/. Last accessed October 26, 2009.

DFCI, 2009: Dana-Farber Cancer Institute. Patient- and Family-Centered Care. Available at http://www.dana-farber.org/pat/pfac/establishing-patient-centered-care.html. Last accessed December 10, 2009.

Denham, 2008: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Dobbins, 2007: Dobbins EH. End-of-life decisions: influence of advance directives on patient care. J Gerontol Nurs 2007 Oct;33(10):50-6.

Fins, 1999: Fins JJ, Miller FG, Acres CA, et al. End-of-life decision-making in the hospital: current practice and future prospects. J Pain Symptom Manage 1999 Jan;17(1):6-15.

Foong, 2009: Foong P. Designing technology to support end of life decision making. Stud Health Technol Inform 2009;143:348-53.

Garas, 2001: Garas N, Pantilat SZ. Advance Planning For End-of-Life Care. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Ch. 49. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2001 Jul: Ch. 49. Available at http://www.ahrq.gov/clinic/ptsafety/Chap49.htm. Last accessed October 20, 2009.

Hansen, 2009: Hansen L, Goodell TT, Dehaven J, et al. Nurses' perceptions of end-of-life care after multiple interventions for improvement. Am J Crit Care 2009 May;18(3):263-71; quiz 272. Available at http://ajcc.aacnjournals.org/cgi/reprint/18/3/263. Last accessed October 14, 2009.

IHI, 2009: [No authors listed.] Advance Care Planning. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=c59202b7-0c05-4e25-b6fe-a5742f286731. Last accessed October 20, 2009.

IHI, N.D.: [No authors listed.] Last Phase of Life. Cambridge (MA): Institute for Healthcare Improvement (IHI); No Date. Available at http://www.ihi.org/IHI/Topics/LastPhaseofLife/. Last accessed October 20, 2009.

James, 2009: James I, Andershed B, Ternestedt BM. The encounter between informal and professional care at the end of life. Qual Health Res 2009 Feb;19(2):258-71. Epub 2008 Dec 17.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standard RI.01.05.01. Oak Brook (IL): Joint Commission Resources; 2010.

Kearney, 2009: Kearney MK, Weininger RB, Vachon ML, et al. Self-care of physicians caring for patients at the end of life: "Being connected... a key to my survival". JAMA 2009 Mar 18;301(11):1155-64, E1. Available at http://jama.ama-assn.org/cgi/reprint/301/11/1155. Last accessed October 14, 2009.

Loomis, 2009: Loomis B. End-of-life issues: difficult decisions and dealing with grief. Nurs Clin North Am 2009 Jun;44(2):223-31.

Luce, 2001: Luce JM, Prendergast TJ. The Changing Nature of Death in the ICU. IN: Managing Death in the Intensive Care Unit: The Transition From Cure to Comfort. Curtis JR, Rubenfeld GD, eds. Oxford (UK): Oxford University Press; 2001: pgs. 19-29.

Meeker, 2009: Meeker MA, Jezewski MA. Metasynthesis: withdrawing life-sustaining treatments: the experience of family decision-makers. J Clin Nurs 2009 Jan;18(2):163-73.

Pieracci, 2008: Pieracci FM, Ullery BW, Eachempati SR, et al. Prospective analysis of life-sustaining therapy discussions in the surgical intensive care unit: a housestaff perspective. J Am Coll Surg 2008 Oct;207(4):468-76. Epub 2008 Jun 30.

SUPPORT Principal Investigators, 1995: [No authors listed.] A controlled trial to improve care for seriously ill hospitalized patients: The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). The SUPPORT Principal Investigators. JAMA 1995 Nov 22-29;274(20):1591-8.

TJC, 2008: The Joint Commission (TJC). 2009 Accreditation Requirements Chapters. Accreditation Program: Hospital. Pre-publication Version. 2008. Available at http://www.jointcommission.org/NR/rdonlyres/8CCED568-76C9-4B3A-AC9C-B99FF0A2ED04/0/HAP_AllChapters.pdf. Last accessed October 20, 2009.

Tucker, 2009: Tucker, KL. Ensuring informed end-of-life decisions. J Palliat Med. 2009 Feb;12(2):119-20.

Zhang, 2009: Zhang B, Wright AA, Huskamp HA, et al. Health care costs in the last week of life: associations with end-of-life conversations. Arch Intern Med 2009 Mar 9;169(5):480-8.

SAFE PRACTICE 7: DISCLOSURE

The Objective

Provide open and clear communication with patients and their families about serious unanticipated outcomes that is supported by systems that foster transparency and performance improvement to reduce preventable harm.

The Problem

Although open communication about unanticipated outcomes is desired by patients, endorsed by ethicists, supported by professional organizations, and required by hospital accreditation standards, many patients fail to receive a full and truthful explanation when bad outcomes occur. [Lamb, 2003; Sheridan, 2008; Gallagher, 2007a] There are many reasons for this failure, including healthcare workers' uncertainty about what to say to patients, limited training in communication skills, concerns about malpractice liability, and insufficient institutional support. Inadequate disclosure leads to patient dissatisfaction and the inability of patients to make informed choices about subsequent care, and it represents a lost opportunity to prevent harm and save lives. [Denham, 2005; Gallagher, 2007b; Gallagher, 2009b; Kern, 2009; McDonald, 2009]

About 4 of every 10 members of the American public have reported a medical error in their own care or a family member's care, and 1 of every 3 physicians has reported that he or she or a member of his or her family has experienced a medical error. [Blendon, 2002] The severity of medical errors was described by one report that suggested that one out of four medical errors results in death, disability, or severe pain. [Blendon, 2002] The emotional ramifications of patient safety incidents are also daunting. [Gallagher, 2009b] Research has shown that the frequency of disclosure is once for every four harmful events. [Blendon, 2002; Schoen, 2005] Patients desire disclosure from clinicians when harmful medical errors occur. [Denham, 2006a; Sheridan, 2008; López, 2009] A survey of medical students found that most trainees (74 percent; 652/881) agreed that medical error is among the most serious healthcare problems. Nearly all (99 percent; 875/884) agreed that serious errors should be disclosed to patients. Personal involvement with medical errors was common among the fourth-year students (78 percent; 164/209) and the residents (98 percent; 182/185). Among residents, 45 percent (83/185) reported involvement in a serious error; 34 percent (62/183) reported disclosing a serious error; and 63 percent (115/183) had disclosed a minor error. While only 33 percent (289/880) of trainees had received training in error disclosure, 92 percent (808/881) expressed interest in such training, particularly at the time of disclosure. [Gallagher, 2006b]

However, when these incidents occur, clinicians often overlook disclosure in fear of the implications of liability. [Leape, 2006; Gallagher, 2006a; Gallagher, 2006b] Dr. Leape points out that serious preventable harm causes emotional trauma for patients and families, who are wounded by those whom the patient trusted for care. The patient-doctor relationship suffers when the truth is not openly discussed. [Denham, 2006b; Denham, 2008a]

To prevent further harm to patients, many organizations have implemented full disclosure programs that include the caregiver, who acknowledges the error, takes responsibility, and apologizes. [Leape, 2006; Liang, 2002; Iedema, 2008; Gallagher, 2009b; Holden, 2009] In fact, patients place great value on the organizational learning, improvements, and changes that result from careful analyses

of the unanticipated outcomes that they have experienced. [Dunbar, 2009] To be done well, the process of disclosure must include the concerned caregivers, and organizations must provide the necessary support systems to assist patients and caregivers throughout the process. [Denham, 2007] Disclosure is also often appropriate for less serious unanticipated outcomes.

The ultimate goal is to prevent medical errors; however, when an error occurs, disclosure and rapid remediation do have a cost impact on organizations. [Gallagher, 2007b; Boothman, 2009; McDonald, 2009] The Lexington Veterans Affairs Medical Center reported an average settlement payout of $16,000, versus the national Department of Veterans Affairs average of $98,000 per settlement; also, only 2 lawsuits went to trial during a 10-year period. [Kraman, 2002] The University of Michigan reported that, after implementation of a full disclosure program, the number of pending lawsuits decreased by half, and reduced litigation costs per case fell from $65,000 to $35,000. This resulted in an annual savings of approximately $2 million in defense litigation bills. [Boothman, 2005; Clinton, 2006; Wojcieszak, 2006]

Safe Practice Statement

Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event. [MCPME, 2006; Gallagher, 2007a; IHI, 2009; UMich, 2009]

Additional Specifications

- The types of serious unanticipated outcomes addressed by this practice include, at a minimum: a) sentinel events; [TJC, 2009] b] b) serious reportable events; [NQF, 2002] and c) any other unanticipated outcomes involving harm that require the provision of substantial additional care (such as diagnostic tests/therapeutic interventions or increased length of stay) or that cause the loss of limb or limb function lasting seven days or longer. [JCR, 2010]
- Organizations must have formal processes for disclosing unanticipated outcomes and for reporting events to those responsible for patient safety, including external organizations, where applicable, and for identifying and mitigating risks and hazards. [Kussman, 2008]
- The governance and administrative leadership should ensure that such information is systematically used for performance improvement by the organization. Policies and procedures should incorporate continuous quality improvement techniques and provide for annual reviews and updates.
- Adherence to the practice and participation with the support system is expected and may be considered as part of credentialing.
- Patient communication should include or be characterized by the following:
  - the "facts"—an explicit statement about what happened that includes an explanation of the implications of the unanticipated outcome for the patient's future health, an explanation of why the event occurred, and information about measures taken for its preventability; [Fein, 2007; Holden, 2009]

- empathic communication of the "facts," a skill that should be developed and practiced in healthcare organizations;
- an explicit and empathic expression of regret that the outcome was not as expected (e.g., "I am sorry that this has happened.");
- a commitment to investigate and as possible prevent future occurrences by collecting the facts about the event and providing them to the organization's patient safety leaders, including those in governance positions;
- feedback of results of the investigation, including whether or not it resulted from an error or systems failure, provided in sufficient detail to support informed decisionmaking by the patient; [McDonnell, 2008]
- "timeliness"—the initial conversation with the patient and/or family should occur within 24 hours, whenever possible. Early and subsequent follow-up conversations should occur, both to maintain the relationship and to provide information as it becomes available;
- an apology from the patient's licensed independent practitioner (LIP) and/or an administrative leader should be offered if the investigation reveals that the adverse outcome clearly was caused by unambiguous errors or systems failures;
- emotional support for patients and their families by trained caregivers should be provided; [HBQI, 2008; Iedema, 2008] and
- a disclosure and improvement support system should be established and maintained to provide the following to caregivers and staff that includes:
  - emotional support for caregivers and administrators involved in such events by trained caregivers in the immediate postevent period that may extend for weeks afterward,
  - education and skill building regarding the concepts, tools, and resources that produce optimal results from this practice, centered on systems improvement rather than blame, and with a special emphasis on creating a just culture, [Frankel, 2006; Sorensen, 2008; Gallagher, 2009a]
  - 24-hour availability of advisory support to caregivers and staff to facilitate rapid responses to serious unanticipated outcomes, including "just-in-time" coaching and emotional support, and
  - education of caregivers regarding the importance and technique of disclosure to care teams of errors or adverse events when they happen. [Keller, 2009; Shannon, 2009]

- Healthcare organizations should implement a procedure to ensure and document that all LIPs are provided with a detailed description of the organization's program for responding to adverse events, including the full disclosure of error(s) that may have caused or contributed to patient harm. This is done with the expectation that the LIPs will provide this information to their individual medical malpractice liability carriers in the event that they are provided liability coverage from entities outside of the organization. All new employees should also receive this information.
- A process should be in place to consider providing information to a Patient Safety Organization that would provide a patient safety evaluation program to protect privileged and confidential information. [AHRQ, 2008; Public Law 109-41]

- A process should be in place to consider early remediation and the waiving of billing for care services provided during the care episode and for subsequent treatment if the event was due to unambiguous systems failures or human error. [Boothman, 2009; McDonald, 2009]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

[Gallagher, 2007a]

- Implement policies and procedures that incorporate the critical practice elements, and provide healthcare workers with disclosure education and "just-in-time" coaching.
- Establish processes and systems to comply with this practice through the collaborative work of governing boards, senior administrative leaders, medical staff (independent and employed by the organization), and risk management leaders.
- Start with simple processes, basic educational strategies, and clear engagement tactics that incorporate the practice into existing meetings that address quality, performance improvement, patient safety, and disclosure, to ensure that it becomes a part of the way an organization operates. [Camiré, 2009; Gunderson, 2009]

Strategies of Progressive Organizations

- Some organizations are experimenting with policies that involve disclosing a broader range of unanticipated outcomes as well as conducting programs to provide early arrangements to meet the financial needs of patients who have experienced unanticipated outcomes. Preliminary reports suggest that the overall outcomes of both approaches are positive. [Boothman, 2009; Gallagher, 2009b; McDonald, 2009] High-performing organizations are tracking waived costs generated because of adverse events and are allocating accountabilities to departments and care providers to assist in appropriate billing when patients return for follow-up care related to adverse events. [McDonald, 2008; McDonald, 2009] Leading academic organizations are teaching disclosure to nursing and medical students, other direct caregivers, and residents in training. [Kaldjian, 2007; White, 2008; Shannon, 2009]

Opportunities for Patient and Family Involvement [Denham, 2008b; López, 2009; Wu, 2009]

- Healthcare organizations should include patients and/or family members on internal committees for the development, maintenance, and optimization of the disclosure process.
- Healthcare organizations should systematically request patient and family input through the disclosure process.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include evidence of disclosure and performance improvement around unanticipated outcomes such as deaths, disabilities, adverse drug events, delayed or missed diagnoses, and other types of preventable harm. These also would include operational and financial outcomes measures related to disclosure, such as events that result in malpractice claims and the costs they generate.
- **Process Measures** include the percentage of staff who have been trained in disclosure as measured against institutionally established targets; the frequency of events requiring disclosure; the percentage of the events requiring disclosure for which the disclosure policy was implemented; satisfaction measures of staff about training; and key issues that were identified for organizational risk reduction and mitigation. [HBQI, 2008]
- **Structure Measures** include verification that someone is available 24 hours a day, 7 days a week, and 365 days a year (24/7/365) to provide "just-in-time" support and disclosure coaching; that the pertinent policies exist and are available; that a simple process is in place to screen all reported unanticipated outcomes that are to be considered for disclosure to the patient; and that there are clear mechanisms in place to track whether and how disclosure has occurred. Another measure is the presence of an internal disclosure reporting structure to senior administrative management and governance board leaders.
- **Patient-Centered Measures** include evaluating whether patients' values and preferences have been respected; providing accessible and customized information for patients and families; and offering emotional support and the relief of fear and anxiety. Although strategies for measuring patient satisfaction with disclosure are still under development, consideration should be given to assessing satisfaction with disclosure among patients who have experienced a serious unanticipated outcome and assessing patients' overall confidence in the transparency of the healthcare setting.

Settings of Care Considerations

- **Rural Healthcare Settings:** This practice applies in rural settings. In many hospitals, risk managers or patient safety officers will fill the role of disclosure coaches who are available 24/7/365. In rural hospitals, suitably trained hospital administrators could fill this role.
- **Children's Healthcare Settings:** The disclosure practice applies to children's healthcare settings. However, in such settings, the recipient of disclosure would be the patient's family rather than the patient. Consideration should be given to involving pediatric patients in disclosure according to existing standards for pediatric assent.
- **Specialty Healthcare Settings:** Specialty healthcare settings are expected to implement this safe practice.

New Horizons and Areas for Research

Although the impact of disclosure on clinical outcomes is being studied and will evolve over time, it is known that the disclosure process will generate information about unanticipated

outcomes that can be used to strengthen performance improvement systems and enhance patient safety. [Karlsen, 2009; Schneider, 2009] The field of disclosure would benefit from further study, including research on how disclosure is currently taking place and how to disclose when multiple patients are adversely affected. [Chafe, 2009] Work is needed to generate greater clarity about how different disclosure strategies affect outcomes such as patient trust and satisfaction, complaints, and litigation. Research also is needed on methods of training, including the best methods for delivering the didactic elements of training, such as multimedia learning presentations or distance learning strategies that can be updated with the latest evidence.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; Safe Practice 4: Identification and Mitigation of Risks and Hazards; and Safe Practice 8: Care of the Caregiver.

Notes

AHRQ, 2008: Agency for Healthcare Research and Quality. Patient Safety Organizations. Legislation and Regulations: Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act): An Overview. Available at http://www.pso.ahrq.gov/regulations/regulations.htm. Last accessed October 13, 2009.

Blendon, 2002: Blendon R, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. N Engl J Med 2002 Dec 12;347(24):1933-40.

Boothman, 2005: Boothman R. How open, honest disclosure can reduce claims, costs, and promote patient safety improvement. New York City (NY): Annual Meeting of Greater New York Hospital Association; May 13, 2005.

Boothman, 2009: Boothman RC, Blackwell AC, Campbell DA Jr, et al. A better approach to medical malpractice claims? The University of Michigan experience. Journal of Health & Life Sciences Law 2009 Jan;2(2):125-59.

Camiré, 2009: Camiré E, Moyen E, Stelfox HT. Medication errors in critical care: risk factors, prevention and disclosure. CMAJ 2009 Apr 28;180(9):936-43. Review.

Chafe, 2009: Chafe R, Levinson W, Sullivan T. Disclosing errors that affect multiple patients. CMAJ 2009 May 26;180(11):1125-7. Review. Available at http://www.cmaj.ca/cgi/reprint/180/11/1125. Last accessed October 13, 2009.

Clinton, 2006: Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. N Engl J Med 2006 May 25;354(21):2205-8. Available at http://content.nejm.org/cgi/reprint/354/21/2205.pdf. Last accessed October 22, 2009.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2006a: Denham CR. From harmony to healing: join the quality choir. J Patient Saf 2006 Dec;2(4):225-32.

Denham, 2006b: Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3):162-70.

Denham, 2007: Denham CR. TRUST: the five rights of the second victim. J Patient Saf 2007 Jun;3(2):107-19.

Denham, 2008a: Denham CR. May I have the envelope please? J Patient Saf 2008 Jun;4(2):119-23.

Denham, 2008b: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Dunbar, 2009: Dunbar JA, Reddy P. Mandatory reporting of professional incompetence. Med J Aust. 2009 Jan 19;190(2):103.

Fein, 2007: Fein SP, Hilborne LH, Spiritus EM, et al. The many faces of error disclosure: a common set of elements and a definition. J Gen Intern Med 2007 Jun;22(6):755-61. Epub 2007 Mar 20.

Frankel, 2006: Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. Health Serv Res 2006 Aug;41(4 Pt 2):1690-709.

Gallagher, 2006a: Gallagher TH, Garbutt JM, Waterman AD, et al. Choosing your words carefully: how physicians would disclose harmful medical errors to patients. Arch Intern Med 2006 Aug 14-28;166(15):1585-93.

Gallagher, 2006b: Gallagher TH, Waterman AD, Garbutt JM, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. Arch Intern Med 2006 Aug 14-28;166(15):1605-11.

Gallagher, 2007a: Gallagher TH, Denham CR, Leape LL, et al. Disclosing unanticipated outcomes to patients: the art and practice. J Patient Saf 2007 Sept;3(3):158-65.

Gallagher, 2007b: Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. N Engl J Med 2007 Jun 28;356(26):2713-9.

Gallagher, 2009a: Gallagher TH, Bell SK, Smith KM, et al. Disclosing harmful medical errors to patients: tackling three tough cases. Chest 2009 Sep;136(3):897-903.

Gallagher, 2009b: Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery: review of medical error. JAMA 2009 Aug 12;302(6):669-77. Epub 2009 Jul 7. Available at http://jama.ama-assn.org/cgi/reprint/302/6/669. Last accessed October 13, 2009.

Gunderson, 2009: Gunderson AJ, Smith KM, Mayer DB, McDonald T, Centomani, N. Teaching medical students the art of medical error full disclosure: evaluation of a new curriculum. Teaching and Learning in Medicine: An International Journal 2009; 21(3):229-232.

HBQI, 2008: [No authors listed.] Use proven strategies for error disclosure to patients. Healthcare Benchmarks Qual Improv 2008 Sep;15(9):94-6.

Holden, 2009: Holden J. Apologies and legal liability. Saying sorry is not the same as admitting legal liability. BMJ 2009 Feb 10;338:b520.

Iedema, 2008: Iedema R, Sorensen R, Manias E, et al. Patients' and family members' experiences of open disclosure following adverse events. Int J Qual Health Care 2008 Dec;20(6):421-32. Epub 2008 Sep 17. Available at http://intqhc.oxfordjournals.org/cgi/reprint/20/6/421. Last accessed October 12, 2009.

IHI, 2009: [No authors listed.] Communication with Patients and Families after an Adverse Event. IHI Improvement Map. Institute for Healthcare Improvement (IHI). 2009. Available at http://www.ihi.org/imap/tool/#Process=e2af2d43-4135-49a2-b145-bbd65d8a2bee. Last accessed October 13, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Chapter: Record of Care, Treatment, and Services. Oak Brook (IL): Joint Commission Resources; 2010.

Karlsen, 2009: Karlsen KA, Hendrix TJ, O'Malley M. Medical error reporting in America: a changing landscape. Qual Manag Health Care 2009 Jan-Mar;18(1):59-70.

Keller, 2009: Keller DR, Bell CL, Dottl SK. An effective curriculum for teaching third-year medical students about medical errors and disclosure. WMJ 2009 Feb;108(1):27-9.

Kern, 2009: Kern SI. It's still not safe to say "I'm sorry". Med Econ 2009 Jan 9;86(1):40.

Kraman, 2002: Kraman SS, Cranfill L, Hamm G, et al. John M. Eisenberg Patient Safety Awards. Advocacy: the Lexington Veterans Affairs Medical Center. Jt Comm J Qual Improv 2002 Dec;28(12):646-50.

Kussman, 2008: Kussman MJ. Disclosure of adverse events to patients. VHA Directive 2008-002. Department of Veterans Affairs. Veterans Health Administration. 2008 Jan 18. Available at http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637. Last accessed October 13, 2009.

Lamb, 2003: Lamb RM, Studdert DM, Bohmer RMJ, et al. Hospital disclosure practices: results of a national survey. Health Aff 2003 Mar-Apr; 22(2):73-83.

Leape, 2006: Leape LL. Full disclosure and apology - an idea whose time has come. Physician Exec. 2006 Mar-Apr;32(2): 16-8.

Liang, 2002: Liang BA. A system of medical error disclosure. Qual Saf Health Care 2002 Mar; 11(1):64-8.

López, 2009: López L, Weissman JS, Schneider EC, et al. Disclosure of hospital adverse events and its association with patients' ratings of the quality of care. Arch Intern Med 2009;169(20):1888-94.

McDonald, 2008: McDonald T, Smith KM, Mayor D. "Full Disclosure" and Residency Education. ACGME Bulletin. Ingrid Philibert, ed. Chicago, IL: Accreditation Council for Graduate Medical Education; May 2008: 5-9. Available at http://www.acgme.org/acWebsite/bulletin/bulletin5_08.pdf. Last accessed October 13, 2009.

McDonald, 2009: McDonald TB, Helmchen L, Smith KM, et al. Responding to Patient Safety Incidents: The Seven Pillars. Qual Saf Health Care [In press].

McDonnell, 2008: McDonnell WM, Guenther E. Narrative review: do state laws make it easier to say "I'm sorry?". Ann Intern Med 2008 Dec 2;149(11):811-6.

MCPME, 2006: [No authors listed.] When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals. Burlington (MA): Massachusetts Coalition for the Prevention of Medical Errors; 2006 March. Available at http://www.macoalition.org/documents/respondingToAdverseEvents.pdf. Last accessed September 14, 2009.

NQF, 2002: [No authors listed.] Serious Reportable Events in Healthcare: A Consensus Report. Washington, DC: National Quality Forum (NQF); 2002. Available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1221. Last accessed October 13, 2009.

Public Law 109-41: Public Law 109-41 - July 29, 2005. Patient Safety and Quality Improvement Act of 2005. Available at http://www.pso.ahrq.gov/statute/pl109-41.pdf. Last accessed October 12, 2009.

Schneider, 2009: Schneider CE, Hall MA. The patient life: can consumers direct health care? Am J Law Med 2009;35(1):7-65.

Schoen, 2005: Schoen C, Osborn R, Huynh PT, et al. Taking the pulse of health care systems: experiences of patients with health problems in six countries. Health Aff (Millwood) 2005 Jul-Dec;Suppl Web Exclusives:W5-509-25.

Shannon, 2009: Shannon SE, Foglia MB, Hardy M, et al. Disclosing errors to patients: perspectives of registered nurses. Jt Comm J Qual Patient Saf 2009 Jan;35(1):5-12.

Sheridan, 2008: Sheridan S, King C, Conrad N, Dingman J, Denham CR. Disclosure Through Our Eyes. J Patient Saf 2008 Mar;4(1):18-26.

Sorensen, 2008: Sorensen R, Iedema R, Piper D, et al. Health care professionals' views of implementing a policy of open disclosure of errors. J Health Serv Res Policy 2008 Oct;13(4):227-32.

TJC, 2009: The Joint Commission (TJC). Sentinel Event. Definition. 2009. Available at http://www.jointcommission.org/SentinelEvents/. Last accessed October 13, 2009.

UMich, 2009: [No authors listed.] Patient Safety Toolkit – Disclosure Chapter. University of Michigan Health System. 2009. Available at http://www.med.umich.edu/patientsafetytoolkit/disclosure.htm. Last accessed October 13, 2009.

White, 2008: White AA, Gallagher TH, Krauss MJ, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. Acad Med 2008 Mar;83(3):250-6.

Wojcieszak, 2006: Wojcieszak D, Banja J, Houk C. The Sorry Works! Coalition: making the case for full disclosure. Jt Comm J Qual Patient Saf 2006 Jun;32(6):344-50.

Wu, 2009: Wu AW, Huang IC, Stokes S, et al. Disclosing medical errors to patients: it's not what you say, it's what they hear. J Gen Intern Med 2009 Jul 4. [Epub ahead of print]

SAFE PRACTICE 8: CARE OF THE CAREGIVER

The Objective

Provide care to the caregivers (clinical providers, staff, and administrators) involved in serious preventable harm to patients, through systems that also foster transparency and performance improvement that may reduce future harmful events.

The Problem

The harm to patients and families from preventable adverse events resulting from systems failures or human error should never be considered less important than the harm that occurs to caregivers involved in their care. However, harm can also occur to caregivers and staff who are directly or indirectly involved in unintentional harm to patients. Caregivers and the institution as a whole may be considered second victims of such events. [Wu, 2000; Denham, 2007; Reason, 2000; Denham, 2008c] For instance, when such events are not actively and adequately managed by administrative leaders, there may in fact be harm to the culture of an organization, making it the "third victim." [Denham, 2007; Denham, 2005a]

Leaders of healthcare organizations have a "special accountability" for the performance systems over which they have authority. [Clinton, 2006; Boothman 2009] These systems include systems of administration, systems of care, and people systems, relating to how the individuals and groups perform within their organizations every day. The systems faults embedded in care processes, caregiver-technology interface systems, and people systems are all elements of this special administrative accountability dimension. For instance, incentives and job requirements that push caregivers out of their safe human factors performance envelopes are such embedded faults that are within the span of control and accountability of administrative leaders, [Denham, 2008c] and others may not be. [Denham 2007]

The frequency of adverse events causing harm to patients may be as low as the often-cited Institute of Medicine Report, *To Err is Human: Building a Safer Health System,* which estimated that there are approximately 100,000 preventable deaths in the United States annually. Yet the impact of subsequent national performance improvement campaigns with a modest number of interventions arguably implies that the number is larger. [IHI, 2006; Saver, 2006; Denham, 2005b]

Numerous estimates indicate that a far greater number of preventable deaths occur internationally, with indications that as many as 1 of every 10 patients is harmed. [Vincent, 2001; Woolcock, 2004] The number of caregivers "directly" associated with a known event causing unintentional harm to a patient would be clearly at least one per event, and likely more, because of the complexity of care, fragmented care trajectories, and our current team-based care systems. We must consider caregivers, frontline staff, support staff, and administrators who are not directly involved in an event as well. It has been estimated nationally that as many as one million total caregivers, staff, and administrative personnel may have been either directly or indirectly involved in known harmful events to patients due to systems failures or human error.

After an adverse event occurs or even a near miss potentially causing harm to patients, there may be immediate, midterm, and

delayed harm to the caregivers involved. Such harm includes increased depression, anxiety about future errors, loss of confidence, sleeping difficulties, reduced job satisfaction, and harm to their reputation. [Waterman, 2007] The harm is not unlike that which occurs to military individuals involved in unintentional "friendly fire" during military incursions.

Harm to caregivers can be profoundly preventable with timely, systematic, and direct action by healthcare organization leaders. The increased risk of future harm and self-perceived medical error by such individuals [West, 2006] can be addressed, and most importantly, the vital information that is gleaned by actively and fully including such caregivers in follow-up investigations of events of patient harm can be used to prevent future occurrences. The harm to organizations after a mismanaged adverse event, when caregivers are named, blamed, and shamed, is just starting to be understood; however, it may be described as a "corporate post-traumatic stress syndrome." [Denham, 2008a]

There are direct and indirect costs sustained by both healthcare organizations and the involved caregivers. For example, organizations are faced with direct costs, such as legal costs if they terminate employees, as well as those of paying for counseling, public relations efforts, and crisis management consultants. Indirect costs include loss of staff time of employees, loss of productivity of involved care units, increased turnover, and collective distraction of the organization from its mission. Caregivers experience loss of work, change of profession, disruption of family life, and many other costs typically associated with crises.

A 2007 multi-institutional study of nearly 3,000 physicians in the United States and Canada revealed that 90 percent believe (37 percent strongly) that healthcare organizations need to provide more systematic support services to them after unintentionally harming a patient. [Waterman, 2007]

Safe Practice Statement

Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events. [Frankel, 2006; MCPME, 2006a; MCPME, 2006b; IHI, 2009; MITSS, 2009]

Additional Specifications

- Indications
  - At a minimum, the types of serious unanticipated outcomes addressed by this practice include a) sentinel events; b) serious reportable events; [Levinson, 2008] or c) any other unanticipated outcomes that involve harm and require substantial additional care (such as diagnostic tests/therapeutic interventions or increased length of stay) or cause loss of limb or limb function lasting seven days or longer. (This definition of events triggering the implementation of this practice is identical to that in *Safe Practice 7: Disclosure*.) [NQF, 2009; AHRQ, N.D.]
  - For the purposes of this practice, caregivers shall mean clinical providers, staff, and administrators "involved" in adverse events as defined above. Involvement is defined as being directly involved AND indirectly involved in the event. Those

who were directly involved may be those whose activities had a direct bearing on the systems failures or error that led to patient harm. Those who were indirectly involved may be individuals who have been impacted by the event and who may be only tangentially involved in the error chain or systems failure that led to the event.

- Formal structures, systems, and policies should be established so that administrative leaders have direct authority and accountability 24/7/365 to ensure that caregivers, staff, and administrators receive: [Denham, 2008c]
  - Treatment That Is Just: A well-organized, evidence-based process should be followed to assess the behavior of individuals directly involved in an adverse event to identify issues of substance abuse, intentional harm, illness, reckless violations of clear policies and procedures, and/or gross negligence, in order to avoid inappropriate blame. [Reason, 1997; Frankel, 2006; Marx, 2007; Wachter, 2009] Those who were involved in an incident that is the result of systems faults or predictable human performance factor failure should be clearly designated as free from direct personal blame by a senior administrative leader in a manner that is visible to the entire organization. This process should be undertaken within 24 hours of having enough factual information to support it. [Denham, 2007; McDonald, 2009] If, after an event investigation, the organization is contemplating a corrective action that could result in a serious loss of livelihood of an individual, [Dunbar, 2009] that individual should be notified of the potential action, and he or she should be advised that he or she may want to exercise the opportunity to seek the advice of legal counsel before providing a formal statement about the corrective action.
  - Respect: A formalized process should be followed by designated administrative senior leaders immediately after an incident to ensure that the individuals who are directly or indirectly involved are treated with respect and dignity. This process should outline who will interact with directly involved individuals and should recognize that these individuals may be undergoing extreme stress and discomfort. As those who interact with directly involved individuals address issues such as continued work, communication with co-workers, and follow-up investigations, they should treat the individuals as they themselves would wish to be treated had they unintentionally harmed a patient. Individuals should be treated as innocent of intentional or reckless harm until proven otherwise. By whatever means will best reach the organization, senior administrators should publicly request that all involved caregivers be treated with respect and dignity. [Reason, 1997; Marx, 2007; Denham, 2007; Denham, 2008c; Denham, 2008a] (See Implementation Example Approach.)
  - Understanding and Compassion: A formalized process should be followed by a designated administrative leader to invite co-workers to express personal understanding and compassion to those directly and indirectly involved in such events as defined above. Designated administrative leaders should be trained in the critical importance of forgiveness and the provision of personal support to individuals involved in unintentionally and seriously harming others. [Denham, 2008b; Berlinger, 2007; Purtilo, 2005]

- Supportive Care: Caregivers, staff, and administrators directly involved in serious unintentional harm as defined above must be considered "patients requiring immediate and ongoing care." A process must be established and regularly updated that must be led by a designated team or leader to ensure that all individuals directly involved and indirectly involved in the incident have the opportunity to receive appropriate professional care and are assessed for fitness for work to ensure their safety, that of their co-workers, and that of the patients they will serve in the future. Such a process should include a structure and system for all who are directly and indirectly involved in an incident to voluntarily request such supportive care, and a structure, system, and accountability should be established for mandatory "fitness for work" assessments of individuals directly involved in events. Such assessments and supportive care should also be considered for "near misses" that are reported to the organization.
- Transparency: Those individuals who are directly or indirectly involved in events should be invited to fully participate in the investigation and analysis of the incident unless, through the process defined above, they were found to have been engaged in substance abuse or gross negligence, or their behavior was found to have intentionally induced harm. [Denham, 2006b; Denham, 2007; Denham, 2008d; McDonald, 2009]

- Formal structures, systems, and policies should be established to educate senior administrators, caregivers, and staff about the vulnerabilities of caregivers who have been involved in unintentional harm and to provide "just-in-time" coaching to administrative leaders who are accountable for executing the actions defined in this practice. [Boothman, 2009]
- The governance and administrative leadership should ensure that the information captured during the administration of this practice is systematically used for performance improvement by the healthcare organization. Policies and procedures should incorporate continuous quality improvement techniques and should provide for quarterly reviews and updates.
- A process should be in place to consider providing information to a Patient Safety Organization that would provide a patient safety evaluation program to protect privileged and confidential information. [AHRQ, 2008; Public Law 109-41]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Early response to an incident: Ideally, those who undertake the initial investigation of a serious adverse event, such as an adverse event response team, [Shannon, 2009] should be trained to competently identify those individuals directly and potentially indirectly involved in the event who may need care. [McDonald, 2009] Because of the infrequency of such events, "just-in-time" coaching may be of value to systematically ensure that consistent processes are reliably administrated. Those responsible for an

early response to an incident should include such activities as clear and careful communication with applicable supervisors, co-workers, academic program leaders, and others, about the steps that will be taken by the team. [Denham, 2006a] It should be noted that the activities defined in the additional specifications should not be undertaken sequentially, but in parallel, and should be applied carefully and with thoughtfulness based on the case.

- Treatment That Is Just: Leaders in patient safety who authorize and typically lead root cause analysis need to be trained in the evidence-based approach that has been established by the organization to identify issues of substance abuse, intentional harm, illness, clearly reckless violations of clear policies and procedures, and/or gross negligence, in order to avoid inappropriate blame. This approach should be applied with each individual directly involved with the case. An optimal approach is to provide regular baseline education on the chosen process on a routine basis across the organization. This is critical to optimizing a culture of safety and gives staff confidence in the values of the organization when stressful events occur. [Frankel, 2006; Wachter, 2009]
- Respect: Ideally, very senior administrative leaders should be "on call" for such critical events, and the teams who are involved in rapidly responding to events that trigger this practice should have an approved "Care of the Caregiver" methodology, supported by tools such as checklists and reference guides. It is important that administrative leaders lead by example in ensuring that caregivers directly or indirectly involved are treated with respect by the organization in the days and weeks following an event. The natural tendency to isolate and even abandon caregivers after an event needs to be countered by an organized corporate approach to continuously maintain a positive relationship with caregivers who are at risk. Each organization may choose the manner in which it decides to broadly communicate its encouragement to staff to be respectful of caregivers involved in patient adverse events. [Denham, 2006a]
- Understanding and Compassion: Leaders also should formally and informally encourage the colleagues of caregivers (those who are directly or indirectly involved in a serious adverse event) to reach out to their colleagues on a personal basis and to care for them as they would any co-worker who has sustained a stressful psychological event. Again, a method should be documented with checklists and reference guide materials to make sure that such outreach is encouraged and not forgotten in the fog of crisis after an event. [Denham, 2006a]
- Supportive Care: Medical and psychological intervention should be provided so that individuals can volunteer for care; and the assessment team, after an event, should have a structured method to recommend the mandatory assessment of individuals for fitness for work, recognizing that, after such events, human factors performance can be degraded. [Waterman, 2007] Some organizations have found that group meetings, with professional facilitation, of those caregivers involved in a specific incident is therapeutic. [Gazoni, 2008]
- Transparency: Clearly, every preventable adverse event will have unique circumstances; however, in every case an organization should seek to engage all caregivers involved in the event in future risk identification and mitigation activities. This will be to the benefit of the organization and the individual caregivers. Their inclusion needs to be built into the follow-up schedule of tactics followed by the adverse event response

team of the organization. [Denham, 2006b; Gallagher, 2007; Sheridan, 2008; McDonald, 2009]

- Optimal implementation of this practice should aim to prevent adverse events related to fatigue, stress, burn-out, and low motivation, by providing a supportive and positive practice environment.

Strategies of Progressive Organizations

- Certain organizations establish long-term follow-up systems to ensure the long-term mental health of their caregivers, recognizing that post-traumatic stress and other conditions can persist or emerge long after an event. Some organizations have come to understand that the "third victim" of a very serious event is the collective culture and psyche of the organization. They have recognized that leaders can provide an appropriate forum for the organization to openly discuss events, finding that the truth can heal following serious adverse events, especially those that strike multiple patients. [Denham, 2007] It is important to care for the collective mental health of the entire workforce.
- Some organizations that have taken such a principled approach to dealing with both caregivers and patients that they have prioritized core values over asset preservation. These organizations have been rewarded with the improved self-esteem of their caregivers, respect by the malpractice legal community, and reduced total legal costs. [Boothman 2009; McDonald, 2009]
- Some academic organizations have been very progressive in providing program advancement incentives for the disclosure of patient safety issues and events, which is rewarding positive deviance from the norm. Such progressive organizations are leading the way in making it not only safe, but an achievement to exhibit principled behavior. [McDonald, 2008] This can only reinforce a more principled approach to care of the caregiver after serious adverse events.
- Leaders in certain organizations actively take responsibility for unintentional preventable adverse events, recognizing that they are accountable for all systems, including people systems, and for predictable human performance-related errors. [Denham, 2008c]

Opportunities for Patient and Family Involvement

- It is very therapeutic for caregivers and patients and families involved in the serious events that are addressed by this practice to interact, forgive, and find closure to such an experience. [Waterman, 2007]
- Patients and families recognize the extreme pain that caregivers can experience after a preventable event, and they can add tremendous value to committees of organizations that allow them to participate in such patient safety initiatives.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include evidence of care of caregivers, staff, and administrators through follow-up surveys after events. Other measures include staff turnover rates and

performance improvement around information that is gleaned from the investigation of events, such as unanticipated outcomes, including deaths, disabilities, adverse drug events, delayed or missed diagnoses, and other types of preventable harm, and operational and financial outcome measures related to staff treatment after events.

- **Process Measures** include the percentage of staff trained in care of the caregiver; the frequency of events requiring the care of caregivers; the percentage of the employees for whom this practice was implemented; satisfaction measures of staff for training; and key issues identified for organizational risk reduction and mitigation.
- **Structure Measures** include verification that an administrative leader is available 24/7/365 to provide "just-in-time" support of caregivers; that the pertinent policies exist and are available; that there is a simple process in place to screen all reported unanticipated outcomes for consideration of care to caregivers; and that there are clear mechanisms to track whether and how such support has occurred. Other measures include the presence of an internal caregiver support reporting structure to senior administrative management and governance board leaders.
- **Patient-Centered Measures** include evaluating such things as evidence of respecting caregivers; patients' values and preferences; the provision of accessible and customized information for patients and families; and the offering of emotional support and the relief of fear and anxiety. While strategies for measuring the employee as an object of patient satisfaction are still under development, consideration should be given to assessing satisfaction with such programs and overall confidence in the transparency of the healthcare setting.

Settings of Care Considerations

- **Rural Healthcare Settings:** In many hospitals, risk managers or patient safety officers will fill the role of administrative leaders and be available 24/7/365.
- **Children's Healthcare Settings:** This practice applies to all children's healthcare settings.
- **Specialty Healthcare Settings:** This practice applies to all specialty hospital and healthcare settings.

New Horizons and Areas for Research

The impact of adverse events on caregivers is being studied and will evolve over time, and more direct involvement of caregivers in serious adverse events will generate information about unanticipated outcomes that can be used to strengthen performance improvement systems and enhance patient safety. Work needs to be undertaken to generate greater clarity about how best to care for caregivers, staff, and administrative leaders who are both directly and indirectly involved in unintentional harm to patients. Methods of training merit research, including the best methods of delivering didactic elements of training, such as multimedia or distance-learning strategies that can be updated with the latest evidence.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; Safe Practice 4: Identification and Mitigation of Risks and Hazards; and Safe Practice 7: Disclosure.

Notes

AHRQ, 2008: Agency for Healthcare Research and Quality. Patient Safety Organizations. Legislation and Regulations: Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act): An Overview. Available at http://www.pso.ahrq.gov/regulations/regulations.htm. Last accessed October 20, 2009.

AHRQ, N.D.: [No authors listed.] Patient Safety Primer: Error Disclosure. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=2. Last accessed October 20, 2009.

Berlinger, 2007: Berlinger N. After Harm: Medical Error and the Ethics of Forgiveness. Baltimore (MD): The Johns Hopkins University Press; 2005.

Boothman, 2009: Boothman RC, Blackwell AC, Campbell DA Jr, et al. A better approach to medical malpractice claims? The University of Michigan experience. Journal of Health & Life Sciences Law 2009 Jan;2(2):125-59.

Clinton, 2006: Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. N Engl J Med 2006 May 25;354(21):2205-8. Available at http://content.nejm.org/cgi/reprint/354/21/2205.pdf. Last accessed October 22, 2009.

Denham, 2005a: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2005b: Denham CR. Patient safety practices: leaders can turn barriers into accelerators. J Patient Saf 2005 Mar;1(1):41-55.

Denham, 2006a: Denham CR. From harmony to healing: join the quality choir. J Patient Saf 2006 Dec;2(4):225-32.

Denham, 2006b: Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3):162-70.

Denham, 2007: Denham CR. TRUST: the five rights of the second victim. J Patient Saf 2007 Jun;3(2):107-19.

Denham, 2008a: Denham CR, Dingman J, Foley ME, et al. Are you listening…are you really listening? J Patient Saf 2008 Sep;4(3):148-61.

Denham, 2008b: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Denham, 2008c: Denham CR. May I have the envelope please? J Patient Saf 2008 Jun:4(2);119-23.

Denham, 2008d: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Dunbar, 2009: Dunbar JA, Reddy P. Mandatory Reporting of Professional Incompetence. Med J Aust. 2009 Jan 19;190(2):103.

Frankel, 2006: Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. Health Serv Res 2006 Aug;41(4 Pt 2):1690-709.

Gallagher, 2007: Gallagher TH, Denham CR, Leape LL, et al. Disclosing unanticipated outcomes to patients: the art and practice. J Patient Saf 2007 Sept;3(3):158-65.

Gazoni, 2008: Gazoni FM, Durieux ME, Wells L. Life after death: the aftermath of perioperative catastrophes. Anesth Analg 2008 Aug;107(2):591-600.

IHI, 2006: Institute for Healthcare Improvement (IHI). Press Release: "IHI announces that hospitals participating in 100,000 Lives Campaign have saved an estimated 122,300 lives." 2006 Jun 14. Available at http://www.ihi.org/NR/rdonlyres/68B891EE-5624-45DC-B7F6-E213C56EB60E/4426/UPDATED100kLivesCampaignJune14milestonepressreleas.pdf. Last accessed October 9, 2009.

IHI, 2009: [No authors listed.] Communication with Patients & Families after an Adverse Event. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=e2af2d43-4135-49a2-b145-bbd65d8a2bee. Last accessed October 20, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 9, 2009.

Marx, 2007: Marx D. Patient Safety and the "Just Culture." The Just Culture Community. Presentation to the New York State Department of Health 2007 Patient Safety Conference. Available at http://www.health.state.ny.us/professionals/patients/patient_safety/conference/2007/docs/patient_safety_and_the_just_culture.pdf. Last accessed October 12, 2009.

McDonald, 2008: McDonald T, Smith KM, Mayor D. "Full Disclosure" and Residency Education. ACGME Bulletin. Ingrid Philibert, ed. Chicago, IL: Accreditation Council for Graduate Medical Education; May 2008: 5-9. Available at http://www.acgme.org/acWebsite/bulletin/bulletin5_08.pdf. Last accessed October 12, 2009.

McDonald, 2009: McDonald TB, Helmchen L, Smith KM, et al. Responding to Patient Safety Incidents: The Seven Pillars. Qual Saf Health Care [accepted]

MCPME, 2006a: [No authors listed.] When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals. Burlington (MA): Massachusetts Coalition for the Prevention of Medical Errors; 2006 March. Available at http://www.macoalition.org/documents/respondingToAdverseEvents.pdf. Last accessed September 14, 2009.

MCPME, 2006b: [No authors listed.] When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals. Burlington (MA): Massachusetts Coalition for the Prevention of Medical Errors; 2006 March. Available at http://www.mitss.org/respondingToAdverseEvents.pdf. Last accessed October 20, 2009.

MITSS, 2009: [No authors listed.] Medically Induced Trauma Support Services (MITSS). For clinicians. 2009. Available at http://www.mitss.org/clinicians_home.html. Last accessed October 20, 2009.

NQF, 2009: National Quality Forum. Safe Practice 7: Disclosure. National Quality Forum. Safe Practices for Better Healthcare 2009 Update – A Consensus Report. Washington, DC: National Quality Forum; 2006. Available at http://www.qualityforum.org/Publications/2009/03/Safe_Practices_for_Better_Healthcare%E2%80%932009_Update.aspx. Last accessed November 2, 2009.

Public Law 109-41: Public Law 109-41. July 29, 2005. Patient Safety and Quality Improvement Act of 2005. Available at http://www.pso.ahrq.gov/statute/pl109-41.pdf. Last accessed October 12, 2009.

Purtilo, 2005: Purtilo RB. Beyond disclosure: seeking forgiveness. Phys Ther 2005 Nov;85(11):1124-6. Available at http://www.ptjournal.org/cgi/content/full/85/11/1124. Last accessed October 12, 2009.

Reason, 1997: Reason JT. Decision Tree for Determining Culpability of Unsafe Acts. IN: Managing the Risks of Organizational Accidents. Aldershot (UK): Ashgate Publishing Limited; 1997. Algorithm ["Decision Tree"] available at http://www.ihi.org/NR/rdonlyres/35B1FAD0-FACC-4595-A0E7-D2A53C3E2F3A/72/FINALDecisionTreeforUnsafeActsCulpability2tool2.ppt#258,1,Slide 1. Last accessed October 12, 2009.

Reason, 2000: Reason J. Human error: models and management. BMJ Mar 18;320(7237):768-70. Available at http://www.bmj.com/cgi/content/full/320/7237/768. Last accessed October 12, 2009.

Saver, 2006: Saver C. Beyond expectations. part 1. Nurs Manage. 2006 Oct;37(10):36-42. Available at http://www.nursingcenter.com/pdf.asp?AID=676934. Last accessed October 12, 2009.

Shannon, 2009: Shannon SE, Foglia MB, Hardy M, et al. Disclosing errors to patients: perspectives of registered nurses. Jt Comm J Qual Patient Saf 2009 Jan;35(1):5-12.

Sheridan, 2008: Sheridan S, King C, Conrad N, Dingman J, Denham CR. Disclosure through our eyes. J Patient Saf 2008 Mar;4(1):18-26.

Vincent, 2001: Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ 2001 Mar 3;322(7285):517-9. Available at http://www.bmj.com/cgi/reprint/322/7285/517. Last accessed October 12, 2009.

Wachter, 2009: Wachter,RM, Pronovost, PJ. Balancing "no blame" with accountability in patient safety. N Engl J Med. 2009 Oct 1;361(14):1401-6.

Waterman, 2007: Waterman AD, Garbutt J, Hazel E, et al. The emotional impact of medical errors on practicing physicians in the United States and Canada. Jt Comm J Qual Patient Saf 2007 Aug;33(8):467-76.

West, 2006: West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006 Sep 6;296(9): 1071-8. Available at http://jama.ama-assn.org/cgi/content/full/296/9/1071. Last accessed October 12, 2009.

Woolcock, 2004: Woolcock N, Henderson M. Blundering hospitals 'kill 40,000 a year'. The Times: London, August 13, 2004. Available at http://www.timesonline.co.uk/tol/news/uk/article468980.ece. Last accessed October 12, 2009.

Wu, 2000: Wu AW. Medical error: the second victim. the doctor who makes the mistake needs help too. BMJ 2000 Mar 18;320(7237):726-7. Available at http://www.bmj.com/cgi/reprint/320/7237/726. Last accessed October 12, 2009.

Chapter 4: Improving Patient Safety by Matching Healthcare Needs with Service Delivery Capability

Background

AN ORGANIZATION'S WORKFORCE AND ITS COMMITMENT of resources for care have a significant impact on outcomes and patient safety. Increased adverse events are associated with the staffing levels and competency of both nursing and non-nursing staff who provide direct care to patients. Inadequate orientation and training of new staff (to an organization or unit, including temporary staff) are also associated with preventable adverse events. With the increased frequency of restructuring and downsizing, the critical shortage of healthcare professionals, and the presence of job dissatisfaction, the quality of patient care is being negatively affected. [Savitz, 2004] The patient safety risk related to workforce issues and the allocation of resources to those risks are major responsibilities of administrative and governance leaders. Striking the right balance of resource allocation to patient safety issues requires that administrative and governance leaders receive the appropriate information.

Registered nurses (RNs) make up the largest group of healthcare professionals, with about 59 percent of them employed in hospitals. [Bureau of Labor Statistics, 2008] Although non-nursing staff who have direct contact with patients, such as radiology technologists, respiratory therapists, admitting staff, laboratory staff, and transporters, do not represent the majority of the workforce, they can directly affect the quality and safety of care delivered as well. Furthermore, a systematic review of the literature has demonstrated a strong association between high-intensity intensive care unit (ICU) staffing (i.e., mandatory intensivist consultation or closed ICU) and lower mortality rates, when compared to low-intensity staffing (i.e., no intensivist consultation). [Pronovost, 2002]

Although there is a lack of specificity regarding how to mitigate the effects of inadequate nurse staffing in each care setting, there has been a charge for hospitals to become more attractive employers. [American Hospital Association, 2008] The Commission on Workforce for Hospitals and Health Systems 2002 report, *In Our Hands: How Hospital Leaders Can*

Build a Thriving Workforce, features publications and examples of how hospital leaders can improve the healthcare work environment and address the nurse workforce shortage. [CWHHS, 2002]

This chapter presents three safe practices that, if implemented, would better align service delivery with patients' needs, resulting in safer and improved care.

Notes

American Hospital Association, 2008: AHA. Advocacy issue paper on workforce. 2008. Available at http://www.aha.org/aha/content/2008/pdf/08-issue-workforce.pdf. Last accessed December 29, 2008.

Bureau of Labor Statistics, 2008: Bureau of Labor Statistics. Occupational Outlook Handbook, 2008-2009 edition. Available at http://www.bls.gov/oco/. Last accessed December 29, 2008.

CWHHS, 2002: American Hospital Association (AHA). AHA Commission on Workforce for Hospitals and Health Systems [CWHHS]. In our hands: how hospital leaders can build a thriving workforce. 2002 Apr. Available at http://www.aha.org/aha/content/2002/pdf/IOHfull.pdf. Last accessed December 29, 2008.

Pronovost, 2002: Pronovost PJ, Angus DC, Dorman T, et al. Physician staffing patterns and clinical outcomes in critically ill patients: a systematic review. JAMA 2002 Nov 6;288(17):2151-62. Available at http://jama.ama-assn.org/cgi/content/full/288/17/2151. Last accessed December 29, 2008.

Savitz, 2004: Savitz LA, Jones CB, Bernard S. Quality indicators sensitive to nurse staffing in acute care settings. Advances in Patient Safety: From Research to Implementation. AHRQ Publication Nos. 050021 (1-4). Rockville (MD): Agency for Healthcare Research and Quality; 2005 Feb: Vol. 4. Available at http://www.ahrq.gov/downloads/pub/advances/vol4/Savitz.pdf. Last accessed December 15, 2008.

SAFE PRACTICE 9: NURSING WORKFORCE

The Objective

Ensure that nursing staff services and nursing leadership at all levels, including senior administrative and unit levels, are competent and adequate to provide safe care.

The Problem

Registered nurses constitute the largest group of healthcare professionals, with about 59 percent of nurses employed in hospitals. [BLS, 2008] Nurses continue to be the primary hospital caregivers. A study of 799 hospitals in 11 states found that nurses provide 11.4 hours of care per patient day, of which 7.8 hours were provided by registered nurses, 1.2 hours by licensed practitioners, and 2.4 hours by nurses' aides. [Needleman, 2002] These results were estimated from administrative data. In comparison, a more detailed time-and-motion study of nurses found that patient care activities accounted for only 19.3 percent (81 minutes) of nursing practice time, and only 7.2 percent (31 minutes) was used for patient assessment and reading vital signs. [Hendrich, 2008] Workload and the changing nature of nursing work have led to decreased satisfaction and increased burn-out, compared to other healthcare workers and workers in other industries in the United States. [Aiken, 2001; Aiken, 2002; Duffield, 2008; Wilson, 2008; Ma, 2009; Zurmehly, 2009] A recent international survey reported that 56 percent of nurses were displeased with their current positions. [Zurmehly, 2009]

Healthcare organizations are questioning whether current nursing education is actually preparing nurses for the new generation of patient care with complex systems, processes, medications, and technologies. [Holzemer, 2008; Regan, 2009] Also a major factor for the changing nature of the profession has been the demographics of an aging nursing population. Buerhaus, 2000; Moseley, 2008; Wilson, 2008; Rafferty, 2009]

In 2007, it was found that 116,000 RN positions were vacant in the U.S., and 33,000 more would become vacant every year until 2016. [Wing, 2009] As a result, numerous studies have tried to measure the impact of this shortage on nurses and on the quality and safety of care provided to patients. A recent poll by the American Nurses Association, in which more than 10,000 nurses participated, found that: [ANA, 2008]

- 51.2 percent of nurses believe the quality of nursing care on their unit has declined;
- 73.1 percent believe that staffing levels on their unit are inadequate;
- 51.8 percent are confident about having someone close to them receive care on their unit;
- 51.9 percent are currently considering leaving their position;
- 59.8 percent know someone on their unit who has left because of concerns about unsafe staffing.

The frequency of harm to which patients are exposed, as a result of insufficient nurse staffing and lower levels of nurse education, is apparent. [Holzemer, 2008] Inadequate staffing has been linked to increased mortality, complications, adverse events, hospital length of stay, and resource usage. [Aiken, 2002; Needleman, 2002; Pronovost, 1999; Needleman, 2006; Amaravadi, 2000; Gelinas, 2004] A study of 232,342 surgical patients demonstrated a positive relationship

between patient-to-nurse ratios and 30-day mortality and failure-to-rescue rates. [Aiken, 2002] One study of intensive care units found that placing more than two patients in the care of one registered nurse was associated with 30 to 50 percent longer patient stays. [Amaravadi, 2000; Pronovost, 1999] Despite the demonstrated relationship among adverse events and nurse staffing, orientation and training, and competency, a specific ratio of skilled nurses-to-patients that improves patient safety for each care setting or type of patient has not yet been identified. [Rafferty, 2009]

Although there is a lack of specificity on the preventability of the effects of inadequate nurse staffing in each care setting, there has been a charge for hospitals to become more attractive employers. [AHA, 2008] The Commission on Workforce for Hospitals and Health Systems has featured publications and examples of how hospital leaders can improve the healthcare work environment and address the nurse workforce shortage. [CWHHS, 2002] In addition, hospital leaders are encouraged to involve nursing leadership in critical decisions that affect safety at all levels of an organization. [Denham, 2006] The nurse executive is expected to participate in the process with the governing body and the medical staff and in the organization's decision-making process; [TJC, 2002; Laschinger, 2009] this has not been the case with the majority of care settings. [ANA, 2005]

Reducing nurse turnover and increasing nurse staffing have been associated with net reductions in costs. [Moseley, 2008] The cost per adjusted discharge increased 36 percent in high-turnover hospitals compared to low-turnover hospitals. [Gelinas, 2004; Gelinas, 2002] Raising the proportion of nursing hours provided by registered nurses without increasing total nursing hours has been associated with cost savings. [Needleman, 2006; Dall, 2009] However, increasing nurse hours without increasing the proportion of hours provided by registered nurses resulted in a net increase in hospital costs of 1.5 percent at the staffing levels used in the study. On the other hand, increasing nurse hours was proven to reduce hospital length of stay, adverse outcomes, and patient deaths. The increase in staffing cost may be offset by improved outcomes, depending upon the value that is placed upon each. [Needleman, 2006] A recent study suggests that the addition of 133,000 full-time registered nurses to the acute care hospital workforce would result in an estimated $6.1 billion in yearly medical savings, as well as 3.6 million fewer hospital days annually. [Dall, 2009]

The global financial recession has created new challenges for nursing school graduates and nursing leaders. Though statistics describe a nursing shortage, many nursing graduates have actually had difficulty finding a job. Many factors contribute to the lack of available positions, including: geographical saturation, institutional bed reductions, retirement postponement by an aging nursing population, and lack of experience in complex healthcare systems. [Clavreul, 2009] Nursing leaders are faced with decreased operating budgets in a time when patient safety and performance improvement programs are critical.

Safe Practice Statement

Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following:

- A nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety. [IOM, 2004; Rother, 2009]

- Senior administrative nursing leaders, such as a Chief Nursing Officer, as part of the hospital senior management team. [IOM, 2004; Laschinger, 2009; Simpson, 2009]
- Governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services. [IOM, 2004]
- Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills. [IOM, 2004; Rafferty, 2009]

Additional Specifications

- Implement explicit organizational policies and procedures, with input from nurses at the unit level, on effective staffing targets that specify the number, competency, and skill mix of nursing staff needed to provide safe, direct care services. [Smith, 2009; JCR, 2010]
- Ensure that the governance board and senior, midlevel, and line managers are educated about the impact of nursing on patient safety.
- Conduct ongoing organization-wide patient safety risk assessments to identify patient safety risks related to nurse staffing, nurse work hours, temporary nurse coverage, and other areas related to the prevention of patient harm. [Seago, 2001; JCR, 2010] This assessment must be reviewed by senior administrative management and the governance board at least annually to ensure that resources are allocated and performance improvement programs are implemented.
- Use the data collected and analyzed from the daily monitoring of actual unit-specific nurse staffing levels to identify and address potential patient safety-related staffing issues. [JCR, 2010] Such data should include, but not be limited to, nursing hours per patient day as defined in the National Quality Forum report, *National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set.* [NQF, 2004]
- Provide regular reports, at intervals determined by leadership, of unit-specific, potential patient safety-related staffing issues to senior nursing leadership, the governance board, and senior administrative leaders. [JCR, 2010]
- Put in place and document performance improvement programs that include the elements of education, skill building, measurement, reporting, and process improvement, and provide evidence of the actions taken to close patient safety gaps related to nursing services. [NWMH, 2003]
- Provide reports at least annually to the public through the appropriate organizations.
- Ensure, through ongoing assessments by managers/leaders in the practice environment, that all nurses are oriented and competent to provide safe care to the patients to whom they are assigned, including nurses who are new to the organization, temporary staff, float pool nurses, contract staff, and temporarily assigned nurses. [IHI, 2003; JCR, 2010] Ongoing education must be provided through in-services, training, and other activities to maintain and improve the competencies specific to the assigned duties [Duffield, 2008] and job responsibilities related to patient safety, infection control, and the population served. [JCR, 2010]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

Activities for a well-designed nursing workforce include the following:

- promoting a diverse nursing workforce to create cultural competencies and increase effective patient-centered care; [AHRQ, 2009a]
- a determination of safe staffing levels within different types of nursing units;
- the use of a valid and reliable patient acuity system;
- consideration for the use of built-in "cues" for staffing adjustments that recognize the importance of "turbulence" (admissions, discharges, transfers) and its overall impact on staffing needs;
- values-grounded behavioral-based interviewing methods to optimize the selection of new staff and to ensure that existing staff mirror the behaviors that represent the values of the organization;
- standardized measures and reporting at the unit level to explicitly monitor whether staffing effectiveness is maintained (a dashboard, including, for example, the use of NQF®-endorsed nursing-sensitive indicators); and
- didactic elements of training delivered through multimedia or distance-learning strategies that can be updated with the latest evidence. This should include documentation of participation to verify compliance and to ensure that new and temporary staff receive such training. (This also provides an opportunity to provide continuing education credits.)

Tactics to accelerate implementation include the following:

- The use of creative methods, such as the "resource nurse program" model or internal float pools, to respond to immediate upsurges in staffing needs.
- Making more experienced nurses available as resources to nurses new to the organization and to those providing temporary coverage. [Bleich, 2009]
- The use of readiness efforts to attain and maintain national recognition for nursing excellence in patient care, such as the "Magnet" designation.
- Developing and sustaining a "healthy work environment" as a nursing retention strategy and as a means to improve overall patient care and safety. [Day, 2009; JCR, 2010]
- Fostering competency enhancement and supporting the pursuit of certifications for specialty units. [Rother, 2009]
- Ensuring recognition of the central role that nurses have in team building and team leadership, and ensuring that their input is included in the design and implementation of teamwork training and team-based performance improvement programs. [Rother, 2009]

Strategies of Progressive Organizations

- Some organizations have undertaken innovative strategies to support nursing staff, such as flexible scheduling, day care, tuition reimbursement, and other methods to

help support professional education and competency. Certain organizations have developed improved patient safety impact by designing and building a hospital environment that supports nursing and prevents patient harm.

Opportunities for Patient and Family Involvement

- Educate the patient and family about how nursing care is delivered in the particular unit. [AHRQ, 2009b]
- Encourage patient and family input on the availability of nursing staff during their care.
- Encourage patient and family members to report recognized health issues or problems to nursing staff in a timely manner.
- Listen to patient and family feedback on the consequences to their care of understaffed shifts and incorporate this information into strategies for improvement and action plans.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcomes Measures** include the NQF-endorsed *National Voluntary Consensus Standards for Nursing-Sensitive Care* measures that are focused on patient-centered outcomes, including failure to rescue, pressure ulcer prevalence, falls prevalence, falls with injury, restraint prevalence, urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients, central line catheter-associated bloodstream infection rate for ICU and high-risk nursery patients, and ventilator-associated pneumonia for ICU and high-risk nursery patients. Other clinical outcome measures may be also considered, in addition to operational and financial outcome measures that are significantly affected by nursing services.
- **Process Measures** include NQF-endorsed *National Voluntary Consensus Standards for Nursing-Sensitive Care* measures focused on interventions to promote health in high-risk populations, including smoking-cessation counseling for patients with acute myocardial infarction, heart failure, and pneumonia. System-centered measures include skill mix, nursing care hours per patient day, Practice Environment Scale-Nursing Work Index, and monitoring of voluntary turnover. Vacancy rates, temporary coverage rates, and adherence to protocols and practices established for nursing within the organization may also be measured.
- **Structure Measures** include the verification of documentation of annual patient safety risk assessments related to nursing services and the implementation of performance improvement programs; nurse staffing plan and regular plan evaluation; and public reporting as defined by the practice.
  - NQF-endorsed® structure measures:
    1. #0190: Nurse staffing hours – 4 parts: Percentage of daily work in hours by the entire group of nurses or nursing assistants spent tending to residents.
    2. #0204: Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract) [Hospital]: NSC-12.1 – Percentage of productive nursing hours worked by

RN staff (employee and contract) with direct patient care responsibilities by type of unit. NSC-12.2 – Percentage of productive nursing hours worked by LPN/LVN staff (employee and contract) with direct patient care responsibilities by type of unit. NSC-12.3 – Percentage of productive nursing hours worked by UAP staff (employee and contract) with direct patient care responsibilities by type of unit. NSC-12.4 – Percentage of productive nursing hours worked by contract staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities by type of unit.

3. #0205: Nursing care hours per patient day (RN, LPN, and UAP) [Hospital]: NSC-13.1 – The number of productive hours worked by RNs with direct patient care responsibilities per patient day. NSC-13.2 – The number of productive hours worked by nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities per patient day.
4. #0206: Practice Environment Scale – Nursing Work Index (composite and five subscales).
5. #0207: Voluntary turnover: NSC-15.1: Total number of full-time and part-time RN and APN voluntary uncontrolled separations occurring during the calendar month. NSC-15.2: Total number of full-time and part-time LPN, LVN voluntary uncontrolled separations occurring during the calendar month. NSC-15.3: Total number of full-time and part-time UAP voluntary uncontrolled separations occurring during the calendar month.

- **Patient-Centered Measures:** Although patient-centered measures are in their infancy, organizations can offer patients the opportunity to provide their perceptions of nursing care by completing the NQF-endorsed HCAHPS [NQF, 2005] survey. Care provided by nurses is evaluated in the following ways: "During this hospital stay, how often did nurses treat you with courtesy and respect?" (Q1); "During this hospital stay, how often did nurses listen carefully to you?" (Q2); "During this hospital stay, how often did nurses explain things in a way you could understand?" (Q3); "During this hospital stay, after you pressed the call button, how often did you get help as soon as you wanted it?" (Q4).

Settings of Care Considerations

- **Rural Healthcare Settings:** Although rural and small healthcare settings have significant resource constraints, they should comply with the specifications of this practice, except as excluded by the specifications.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings, except as excluded by the specifications.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings, except as excluded by the specifications.

New Horizons and Areas for Research

Research needs to be undertaken to verify the impact nurses make when they play a major role on senior administrative leadership teams and governance boards. Needed is research that provides specific information about the correlation between nursing leadership and patient safety that is already being seen. Research must quantify the business case for investing in high-quality nursing services that will complement the existing strong evidence of the impact of nursing on patient safety. The NQF-endorsed *National Voluntary Consensus Standards for Nursing-Sensitive Care* also established a recommended research agenda.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 10: Direct Caregivers; Safe Practice 12: Patient Care Information; Safe Practice 15: Discharge Systems; Safe Practice 27: Pressure Ulcer Prevention; and Safe Practice 28: Venous Thromboembolism Prevention.

Notes

AHA, 2008: [No authors listed.] Advocacy issue paper on workforce. Chicago (IL): American Hospital Association (AHA); 2008. Available at http://www.aha.org/aha/content/2008/pdf/08-issue-workforce.pdf. Last accessed November 2, 2009.

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Aiken, 2001: Aiken L, Clark SP, Sloane DM, et al. Nurses' reports on hospital care in five countries. Health Aff (Millwood) 2001 May-Jun;20(3):43-53. Available at http://content.healthaffairs.org/cgi/content/full/20/3/43. Last accessed September 29, 2009.

Aiken, 2002: Aiken LH, Clarke SP, Sloane DM, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. JAMA 2002 Oct 23-30;288(16):1987-93. Available at http://jama.ama-assn.org/cgi/content/full/288/16/1987. Last accessed September 29, 2009.

Amaravadi, 2000: Amaravadi RK, Dimick JB, Pronovost PJ, et al. ICU nurse-to-patient ratio is associated with complications and resource use after esophagectomy. Intensive Care Med 2000 Dec;26(12):1857-62. Available at http://www.springerlink.com/content/y23r8q2mu9g3v0j0/fulltext.pdf. Last accessed September 29, 2009.

ANA, 2005: [No authors listed.] Utilization guide for the ANA Principles for Nurse Staffing. Silver Spring (MD): American Nurses Association (ANA); 2005 Sep. Available at: http://www.safestaffingsaveslives.org/WhatisSafeStaffing/SafeStaffingPrinciples/UtilizationGuide.aspx. Last accessed November 2, 2009.

ANA, 2008: [No authors listed.] Safe nursing staffing poll results. Silver Spring (MD): American Nurses Association (ANA); 2008. Available at http://safestaffingsaveslives.org/WhatisANADoing/PollResults.aspx. Last accessed November 2, 2009.

Bleich, 2009: Bleich MR, Cleary BL, Davis K, et al. Mitigating knowledge loss: a strategic imperative for nurse leaders. J Nurs Adm 2009 Apr;39(4):160-4.

BLS, 2008: [No authors listed.] Occupational Outlook Handbook, 2008-2009 edition. Washington, DC: Bureau of Labor Statistics; 2009. Available at http://www.bls.gov/oco/. Last accessed November 2, 2009.

Buerhaus, 2000: Buerhaus PI, Staiger DO, Auerbach DI. Implications of an aging registered nurse workforce. JAMA 2000 Jun 14;283(22):2948-54. Available at http://jama.ama-assn.org/cgi/content/full/283/22/2948. Last accessed September 29, 2009.

Clavreul, 2009: Clavreul GM. Why nursing school grads can't find jobs. Working Nurse 2009 Feb 16. Available at http://www.solutionsoutsidethebox.net/documents/2009/Nursing_School_Graduates.pdf. Last accessed November 10, 2009.

CWHHS, 2002: [No authors listed.] AHA Commission on Workforce for Hospitals and Health Systems [CWHHS]. In our hands: how hospital leaders can build a thriving workforce. Chicago (IL): American Hospital Association (AHA); 2002 Apr. Available at http://www.aha.org/aha/content/2002/pdf/IOHfull.pdf. Last accessed November 2, 2009.

Dall, 2009: Dall TM, Chen YJ, Seifert RF, et al. The economic value of professional nursing. Med Care 2009 Jan;47(1):97-104.

Day, 2009: Day C. Engaging the nursing workforce: an evidence-based tool kit. Nurs Adm Q 2009 Jul-Sep;33(3):239-44.

Denham, 2006: Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3):162-70.

Duffield, 2008: Duffield C, Gardner G, Catling-Paull C. Nursing work and the use of nursing time. J Clin Nurs 2008 Dec;17(24):3269-74.

Gelinas, 2002: Gelinas L, Bohlen C. The business case for retention. Journal of Clinical Systems Management 2002;4(78):14-16.

Gelinas, 2004: Gelinas LS, Loh DY. The effect of workforce issues on patient safety. Nurs Econ 2004 Sep-Oct;22(5):266-72, 279.

Hendrich, 2008: Hendrich A, Chow M, Skierczynski BA, et al. A 36-hospital time and motion study: how do medical-surgical nurses spend their time? The Permanente Journal 2008 Summer:12(3):25-34. Available at http://xnet.kp.org/permanentejournal/sum08/time-study.pdf. Last accessed September 29, 2009.

Holzemer, 2008: Holzemer WL. Building a qualified global nursing workforce. Int Nurs Rev 2008 Sep;55(3):241-2.

IHI, 2003: [No authors listed.] Transforming care at the bedside how-to guide: increasing nurses' time in direct patient care. Institute for Healthcare Improvement (in collaboration with the Robert Wood Johnson Foundation). 2003. Available at http://www.ihi.org/IHI/Topics/MedicalSurgicalCare/MedicalSurgicalCareGeneral/Tools/TCABHowToGuideIncreasingNursesTimeinDirectPatientCare.htm. Last accessed October 12, 2009.

IOM, 2004: Page A, ed.; Committee on the Work Environment for Nurses and Patient Safety. Institute of Medicine (IOM). Keeping Patients Safe: Transforming the Work Environment of Nurses. Washington, DC: The National Academies Press; 2004. Available at http://www.nap.edu/catalog.php?record_id=10851. Last accessed September 29, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards LD.03.06.01; PI.01.01.01; PI.02.01.01; PI.04.01.01; HR.01.04.01; EC.03.01.01; HR.01.05.03; HR.01.06.01; HR.01.07.01. Oak Brook (IL): Joint Commission Resources; 2010.

Laschinger, 2009: Laschinger HK, Finegan J, Wilk P. Context matters: the impact of unit leadership and empowerment on nurses' organizational commitment. J Nurs Adm 2009 May;39(5):228-35.

Ma, 2009: Ma JC, Lee PH, Yang YC, et al. Predicting factors related to nurses' intention to leave, job satisfaction, and perception of quality of care in acute care hospitals. Nurs Econ. 2009 May-Jun;27(3):178-84, 202.

Moseley, 2008: Moseley A, Jeffers L, Paterson J. The retention of the older nursing workforce: a literature review exploring factors which influence the retention and turnover of older nurses. Contemp Nurse 2008 Aug;30(1):46-56.

Needleman, 2002: Needleman J, Buerhaus P, Mattke S, et al. Nurse staffing levels and the quality of care in hospitals. N Engl J Med 2002 May 30;346(22):1715-20. Available at http://content.nejm.org/cgi/reprint/346/22/1715.pdf. Last accessed September 29, 2009.

Needleman, 2006: Needleman J, Buerhaus PI, Steward M, et al. Nurse staffing in hospitals: is there a business case for quality? Health Aff (Millwood) 2006 Jan-Feb;25(1):204-211.

NQF, 2004: [No authors listed.] National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set. A Consensus Report. Washington, DC: National Quality Forum; 2004. Available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1228. Last accessed November 2, 2009.

NQF, 2005: [No authors listed.] Standardizing a measure of patient perspectives of hospital care: A Consensus Report. Washington, DC: National Quality Forum; 2005 Nov: 1-4.

NWMH, 2003: [No authors listed.] Impact Learning Session. Northwestern Memorial Hospital Workforce Domain. Boston (MA): Northwestern Memorial Hospital; 2003 Jun 18-19. Available at http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Tools/NorthwesternMemorialHospitalsWorkforceInitiative.htm. Last accessed October 12, 2009.

Pronovost, 1999: Pronovost PJ, Jenckes MW, Dorman T, et al. Organizational characteristics of intensive care units related to outcomes of abdominal aortic surgery. JAMA 1999 Apr 14;281(14):1310-7. Available at http://jama.ama-assn.org/cgi/content/full/281/14/1310. Last accessed September 29, 2009.

Rafferty, 2009: Rafferty AM, Clarke SP. Nursing workforce: a special issue. Int J Nurs Stud 2009 Jul;46(7):875-8.

Regan, 2009: Regan S, Thorne S, Mildon B. Uncovering blind spots in education and practice leadership: towards a collaborative response to the nurse shortage. Nurs Leadersh (Tor Ont) 2009;22(2):30-40. Available at http://www.longwoods.com/product.php?productid=20796. Last accessed July 21, 2009.

Rother, 2009: Rother J, Lavizzo-Mourey R. Addressing the nursing workforce: a critical element for health reform. Health Aff (Millwood) 2009 Jul-Aug;28(4):w620-4. Epub 2009 Jun 12.

Seago, 2001: Seago JA. Nurse staffing, models of care delivery, and interventions. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Ch. 38. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2001 Jul. Available at http://www.ahrq.gov/clinic/ptsafety/chap39.htm. Last accessed October 12, 2009.

Simpson, 2009: Simpson MR. Engagement at work: a review of the literature. Int J Nurs Stud 2009 Jul;46(7):1012-24. Epub 2008 Aug 12.

Smith, 2009: Smith CA. Nursing workforce planning: the key to success. Healthc Q 2009;12(2):78-85.

TJC, 2002: The Joint Commission (TJC) [formerly Joint Commission on Accreditation of Healthcare Organizations]. Health Care at the Crossroads: Strategies for Addressing the Evolving Nursing Crisis. Oakbrook Terrace (IL): Joint Commission on Accreditation of Healthcare Organizations; 2002 Aug. Available at http://www.jointcommission.org/NR/rdonlyres/5C138711-ED76-4D6F-909F-B06E0309F36D/0/health_care_at_the_crossroads.pdf. Last accessed September 29, 2009.

Wilson, 2008: Wilson B, Squires M, Widger K, et al. Job satisfaction among a multigenerational nursing workforce. J Nurs Manag 2008 Sep;16(6):716-23.

Wing, 2009: Wing KT. Free: 375,000 nurses: it's not a nursing shortage, it's a nursing wastage. Hospitals & Health Networks 2009 Jun 15. Available at http://www.hhnmag.com/hhnmag_app/jsp/printer_friendly.jsp?dcrPath=HHNMAG/Article/data/06JUN2009/090615HHN_Online_Wing&domain=HHNMAG. Last accessed August 11, 2009.

Zurmehly, 2009: Zurmehly J, Martin PA, Fitzpatrick JJ. Registered nurse empowerment and intent to leave current position and/or profession. J Nurs Manag 2009 Apr;17(3This issue: Discussions on Job Satisfaction, Work Environment and Burnout Issue editors: Kristiina Hyrkas and Denise Dende):383-391.

SAFE PRACTICE 10: DIRECT CAREGIVERS

The Objective

Ensure that the staffing levels and the competency of those non-nursing staff who provide direct care to patients and their families are adequate to provide safe care.

The Problem

Increased adverse events are associated with the staffing levels and competency of both nursing and non-nursing staff that provide direct care to patients. [Denham, 2008] Inadequate orientation and training of new staff (to an organization or unit, including temporary staff) is also associated with preventable adverse events. Although non-nursing staff that have direct contact with patients, such as radiology technologists, respiratory therapists, admitting staff, laboratory staff, and transporters, do not represent the majority of the workforce, they can directly affect the quality and safety of care delivered.

With the increased frequency of restructuring and downsizing, the critical shortage of healthcare professionals, and job dissatisfaction, it is not surprising that the quality of patient care is being negatively affected. [Savitz, 2004; Clark, 2009] Numerous studies have illuminated the connection between nurse staffing levels and nursing-sensitive outcomes. [Aiken, 2002; Kovner, 2002; Needleman, 2002; Savitz, 2004] It is not far-reaching to think that this impact can be generalized to other healthcare professionals. The American Hospital Association has commented on the declining enrollment in health education programs and how this affects the critical shortages of healthcare professionals. A shortage of qualified staff leads to the inability to orient and train new employees adequately in order to provide safe care to patients.

Unfortunately, the severity of insufficient staffing levels and inadequate training is difficult to capture in research. Studies have attempted to consolidate small studies in order to identify a standardized mechanism for evaluating organizational structures. [Savitz, 2004] Savitz and colleagues identified the following barriers in examining profession-specific quality of care: lack of standardized performance measures; lack of consensus on a core set of evidence-based measures; and limited availability of data at the unit and/or shift level. [Savitz, 2004]

Communication of health information is vital to the provision of safe care to patients, and it affects the preventability of error. [Clark, 2009] All employees who come in direct contact with patients and their families play a critical role in transmitting information between patients and their care deliverers. Governance boards, senior administrative leaders, midlevel managers, independent practitioners, and frontline staff must recognize that all employees play an important part in the delivery of safe, effective, patient-centered, timely, efficient, and equitable care, and should take accountability for reducing patient safety risks related to non-nursing direct care staffing levels and staff competency. [Denham, 2006] Leaders of organizations must not only be aware of the risks and impact on quality that are associated with staffing levels and the competency of non-nursing direct-care staff, but they must also take actions to reduce the related potential for harm to patients by ensuring that the right number of qualified staff members are on duty to meet patient needs.

The patient safety impact of reducing resources in education, quality programs, and the workforce is far more detrimental than

the benefit of reducing the cost impact of the facility. Unfortunately, when organizations cut costs to achieve financial objectives, quality care suffers. It is imperative that non-nursing, direct care staffing levels be adequate, that the staff be competent, and that they have had adequate orientation, training, and education to perform their assigned direct patient care duties.

Safe Practice Statement

Ensure that non-nursing direct care staffing levels are adequate, that the staff are competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties.

Additional Specifications

- Establish a staffing plan that is adequately resourced and actively managed, and the effectiveness of which is regularly evaluated with respect to patient safety. [NWMH, 2003; IHI, 2007]
- Conduct ongoing patient safety risk assessment to identify the patient safety risks related to non-nursing direct care worker staffing, work hours, temporary staff coverage, and other areas related to the prevention of patient harm. [JCR, 2010] This assessment must be reviewed by senior administrative management and the governance board at least annually to ensure that resources are allocated and performance improvement programs are implemented.
- Senior administrative management and the governance board should ensure that resources are allocated and performance improvement programs are implemented based on their review of patient risk assessments related to non-nursing direct care worker staffing. Ideally all non-nursing direct care staff areas are assessed; however, at a minimum, the categories of direct care staff that in aggregate have direct contact with patients must be assessed.
- Establish and consistently implement explicit policies and procedures to ensure that effective staffing targets are met. These should specify the number, competency, and skill mix of staff related to safe care, with input from frontline staff at the unit level.
- Put in place and document performance improvement programs that include the elements of education, skill building, measurement, reporting, and process improvement, and provide evidence of the actions taken to close the patient safety gaps that are related to non-nursing direct caregiver services.
- Provide reports, at least annually, about the impact of non-nursing direct caregivers on patient safety to the governance board and senior administrative leaders.
- Ensure, through ongoing assessments by managers/leaders in the practice environment, that all staff are oriented and competent to provide safe care to the patients to whom they are assigned, [JCR, 2010] including staff who are new to the organization, temporary staff, float pool staff, or contract staff, or those who are temporarily assigned. Ongoing education must be provided through in-services, training, and other activities to maintain and improve the competencies specific to the assigned duties and job responsibilities related to patient safety, infection control, and the populations served. [Clark, 2009; Regan, 2009; JCR, 2010]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

Activities for a well-designed direct care workforce include the following:

- the identification and maintenance of safe staffing levels within specific services;
- values-grounded behavioral-based interviewing techniques to provide an evidence-based method for hiring practices that will attract and retain more competent staff;
- consideration for the use of built-in "cues" for staffing adjustments, recognizing the importance of "turbulence" (admissions, discharges, transfers) and its overall impact on staffing needs;
- standardized measures using data such as clinical service screening indicators and human resource screening indicators, as well as unit-level or service-line dashboards that include indicators pertinent to patient safety, to explicitly monitor staffing effectiveness; and
- didactic elements of training delivered through multimedia or distance learning strategies that can be updated with the latest evidence. Documentation of participation is needed to verify compliance and to ensure that new and temporary staff receive such training. (This also provides an opportunity to provide continuing education credits.) [AHRQ, 2009a; AHRQ, 2009b]

Tactics to accelerate implementation include the following:

- Implement creative methods such as internal resource pools to respond to immediate upsurges in staffing needs.
- Make more experienced direct care staff available to those who are new to the organization and to those who are providing temporary coverage.
- Develop and sustain a "healthy work environment" as a direct care staff retention strategy and as a way to improve overall patient care and safety.
- Foster competency enhancement and support the pursuit of certifications by staff in their areas of expertise.
- Ensure that all direct care staff are included in the design and implementation of teamwork training and team-based performance improvement programs.

Strategies of Progressive Organizations

- Some organizations have undertaken innovative strategies to support nursing staff, such as flexible scheduling, day care, tuition reimbursement, and other methods to help support professional education and competency. Certain organizations have developed improved patient safety impact by designing and building a hospital environment that supports nursing and prevents patient harm.

Opportunities for Patient and Family Involvement

- Encourage patient and family input about the availability of direct caregivers during their care. [AHRQ, 2009b]
- Encourage patient and family members to report recognized health issues or problems to staff in a timely manner.

- Listen to and incorporate patient and family feedback, about the consequences on their care of understaffed shifts, into strategies for improvement and action plans.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include those processes that have a direct impact on patient outcomes, delay in diagnosis and/or care, and adverse events. For example, the staff level and competency of radiology technologists in radiology departments can have a direct impact on the quality of diagnostic studies, the closure of information loops between caregivers, the incidence of falls in radiology departments, and the transit time for emergency studies.
- **Process Measures** that provide a way to evaluate competencies will be specific to staff accountabilities and organizational policies and procedures. For example, the completion of a comprehensive nutritional assessment by a dietician within specific time parameters, or compliance with safety checks by the transporter for patients in wheelchairs, may be monitored.
- **Structure Measures** include screening indicators to evaluate how they affect productivity and the delivery of services, such as The Joint Commission's measure set that looks at overtime, staff vacancy rate, staff turnover rate, understaffing as compared to a hospital's staffing plan, caregiver hours per patient day, on-call or per diem use, and sick-time use.
  - NQF-endorsed® measure:
    1. #0204: Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract) [Hospital]: NSC-12.1 – Percentage of productive nursing hours worked by RN staff (employee and contract) with direct patient care responsibilities by type of unit. NSC-12.2 – Percentage of productive nursing hours worked by LPN/LVN staff (employee and contract) with direct patient care responsibilities by type of unit. NSC-12.3 – Percentage of productive nursing hours worked by UAP staff (employee and contract) with direct patient care responsibilities by type of unit. NSC-12.4 – Percentage of productive nursing hours worked by contract staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities by type of unit.
- **Patient-Centered Measures** are still in their infancy, but The Joint Commission staffing effectiveness screening indicators include patient-centered measures such as patient and family complaints.

Settings of Care Considerations

- **Rural Healthcare Settings:** Although rural and small organizations have significant resource constraints, they should comply with the specifications of this practice, except as excluded by the specifications.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings, except as excluded by the specifications.
- **Specialty Healthcare Settings:** All requirements of the practice apply to specialty healthcare settings, except as excluded by the specifications.

New Horizons and Areas for Research

Research must quantify the business case for investing in high-quality staff. Such research will complement the existing strong evidence of the impact of staff on patient safety.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 12: Patient Care Information and Safe Practice 15: Discharge Systems.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Aiken, 2002: Aiken LH, Clarke SP, Sloane DM, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. JAMA 2002 Oct 23-30;288 (16):1987-93. Available at http://jama.ama-assn.org/cgi/content/full/288/16/1987. Last accessed October 1, 2009.

Clark, 2009: Clark PR. Teamwork: Building Healthier Workplaces and Providing Safer Patient Care. Crit Care Nurs Q. 2009 Jul-Sep;32(3):221-31.

Denham, 2006: Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3):162-70.

Denham, 2008: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

IHI, 2007: [No authors listed.] When it comes to clinical quality, everybody makes the team. Institute for Healthcare Improvement. 2007 Mar 27. Available at http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/ImprovementStories/FSWhenItComestoClinicalQualityEverybodyMakestheTeam.htm. Last accessed October 11, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards PI.01.01.01; HR.01.04.01; HR.01.05.03; HR.01.06.01; and HR.01.07.01. Oak Brook (IL): Joint Commission Resources; 2010.

Kovner, 2002: Kovner C, Jones C, Zhan C, et al. Nurse staffing and postsurgical adverse events: an analysis of administrative data from a sample of U.S. hospitals, 1990-1996. Health Serv Res 2002;37(3):611-30. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1434654&blobtype=pdf. Last accessed October 1, 2009.

Needleman, 2002: Needleman J, Buerhaus P, Mattke S, et al. Nurse-staffing levels and the quality of care in hospitals. N Engl J Med. 2002 May 30;346(22):1715-22. Available at http://content.nejm.org/cgi/reprint/346/22/1715.pdf. Last accessed October 1, 2009.

NWMH, 2003: [No authors listed.] Impact Learning Session. Northwestern Memorial Hospital Workforce Domain. Boston (MA): Northwestern Memorial Hospital; 2003 Jun 18-19. Available at http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Tools/NorthwesternMemorialHospitalsWorkforceInitiative.htm. Last accessed October 11, 2009.

Regan, 2009: Regan S, Thorne S, Mildon B. Uncovering blind spots in education and practice leadership: towards a collaborative response to the nurse shortage. Nurs Leadersh (Tor Ont) 2009;22(2):30-40. Available at http://www.longwoods.com/product.php?productid=20796. Last accessed July 21, 2009.

Savitz, 2004: Savitz LA, Jones CB, Bernard S. Quality indicators sensitive to nurse staffing in acute care settings. Advances in Patient Safety: From Research to Implementation. AHRQ Publication Nos. 050021 (1-4). Rockville (MD): Agency for Healthcare Research and Quality; 2005 Feb: Vol. 4. Available at http://www.ahrq.gov/downloads/pub/advances/vol4/Savitz.pdf. Last accessed October 1, 2009.

SAFE PRACTICE 11: INTENSIVE CARE UNIT CARE

The Objective

Ensure that those who are most critically ill or injured have appropriately skilled caregivers in the intensive care unit (ICU).

The Problem

The Society of Critical Care Medicine has long supported the need for intensivist-led critical care services within hospitals. In 1999, The Leapfrog Group implemented an Intensive Care Unit Physician Standard (IPS), which is identical to the National Quality Forum's Safe Practice on ICU care. [Birkmeyer, 2004; LFG, 2008]

Despite the health and cost benefits associated with this safe practice, hospitals are failing with an alarming frequency to meet this standard. Between 63 percent and 93 percent of the estimated 4.4 million ICU admissions in 2004 did not receive treatment required by the IPS. [Pronovost, 2004a; Birkmeyer, 2004; Pronovost, 2004b] An inadequate supply of critical care physicians and perceived costs are the major barriers for hospitals to meet the IPS. [Birkmeyer, 2004] The imbalance between supply and demand is expected to worsen in the future as a result of the large, aging "baby boomer" population. [Angus, 2000; Pronovost, 2001]

The harm severity of not adhering to the IPS has been demonstrated to result in significant increases in hospital mortality. Decreased mortality has been strongly linked to treatment by critical care specialists compared to non-critical care specialists. A systematic review of the literature demonstrated a strong association between high-intensity ICU staffing (i.e., mandatory intensivist consultation or closed ICU) and lower mortality rates, as compared to low-intensity staffing (i.e., no intensivist consultation). [Pronovost, 2002] Multiple studies also demonstrate an association between high-intensity staffing and reduced ICU and hospital length of stay, as well as reduced incidence of complications. [Pronovost, 2002]

Mortality preventability comes from staffing appropriately. [Denham, 2008] Most research studies linking hospital mortality to ICU physician staffing adjust for confounding variables (i.e., clinical characteristics, demographics) associated with mortality. Through this mechanism, researchers are able to establish the direct effects of ICU physician staffing and to extrapolate the number of preventable deaths that occur over a predetermined period. A meta-analysis conducted in 2004 estimated the total number of annual preventable deaths to be 134,640, with a range of 110,880 to 158,400. [Pronovost, 2004b] The Leapfrog Group estimated a 30 percent reduction in mortality with increased ICU physician staffing. Implementing the IPS would result in 54,133 lives saved annually. [Birkmeyer, 2004] A recent study demonstrated that an intensivist-led ICU decreased mortality rates by 39 percent. [Lettieri, 2009]

ICU care in the United States is estimated to cost more than $90 million annually, accounting for more than 20 percent of acute care hospital costs. [Pronovost, 2004a] The costs of increasing ICU physician staffing have been well studied, and a business case for implementing the IPS has been developed. The greatest cost of implementation is intensivist salaries, along with the salaries of nurse practitioners and physician assistants. [Pronovost, 2004a] However, these costs are believed to be offset by reductions in inappropriate ICU admissions, reduced ICU and hospital length of stay, and lower rates of complications.

[Birkmeyer, 2004; Pronovost, 2002] A 2001 Leapfrog study estimated that implementing the IPS would result in annual hospital net savings ranging from $800 thousand for a small hospital to $3.4 million for a larger hospital. [Birkmeyer, 2001; Conrad, 2005] A similar study on implementing the IPS demonstrated cost savings from $510 thousand to $3.3 million for 6- to 18-bed ICUs, respectively. [Pronovost, 2004a]

Safe Practice Statement

All patients in general intensive care units (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine ("critical care certified").

Additional Specifications

- A "critical care certified" physician is one who has obtained critical care subspecialty certification by the American Board of Anesthesiology, the American Board of Internal Medicine, the American Board of Pediatrics, or the American Board of Surgery, or has completed training prior to the availability of subspecialty board certification in critical care in his or her specialty, and is board certified in one of these four specialties and has provided at least six weeks of full-time intensive care unit (ICU) care annually since 1987. [JCR, 2010; IHI, N.D.a; Rothschild, 2001]
- Dedicated, critical care certified physicians shall be present in the ICU during daytime hours, a minimum of eight hours per day, seven days per week, and shall provide clinical care exclusively in the ICU during this time.
- When a critical care certified physician is not present in the ICU, such a physician shall provide telephone coverage to the ICU and return more than 95 percent of ICU pages within five minutes (excluding low-urgency pages, if the paging system can designate them). When not in the hospital, the critical care certified physician should be able to rely on an appropriately trained onsite clinician to reach ICU patients within five minutes in more than 95 percent of cases.
- If it is not possible to have a dedicated, critical care certified physician in the ICU eight hours daily, an acceptable alternative is to provide exclusively dedicated round-the-clock ICU telemonitoring by a critical care certified physician, if the system allows real-time access to patient information that is identical to onsite presence (except for manual physical examination). [Rosenfeld, 1999; Rosenfeld, 2000]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include inpatient service/hospital.

Example Implementation Approaches

The benefits of intensivist staffing seem to accrue from four attributes: 1) they are present; 2) they have specialized knowledge; 3) they communicate with other members of the care team and families; and 4) they manage at the ICU level—that is, they develop protocols and policies, and they monitor and improve quality. [Kahn, 2007]

- The intensivist typically should lead daily multidisciplinary team rounds on all patients.

- ICU teams typically should include a physician or physicians, nurses, pharmacists, and other allied health professionals.
- ICU teams should create daily and long-term goals for patients, manage to those goals, and ensure that the entire care team, patients (if possible), and family members are aware of these goals.
- To increase the efficiency of intensivists, hospitals can consider using e-ICU systems, including the use of protocols, standardization of care, and trigger and alerting systems. [Murias, 2009]

Strategies of Progressive Organizations

- Leaders in progressive organizations are using ICU safety dashboards to monitor performance improvement and are seeking improvement in teamwork and safety through culture measurement and improvement initiatives. [Denham, 2006; Gajic, 2009]

Opportunities for Patient and Family Involvement

- Encourage patient and family members to be active members of the treatment team.
- Encourage patient and family members to ask questions about the patient's care.
- Educate patients about the frequency of medical and medication errors.
- Patient and family should know whom they should talk to first about their plan of care by asking questions.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** in use or in pilot testing include The Joint Commission ICU Measures: ICU 5 Length of Stay (risk adjusted); ICU 6 Hospital Mortality for ICU Patients; and ICU 4 Central Line-Associated Bloodstream Infection. Unit-level serious events and adverse drug events may be monitored as part of the ICU's safety and performance improvement program.
  - NQF-endorsed® measures:
    1. #0138: Catheter-associated urinary tract infection for intensive care unit (ICU) patients: Percentage of intensive care unit patients with catheter-associated urinary tract infections.
    2. #0139: Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients: Percentage of ICU and high-risk nursery patients, who acquired a central line catheter-associated bloodstream infection over a specified number of line-days.
    3. #0140: Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients: Percentage of ICU and HRN patients who, over a certain number of days, have ventilator-associated pneumonia.

- **Process Measures** currently in use include The Joint Commission ICU Core Measures: ICU 1 VAP Prevention-Patient Positioning; ICU 2 SUD Prophylaxis; and ICU 3 DVT Prophylaxis.
  - NQF-endorsed measures:
    1. #0372: Intensive Care Unit (ICU) VTE Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).
    2. #0451: Call for a Measure of Glycemic Control with Intravenous Insulin Implementation [Hospital, Other]: Intravenous insulin glycemic control protocol implemented for cardiac surgery patients with diabetes or hyperglycemia admitted into an intensive care unit.
- **Structure Measures** include verification of the existence of an intensivist service that complies with the specifications of this practice, and verification of documentation that performance is being monitored.
- **Patient-Centered Measures** include monitoring and trending, using tools such as the HCAHPS survey, which includes questions about patient perception of responsiveness of staff, communication, and pain management. Organizations may measure patient awareness and satisfaction about communication of care goals, prog-nosis, and treatment options.

Settings of Care Considerations

- **Rural Healthcare Settings:** It is recognized that small and rural healthcare settings may have resource constraints. However, they should strive, within their resources, to meet the four attributes of intensivists. They also may consider using e-ICU technologies and services, as well as forming regional alliances with other institutions to ensure the best ICU care for patients in their region.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings. Ideally, children in ICUs would receive care from an intensivist certified in pediatric critical care. [IHI, N.D.b]
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Although it is believed that there is a shortage of intensivists, because ICU care is not organized around an intensivist model, [Gajic, 2009] the magnitude of this shortage is unknown, and the science of linking how care is organized to patient outcomes is immature. Although the evidence to support intensivist staffing is strong, [Lettieri, 2009] many important questions remain unanswered. For example, the relative importance of each of the intensivist attributes defined above is unknown, which limits the ability to evaluate the risks and benefits of alternative staffing models. In addition, further research is needed to clarify the potential of nurses, pharmacists, and other allied health professionals to augment the attributes identified as benefits of intensivist staffing, to improve teamwork among ICU staff, and to identify effective and efficient ways to staff ICUs.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 9: Nursing Workforce; Safe Practice 10: Direct Caregivers; Safe Practice 12: Patient Care Information; Safe Practice 15: Discharge Systems; Safe Practice 23: Care of the Ventilated Patient; Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention; and Safe Practice 28: Venous Thromboembolism Prevention.

Notes

Angus, 2000: Angus DC, Kelly MA, Schmitz RJ, et al. Caring for the critically ill patient. Current and projected workforce requirements for care of the critically ill and patients with pulmonary disease: can we meet the requirements of an aging population? JAMA 2000 Dec 6;284(21);2762-70. Available at http://jama.ama-assn.org/cgi/content/full/284/21/2762. Last accessed September 29, 2009.

Birkmeyer, 2001: Birkmeyer JD, Birkmeyer CM, Skinner JS. Leapfrog Patient Safety Standards. Economic Implications. Washington, DC: The Leapfrog Group; 2001 Jun.

Birkmeyer, 2004: Birkmeyer JD, Dimick JB. The Leapfrog Group's Patient Safety Practices, 2003: The Potential Benefits of Universal Adoption. 2004 Feb. Available at http://www.leapfroggroup.org/media/file/Leapfrog-Birkmeyer.pdf. Last accessed September 29, 2009.

Conrad, 2005: Conrad DA, Gardner M. Updated Economic Implications of the Leapfrog Group Patient Safety Standards: Final Report to the Leapfrog Group. 2005 May 2. Available at http://www.leapfroggroup.org/media/file/Conrad_Updated_Economic_Implications_2_.pdf. Last accessed September 29, 2009.

Denham, 2006: Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3):162-70.

Denham, 2008: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Gajic, 2009: Gajic O, Afessa B. Physician staffing models and patient safety in the ICU. Chest 2009 Apr;135(4):1038-44.

IHI, N.D.a: [No authors listed.] Implement an Intensivist Model in the Intensive Care Unit (ICU). Institute for Healthcare Improvement (IHI). No date. Available at http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Changes/ImplementanIntensivistModelintheIntensiveCareUnitICU.htm. Last accessed October 13, 2009.

IHI, N.D.b: [No authors listed.] Neonatal Intensive Care Unit (NICU) Standard Care. IHI Improvement Map. Institute for Healthcare Improvement (IHI). No date. Available at http://www.ihi.org/imap/tool/#Process=08fb57c2-7b98-4dea-b863-4257ac7be444. Last accessed October 13, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Oakbrook (IL): The Joint Commission; 2010.

Kahn, 2007: Kahn JM, Brake H, Steinberg KP. Intensivist physician staffing and the process of care in academic medical centres. Qual Saf Health Care 2007 Oct;16(5):329-33.

Lettieri, 2009: Lettieri CJ, Shah AA, Greenburg DL. An intensivist-directed intensive care unit improves clinical outcomes in a combat zone. Crit Care Med 2009 Apr;37(4):1256-60.

LFG, 2008: [No authors listed.] ICU Physician Staffing (IPS). The Leapfrog Group. Revised 2008 Apr 9. Washington, DC: The Leapfrog Group; 2008. Available at http://www.leapfroggroup.org/media/file/Leapfrog-ICU_Physician_Staffing_Fact_Sheet.pdf. Last accessed October 13, 2009.

Murias, 2009: Murias G, Sales B, Garcia-Esquirol O, et al. Telemedicine in critical care. Open Respir Med J 2009 Mar 12;3:10-6. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2682923&blobtype=pdf. Last accessed October 8, 2009.

Pronovost, 2001: Pronovost PJ, Waters H, Dorman T. Impact of critical care physician workforce for intensive care unit staffing. Curr Opin Crit Care 2001 Dec;7(6):456-9.

Pronovost, 2002: Pronovost PJ, Angus DC, Dorman T, et al. Physician staffing patterns and clinical outcomes in critically ill patients: a systematic review. JAMA 2002 Nov 6;288(17):2151-62. Available at http://jama.ama-assn.org/cgi/content/full/288/17/2151. Last accessed September 29, 2009.

Pronovost, 2004a: Pronovost P, Needham D, Waters H, et al. Intensive care unit physician staffing: financial modeling of the Leapfrog standard. Crit Care Med 2004 Jun;32(6):1247-53.

Pronovost, 2004b: Pronovost PJ, Rinke ML, Emery K, et al. Interventions to reduce mortality among patients treated in intensive care units. J Crit Care 2004 Sep;19(3);158-64.

Rosenfeld, 1999: Rosenfeld B, Dorman T, Pronovost PJ, et al. Remote management improves ICU outcomes. Crit Care Med 1999 Jan;27(1S):153A.

Rosenfeld, 2000: Rosenfeld BA, Dorman T, Breslow MJ, et al. Intensive care unit telemedicine: alternate paradigm for providing continuous intensivist care. Crit Care Med 2000 Dec;28(12):3925-31.

Rothschild, 2001: Rothschild JM. "Closed" intensive care units and other models of care for critically ill patients. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058, Ch. 38. Rockville (MD): Agency for Healthcare Research and Quality: 2001 Jul. Available at http://www.ahrq.gov/clinic/ptsafety/chap38.htm. Last accessed October 13, 2009.

Chapter 5: Improving Patient Safety by Facilitating Information Transfer and Clear Communication

Background

IN OUR NATION TODAY, we are treating sicker and sicker patients, faster and faster, with more complex treatment methods provided by a greater number of caregivers. [Denham, 2005] This increases fragmentation of care and reduces the probability that the right information for the right patient will be provided at the right time to ensure safe and optimal care.

The risk of delayed diagnosis, missed diagnosis, and improper care is directly related to information transfer. Misuse, overuse, and underuse of treatment have an enormous impact on generating adverse events. Such events can be decreased by the use of certain practices that facilitate complete information transfer and clear communication.

This chapter presents five such practices to include: Patient Care Information, Labeling of Diagnostic Studies, Order Read-Back and Abbreviations, Discharge Systems, and Computerized Prescriber Order Entry.

The lack of continuity of care has been recognized by the National Priorities Partnership. The National Quality Forum is the convening member of 32 major national organizations representing those who receive, pay for, deliver, and evaluate care. One of the National Priority Partnership's six crosscutting Priorities is care coordination to ensure that patients receive well-coordinated care within and across all healthcare organizations, settings, and levels of care. [NPP, 2009] The practices presented in this chapter begin to address this priority.

Today, nonphysicians provide most of the hands-on care that patients receive, while multiple specialist physicians typically focus on one particular problem or set of problems. In addition to the fact that many caregivers participate in care, that care is provided across multiple sites, which can be problematic because accurate and complete information about a patient's care, both previous and current, is often not shared among the disparate

healthcare providers. More specifically, office or clinic paper records often do not contain reports of emergency department visits, hospital discharge summaries, inpatient consultations, and laboratory or radiograph findings.

There is increasing information supporting the case for aggressive attention to the discharge process to the outpatient space and discharge of patients to nursing homes. [Jack, 2009] The ability to improve patient-centered care and reduce financial risk with more efficient and reliable discharge processes and coordination of hand-offs appears to be substantial.

In addition, diagnostic and treatment reports may not be entered into the ambulatory care record in a timely manner. Also, the use of nonstandard abbreviations when writing prescriptions and other orders, and inconsistent prescribing rules have been shown to increase the risk of medical errors. As a result, healthcare providers frequently lack critical information when making diagnostic or treatment decisions, a frequently cited cause of medical errors and unnecessary duplication of services. This is an especially acute problem for patients who have special needs.

The practices in this chapter demonstrate opportunity for organizations to tackle some of the hidden causes of patient harm and suffering that occur beyond the walls of healthcare institutions, yet may be the results of cascading events that actually start with the caregiver-patient interface.

Notes

Denham, 2005: Denham CR. Digital hospitals succeed: old fashioned values – new fashioned roles. J Patient Saf 2005 Dec;1(4):220-5.

Jack, 2009: Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009 Feb 3;150(3):178-87.

NPP, 2009: National Priorities Partnership. National Quality Forum. Available at http://www.nationalprioritiespartnership.org/Home.aspx. Last accessed October 15, 2009.

SAFE PRACTICE 12: PATIENT CARE INFORMATION

The Objective

Promote accurate and timely communication of information among caregivers about patients' medical history, diagnostic tests, medications, treatments, procedure findings, and plan of care.

The Problem

Critical information about medical history, diagnostic test results, medications, treatments, and procedures that occur within a care setting often are not communicated to all who are providing care for a patient. Even more common, such information is not communicated between care settings. The primary objective of a patient hand-off is to provide accurate information about the patient's, client's, or resident's care, treatment and services, current condition, and any recent or anticipated changes. [Schiff 2006; JCR, 2010b] When hand-offs are incomplete or poorly organized, practitioners and patients often miss information that is important in making diagnosis and treatment decisions. [Denham, 2008a]

The frequency of patient safety risks associated with missing care information that results from delayed or incomplete closure of information loops is high. One study found that only 51 percent of potentially "life-threatening" critical test results received appropriate attention. [Tate, 1990] An audit of patient charts revealed that 15 percent contained no documentation that clinicians were ever aware of the critical test result or that any corrective action was taken. [Tate, 1993] A study of anonymously reported incidents related to diagnostic testing in primary care found that approximately 25 percent of identified errors involved failures in reporting results *to clinicians,* while 7 percent involved response failures *by clinicians*. [Hickner, 2008] In general, clinicians did not have a systematized method for following up on results. A recent study reviewed results management in 19 community practices and four academic medical centers, and found that the failure rate to inform patients, or to document doing so, was 7.1 percent. [Casalino, 2009]

The lack of timely communication of care information and incomplete closure of information loops affect the severity of the causes of preventable harm to patients, including incorrect diagnosis, delayed treatment, and the use of less optimal tests and treatments. [White House, 2004; Denham, 2008b; Levinson, 2008a; Levinson, 2008b; Gordon, 2009; Rao, 2009; Schiff, 2009; Singh, 2009] Patients often find it difficult to get their medical records, despite the fact that these records can provide a vital link in the transmission of information between patients and caregivers. Fifty-nine percent of diagnostic errors found in an ambulatory care setting were associated with serious patient harm, and 30 percent resulted in death. The adverse consequences associated with 590 independent testing process events occurring in 8 primary care offices included time lost and financial consequences (22 percent), delays in care (24 percent), pain and suffering (11 percent), and adverse clinical consequences (2 percent). [Hickner, 2008] Eighteen percent resulted in some harm to the patient. Overuse, underuse, and misuse of diagnostic and therapeutic care also cause preventable waste. Cancer is emerging as a particularly troubling diagnosis in which failure to follow up on abnormal test results can lead to delays, malpractice allegations, and lost opportunities for timely treatment. [Singh, 2007; Singh, 2009]

Several interventions dealing with the preventability of failures in the communication and transfer of critical patient information [Schiff, 2006; Hanna, 2005] already have been endorsed and adopted by the healthcare community. Standardized communication tools, such as the Situation, Background, Assessment, and Recommendation (SBAR) technique, have gained popularity as tools that can be used to improve the quality of hand-offs between providers. [Haig, 2006; KP, 2006; Denham, 2008c; Velji, 2008] Team training programs have also demonstrated a positive effect in improving the communication of critical patient information during hand-offs. [Berkenstadt, 2008] Limited research has been published on the effectiveness of interventions developed to reduce errors and adverse events related to the transfer of critical patient information.

The annual impact, or cost of adverse events resulting from failures in managing or communicating patient care information, is not known. Performance improvement programs must increase awareness of performance gaps common to organizations through education from internal or external sources. This awareness can only be obtained through measurement. The organization must identify the administrative and medical leaders who will be personally accountable for closing the identified gaps, and then it must define the explicit actions to be taken, actively manage and regularly evaluate the program, and invest in the ability to close the gaps by allocating financial and human resources appropriately. Eliminating redundant tests would have saved an additional $8 billion (2.7 percent). Addressing these situations could generate major savings to the system while improving patient care. [Jha, 2009]

Safe Practice Statement

Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and appropriate family and caregivers, and to all of the patient's healthcare providers/professionals, within and between care settings, who need that information to provide continued care. [MCPME, N.D.]

Additional Specifications

- Identify communication gaps and/or failures about critical test results, implement performance improvement programs to ensure timely closure of information loops, and report the gaps and improvement progress to senior leadership and the board of governance.
- Implement a standardized process to ensure that critical results are communicated quickly to a licensed healthcare provider so that action can be taken. [Valenstein, 2008; Rensburg, 2009] Values defined as critical by the laboratory must be reported to the responsible licensed practitioner within the timeframes established by the laboratory in cooperation with nursing and medical staff. [Valenstein, 2008; Huang, 2009]
- Put in place intra- and intercare setting processes to ensure that, when the patient's responsible licensed practitioner is not available within the specified timeframes, there is a mechanism to report critical information to an alternate responsible practitioner. [JCR, 2010a] Also, include a process of how to communicate critical test results that are completed after the patient has been discharged from the organization.

- Ensure that patients have access to their medical records, which should include, but not be limited to, medical histories and consultations, test results, including laboratory reports and imaging (including copies of imaging studies), medication lists, advance directives, and procedural reports, within 24 hours of a written request that includes the appropriate release documentation. Use technology to facilitate patient care information when possible. [Matheny, 2007; Reid, 2008; Piva, 2009]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Service care settings to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- To close information loops, start by identifying the critical information and the communication loops between practitioners that pose the greatest patient safety risks. Typically, opportunities for performance improvement exist in the areas of medication and treatment records and in critical laboratory, imaging, and pathology test results. [Reid, 2008; Valenstein, 2008] Educational programs should include content related to the concepts of high-reliability organizations, human factors principles, performance improvement principles, and evidence-based studies that identify high-impact, high-volume care areas and conditions offering early improvement opportunities. Participation in teamwork training that is addressed in *Safe Practice 3: Teamwork Training and Skill Building* would satisfy this requirement.
- Consider the use of technologies to enable the closure of information loops only after the workflow and care process systems are clearly understood. This could include providing patients access to electronic personal health records or to suppliers of secure services so that they may be enabled to manage certain health information. [Matheny, 2007; Reid, 2008; Piva, 2009]
- Ensure that processes are in place to confirm that patients can keep appointments for tests, treatments, and consultant appointments within and between care settings.
- Train staff and licensed practitioners (both those employed by the organization and those working independently) about the importance of hand-offs.
- Didactic elements of training may be delivered through multimedia approaches or distance learning strategies that can be updated with the latest evidence. Documentation of participation can be kept to verify compliance, ensure that new and temporary staff receive such training, and provide continuing education credits.

Strategies of Progressive Organizations

- Some organizations have provided access to the entire medical record for patients online. Others provide a personal health record repository or access to outsource services that allow patients to keep digital versions of their records. [Matheny, 2007; Reid, 2008; Piva, 2009]

Opportunities for Patient and Family Involvement

- Partner with patients in communications about test results. Increased patient access to results facilitates patient-centered care by treating patients and their caregivers as partners in the patient's medical care.
- Engage patients as partners in their care to ensure timely caregiver follow-up on test results.
- Encourage patients to maintain documentation of and be proactive in obtaining their test results.
- Include family, when appropriate, in the collection of intake information, whenever appropriate.
- Consider including patients or families of patients who have experienced a failure of critical information communication to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures** include the reduction in direct harm associated with adverse drug events and treatment misadventures including death, disability (permanent or temporary), or preventable harm requiring further treatment; missed diagnoses; delayed treatment; and inaccessible prior test information and medical records.
- **Process Measures** include the percent of critical or abnormal test results received by practitioners; the number of patients who receive medical records; and the timeliness with which medical records are provided to patients who request them with appropriate documentation; number of problematic cases identified or reported (e.g., malpractice allegations, patient complaints, incident reports) related to test or other information hand-off failures.
  - NQF-endorsed® process measures:
    1. #0045: Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture [Ambulatory Care (office/clinic)]: Percentage of patients aged 50 years and older treated for a hip, spine, or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis.
    2. #0291: Administrative Communication [Emergency Department]: Percentage of patients transferred to another acute hospital whose medical record documentation indicated that administrative information was communicated to the receiving hospital within 60 minutes of departure.
    3. #0292: Vital Signs [Emergency Department]: Percentage of patients transferred to another acute hospital whose medical record documentation indicated that the entire vital signs record was communicated to the receiving hospital within 60 minutes of departure.

4. #0293: Medication Information [Emergency Department]: Percentage of patients transferred to another acute hospital whose medical record documentation indicated that medication information was communicated to the receiving hospital within 60 minutes of departure.
5. #0294: Patient Information [Emergency Department]: Percentage of patients transferred to another acute hospital whose medical record documentation indicated that patient information was communicated to the receiving hospital within 60 minutes of departure.
6. #0295: Physician Information [Emergency Department]: Percentage of patients transferred to another acute hospital whose medical record documentation indicated that physician information was communicated to the receiving hospital within 60 minutes of departure.
7. #0296: Nursing Information [Emergency Department]: Percentage of patients transferred to another acute care hospital whose medical record documentation indicated that nursing information was communicated to the receiving hospital within 60 minutes of departure.
8. #0297: Procedures and Tests [Emergency Department]: Percentage of patients transferred to another acute care hospital whose medical record documentation indicated that procedure and test information was communicated to the receiving hospital within 60 minutes of departure.
9. #0381: Oncology: Treatment Summary Documented and Communicated – Radiation Oncology [Ambulatory Care (office/clinic)]: Percentage of patients with a diagnosis of cancer who have undergone brachytherapy or external beam radiation therapy who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care within one month of completing treatment.

- **Structure Measures** include verification of the existence of a performance improvement program and explicit organizational policies and procedures that address the communication of critical patient care information; verification of educational programs; the existence of formal reporting structures for accountability across governance, administrative leadership, and frontline caregivers; and the existence of structures and systems to ensure that an organization provides medical records to patients.
  - NQF-endorsed structure measure:
    1. #0491: Tracking of Clinical Results Between Visits: Documentation of the extent to which a provider uses a certified/qualified electronic health record (EHR) system to track pending laboratory tests, diagnostic studies (including common preventive screenings) or patient referrals. The Electronic Health Record includes provider reminders when clinical results are not received within a predefined timeframe.
- **Patient-Centered Measures** include surveys of patients on their satisfaction related to communication by caregivers; surveys that address performance along the dimensions of patient-centered care that include the objectives of continuous collaboration,

coordination, and integration of care among providers; the accessibility of customized information, communication, and education; and methods and tools that help patients manage their own records and improve self-efficacy and self-management as well as assess the effectiveness of patient decision support tools.

Settings of Care Considerations

- **Rural Healthcare Settings:** It is recognized that although small and rural healthcare settings, including hospitals, have constraints on their resources, the issue of providing critical care information often is more important in these settings because many patients later require more complex care in larger centers. This involves transferring vital diagnostic and other patient care information.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings. Clearly, parents must have access to medical records in order to facilitate the transfer of information, especially in the case of younger children who cannot communicate this information to their caregivers.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings, including hospitals. Such organizations must be focused on transmitting medical records and critical care information, such as diagnostic tests and procedural information, since their patients likely will be admitted to care centers for conditions that cannot be addressed by specialty facilities.
- **Outpatient Testing Facilities:** Imaging centers and other test facilities must address the closure of communication loops about test results. Incomplete closure of such loops leads to missed and delayed diagnosis. Incomplete access to prior tests leads to less-than-optimal interpretation of such studies.

New Horizons and Areas for Research

The communication of care information must be better understood in order to leverage the products, services, and technologies that are needed to enable practices that will reduce preventable harm to patients across the healthcare organization and between care settings. Best practices in the adoption of health information technologies must be developed and tested.

Point-of-care testing can shorten reporting turnaround time but is currently more costly, and may be subject to significant result variability. Reliability and accuracy will improve as the technology improves.

Automated electronic notification of critical test results with the capability of requiring the ordering practitioner to document receipt of the information could, in the future, ensure accurate and immediate delivery of the critical test results. The adoption and use of advanced communication technologies, such as intranet, secure Internet, and other digital messaging methods, can improve the speed of test results notification.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 15: Discharge Systems; Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry; and Safe Practice 17: Medication Reconciliation.

Notes

Berkenstadt, 2008: Berkenstadt H, Haviv Y, Tuval A, et al. Improving handoff communications in critical care: utilizing simulation-based training toward process improvement in managing patient risk. Chest 2008 Jul;134(1):158-62.

KP, 2006: Kaiser Permanente. SBAR Technique for communication: A situational briefing model. Available at: http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARTechniqueforCommunicationASituationalBriefingModel.htm Last accessed November 10, 2009.

Casalino, 2009: Casalino LP, Dunham D, Chin MH, et al. Frequency of failure to inform patients of clinically significant outpatient test results. Arch Intern Med 2009 Jun 22;169(12):1123-9. Available at http://archinte.ama-assn.org/cgi/reprint/169/12/1123. Last accessed November 2, 2009.

Denham, 2008a: Denham CR, Dingman J, Foley ME, et al. Are you listening…are you really listening? J Patient Saf 2008 Sep;4(3):148-61

Denham, 2008b: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Denham, 2008c: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Gordon, 2009: Gordon JR, Wahls T, Carlos RC, Pipinos II, Rosenthal GE, Cram P. Failure to recognize newly identified aortic dilations in a health care system with an advanced electronic medical record. Ann Intern Med 2009; 151(1):21-7, W5.

Haig, 2006: Haig KM, Sutton S, Whittington J. SBAR: a shared mental model for improving communication between clinicians. Jt Comm J Qual Patient Saf 2006 Mar;32(3):167-75.

Hanna, 2005: Hanna D, Griswold P, Leape LL, et al. Communicating critical test results: safe practice recommendations. Jt Comm J Qual Patient Saf 2005 Feb; 31(2):68-80.

Hickner, 2008: Hickner J, Graham DG, Elder NC, et al. Testing process errors and their harms and consequences reported from family medicine practices: a study of the American Academy of Family Physicians National Research Network. Qual Saf Health Care 2008 Jun;17(3):194-200.

Huang, 2009: Huang EC, Kuo FC, Fletcher CD, et al. Critical diagnoses in surgical pathology: a retrospective single-institution study to monitor guidelines for communication of urgent results. Am J Surg Pathol 2009 Apr 22. Epub 2009 Apr 22.

IHI, N.D.: [No authors listed.] Critical Results Reporting. IHI Improvement Map. Institute for Healthcare Improvement (IHI). No date. Available at http://www.ihi.org/imap/tool/#Process=f7eb9f4c-362e-4a54-b3ea-a2d38e94a32a. Last accessed November 9, 2009.

JCR, 2010a: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.02.03.01. Oak Brook (IL): Joint Commission Resources; 2010.

JCR, 2010b: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standard PC.02.02.01. Oak Brook (IL): Joint Commission Resources; 2010.

Jha, 2009: Jha AK, Chan DC, Ridgway AB, et al. Improving safety and eliminating redundant tests: cutting costs in U.S. hospitals. Health Aff (Millwood) 2009 Sep-Oct;28(5):1475-84.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed October 14, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 14, 2009.

Matheny, 2007: Matheny ME, Gandhi TK, Orav EJ, et al. Impact of an automated test results management system on patients' satisfaction about test result communication. Arch Intern Med 2007 Nov 12;167(20):2233-9. Available at http://archinte.ama-assn.org/cgi/reprint/167/20/2233. Last accessed November 2, 2009.

MCPME, N.D.: Massachusetts Coalition for the Prevention of Medical Errors. Available at http://www.macoalition.org/index.shtml. Last accessed October 14, 2209.

Piva, 2009: Piva E, Sciacovelli L, Zaninotto M, et al. Evaluation of effectiveness of a computerized notification system for reporting critical values. Am J Clin Pathol 2009 Mar;131(3):432-41.

Rao, 2009: Rao SK, Schilling TF, Sequist TD. Challenges in the management of positive fecal occult blood tests. J Gen Intern Med 2009; 24(3):356-360.

Reid, 2008: Reid RJ, Wagner EH. Strengthening primary care with better transfer of information. CMAJ 2008 Nov 4;179(10):987-8. Available at http://www.pubmedcentral.nih.gov.ezp-prod1.hul.harvard.edu/picrender.fcgi?artid=2572662&blobtype=pdf. Last accessed October 9, 2009.

Rensburg, 2009: Rensburg MA, Nutt L, Zemlin AE, et al. An audit on the reporting of critical results in a tertiary institute. Ann Clin Biochem 2009 Mar;46(Pt 2):162-4.

Schiff, 2006: Schiff G, ed. Getting Results: Reliably Communicating and Acting on Critical Test Results. Oakbrook Terrace, IL: Joint Commission Resources; 2006. ISBN: 1599400014. Available at http://psnet.ahrq.gov/resource.aspx?resourceID=3994. Last accessed October 14, 2009.

Schiff, 2009: Schiff GD, Hasan O, Kim S, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med 2009 Nov 9;169(20):1881-7.

Singh, 2007: Singh H, Sethi S, Raber M, Petersen LA. Errors in cancer diagnosis: current understanding and future directions. J Clin Oncol 2007; 25(31):5009-5018.

Singh, 2009: Singh H, Daci K, Petersen LA, et al. Missed Opportunities to Initiate Endoscopic Evaluation for Colorectal Cancer Diagnosis. Am J Gastroenterol 2009 Oct;104(10):2543-54. Epub 2009 Jun 23.

Tate, 1990: Tate KE, Gardner RM, Weaver LK. A computerized laboratory alerting system. MD Comput 1990 Sep-Oct;7(5):296-301.

Tate, 1993: Tate KE, Gardner RM. Computers, quality and the clinical laboratory: a look at critical value reporting. Proc Annu Symp Comput Appl Med Care 1993:193-7.

Valenstein, 2008: Valenstein PN, Wagar EA, Stankovic AK, et al. Notification of critical results: a College of American Pathologists Q-Probes study of 121 institutions. Arch Pathol Lab Med 2008 Dec;132(12):1862-7. Available at http://arpa.allenpress.com/pdfserv/10.1043%2F1543-2165-132.12.1862. Last accessed November 5, 2009.

Velji, 2008: Velji K, Baker GR, Fancott C, et al. Effectiveness of an Adapted SBAR Communication Tool for a Rehabilitation Setting. Healthc Q 2008;11(3 Spec No.):72-9.

White House, 2004: Transforming Health Care: The President's Health Information Technology Plan. The White House, 2004. www.starcareonline.com/Transforming_HealthCare_WhiteHousePaper.doc. Last accessed October 14, 2009.

SAFE PRACTICE 13: ORDER READ-BACK AND ABBREVIATIONS

The Objective

For verbal or telephone orders, or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and read back the complete order or test result.

The Problem

Communication quality, written or verbal, has been strongly linked to the frequency of the occurrence of medical errors and overall patient safety. Poor communication has been cited as the most frequent root cause of sentinel events, accounting for more than 60 percent of events between 2006 and 2008. [Brunetti, 2007; JCR, 2010b] For written communication, the use of easily misinterpreted nomenclature and abbreviations has been determined to be hazardous by The Joint Commission, especially with respect to medication and laboratory orders. A large study conducted by the United States Pharmacopeia collected medication error reports from 682 separate facilities; 643,151 errors were reported, with 29,974 (4.7 percent) of them attributable to abbreviation use. [Brunetti, 2007] Abbreviation errors have spurred The Joint Commission to create a list of "Do Not Use" abbreviations and nomenclatures. [TJC, 2005] Compliance with this list has been tracked, and, despite the list's availability in 2004, noncompliance remains frequent (23 percent). Moreover, The Joint Commission survey results have demonstrated a decreasing trend from 2004 (75.2 percent) to 2006 (64.2 percent). [Brunetti, 2007; TJC 2006] Ineffective verbal communication, over the phone or in person, leads to errors that might be prevented by simply having the receiving person read back the information. An observational study of 822 telephone calls from 3 institutions detected 29 (3.5 percent) errors. The major categories of error were incorrect patient name, incorrect test result, incorrect specimen or test repeated, and refusal of recipient to repeat the message. [Barenfanger, 2008] A large survey of 1,264 hospitals conducted by the American Society of Health-System Pharmacists found that 78.7 percent of hospitals reported compliance with read-back protocol compared to 81.9 percent in 2004 and 31.4 percent in 2001. [Pedersen, 2008]

Adverse events associated with errors from written or verbal miscommunication can range in severity. Errors of medication names, dosage, frequency, and strength have the potential to gravely harm patients. [Levinson, 2008] Experts have estimated that 25 percent of medication errors involve similar medication names. [Hendrickson, 2007; ISMP, 2001; Waters, 1999] For written communication, the most common abbreviation resulting in a medication error was "QD" in place of "once daily," accounting for 43.1 percent of errors. [Brunetti, 2007] Of all of the 29,974 errors reported by the United States Pharmacopeia program, only 0.3 percent were categorized by the National Coordinating Council for Medication Error Reporting and Prevention as indicating patient harm. [Brunetti, 2007; NCC MERP, 2007] Medical errors associated with miscommunicating critical laboratory values have been recognized in the literature, but to our knowledge, no studies have linked these types of errors to specific adverse events.

Two research studies have focused in part on the preventability of harm due to the read-back protocol. Of the 29 errors detected during the observational study of 822 telephone calls, each error was corrected by performing read-back. [Barenfanger, 2008] A study of critical lab-value reporting procedures found

100 percent compliance for read-back recommendations. [Saxena, 2005] Read-back of verbal orders in the operating room setting is particularly important, because providers wear masks. [Hendrickson, 2007] Written and verbal communication about drug information is prevalent, but is decreasing because of implementation of electronic drug information systems. Pharmacies' most common means of receiving medication orders is still handwritten copies (38.3 percent), followed by some form of digital image capture (32.7 percent), faxes (23.7 percent), and then electronic receipt through computerized prescriber order entry (CPOE) systems (5.1 percent). [JCR, 2010a] Integrating CPOE into a comprehensive strategy to improve medication order/receipt practices is a recommended method of preventing errors, [Wakefield, 2009b; Ehringer, N.D.], but to date, only 10.4 percent of hospitals operate with them. [Pedersen, 2007] One hospital study revealed that after implementing a CPOE system, verbal order rates dropped from 23 percent to 10 percent of all orders, and unsigned verbal orders decreased from 43 percent to 9 percent. [Wakefield, 2008] Adding a pediatric medication quick-list to the CPOE system showed an improvement in lowering prescription errors by 89 percent. [Sard, 2008]

Costs associated with written and verbal communication compliance are difficult to delineate. Applicable costs include those incurred by adverse patient events, as well as time and training costs associated with implementing and evaluating safe practices. Introducing information technology (e.g., CPOE) is an increasingly common method of preventing communication errors, but the costs are significant.

Safe Practice Statement

Incorporate within your organization a safe, effective communication strategy, structures, and systems to include the following: [ISMP, 2007; JCR, 2010a; IHI, N.D.a; IHI, N.D.b]

- For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and "read-back" the complete order or test result. [JCR, 2010a]
- Standardize a list of "Do Not Use" abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.

Additional Specifications

- The process of verbal orders should be avoided except when it is impossible or impractical for the prescriber to write the order or enter it in the computer. [Baum, 2009] Explicit organizational policies and procedures on verbal and telephone orders should include, at a minimum:
  - strategies to minimize the use of verbal and telephone orders, [JCR, 2010a] and
  - the identification of items that cannot be ordered or reported verbally or by telephone.
- The receiver of verbal information writes down the complete order or test result or enters it into a computer.
- The receiver reads back the order or test result.
- The receiver receives confirmation from the individual who gave the order or test result.

- Rigorously prohibit the use of terms known to lead to misinterpretation including, at a minimum, *u, IU, qd, qod, trailing zero, absence of leading zero, MS, MSO4, MgSO4.*
- At a minimum, prohibit terms known to lead to misinterpretation from all orders and other medication-related documentation when handwritten, entered as free text into a computer, or on preprinted forms.
- Use the metric system to express all doses on prescription orders, except for therapies that use standard units, such as insulin and vitamins.
- Trailing zeros may be used in nonmedication-related documentation when there is a clear need to demonstrate the level of precision, such as for laboratory values.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- The Institute of Safe Medication Practices (ISMP) has conducted extensive research, based on what organizations have reported, on frequently misinterpreted abbreviations, particularly related to medication errors and subsequent harm to patients. Organizations are encouraged to consider incorporating ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations as part of their approved "do not use" list. [ISMP, 2007] This list has been cross-referenced with the minimum requirements established by The Joint Commission. [Wakefield, 2009b]
- Organizations may choose to implement policies that verbal orders should never be used for chemotherapy orders, including initial orders or updates and modifications to previously handwritten or electronic orders.
- Order read-back and abbreviation training are ideal subject matter areas to be addressed in teamwork training (refer to Safe Practice 3).

Strategies of Progressive Organizations

- New communication technology is emerging and in use to support the read-back process. Some organizations have focused on best practices in strategies for adoption of this practice, such as providing frequent feedback to the prescriber and providing de-identified examples of misinterpreted orders. [TJC, 2005]

Opportunities for Patient and Family Involvement

- Encourage patients to ask questions if they do not understand abbreviations, especially on medication instructions.
- Consider including patients or families of patients who have experienced healthcare system communication-related adverse events to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include errors and near misses attributable to or associated with verbal or telephone orders, stratified by degree of harm or required intervention using a system such as the nine-category classification of the MedMarx reporting program. For example, clinical outcomes such as death, disability (permanent or temporary), or preventable harm requiring further treatment could be measured relative to implementation of the practice. Operational and financial outcomes relative to re-work that occurs when ineffective communication occurs may also be tracked. Monitor and trend adverse drug events attributed to inappropriate use of abbreviations.
- **Process Measures** include periodic audits of compliance with policies and procedures for the receipt of verbal and telephone orders and critical test results, or intermittent observational studies of a representative sample of care units and shifts to assess the process of receiving, recording, and reading back orders and critical test results.
    - Also included are evaluation of compliance with the organization's "do not use" list, and periodic audits of samples of medical records, medication administration records (MARs), and other patient-specific documentation for the presence of "do not use" terms. Compliance is calculated using as the denominator the number of times that terms that should not be abbreviated are used (whether in full form or abbreviated), and the numerator is the number of times such terms are not abbreviated.
- **Structure Measures** include the verification of periodic review and updating of relevant policies and procedures, such as those related to the receipt, recording, and read-back of orders and critical test results. (This should include the organization's definitions of "critical test results.")
    - Also included are verification of periodic review and update of policies and procedures relating to the use of abbreviations included in the organization's "do not use" list.
- **Patient-Centered Measures** include assessment of read-back and "teach-back" use, and confirmation of patient understanding. Patient-centered measures are not applicable with respect to abbreviations.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Technologies may hold new opportunities to reduce risk, such as the adoption of CPOE systems in which the opportunity is provided to omit dangerous abbreviations through the use of a forcing function. [Wakefield, 2009a]

Communication between caregivers and patients requires further research to attain accurate and sustainable best practices. [Krimsky, 2009; Wakefield, 2009b]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 12: Patient Care Information; Safe Practice 14: Labeling of Diagnostic Studies; and Safe Practice 15: Discharge Systems. Also relevant are the practices related to medication management, including Safe Practice 17: Medication Reconciliation and Safe Practice 18: Pharmacist Leadership Structures and Systems.

Notes

Barenfanger, 2008: Barenfanger J, Sautter RL, Lang DL, et al. Improving patient safety by repeating (read-back) telephone reports of critical information. Am J Clin Pathol 2004 Jun;121(6):801-3. Available at http://ajcp.metapress.com/media/804t6y88tk4ypjcaulft/contributions/9/d/y/m/9dym6r0tm830u95q.pdf. Last accessed September 28, 2009.

Baum, 2009: Baum KD. Getting your point across: verbal orders and patient safety. Qual Saf Health Care 2009 Jun;18(3):164.

Brunetti, 2007: Brunetti L, Santell JP, Hicks RW. The impact of abbreviations on patient safety. Jt Comm J Qual Patient Saf 2007 Sep;33(9):576-83.

Ehringer, N.D.: Ehringer G, Duffy B. Promoting best practice and safety through preprinted physician orders. Agency for Healthcare Research and Quality. No date. Available at http://www.ahrq.gov/downloads/pub/advances2/vol2/Advances-Ehringer_17.pdf. Last accessed October 13, 2009.

IHI, N.D.a: [No authors listed.] Cutting the Use of Dangerous Abbreviations: SSM Health Care. Institute for Healthcare Improvement (IHI). No date. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/ImprovementStories/CuttingtheUseofDangerousAbbreviations.htm. Last accessed October 13, 2009.

IHI, N.D.b: [No authors listed.] Medication Ordering. IHI Improvement Map. Institute for Healthcare Improvement (IHI). No date. Available at http://www.ihi.org/imap/tool/#Process=09361f0e-4fd6-4b02-af72-0f662a11282f. Last accessed October 13, 2009.

ISMP, 2001: Institute of Safe Medication Practices (ISMP). Instilling a measure of safety in those "whispering down the lane" verbal orders. ISMP Medication Safety Alert. 2001 Jan 24. Available at http://www.ismp.org/Newsletters/acutecare/articles/20010124.asp?ptr=y. Last accessed September 28, 2009.

ISMP, 2007: [No authors listed.] ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations. Institute for Safe Medication Practices (ISMP). 2007. Available at http://www.ismp.org/Tools/errorproneabbreviations.pdf. Last accessed October 13, 2009.

JCR, 2010a: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards PC.02.01.03 and MM.04.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

JCR, 2010b: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goals. Oak Brook (IL): Joint Commission Resources; 2010.

Krimsky, 2009: Krimsky WS, Mroz IB, McIlwaine JK, et al. A model for increasing patient safety in the intensive care unit: increasing the implementation rates of proven safety measures. Qual Saf Health Care 2009 Feb;18(1):74-80.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 28, 2009.

NCC MERP, 2007: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP): About Medication Errors. Feb. 20, 2001. Available at http://www.nccmerp.org/medErrorCatIndex.html. Last accessed September 28, 2009.

Pedersen, 2007: Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: monitoring and patient education – 2006. Am J Health Syst Pharm 2007 Mar 1;64(5):507-20.

Pedersen, 2008: Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: prescribing and transcribing – 2007. Am J Health Syst Pharm 2008 May 1;65(9):827-43.

Sard, 2008: Sard BE, Walsh KE, Doros G, et al. Retrospective evaluation of a computerized physician order entry adaptation to prevent prescribing errors in a pediatric emergency department. Pediatrics 2008 Oct;122(4):782-7.

Saxena, 2005: Saxena S, Kempf R, Wilcox S, et al. Critical laboratory value notification: a failure mode effects and criticality analysis. Jt Comm J Qual Patient Saf 2005 Sep;31(9):495-506.

TJC, 2005: The Joint Commission. Official "Do Not Use" List. 2005. Available at http://www.jointcommission.org/NR/rdonlyres/2329F8F5-6EC5-4E21-B932-54B2B7D53F00/0/dnu_list.pdf. Last accessed September 28, 2009.

Wakefield, 2008: Wakefield DS, Ward MM, Groath D, et al. Complexity of medication-related verbal orders. Am J Med Qual 2008 Jan-Feb;23(1):7-17.

Wakefield, 2009a: Wakefield DS, Brokel J, Ward MM, et al. An exploratory study measuring verbal order content and context. Qual Saf Health Care 2009 Jun;18(3):169-73.

Wakefield, 2009b: Wakefield DS, Wakefield BJ. Are verbal orders a threat to patient safety? Qual Saf Health Care 2009 Jun;18(3):165-8.

Waters, 1999: Waters R. Could my doctor's handwriting hurt me? Health 1999;13(3):26.

SAFE PRACTICE 14: LABELING DIAGNOSTIC STUDIES

The Objective

Reduce the risk of misinterpretation of radiology, laboratory, and pathology studies due to miscommunication or inaccurate labeling.

The Problem

Mislabeling or incompletely labeling radiology, laboratory, and pathology specimens can lead to misinterpretation of results and to potential harm to patients. Literature relevant to this safe practice focuses entirely on examining the process and accuracy of labeling laboratory tests and specimens. [Hunt, 2008] More than 7 billion laboratory tests are performed in the United States annually. It is estimated that these tests influence 70 percent of medical decisions. [Silverstein, 2004]

Several large studies have determined that specimen identification errors occur at a frequency of between 0.1 and 5 percent. [Ibojie, 2000; Novis, 2004; Valenstein, 2004; Howanitz, 2005; Wagar, 2006; Lippi, 2009] The most comprehensive and recent study by Wagar et al. reviewed 3.3 million specimen labels from 147 laboratories. Labeling errors were identified in 0.92 per 1,000 specimens. [Wagar, 2006] Of these labeling errors, 29.9 percent were mislabeled; 22.7 percent were partially labeled; 21.9 percent were unlabeled; 20.7 percent were incompletely labeled; and 6.1 percent were illegibly labeled. [Wagar, 2006] A similar analysis of 21,351 surgical specimens found 4.3 per 1,000 identification errors, made up of 0.512 percent (53/10,354) identification errors for specimens originating in an outpatient clinic, and 0.346 percent (38/10,997) errors for specimens originating in the operating room. [Makary, 2007] In comparison, a multicenter (97) study in 2008 concluded that computer order entry errors for send-out tests occurred twice as frequently as order entry errors for other types of tests. [Valenstein, 2008]

The severity of iatrogenic injury resulting from laboratory specimen identification errors is wide ranging. [Levinson, 2008a; Levinson, 2008b] Errors can potentially result in delayed diagnosis, additional laboratory testing, severe transfusion reactions, and treating a patient for the wrong disease. [Wagar, 2006] Wrong-patient cancer resection cases have appeared in the news. [Fischer, 2005; CBS News, 2003] A more recent five-week study in 2006 examined the occurrence of adverse events from laboratory identification errors for 120 separate clinical laboratories. Of 345 adverse events reported (1 of 18 identification errors), 72.8 percent resulted in significant patient inconvenience with no change in treatment or outcome; 22.6 percent resulted in an unknown patient impact; and 4.6 percent resulted in a change in patient treatment, but with no known change in patient outcome. [Valenstein, 2006]

Most laboratory errors are attributable to specimen misidentification; thus, an effective labeling process will dramatically increase the preventability of such cases. [Bonini, 2002; Denham, 2005; Denham, 2008; Lippi, 2009; O'Neill, 2009] Reported error rates have improved, and the College of American Pathologists Q-Probes and Q-Tracks programs, as well as advancements in technology (e.g., barcoding), have fostered this. Radio frequency identification tags have been proven, in conjunction with a two-healthcare-provider accuracy confirmation, to decrease specimen labeling errors by 90 percent. [Francis, 2009] Also, at the Beth Israel Deaconess Medical Center in Boston, it was shown that through educational awareness

and strict labeling techniques, blood specimen labeling errors decreased by almost 80 percent. [O'Neill, 2009]

Healthcare costs associated with laboratory specimen identification errors have not been formally studied. These specifically involve costs to re-perform tests and costs associated with adverse patient events. This may include legal claims. An analysis of 272 surgical pathology legal claims found that 5 percent involved allegations of specimens being mislabeled and mixed between patients. [IOM, 2000] Hospital costs associated with error prevention involve the investment of staff time in ensuring high-quality coordination between the clinical laboratory and interacting departments within the hospital, as well as investments in information technology to assist in labeling and reporting.

Safe Practice Statement

Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time. [IHI, 2004; JCR, 2010]

Additional Specifications

- Label laboratory specimen containers at the time of use and in the presence of the patient. [AHRQ, N.D.a]
- Take the critical steps of identifying the individual and matching the intended service or treatment, including read-back, to that individual to prevent miscommunication or inaccurate labeling. [AHRQ, N.D.b]
- Use at least two patient identifiers (neither to be the patient's room number or physical location) when taking blood samples or other specimens for clinical testing, imaging, or providing any other treatments and procedures. [JCR, 2010]
- Label x-ray imaging studies with the correct patient information while in the darkroom or close to the imaging device.
- Mark "left" or "right" on each radiographic image to prevent misinterpretation on the light box.
- Monitor and report errors and harm related to mislabeling to the organization-wide risk-assessment activity as part of a performance improvement program that addresses mislabeling of specimens or diagnostic studies.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Acceptable person-specific identifiers that may be used are the individual's name, an assigned identification number, a telephone number, a photograph, or another person-specific identifier. [JCR, 2010] Technologies such as the use of barcoding that include two or more person-specific identifiers (not including room number) should be considered as acceptable identifiers. [Francis, 2009; JCR, 2010]
- Didactic elements of training on the mislabeling of studies or specimens may be delivered through multimedia or distance learning strategies that can be updated with the latest evidence. Documentation

of participation can be kept to verify com-pliance, ensure that new and temporary staff receive such training, and provide continuing education credits.

- In pathological studies, sequentially inking specimens with different colors is an effective method for decreasing labeling errors. [Raff, 2009]

Strategies of Progressive Organizations

- Machine-readable patient identification systems are replacing conventional wristbands in some organizations to reduce patient identification errors. [Da Rin, 2009; Zarbo, 2009] Monitoring of pre- and postimplementation phases provides information on risk reduction opportunities and near misses. Numerous technologies are being studied to reduce the risk of human error involved in the labeling of studies.

Opportunities for Patient and Family Involvement

- Include patient and/or family members during the care team planning of appropriate communication of labeling studies.
- Inform patients and family about the identification protocols so they are aware and know what to expect.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures** include reduction in direct harm associated with adverse drug events and procedural treatment; misadventures, including death, disability (permanent or temporary), or preventable harm requiring further treatment; missed diagnoses; unnecessary, inappropriate, and/or delayed treatment associated with incomplete information; repeated testing; cost of unnecessary treatment; and malpractice liability.
- **Process Measures** include assessing initial performance gaps and the impact of performance improvement, such as frequency of repeat laboratory or imaging studies resulting from mislabeling errors and frequency of adherence to policies and procedures.
  - NQF-endorsed® process measure:
    1. #0511: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy [Other]: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT) that were performed.
- **Structure Measures** include verification of the existence of a performance improvement program and explicit organizational policies and procedures addressing the appropriate labeling of specimens, and diagnostic and imaging studies; the verification of educational programs; and the existence of formal reporting structures for accountability across governance, administrative leadership, and frontline caregivers.

- **Patient-Centered Measures** include patient involvement as part of the care team and perception of the quality of communication during the identification process.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Research continues to advance the use of technologies that consistently and accurately complete patient identification as a vital component of the labeling process. Applied human factors training workflow design is being researched and will likely provide insights about the design of best practices. [Hunt, 2008; Zarbo, 2009]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 12: Patient Care Information; Safe Practice 15: Discharge Systems; and Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry.

Notes

AHRQ, N.D.a: [No authors listed.] Patient Safety and Quality: Applying strategies that focus on laboratory specimen labeling errors can significantly reduce specimen identification errors. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.ahrq.gov/research/may07/0507RA15.htm. Last accessed October 21, 2009.

AHRQ, N.D.b: [No authors listed.] Patient Safety Primer: Diagnostic Errors. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality; No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=12. Last accessed October 21, 2009.

Bonini, 2002: Bonini P, Plebani M, Ceriotti F, et al. Errors in laboratory medicine. Clin Chem 2002 May;48(5):691-8. Available at http://www.clinchem.org/cgi/content/full/48/5/691. Last accessed October 14, 2009.

CBS News, 2003: CBS News. Mastectomy mistake fuels debate. CBS Evening News Early Show. 2003 Jan 1. Available at http://www.cbsnews.com/stories/2003/01/18/health/main537085.shtml?source=search_story. Last accessed October 14, 2009.

Da Rin, 2009: Da Rin G. Pre-analytical workstations: a tool for reducing laboratory errors. Clin Chim Acta 2009 Jun;404(1):68-74. Epub 2009 Mar 18.

Denham, 2005: Denham CR. Radiology: can it be a performance impact center? J Patient Saf 2005 Jun;1(2):114-7.

Denham, 2008: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Fischer, 2005: Fischer B. U. of C. hospitals sued for error that resulted in removal of breast. Chicago Sun Times. 2005 May 11. Available at http://nl.newsbank.com/nl-search/we/Archives?p_product=CSTB&p_theme=cstb&p_action=search&p_maxdocs=200&s_dispstring=(U.%20of%20C.%20hospitals%20sued%20for%20error%20that%20resulted%20in%20removal%20of%20breast)%20AND%20AND%20date(all)&p_field_advanced-0=&p_text_advanced-0=("U.%20of%20C.%20hospitals%20sued%20for%20error%20that%20resulted%20in%20removal%20of%20breast")&xcal_numdocs=20&p_perpage=10&p_sort=YMD_date:D&xcal_useweights=no. Last accessed October 8, 2009.

Francis, 2009: Francis DL, Prabhakar S, Sanderson SO. A quality initiative to decrease pathology specimen-labeling errors using radiofrequency identification in a high-volume endoscopy center. Am J Gastroenterol 2009 Apr;104(4):972-5. Epub 2009 Mar 3.

Howanitz, 2005: Howanitz P. Errors in laboratory medicine: practical lessons to improve patient safety. Arch Pathol Lab Med 2005 Oct;129(10):1252-61.

Hunt, 2008: Hunt JL. Identifying cross contaminants and specimen mix-ups in surgical pathology. Adv Anat Pathol 2008 Jul;15(4):211-7.

Ibojie, 2000: Ibojie J, Urbaniak S. Comparing near misses with actual mistransfusion events: a more accurate reflection of transfusion errors. Br J Haematol 2000 Feb;108(2):458-60.

IHI, 2004: [No authors listed.] Improvement Report: Eliminating Pathology Specimen Handling and Labeling Errors/Deficiencies. Institute for Healthcare Improvement. Urbana (IL): Carle Foundation Hospital and Carle Clinic Association; presented at IHI's National Forum 2004 Dec. Available at http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/ImprovementStories/EliminatingPathologySpecimenHandlingandLabelingErrorsDeficiencies.htm. Last accessed October 21, 2009.

IOM, 2000: Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000. Available at http://www.nap.edu/catalog.php?record_id=9728. Last accessed October 8, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.01.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed October 8, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 8, 2009.

Lippi, 2009: Lippi G, Blanckaert N, Bonini P, et al. Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics. Clin Chem Lab Med 2009;47(2):143-53.

Makary, 2007: Makary M, Epstein J, Pronovost P, et al. Surgical specimen identification errors: a new measure of quality in surgical care. Surgery 2007 Apr;141(4):450-5. Epub 2007 Jan 24.

Novis, 2004: Novis D. Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years of experience with the College of American Pathologists Q-PROBES and Q-TRACKS programs. Clin Lab Med 2004 Dec;24(4):965-78.

O'Neill, 2009: O'Neill E, Richardson-Weber L, McCormack G, et al. Strict adherence to a blood bank specimen labeling policy by all clinical laboratories significantly reduces the incidence of "wrong blood in tube". Am J Clin Pathol 2009 Aug;132(2):164-8; quiz 306.

Raff, 2009: Raff LJ, Engel G, Beck KR, et al. The effectiveness of inking needle core prostate biopsies for preventing patient specimen identification errors: a technique to address Joint Commission patient safety goals in specialty laboratories. Arch Pathol Lab Med 2009 Feb;133(2):295-7. Available at http://arpa.allenpress.com/pdfserv/10.1043%2F1543-2165-133.2.295. Last accessed October 8, 2009.

Silverstein, 2004: Silverstein M. White Paper: An approach to medical errors and patient safety in laboratory services. Division of Laboratory Systems, Center for Disease Control and Prevention; 2004 Apr. Available at http://www.safer.healthcare.ucla.edu/gl/pdf/FinalWhitePaper_QIConference033103.pdf. Last accessed October 8, 2009.

Valenstein, 2004: Valenstein P, Sirota R. Identification errors in pathology and laboratory medicine. Clin Lab Med 2004 Dec;24(4):979-96, vii.

Valenstein, 2008: Valenstein P, Walsh M, Stankovic A. Accuracy of send-out test ordering: a College of American Pathologists Q-Probes study of ordering accuracy in 97 clinical laboratories. Arch Pathol Lab Med 2008 Feb;132(2):206-10.

Wagar, 2006: Wagar E, Stankovic A, Raab S, et al. Specimen labeling errors: a Q-Probes analysis of 147 clinical laboratories. Arch Pathol Lab Med 2008 Oct;132(10):1617-22.

Zarbo, 2009: Zarbo RJ, Tuthill JM, D'Angelo R, et al. The Henry Ford Production System: reduction of surgical pathology in-process misidentification defects by bar code-specified work process standardization. Am J Clin Pathol 2009 Apr;131(4):468-77.

SAFE PRACTICE 15: DISCHARGE SYSTEMS

The Objective

Ensure that effective transfer of clinical information to the patient and ambulatory clinical providers occurs at the time of discharge from healthcare organizations.

The Problem

The transfer of patient care from a hospital to primary care or other community providers has been characterized as an unsystematic, non-standardized, fragmented process that creates high risk for adverse events postdischarge.

The frequency of a lack of understanding of discharge instructions is secondary to high rates of low health literacy; to a lack of coordination in the hand-off from the hospital to community care; and to gaps in social supports. These and other limitations can affect the frequency of adverse events and rates of readmissions. [Anthony, 2005; Chugh, 2009] Recent focus on episodes of care and hospitalizations reveals that significant harm occurs after discharge from acute care hospitals, be they to the ambulatory space or to nursing homes. [Jencks, 2009] Many adverse events lead to subsequent rehospitalizations. There is controversy about whether rehospitalization rates are a good measure of the quality of care and the quality of discharge processes. [Benbassat, 2000] However, measuring rehospitalization rates within hospitals and comparing them to predicted rates, based upon national models adjusting for case mix, is a means of determining postdischarge adverse events that are attributable to poor quality. In 2006, there were approximately 34.9 million hospital discharges, excluding infants. [DeFrances, 2008] It was estimated from a large sample of Medicare beneficiaries that approximately 18 percent of these patients were 30-day readmissions. [CWF, 2008] Approximately one out of five Medicare fee-for-service beneficiaries were readmitted within 30 days, and 34 percent within 90 days. Fifty percent of those readmitted within the 30-day timeframe had not seen their physicians since they were discharged. [Jencks, 2009] Readmissions to hospital from nursing homes pose unique opportunities to improve patient care and save preventable harm and cost to the healthcare system. An evolving area of focus is discharges to nursing homes and extended care facilities, and the reduction of potential readmissions to such facilities through optimization of information transfer and careful matching of facilities to patients' needs.

The severity of adverse events attributable to discharge systems is similar to measured outcomes associated with typical categories of adverse events. [Levinson, 2008] A study conducted in 2003 directly measured adverse events postdischarge and concluded that 19 percent of patients experience adverse events; of these, 6 percent had preventable adverse events, and 6 percent had ameliorable adverse events. A prospective observational review of discharge summaries found that 66 percent of 577 evaluated had a medication inconsistency of either a drug omission or unjustified medication. Of the drug omissions, 32 percent were considered potentially harmful. [Perren, 2009] In a retrospective study evaluating discharge summaries, Were and colleagues found that 75 percent of discharge summaries lacked information on pending tests, and follow-up provider information was available in only 67 percent of the summaries. [Were, 2009] It has been reported that the readmission and mortality of seniors after acute-care hospital admissions may be much

higher than previously presumed. [Boutwell, 2008; Denham, 2009]

The preventability of many of these events could have been increased by implementing simple strategies at discharge. [Forster, 2003] Of the postdischarge adverse events, 66 percent were adverse drug events caused by antibiotics (38 percent), corticosteroids (16 percent), cardiovascular drugs (14 percent), analgesics (10 percent), and anticoagulants (8 percent). [Forster, 2003] The discharge process must effectively address the patient's needs for continuing care and treatment and must effectively communicate this information to patients and responsible caregivers in a timely fashion. [Greenwald, 2007] As part of this process, hospitals should identify the critical components of the discharge plan that pose the greatest patient safety risks; typically, these exist in the area of medication reconciliation. [Williams, 2009]

A recent systematic review uncovered that direct communication between hospital and primary care physicians occurred infrequently (3 to 20 percent of the time), and that the availability of the postdischarge summary at the first postdischarge visit was low (12 to 34 percent), affecting the quality of care in an estimated 25 percent of follow-up visits. [Kripalani, 2007] The Agency for Healthcare Research and Quality has supported research using process mapping, failure mode effect analysis, qualitative analysis, and iterative group process to define a Re-Engineered Discharge (RED). RED is a set of mutually reinforcing components that demonstrates a high-quality hospital discharge. The components of the RED were endorsed by the National Quality Forum (NQF) and form the basis of this practice on hospital discharge. Working with design and health literacy consultants, the RED was operationalized using a tool called the "After Hospital Care Plan" (AHCP). A randomized controlled trial of 749 subjects comparing the impact of the RED process showed a lower rate of hospital utilization in the intervention group compared to usual care. One readmission or emergency department visit was prevented for every 7.3 subjects receiving the intervention. [Jack, 2009; Clancy, 2008]

The cost of rehospitalizations has been estimated to account for 60 percent of hospital charges. [Zook, 1980a; Zook, 1980b] The RED intervention showed a difference between RED intervention group and care as usual to be a total cost of $149,995—or an average of $412 less cost per person who received the intervention. This represents a 33.9 percent lower observed cost for those patients receiving the AHCP. [Jack, 2009]

Safe Practice Statement

A "discharge plan" must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for postdischarge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge. [Jack, 2009; JCR, 2010]

Additional Specifications

- Discharge policies and procedures should be established and resourced and should address: [Clancy, 2009; SHM, 2008]
  - explicit delineation of roles and responsibilities in the discharge process;
  - preparation for discharge occurring, with documentation, throughout the hospitalization;

- reliable information flow from the primary care physician (PCP) or referring caregiver on admission, to the hospital caregivers, and back to the PCP, after discharge, using standardized communication methods; [Sherman, 2009]
- completion of discharge plan and discharge summaries before discharge; [Jack, 2009]
- patient or, as appropriate, family perception of coordination of discharge care; and
- benchmarking, measurement, and continuous quality improvement of discharge processes.

- A written discharge plan must be provided to each patient at the time of discharge that is understandable to the patient and/or his family or guardian and appropriate to each individual's health literacy and English language proficiency. [Chugh, 2009; Were, 2009] At a minimum, the discharge plan must include the following:
  - reason for hospitalization;
  - medications to be taken postdischarge, including, as appropriate, resumption of pre-admission medications, how to take them, and how to obtain them;
  - instructions for the patient on what to do if his or her condition changes; and
  - coordination and planning for follow-up appointments that the patient can keep and follow-up of tests and studies for which confirmed results are not available at the time of discharge. [Cook, 2009; Sherman, 2009]
- A discharge summary must be provided to the ambulatory clinical provider who accepts the patient's care after hospital discharge. [IHI, 2009b] At a minimum, the discharge summary should include the following:
  - reason for hospitalization;
  - significant findings;
  - procedures performed and care, treatment, and services provided to the patient;
  - the patient's condition at discharge;
  - information provided to the patient and family;
  - a comprehensive and reconciled medication list; [IHI, 2009a] and
  - a list of acute medical issues, tests, and studies for which confirmed results are unavailable at the time of discharge and require follow-up.
- Original source documents (e.g., laboratory or radiology reports or medication administration records) should be in the transcriber's immediate possession and should be visible when it is necessary to transcribe information from one document to another.
- The organization should ensure and document receipt of discharge information by caregivers who assume responsibility for postdischarge care. This confirmation may occur through telephone, fax, e-mail response, or other electronic response using health information technologies. [Zsenits, 2009]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

[Greenwald, 2007]

- Before discharge, present a clear explanation that the patient understands that addresses postdischarge medications, how to take them, and how and where prescriptions can be filled. [AHRQ, 2009b] This information must also be communicated to the accepting physician.
- Discharge policies and procedures should include processes for educating patients [AHRQ, 2009a] and caregivers about: 1) the diagnoses and comorbidities; 2) post-discharge follow-up appointments that are scheduled on days and times that allow the patient to attend; 3) plans to follow up tests performed during the hospitalization for which results have not been finalized, as well as tests or studies to be completed after discharge; 4) plans for postdischarge home care, such as physical therapy, occupational therapy, speech therapy, and visiting nurses; 5) durable medical equipment needs and the means to obtain them; and 6) assessment of the degree of understanding. [Kanaan, 2009]
- Put in place systematic and timely processes to monitor and provide feedback to discharging and accepting practitioners about discrepancies in adherence to such guidelines. [Bergkvist, 2009] This should reduce the number of patients discharged with plans that do not conform to accepted national guidelines for care of that condition (e.g., ACE inhibitor for congestive heart failure, aspirin or beta blocker for cardiac disease).
- The time from discharge to the first appointment with the accepting physician represents a period of high risk. All patients discharged from hospitals should be told what to do if a question or problem arises, including whom to contact and how to contact them. Guidance should also be provided about resources for patients' questions once they are discharged.
- Patients discharged to nursing homes and extended care facilities pose unique problems and opportunities for improvement. Careful documentation at discharge, and selection of nursing home facilities, can improve readmission rates to hospitals and can reduce preventable harm at nursing home facilities. [Kramer, 2008]
- Prospectively identify and provide a mechanism to contact patients (via phone or home visit) with incomplete or complex discharge plans after discharge to assess the success of the discharge plan, address questions or issues that have arisen surrounding it, and reinforce its key components, in order to avoid post-discharge adverse events and unnecessary readmissions. [Boutwell, 2009; Williams, 2009]

Strategies of Progressive Organizations

- Some organizations have provided to patients access to the entire medical record online. Others provide a personal health record repository for patients to keep digital versions of their records. In addition to providing medical records online, some organizations monitor the quality of the discharge summaries by collecting data on whether critical elements are accurate and complete. Collaboration between acute-care hospitals and nursing homes improves continuity of care and benefits all stakeholders, including families, across the care settings. The Care Transition Intervention provided a "transition coach" to work with discharge patients over a four-week period to improve

patient care outcomes. This intervention focused patient support in four key areas: managing medications, maintaining updated health record information and sharing with providers as needed, scheduling follow-up physician appointments, and assessing for worsening of clinical condition and how the patient should access assistance. [Coleman, 2006]

Opportunities for Patient and Family Involvement

- Engage patients in survey feedback, including the NQF-endorsed® 3-Item hospital care transition measure and NQF-endorsed HCAHPS survey questions about discharge.
- Include patients and family members on the discharge/transition of care planning committee.
- Encourage patients and family members to ask questions about the medical plan and medications and be active participants in their healthcare planning. [Boling, 2009].
- Engage patient and family members to carry accurate medication lists and medical diagnoses to share with healthcare professionals during all health-related office visits, hospitalizations, and community pharmacy encounters.
- Use the "teach-back" process to ensure patient understanding of transition-of-care planning.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested to support internal healthcare organization quality improvement efforts and may not all necessarily address external reporting needs.

- **Outcomes Measures** include reduction in direct harm associated with adverse drug events and treatment misadventures, including death, disability (permanent or temporary), or preventable harm requiring further treatment; missed diagnoses and delayed treatment; and inaccessible prior test information and medical records.
- **Process Measures** include the percent of discharge summaries received by accepting practitioners; the number of patients who have and attend a posthospital follow-up appointment; and the timeliness of receipt and discussion of posthospital follow-up tests with the accepting provider.
  - NQF-endorsed process measures:
    1. #0338: Home Management Plan of Care Document Given to Patient/Caregiver [Hospital]: Documentation exists that the Home Management Plan of Care (HMPC), as a separate document, specific to the patient, was given to the patient/caregiver, prior to or upon discharge.
    2. #0045: Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture [Ambulatory Care (office/clinic)]: Percentage of patients aged 50 years and older treated for a hip, spine, or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis.

3. #0136: Heart Failure (HF): Detailed discharge instructions [Hospital]: Material given to patient or caregiver at discharge or during the hospital stay addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen.
4. #0375: VTE Discharge Instructions [Hospital]: This measure assesses the number of patients diagnosed with confirmed VTE who are discharged to home, to home with home health, or home hospice on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.
5. #0557: HBIPS-6 Post discharge continuing care plan created [Hospital]: Patients discharged from a hospital-based inpatient psychiatric setting with a continuing care plan created.
6. #0558: HBIPS-7 Post discharge continuing care plan transmitted to next level of care provider upon [Hospital]: Patients discharged from a hospital-based inpatient psychiatric setting with a continuing care plan provided to the next level of care clinician or entity.
7. #0560: HBIPS-5 Patients discharged on multiple antipsychotic medications with appropriate justification [Hospital]: Patients discharged from a hospital-based inpatient psychiatric setting on two or more antipsychotic medications with appropriate justification.

- **Structure Measures** include verification of the existence of a systematic hospital discharge performance improvement program and explicit organizational policies and procedures addressing communication of discharge information; verification of educational programs; and the existence of formal reporting structures for accountability across governance, administrative leadership, and frontline caregivers.

- **Patient-Centered Measures** include surveys of patient satisfaction about hospital discharge at the time of and after discharge. The NQF-endorsed HCAHPS survey includes two relevant measures: "During your hospital stay, did hospital staff talk with you about whether you would have the help you needed when you left the hospital?" (Q19); and "During your hospital stay, did you get information in writing about what symptoms or health problems to look out for after you left the hospital?" (Q20).
  - NQF-endorsed patient-centered measures:
    1. #0166: HCAHPS [Hospital]: 27-item survey instrument with 7 seven domain-level composites including: communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness, and quiet of the hospital environment, and discharge information.
    2. #0228: 3-Item Care Transition Measure (CTM-3) [Hospital]: Unidimensional self-reported survey that measures the quality of preparation for care transitions.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural acute care settings. Although small and rural

acute care settings are resource constrained, the transmission of appropriate discharge information is often more important in these settings, because many patients receive part of their diagnostic work-up in small communities and then require more complex care in larger centers. Such information transfer can be vital to patient safety bi-directionally—both when patients go to larger centers and when they return to be seen by primary practitioners in their home communities. Patients must have access to their records to help with the transfer of information.

- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's acute care settings. Parents need access to medical records to facilitate the transfer of information, especially in the case of young children who cannot communicate the information to caregivers.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty acute care settings. Such organizations must transmit medical records and critical care information, because patients will likely be admitted to other centers when they have conditions that cannot addressed in specialty settings. Diagnostic test and procedural information can have a direct and substantial impact on future treatment.
- **Outpatient Testing Facilities:** Imaging centers and other test facilities providing services to patients receiving care by other organizations must address closure of communication loops about test results. Incomplete closure can lead to missed and delayed diagnosis. Incomplete access to prior tests leads to less-than-optimal interpretation of such studies. When such diagnostic services are provided to patients while they are in acute care or in extended care facilities requiring transportation offsite, significant opportunities for breakdowns in information loops exist, leading to incomplete discharge information sets.

New Horizons and Areas for Research

Improving and standardizing discharge processes is critical in preventing harm, whether a patient is discharged as an outpatient or to a nursing home. The processes undertaken by caregivers assuming the care of patients, in private practice or in institutions such as nursing homes, must also be optimized and supported by new tools. Federal payers are establishing value-based purchasing demonstration programs for nursing homes to develop incentives in order to reduce potentially preventable readmissions to acute-care hospitals. [White, 2009] The development of information technology systems to collect discharge information and create discharge plans from existing hospital databases could enable components of the discharge plan to be easily collected. [Graumlich, 2009] The development of interactive health information technologies could enhance patient education before discharge.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 12: Patient Care Information and Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Anthony, 2005: Anthony D, Chetty VK, Kartha A, et al. Re-engineering the hospital discharge: an example of a multifaceted process evaluation. IN: Advances in Patient Safety: From Research to Implementation. Volumes 1-4, AHRQ Publication Nos. 050021 (1-4). Rockville (MD): AHRQ: 2005 Feb: Vol. 2. Available at http://www.ahrq.gov/downloads/pub/advances/vol2/Anthony.pdf. Last accessed October 12, 2009.

Benbassat, 2000: Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 2000 Apr 24;160(8):1074-81. Available at http://archinte.ama-assn.org/cgi/content/full/160/8/1074. Last accessed October 12, 2009.

Bergkvist, 2009: Bergkvist A, Midlöv P, Höglund P, et al. Improved quality in the hospital discharge summary reduces medication errors – LIMM: Landskrona Integrated Medicines Management. Eur J Clin Pharmacol 2009 Jun 26. [Epub ahead of print]

Boling, 2009: Boling PA. Care transitions and home health care. Clin Geriatr Med 2009 Feb;25(1):135-48, viii.

Boutwell, 2008: Boutwell A, Jencks S, Nielsen G, et al. Reducing re-hospitalizations in a state or region. Minicourse M1. Presented at the Institute for Healthcare Improvement's 20th Annual National Forum on Quality Improvement in Health Care; November 19, 2008; Nashville, TN. Available at http://www.ihi.org/ihi/files/Forum/2008/Handouts/M1_ReducReHosp_Boutwell.pdf. Last accessed October 12, 2009.

Boutwell, 2009: Boutwell A, Griffin F, Hwu S, et al. Effective Interventions to Reduce Rehospitalizations: A Compendium of 15 Promising Interventions. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://ah.cms-plus.com/files/STAAR_A_Compendium_of_Promising_Interventions.pdf. Last accessed November 5, 2009.

Chugh, 2009: Chugh A, Williams MV, Grigsby J, et al. Better transitions: improving comprehension of discharge instructions. Front Health Serv Manage 2009 Spring;25(3):11-32.

Clancy, 2008: Clancy C. Better information helps patients when they leave the hospital. Navigating the Health Care System: Advice Columns from Dr. Carolyn Clancy. Rockville (MD): Agency for Healthcare Research and Quality; 2008 Dec 2. Available at http://www.ahrq.gov/consumer/cc/cc120208.htm. Last accessed October 12, 2009.

Clancy, 2009: Clancy CM. Reengineering hospital discharge: a protocol to improve patient safety, reduce costs, and boost patient satisfaction. Am J Med Qual 2009 Jul-Aug;24(4):344-6. Epub 2009 Jun 5.

Coleman, 2006: Coleman EA, Parry C, Chalmers S, et al. The care transitions intervention: results of a randomized controlled trial. Arch Intern Med 2006 Sep 25;166(17):1822-8. Available at http://archinte.ama-assn.org/cgi/reprint/166/17/1822. Last accessed November 5, 2009.

Cook, 2009: Cook CB, Seifert KM, Hull BP, et al. Inpatient to outpatient transfer of diabetes care: planning for an effective hospital discharge. Endocr Pract 2009 May-Jun;15(3):263-9.

CWF, 2008: The Commonwealth Fund. Commission on a High Performance Health System. National Scorecard on U.S. Health System Performance, 2008. Chartpack. 2008 Jul. Available at http://www.commonwealthfund.org/usr_doc/Scorecard_Chartpack_2008.pdf?section=4039. Last accessed October 12, 2009.

DeFrances, 2008: DeFrances CJ, Lucas CA, Buie VC, et al. National Health Statistics Report. 2006 National Hospital Discharge Survey. 2008 Jul 30. Available at http://www.cdc.gov/nchs/data/nhsr/nhsr005.pdf. Last accessed October 12, 2009.

Denham, 2009: Denham CR. The no outcome no income tsunami is here. Are you a surfer, swimmer or sinker? J Patient Saf 2009 Mar;5(1):42-52.

Forster, 2003: Forster A, Murff H, Peterson J, et al. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med 2003 Feb 4;138(3):161-7. Available at http://www.annals.org/cgi/reprint/138/3/161.pdf. Last accessed October 12, 2009.

Graumlich, 2009: Graumlich JF, Novotny NL, Nace GS, et al. Patient readmissions, emergency visits, and adverse events after software-assisted discharge from hospital: Cluster randomized trial. J Hosp Med 2009 May 28. [Epub ahead of print]

Greenwald, 2007: Greenwald JL, Denham CRD, Jack BW. The Hospital Discharge: A Review of a Care Transition with a High Potential for Errors and Highlights of a Re-Engineered Discharge Process. J Patient Saf 2007 Jun;3(2):97-106.

IHI, 2009a: [No authors listed.] Medication Reconciliation At All Transitions. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=7ce51016-b4f0-423c-9f8b-5e1ea8d7b810. Last accessed October 22, 2009.

IHI, 2009b: [No authors listed.] Patient Transitions & Handoffs. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=21e273fb-81fc-4dd2-b89b-883c10afc4bc. Last accessed October 22, 2009.

Jack, 2009: Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009 Feb 3;150(3):178-87.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards PC.04.01 and PC.04.02. Oak Brook (IL): Joint Commission Resources; 2010.

Jencks, 2009: Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med 2009 Apr 2;360(14):1418-28.

Kanaan, 2009: Kanaan SB. Homeward bound: nine patient-centered programs cut readmissions. Oakland (CA): California HealthCare Foundation; 2009 September. Available at http://www.chcf.org/documents/hospitals/ReducingReadmissionsCaseStudies.pdf. Last accessed November 5, 2009.

Kramer, 2008: Kramer A, Min S, Goodrich G, et al. Trends between 2000 and 2005 in SNF rates of community discharge and rehospitalization. No. 08-3. Washington, DC: MedPAC; 2008 Mar.

Kripalani, 2007: Kripalani S, LeFevre F, Phillips C, et al. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. JAMA 2007 Feb 28;297(8): 831-41. Available at http://jama.ama-assn.org/cgi/content/full/297/8/831. Last accessed October 12, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed October 12, 2009.

NQF, 2009: [No authors listed.] Care Coordination Practices & Measures. Endorsing Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination. Washington, DC: National Quality Forum; 2009. Available at http://www.qualityforum.org/projects/care_coordination.aspx. Last accessed November 5, 2009.

Perren, 2009: Perren A, Previsdomini M, Cerutti B, et al. Omitted and unjustified medications in the discharge summary. Qual Saf Health Care 2009 Jun;18(3):205-8.

Schyve, 2009: Schyve PM. The Importance of Discharge Planning. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.commonwealthfund.org/~/media/Files/Resources/2009/Reducing%20Readmissions/Schyve_commonwealth.pdf. Last accessed November 5, 2009.

Sherman, 2009: Sherman FT. Rehospitalizations: packaging discharge and transition services to prevent "bounce backs". Geriatrics 2009 May;64(5):8-9.

SHM, 2008: [No authors listed.] BOOSTing Care Transitions Resource Room. Society of Hospital Medicine (SHM). 2008. Available at http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_CareTransitions/html_CC/12ClinicalTools/01_Toolkits.cfm. Last Accessed October 21, 2009.

TJC, 2009: [No authors listed.] Facts about Speak UpTM Initiatives. Oakbrook Terrace (IL): The Joint Commission; 2009 Aug 7. Available at http://www.jointcommission.org/GeneralPublic/Speak+Up/about_speakup.htm. Last accessed November 5, 2009.

Were, 2009: Were MC, Li X, Kesterson J, et al. Adequacy of hospital discharge summaries in documenting tests with pending results and outpatient follow-up providers. J Gen Intern Med 2009 Sep;24(9):1002-6. Epub 2009 Jul 3.

White, 2009: White A, Hurd D, Moore T, et al. Nursing Home Value-Based Purchasing Demonstration. Contract # 500-00-0032, T.O. #1. Design Refinements. Cambridge (MA): Abt Associates Inc.; 2009 Mar. Available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/NHP4P_Refinements_Report.pdf. Last accessed November 9, 2009.

Williams, 2009: Williams TA, Leslie GD, Elliott N, et al. Introduction of discharge plan to reduce adverse events within 72 hours of discharge from the ICU. J Nurs Care Qual 2009 Jul 3. [Epub ahead of print]

Zook, 1980a: Zook CJ, Moore FD. High cost users of medical care. N Engl J Med 1980 May 1;302(18):996-1002.

Zook, 1980b: Zook CJ, Savickis SF, Moore FD. Repeated hospitalization for the same disease: a multiplier of national health costs. Milbank Mem Fund Q Health Soc 1980 Summer;58(3):454-71.

Zsenits, 2009: Zsenits B, Polashenski WA, Sterns RH, et al. Systematically improving physician assignment during in-hospital transitions of care by enhancing a preexisting hospital electronic health record. J Hosp Med 2009 May;4(5):308-12.

SAFE PRACTICE 16: SAFE ADOPTION OF COMPUTERIZED PRESCRIBER ORDER ENTRY

The Objective

Promote the safe use of medications, tests, and procedures through the successful implementation of integrated clinical information technologies that reduce preventable harm to patients.

The Problem

Medical errors related to medication and other clinical ordering errors are common. The majority of such events are preventable. In 2006, the Institute of Medicine (IOM) estimated that 400,000 preventable drug-related injuries occur in hospitals and that an additional 800,000 injuries occur in long-term care settings each year. [IOM, 2007]

The frequency of such errors is alarming: More than 500,000 Medicare recipients experience a medication-related injury during visits to outpatient clinics each year. A recent study estimated that 1 of every 10 adult patients suffers a serious medication-related adverse event. [Adams, 2008] The rate for pediatric patients is estimated to be three times higher than the rate for adults. [Kaushal, 2001] These estimates are likely low because of under-reporting. Integrated clinical information technologies offer clear benefits in increasing the preventability of errors and of patient harm by standardizing optimal care processes. [Kilbridge, 2006] However, the adoption of such innovations may also introduce new risks and hazards. [Campbell, 2007] According to the United States Pharmacopeia (USP), the nearly 20 percent frequency of hospital and health system medication errors reported to the MEDMARXSM program in 2003 involved computerization or automation. [USP, 2003] Koppel et al. found that computerized prescriber order entry (CPOE) facilitated 22 types of medication error risks. [Koppel, 2005] Han et al. reported that CPOE remained independently associated with increased odds of mortality after adjustment for other mortality covariables. [Han, 2005] Other recent studies did not find an association between CPOE initiation and increased patient mortality. [Del Beccaro, 2006; Keene, 2007] These findings demonstrate that significant care and planning are required to adopt new technologies successfully and safely, including CPOE. [Denham, 2008] Safe adoption typically requires clinical re-engineering of care pro-cesses, especially the ordering and administration of medications. It also requires the readiness of the healthcare staff and independent practitioners and the availability of integrated information systems at the point of care. [Kilbridge, 2008]

The National Coordinating Council for Medication Error Reporting and Prevention adopted the Medication Error Index that classifies medication errors according to the severity of the outcome. [Hartwig, 1991; Levinson, 2008] Medication errors represent the largest single cause of errors in the hospital setting, accounting for more than 7,000 deaths (Category I events) annually. [IOM, 2000] The proportion of these deaths attributed to CPOE is not known.

With appropriate clinical decision support to guide and check medication orders, CPOE could likely prevent 81 percent of adverse events in adults and 93 percent in pediatric patients, respectively. [Adams, 2008] A systematic approach to developing the foundational elements of evidence-based care re-engineering, assurance of healthcare organization staff and independent practitioner readiness, and foundational components of integrated information

technology infrastructure must be established prior to the implementation of complex technologies such as CPOE systems. [Denham, 2005] Implementation of CPOE systems may occur with a staged or incremental approach. However, such systems, once implemented, should have certain verifiable functional characteristics.

There are insufficient data to determine accurately all the costs associated with medication errors. IOM estimated that preventable drug-related injuries in hospitals result in at least $3.5 billion in extra medical costs each year. A study of outpatient clinics found that medication-related injuries in Medicare patients alone resulted in roughly $887 million in extra medical costs. [IOM, 2007] These figures did not take into account lost wages and productivity or other costs. The acquisition cost for a CPOE system is about $2.1 million, and hospitals can expect annual operating expenses of about $450,000 a year. After breaking even on the initial investment, hospitals with 70 percent use ratings for CPOE can expect a net savings of about $2.7 million per year. [Everett, 2008]

Safe Practice Statement

Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure. [Kaushal, 2001b; Alfreds, 2009]

Additional Specifications

- Providers enter orders using an integrated, electronic information management system that is based on a documented implementation plan that includes or provides for the following:
  - Risks and hazards assessment to identify the performance gaps to be closed, including the lack of standardization of care; high-risk points in medication management systems such as at the point of order entry and upon the administration of medications; and the introduction of disruptive innovations. [Singh, 2009]
  - Prospective re-engineering of care processes and workflow. [Niazkhani, 2009]
  - Readiness of integrated clinical information systems that include, at a minimum, the following information and management systems: [ASHP, 2001]
    - Admit Discharge and Transfer (ADT);
    - Laboratory with Electronic Microbiology Output;
    - Pharmacy;
    - Orders;
    - Electronic Medication Administration Record (including patient, staff, and medication ID) (eMAR);
    - Clinical Data Repository with Clinical Decision Support Capability;
    - Scheduling;
    - Radiology; and
    - Clinical Documentation.
  - Readiness of hospital governance, staff, and independent practitioners, including board governance, senior administrative management, frontline caregivers, and independent practitioners. [Kilbridge, 2001]
  - The following CPOE specifications, which: [AHRQ, N.D.]
    - facilitate the medication reconciliation process;

- are part of an Electronic Health Record Information System or an existing clinical information system that is bi-directionally and tightly interfaced with, at a minimum, the pharmacy, the clinical documentation department (including medication administration record), and laboratory systems, to facilitate review of all orders by all providers;
- are linked to prescribing error-prevention software with effective clinical decision support capability;
- require prescribers to document the reasons for any override of an error prevention notice;
- enable and facilitate the timely display and review of all new orders by a pharmacist before the administration of the first dose of medication, except in cases when a delay would cause harm to a patient;
- facilitate the review and/or display of all pertinent clinical information about the patient, including allergies, height and weight, medications, imaging, laboratory results, and a problem list, all in one place;
- categorize medications into therapeutic classes or categories (e.g., penicillin and its derivatives) to facilitate the checking of medications within classes and retain this information over time; and
- have the capability to check the medication ordered as part of effective clinical decision support for dose range, dosing, frequency, route of administration, allergies, drug-drug interactions, dose adjustment based on laboratory results, excessive cumulative dosing, and therapeutic duplication.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include inpatient service/hospital.

Example Implementation Approaches

- Providing training early in the development of a CPOE system will increase user familiarity and enhance safety and efficiency. [Ghahramani, 2009; Niazkhani, 2009]
- During the pre-implementation phase, address concerns of staff to ensure better user receptivity and effectiveness with the CPOE system. [Georgiou, 2009]
- CPOE may be adopted with a staged approach once integrated information systems are in place to support safe and effective CPOE systems. At least 75 percent of all inpatient medication orders should be entered directly by a licensed prescriber:
  - Stage 1: CPOE is in place on at least one ward/unit in the hospital.
  - Stage 2: CPOE is in place on three or more wards/units in the hospital.
  - Stage 3: CPOE is in place on more than 50 percent of the wards in the hospital.
  - Stage 4: Full compliance with at least 75 percent of all medications entered through the CPOE system by the prescriber.
- The CPOE system is tested against The Leapfrog Group Inpatient CPOE Testing Standards. These standards were developed to provide organizations that are implementing CPOE with appropriate decision support about alerting levels; these alerting levels need to be carefully set to avoid overalerting and underalerting. [Anderson, 2009] One way to ensure effective alerting is through

the use of tiered alerts, according to severity. [Paterno, 2009]

- Pharmacists, nurses, and prescribers need to be key players in the re-engineering of care and workflow because they are accountable for the proper use of the medication management systems and because of their knowledge of medication use throughout the organization.
- The disruptive nature of health information technology that occurs with initial use creates risks and hazards that can be mitigated by aggressively addressing—for all staff and practitioners who are involved in the use of technology—issues involving its adoption. Clinical decision support systems must be designed in the context of a readiness assessment and must be linked to care re-engineering and workflow strategies and plans to address patient safety risks.
- The appropriateness of clinical tests/studies is a key issue for purchasers and quality organizations. Because of this, real-time evidence-based decision support that can be incorporated into CPOE solutions to reduce unnecessary or inappropriate studies that can increase cost, delay diagnoses, and put patients at risk for preventable harm should be considered in any implementation plan.

Strategies of Progressive Organizations

- Certain progressive organizations have leveraged the integration of health information technologies and CPOE to optimize imaging, laboratory, and other areas of diagnostic testing. Some organizations are leveraging clinical decision support to maximize performance improvement, quality, and patient safety.

Opportunities for Patient and Family Involvement

- When appropriate, and within privacy standards, allow patients access to their healthcare information.
- Encourage patients to ask questions about their healthcare information and how they can best utilize their information to make informed healthcare decisions.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures** include reduced harm such as adverse drug events, death, disability (permanent or temporary), or preventable harm requiring further treatment; increased staff efficiency and throughput; return on investment calculations; reductions in medication; space and paper management cost; transcription cost savings; and reduced billing cycle costs with revenue cycle improvement. [Stone, 2009]
- **Process Measures** include medication errors; order to administration turn-around time; compliance with The Joint Commission core measure requirements; medication management system performance metrics; compliance with local clinical protocols; and performance against Leapfrog CPOE testing standards and other performance metrics. [Anderson, 2009]

- **Structure Measures** include verification of oversight or operational structures, and documentation of readiness plans, including care re-engineering and workflow design. [NQF, 2008]
  - NQF-endorsed® structure measures:
    1. #0486: Adoption of Medication e-Prescribing [Ambulatory Care (office/clinic), Community Healthcare, Other]: Documents whether provider has adopted a qualified e-Prescribing system and the extent of use in the ambulatory setting.
    2. #0487: EHR with EDI prescribing used in encounters where a prescribing event occurred [Can be used in all healthcare settings]: of all patient encounters within the past month that used an electronic health record (EHR) with electronic data interchange (EDI) where a prescribing event occurred, how many used EDI for the prescribing event.
- **Patient-Centered Measures:** There are no published or validated patient-centered measures for CPOE.

Settings of Care Considerations

- **Rural Healthcare Settings:** It is recognized that small and rural healthcare settings are resource constrained. Clearly, achievement of widespread implementation of CPOE in rural healthcare settings may require special financial and technical assistance. However, it is not apparent from studies that limited application of CPOE or discrete aspects of CPOE (presumably at lower cost) will provide significant safety benefits. Indeed, studies suggest that CPOE, when implemented in rural hospitals, should conform to the specifications included in this practice without exception.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings, with the understanding that there are special considerations for pediatrics, including that of availability of proven pediatric decision support electronic tools.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings. The development of specialized standardized order sets for chemotherapy provides a good example that other specialty healthcare settings can follow.

New Horizons and Areas for Research

The area of clinical decision support and appropriateness offers a ripe avenue of investigation to further enhance the impact of CPOE on patient safety and quality of care. CPOE has emphasized medication safety; however, its ultimate impact may be through improved medical decisionmaking and standardization of care. The study of implementation approaches involving the use of electronic medical records and CPOE, the short-term impact of risks to patients involved with rapid implementation, and the long-term risks of impact on gains in safety warrant further investigation. [Weir, 2009a; Weir, 2009b]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 12: Patient Care Information; Safe Practice 15: Discharge Systems; Safe Practice 17: Medication Reconciliation; and Safe Practice 18: Pharmacist Leadership Structures and Systems.

Notes

Adams, 2008: Adams M, Bates DW, Coffman G, et al. Saving lives, saving money: the imperative for computerized physician order entry in Massachusetts hospitals. Westborough and Cambridge (MA): Massachusetts Technology Collaborative and New England Healthcare Institute; 2008 Feb. Available at http://web3.streamhoster.com/mtc/cpoe20808.pdf. Last accessed September 24, 2009.

AHRQ, N.D.: [No authors listed.] Patient Safety Primer: Computerized Provider Order Entry. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=6. Last accessed October 26, 2009.

Alfreds, 2009: Alfreds ST, Tutty M, Savageau JA, et al. Clinical Health Information Technologies and the Role of Medicaid. Health Care Finance Review 2006-2007 Winter;28(2):11-20.

Anderson, 2009: Anderson HJ. CPOE: it don't come easy. Health Data Manag 2009 Jan;17(1):18-20, 22, 24 passim.

ASHP, 2001: [No authors listed.] Computerized Provider Order Entry (CPOE) Resources. Bethesda (MD): American Society of Health-System Pharmacists (ASHP); 2001. Available at http://www.ashp.org/Import/MEMBERCENTER/Sections/SectionofPharmacyInformaticsandTechnology/Resources/CPOE.aspx. Last accessed October 26, 2009.

Campbell, 2007: Campbell EM, Sittig DF, Guappone KP, et al. Overdependence on technology: an unintended adverse consequence of computerized provider order entry. AMIA Annu Symp Proc 2007 Oct 11:94-8.

Del Becarro, 2006: Del Beccaro MA, Jeffries HE, Eisenberg MA, et al. Computerized provider order entry implementation: no association with increased mortality rates in an intensive care unit. Pediatrics 2006 Jul;118(1):290-5.

Denham, 2005: Denham CR. Digital hospitals succeed: old fashioned values – new fashioned roles. J Patient Saf 2005 Dec;1(4):220-5.

Denham, 2008: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Everett, 2008: Everett W. The Clinical and Financial Impact of CPOE. Ho-Ho-Kus (NJ): Pharmacy Purchasing & Products; 2008 Jul. Available at http://www.pppmag.com/documents/V5N7/p2_4.pdf. Last accessed September 24, 2009.

Georgiou, 2009: Georgiou A, Ampt A, Creswick N, et al. Computerized Provider Order Entry – what are health professionals concerned about? A qualitative study in an Australian hospital. Int J Med Inform 2009 Jan;78(1):60-70. Epub 2008 Nov 17.

Ghahramani, 2009: Ghahramani N, Lendel I, Haque R, et al. User satisfaction with computerized order entry system and its effect on workplace level of stress. J Med Syst 2009 Jun;33(3):199-205.

Han, 2005: Han YY, Carcillo JA, Venkataraman ST, et al. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. Pediatrics 2005 Dec;116(6):1506-12. Available at http://pediatrics.aappublications.org/cgi/content/full/116/6/1506. Last accessed September 24, 2009.

Hartwig, 1991: Hartwig SC, Denger SD, Schneider PJ. (1991) Severity-indexed, incident report-based medication error-reporting program. Am J Hosp Pharm 1991 Dec;48(12):2611-6.

IOM, 2000: Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000. Available at http://www.nap.edu/catalog.php?record_id=9728. Last accessed September 24, 2009.

IOM, 2007: Institute of Medicine (IOM). Committee on Identifying and Preventing Medication Errors, Aspden P, Wolcott J, Bootman JL, et al., eds. Preventing Medication Errors: Quality Chasm Series. Washington, DC: The National Academies Press; 2007: pg. 480. Available at http://www.nap.edu/catalog.php?record_id=11623. Last accessed September 24, 2009.

Kaushal, 2001a: Kaushal R, Bates DW, Landrigan C, et al. (2001). Medication errors and adverse events in pediatric inpatients. JAMA 2001 Apr 25;285(16):2114-20. Available at http://jama.ama-assn.org/cgi/content/full/285/16/2114. Last accessed September 24, 2009.

Kaushal, 2001b: Kaushal R, Bates DW. Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs). IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Ch. 6. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2001 Jul. Available at http://www.ahrq.gov/clinic/ptsafety/chap6.htm. Last accessed October 22, 2009.

Keene, 2007: Keene A, Ashton L, Shure D, et al. Mortality before and after initiation of a computerized physician order entry system in a critically ill pediatric population. Pediatr Crit Care Med 2007 May;8(3):268-71.

Kilbridge, 2001: Kilbridge P, Welebob E, Classen D. Overview of the Leapfrog Group Evaluation Tool for Computerized Physician Order Entry. 2001 Dec. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/CPOEEvalTool.htm. Last accessed October 26, 2009.

Kilbridge, 2006: Kilbridge, PM, Classen D, Bates DW, Denham CR. The National Quality Forum Safe Practice standard for computerized physician order entry: updating a critical patient safety practice. J Patient Saf 2006 Dec;(2)4:183-90.

Kilbridge, 2008: Kilbridge PM, Classen DC. The informatics opportunities at the intersection of patient safety and clinical informatics. J Am Med Inform Assoc 2008 Jul-Aug;15(4): 397-407. Epub 2008 Apr 24.

Koppel, 2005: Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. JAMA 2005 Mar 9;293(10):1197-203. Available at http://jama.ama-assn.org/cgi/content/full/293/10/1197. Last accessed September 24, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 24, 2009.

Niazkhani, 2009: Niazkhani Z, van der Sijs H, Pirnejad H, et al. Same system, different outcomes: comparing the transitions from two paper-based systems to the same computerized physician order entry system. Int J Med Inform 2009 Mar;78(3):170-81. Epub 2008 Aug 28.

NQF, 2008: [No authors listed.] National Voluntary Consensus Standards for Health Information Technology: Structural Measures 2008. A Consensus Report. Washington, DC: National Quality Forum; 2008.

Paterno, 2009: Paterno MD, Maviglia SM, Gorman PN, et al. Tiering drug-drug interaction alerts by severity increases compliance rates. J Am Med Inform Assoc 2009 Jan-Feb;16(1):40-6. Epub 2008 Oct 24. Available at http://www.jamia.org/cgi/reprint/16/1/40. Last accessed October 12, 2009.

Singh, 2009: Singh H, Mani S, Espadas D, et al. Prescription errors and outcomes related to inconsistent information transmitted through computerized order entry: a prospective study. Arch Intern Med 2009 May 25;169(10):982-9.

Stone, 2009: Stone WM, Smith BE, Shaft JD, et al. Impact of a computerized physician order-entry system. J Am Coll Surg 2009 May;208(5):960-7; discussion 967-9.

USP, 2003: MEDMARX 5th Anniversary Data Report: A Chartbook of 2003 Findings and Trends 1999-2003. Rockville (MD): United States Pharmacopeia; 2003.

Weir, 2009a: Weir CR, McCarthy CA. Using implementation safety indicators for CPOE implementation. Jt Comm J Qual Patient Saf 2009 Jan;35(1):21-8.

Weir, 2009b: Weir CR, Staggers N, Phansalkar S. The state of the evidence for computerized provider order entry: a systematic review and analysis of the quality of the literature. Int J Med Inform 2009 Jun;78(6):365-74. Epub 2009 Jan 25.

Chapter 6: Improving Patient Safety Through Medication Management

Background

DESPITE CAREFUL STUDY IN medication management of patients safety and system improvement, there continues to be an enormous number of clearly preventable adverse drug events that cause tremendous harm and suffering to patients and families.

Hospitals and other healthcare facilities dispense hundreds of thousands of doses of medications daily. The adverse events in acute care hospitals and in the ambulatory care space continue to be a daunting problem. [Budnitz, 2006; Bates, 2008] Leadership, resources, and systems are vital. It is important to mesh engaged leadership, application of resources, and a systematic implementation of best practices to develop sustainable gain.

Medication-use systems are complex and inherently high-risk and error-prone, with preventable adverse drug events often occurring as a consequence of a combination of human and environmental factors. Care and some technologies that affect the prescribing, dispensing, and distribution methods and systems have become increasingly complicated. Both are factors in the increased risk of preventable patient harm. The introduction of many new drugs each year also contributes to adverse events resulting from medication errors.

A number of clinical practices are known to be effective in preventing medication errors. Evidence has shown that pharmacists are most effective in leading medication management teams in the implementation of practices related to medication management and the design of medication error reduction strategies. Thus, pharmacists should lead the processes and programs to implement the safe practices that are discussed in this chapter.

Though medication reconciliation continues to be a challenge to implement, accurate medications are critical to the prevention of harm to patients during their healthcare encounters and when discharged from the care setting. Organizations committed to

medication safety will create structures, systems, and enterprise-wide risk assessment that go far beyond the walls of a hospital or community pharmacy. As time passes, there will be new opportunities to capture accurate medication histories, educate patients and family members regarding appropriate medication use, and prevent adverse drug events.

The Pharmacist Leadership Structures and Systems practice was created as a roadmap focusing on pharmacist leadership to develop and implement streamlined medication systems and a comprehensive medication safety program. Leadership at the front lines must be matched by improved leadership on the part of midlevel managers and must be supported by senior leadership and the board of governance. For sustainable change, pharmacist leaders must have regular, direct communication with the senior leaders of their organization.

Leadership, resources, and systems—safety succeeds or fails where they intersect.

Notes

Bates, 2008: Bates DW. Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry in Massachusetts. Massachusetts Technology Collaborative and New England Healthcare Institute. 2008 Feb. Available at http://www.nehi.net/uploads/full_report/cpoe20808_final.pdf. Last accessed October 14, 2009.

Budnitz, 2006: Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006 Oct 18;296(15):1858-66. Available at http://jama.ama-assn.org/cgi/content/full/296/15/1858. Last accessed October 14, 2009.

SAFE PRACTICE 17: MEDICATION RECONCILIATION

The Objective

The healthcare organization must develop, reconcile, and communicate an accurate medication list throughout the continuum of care.

The Problem

Medication reconciliation is a process of identifying the most accurate list of all medications a patient is currently taking, and using this list to provide correct medications for the patient in all care settings within the healthcare system. [IHI, 2008] The goal of medication reconciliation is to reduce adverse drug events (ADEs) during transitions of care. [TJC, 2006] A meta-analysis of 22 studies focusing on medication history discrepancies found that 10 to 67 percent of patients had at least one prescription medication history error at hospital admission. When nonprescription drugs were included, the frequency was 27 to 83 percent; and when information on drug allergies and prior adverse events was included, the frequency was 34 to 95 percent. [Tam, 2005; Gleason 2004] Many of these medication history errors occur upon admission to or discharge from a clinical unit of the hospital. A study of 4,108 patients found that 46 percent of errors occur at these junctions. [Bates, 1997] A similar study of 250 medication history errors found that approximately 60 percent of errors occurred at these times. [Rodehaver, 2005]

The frequency of medication reconciliation errors is estimated to be 20 percent of adverse drug events (ADEs) within hospitals. [Rozich, 2001] A large study of 2,022 medication errors involving reconciliation, conducted by the United States Pharmacopeia, found that 22 percent occurred at admission, 66 percent occurred during transitions in care, and 12 percent occurred at the time of discharge. [Santell, 2006] A study following patients two weeks after hospital discharge found that ADEs occur in approximately 12 percent of patients. [Forster, 2003]

The severity of these events has been measured in several studies. Cornish et al. found that 61.4 percent of errors had no potential to cause serious harm, and the remaining 38.6 percent had potential to cause moderate to severe discomfort or clinical deterioration. [Cornish, 2005; Levinson, 2008a; Levinson, 2008b] A study in 1990 reported that about 6 percent of patients may experience a drug discrepancy of a serious nature at hospital admission. [Van Hessen, 1990; Etchells, 2006] Gleason et al. reported that 55 percent of medication discrepancies would have been unlikely to cause harm, 23 percent would have necessitated monitoring or precluded harm, and 22 percent would have resulted in serious harm had the pharmacist not intervened. [Gleason, 2004] Patients with a higher severity of illness, or who were taking numerous medications, were more likely to have a higher risk for ADEs. [Gleason, 2004] Another study of 1,459 emergency department admissions showed that 41 percent of medication reconciliation errors were clinically important. [Akwagyriam, 1996] Another found that 3 percent of patients had missing medications in their history that were "life-saving," and that 24 percent of patients would have gained significant benefit if their missing medications had been included. [Cohen, 1998] In a study of 180 patients on a general medicine service, 939 unintentional medication discrepancies were found, of which 257 had potential for patient harm (1.4 potential adverse drug events [PADEs] per patient); 54 percent had at

least one PADE. Seventy-two percent of these PADEs related to the reconciliation process were due to errors in taking the medication history rather than in reconciling the medications with admission or discharge orders. The majority of PADEs occurred at discharge (75 percent) as opposed to at admission, and 60 percent were due to omissions of medications. [Pippins, 2008]

Preventable adverse events from medication errors affect approximately 2 out of every 100 patients admitted to the hospital, and adverse events outside the hospital are estimated to account for 4.7 percent of hospital admissions. [Leape, 1994; Kanjanarat, 2003; Lazarou, 1998] Effective preventability strategies for the reduction of medication errors and subsequent ADEs have been found through successful medication reconciliation processes. [Nickerson, 2005; Bartick, 2006; Boockvar, 2006; Vira, 2006] A multicenter study of 50 hospitals found that reduction of errors and ADEs is most strongly correlated with active physician, pharmacist and nurse engagement; having an effective improvement team; using small tests of change; having an actively engaged senior administrator; and sending teams to multiple collaborative sessions. [Rogers, 2006] A study of one critical care unit found that the use of a discharge survey resulted in a reduction from 94 percent of patients having orders changed to 0 percent. [Pronovost, 2003] Another study performed in an outpatient setting found that: 1) mailing letters prior to appointments to remind patients to bring medication bottles and updated medication lists; 2) verifying updated lists; and 3) correcting medication lists in the electronic medical record decreased medication discrepancies by 50 percent from 5.24 discrepancies per patient to 2.46. [Varkey, 2007] Involving a pharmacist in medication history taking has also been reported to reduce medication errors by 51 percent. [Bond, 2002] Computerized prescriber order entry (CPOE) systems can effectively reconcile medications, but these systems are only as good as the data entered into them. CPOE systems alone, without effective reconciliation strategies, are likely to be ineffective. [Anderson, 2007; Groeschen, 2007; Lawrence, 2007; TJC, 2007; Yu, 2007; Bails, 2008] A recent two-site randomized controlled trial of an information technology-assisted medication reconciliation intervention found a 38 percent relative risk reduction in potential ADEs. Patients at highest risk for PADEs were more likely to benefit from the intervention. Errors still remained even in the intervention group, most often due to incomplete and inaccurate electronic sources of ambulatory medication information, lack of patient and caregiver knowledge of preadmission medication regimens, lack of clinician adherence with the reconciliation process, and software usability issues. [Turchin, 2008; Schnipper, 2009]

The costs associated with all ADEs are estimated to be about $3.8 million per year per hospital, of which approximately $1 million is preventable. [Classen, 1997] Another study found that ADEs increased patients' length of stay by 2.2 days and increased costs by $3,244 and that preventable events caused an increased length of stay of 4.6 days and an increased cost of $5,857 per patient. For the 700-bed teaching hospital studied, annual costs for ADEs and preventable ADEs were $5.6 million and $2.8 million, respectively. [Bates, 1997]

Although reducing medication errors related to medication reconciliation has been a Joint Commission safety goal since 2005, hospital implementation is still in the early stages, and these changes are yet to be fully tested. In 2007, The Joint Commission hosted a one-day Summit on Medication Reconciliation, with the goal of discussing the challenges associated

with reconciling medications in various healthcare settings, identifying best practices, and bringing forth potential refinements to medication reconciliation practices. The consensus was that the process of medication reconciliation, obtaining an accurate medication list from the patient, and ensuring its accuracy throughout the care continuum improves patient safety; however, more guidance on implementation is required. [TJC, 2009] Preliminary data suggest that an accurate medication history, coupled with an electronic medication reconciliation process, may reduce adverse drug events due to medication discrepancies. [Schnipper, 2009] Processes using both electronically available medication records as well as data from patient/family interviews have been proposed as potential solutions. [Agrawal, 2009; Cutler, 2009]

NQF recognizes that medication reconciliation is critically important for patient safety but that it also represents a set of processes that are difficult for organizations to implement. NQF continues to monitor the scientific evidence and the availability of best practices for medication reconciliation. As further evidence clarifies the issues of medication reconciliation, NQF will adjust this safe practice.

Safe Practice Statement

The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care. [LMMHS, 2004; SHM, 2008; ASHP, 2009; IHI, 2009; JCR, 2010]

Additional Specifications [JCR, 2010]

- Educate clinicians upon hire on the importance of medication reconciliation; frequency of ongoing education is based on the risk of noncompliance and adverse drug events as determined by the organization. [AHRQ, N.D.b]
- Providers receiving the patient in a transition of care should check the medication reconciliation list to make sure it is accurate and in concert with any new medications that are ordered/prescribed.
- The list should include the full range of medications as defined by accrediting organizations such as The Joint Commission. At a minimum, the list should include the following:
  - prescription medications;
  - sample medications;
  - vitamins;
  - nutriceuticals;
  - over-the-counter drugs;
  - complementary and alternative medications;
  - radioactive medications;
  - respiratory therapy-related medications;
  - parenteral nutrition;
  - blood derivatives;
  - intravenous solutions (plain or with additives);
  - investigational agents; and
  - any product designated by the Food and Drug Administration (FDA) as a drug.
- At the time the patient enters the organization or is admitted, a complete list of medications the patient is taking at home (including dose, route, and frequency) is created and documented. The patient, and family, as needed, are involved in creating this list.
- The medications ordered for the patient while under the care of the organization are compared to those on the list created

at the time of entry to the organization or admission. According to The Joint Commission's FAQ, organizations should keep two lists during the hospitalization. The "home medications" list should be maintained unchanged and available for subsequent use in the reconciliation process. The list of the patient's current medications while in the hospital is a dynamic document that will require updating whenever changes are made to the patient's medication regimen. Both lists should be considered whenever reconciliation is carried out. The reason for referring to the "home" medication list is that some "home" medications may be held when a patient is admitted or goes to surgery. They may need to be resumed upon transfer to a different level of care, return from the operating room, or at discharge. [JCR, 2010]

- Any discrepancies (i.e., omissions, duplications, adjustments, deletions, additions) are reconciled and documented while the patient is under the care of the organization.
- When the patient's care is transferred within the organization (e.g., from the ICU to a floor), the current provider(s) inform(s) the receiving provider(s) about the up-to-date reconciled medication list and documents the communication.
- The patient's most current reconciled medication list is communicated to the next provider of service, either within or outside the organization. The communication between providers is documented.
- At the time of transfer, the transferring organization informs the next provider of service of how to obtain clarification on the list of reconciled medications.
- When the patient leaves the organization's care, the current list of reconciled medications is provided to the patient, and family, as needed, and is explained to the patient and/or family, and the interaction is documented. [Jack, 2009; AHRQ, N.D.a]
- In settings where medications are used minimally, or are prescribed for a short duration, modified medication reconciliation processes are performed:
  - The organization obtains and documents an accurate list of the patient's current medications and known allergies in order to safely prescribe any setting-specific medications (e.g., IV contrast, local anesthesia, antibiotics) and to assess for potential allergic or adverse drug reactions.
  - If no changes are made to the patient's current medication list, or when only short-term medications (e.g., a preprocedure medication or a short-term course of an antibiotic) will be prescribed, the patient, and family, as needed, are provided with a list containing the short-term medication additions that the patient will continue after leaving the organization.
  - In these settings, there is a complete, documented medication reconciliation process when:
    - Any new long-term (chronic) medications are prescribed.
    - There is a prescription change for any of the patient's current known long-term medications.
    - The patient is required to be subsequently admitted to an organization from these settings for ongoing care.

- When a complete, documented, medication reconciliation is required in any of these settings, the complete list of reconciled medications is provided to the patient and the patient's family, as needed, and to the patient's known primary care provider or original referring provider, or a known next provider of service.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Develop and use a template medication reconciliation form to gather information about current medications and medication allergies, to standardize care, and to prevent errors.
- The Medical Executive Committee should aid in the creation and reinforcement of medication reconciliation.
- Identify internal champions to lead implementation of the practice within the organization.
- Educate providers about reviewing the necessity of medications upon admission and discharge, to further streamline medication lists and reduce ADEs.
- Any changes from the "home" medication list should be clearly noted and explained to the patient. [Jack, 2009; AHRQ, N.D.a]
- Include patient health literacy, feasible dosing schedules, and affordability, as well as cultural, physical, or environmental barriers, when creating individual patient medication regimens.
- Review and draw upon sources of fully developed implementation solutions, such as those of the Massachusetts Coalition for Prevention of Medical Errors (http://www.macoalition.org/) and the Institute for Healthcare Improvement. [MCPME, N.D.; IHI, 2008]
- Use of over-the-counter or complementary and alternative medication (CAM) should be included in provider education about medications, and providers should then educate patients about the state of scientific knowledge with respect to CAM therapies that the patient may be using or thinking about using.
- Encourage patients to carry an accurate medication list with them and share with their healthcare providers, including the community pharmacist. [ISMP, 2007; ASHP, 2008]
- Some organizations have referred to patient home medication bottles and contacting the patient's home pharmacy to assist in the creation of an accurate home medication list to help clinicians when making medication decisions.
- Use consumer-based kiosk technology to improve medication reconciliation and decrease facility costs. [Lesselroth, 2009]
- Safe medication ordering practices, such as use of order sets or preprinted orders, drug interaction software, and implementation of other performance improvement methods, may be led by pharmacy leaders across the organization.

Strategies of Progressive Organizations

- According to recently published research, implementation strategies most strongly correlated with success include an active interdisciplinary focus (physician, pharmacist, and nurse engagement); having an effective improvement team; using small tests of change; having an actively engaged senior administrator; and having teams participate in collaborative initiatives.
- High-performing organizations have required second check systems by a separate care provider to validate patient medication home lists.
- Consider including budgetary resources to financially support the medication reconciliation process through additional dedicated staff or technology support systems.
- Institutions with Computerized Practitioner Order Entry should consider IT-supported medication reconciliation systems. [Schnipper, 2009]
- Conduct pharmacist review of admission, transfer, and discharge medication lists.
- Have pharmacists collect accurate medication histories on patients identified as high risk for medication errors. [Kaboli, 2006; Schnipper, 2006]

Opportunities for Patient and Family Involvement

- Encourage patient and family members to ask questions about the appropriate usage of their medications.
- Engage patient and family members to carry accurate medication lists, and to share those lists with healthcare professionals during office visits, hospitalizations, and community pharmacy encounters. The list should be updated with each medication change, and patients should encourage their healthcare provider to assist them in verifying accuracy of the list every six months.
- Use the teach-back method to ensure patient/family understanding of appropriate medication use. Example: Have patients or family members, as appropriate, demonstrate the administration of medications that involve injections or inhalation devices.
- Patient and family members should be instructed how to identify and manage routine side effects and to know when and whom to contact if they believe the patient is experiencing any serious adverse effects of drug therapy. Pharmacists involved in this education during discharge can offer accurate information about changes in the patient's previous medication list and the discharge medication list and can assist with managing barriers to medication adherence. [Dudas, 2001; Coleman, 2006; Karapinar-Çarkit, 2009]
- Consider including patients or families of patients who have experienced medication-related adverse events to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include ADEs causing harm to patients, including death, disability (permanent or temporary), or preventable harm requiring further treatment, and operational and financial outcomes, including break-even analysis.
- **Process Measures** include evidence of reconciliation having occurred; number of unreconciled medications per a specified number (e.g., per 100) of patient admissions; unreconciled medications per patient; and/or total number of patients with unreconciled medications in the area of focus. A reasonable goal for an organization is to reduce the percentage of unreconciled medications in an area of focus (admission, transfer, or discharge) by 75 percent or more. Furthermore, if the medication history has been taken, the medication list drawn up, and the reconciliation process has occurred, their accuracy, can be measured. [NQF, 2009; Stock, 2009]
  - National Quality Forum (NQF)-endorsed® process measures:
    1. #0019: Documentation of medication list in the outpatient record (Ambulatory): Percentage of patients having a medication list in the medical record.
    2. #0020: Documentation of allergies and adverse reactions in the outpatient record (Ambulatory): Percentage of patients having documentation of allergies and adverse reactions in the medical record.
    3. #0097: Medication Reconciliation [Ambulatory Care (office/clinic)]: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g., hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing ongoing care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.
    4. #0293: Medication Information [Emergency Department]: Percentage of patients transferred to another acute hospital whose medical record documentation indicated that medication information was communicated to the receiving hospital within 60 minutes of departure.
    5. #0419: Universal Documentation and Verification of Current Medications in the Medical Record [Hospital, Nursing home/Skilled Nursing Facility (SNF), Ambulatory Care (office/clinic)]: Percentage of patients aged 18 years and older with a list of current medications with dosages (includes prescription, over-the-counter, herbals, vitamin/mineral/dietary [nutritional] supplements) and verified with the patient or authorized representative documented by the provider.
    6. #0553: Care for Older Adults – Medication Review (COA) [Ambulatory Care (office/clinic), Health Plan]: Percentage of adults 65 years and older who had a medication review.
    7. #0554: Medication Reconciliation Post-Discharge (MRP) [Ambulatory Care (office/clinic), Health Plan]: Percentage of discharges from January 1 to December 1 of the measurement year for patients 65 years of age and older for whom medications were reconciled on or within 30 days of discharge.

8. #0560: HBIPS-5 Patients discharged on multiple antipsychotic medications with appropriate justification [Hospital]: Patients discharged from a hospital-based inpatient psychiatric setting on two or more antipsychotic medications with appropriate justification.

- **Structure Measures** include verification of the implementation of medication reconciliation and the formal reporting to governance and senior management of performance improvement toward established target aims and goals.
  - NQF-endorsed structure measures:
    1. #0486: Adoption of Medication e-Prescribing [Ambulatory Care (office/clinic), Community Healthcare, Other]: Documents whether provider has adopted a qualified e-Prescribing system and the extent of use in the ambulatory setting.
    2. #0487: EHR (electronic health record) with EDI (electronic data interchange) prescribing used in encounters where a prescribing event occurred [Can be used in all healthcare settings]: Of all patient encounters within the past month that used an EHR with EDI where a prescribing event occurred, how many used EDI for the prescribing event.
- **Patient-Centered Measures** include medication management metrics, synthesized from surveys of patients about their satisfaction related to medication management and communication by caregivers. The NQF-endorsed HCAHPS survey [NQF, 2005] addresses this through the following questions: "During this hospital stay, were you given any medicine you had not taken before?" (Q.15); "Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?" (Q.16); and "Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?" (Q.17). Measures of patient participation in maintaining their medication lists may also be undertaken.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to small and rural healthcare settings as specified.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings as specified.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings as specified.

New Horizons and Areas for Research

It is critical that medication management systems be better understood in order to leverage products, services, and technologies that can enable best practices to reduce preventable harm to patients across the healthcare organization. Research in the areas of enabling technologies may hold promise. [Lesselroth, 2009] Evaluation of the improvement in medication accuracy by actively communicating with the patient's community pharmacy for medication verification and communication of medication discharge lists should also be included for further research. Evaluation of a secure electronic medicine list to which the patient may designate access by caregivers, such as Google Health or HealthVault, could be considered for future medication list access.

Other Relevant Safe Practices

Relevant practices include Safe Practice 1: Leadership Structures and Systems; Safe Practice 4: Identification and Mitigation of Risks and Hazards; Safe Practice 12: Patient Care Information; and Safe Practice 15: Discharge Systems. Safe Practice 18: Pharmacist Leadership Structures and Systems is vitally important to a successful medication reconciliation program.

Notes

Agrawal, 2009: Agrawal A. Medication errors: prevention using information technology systems. Br J Clin Pharmacol 2009 Jun;67(6):681-6.

AHRQ, N.D.a: [No authors listed.] Patient Safety Primer: Adverse Events after Hospital Discharge. AHRQ PSNET Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=11. Last accessed October 22, 2009.

AHRQ, N.D.b: [No authors listed.] Patient Safety Primer: Medication Reconciliation. AHRQ PSNET Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=1. Last accessed October 22, 2009.

Akwagyriam, 1996: Akwagyriam I, Goodyer L, Harding L, et al. Drug history taking and the identification of drug related problems in an accident and emergency department. J Accid Emerg Med 1996 May;13(3):166-8.

Anderson, 2007: Anderson HJ. Medication reconciliation: what role will I.T. play? Health Data Manag 2007 Jul;15(7):44, 46, 48.

ASHP, 2008: [No authors listed.] Safe Medication: My Medication List. Bethesda (MD): American Society of Health-System Pharmacists (ASHP); 2008. Available at http://www.safemedication.com/safemed/MyMedicineList.aspx. Last accessed October 22, 2009.

ASHP, 2009: [No authors listed.] ASHP Medication Reconciliation (Med Rec) Toolkit. Bethesda (MD): American Society of Health-System Pharmacists (ASHP); 2009. Available at http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/PatientSafety/ASHPMedicationReconciliationToolkit_1.aspx. Last accessed October 22, 2009.

Bails, 2008: Bails D, Clayton K, Roy K, et al. Implementing online medication reconciliation at a large academic medical center. Jt Comm J Qual Patient Saf 2008 Sep;34(9):499-508.

Bartick, 2006: Bartick M, Baron D. Medication reconciliation at Cambridge Health Alliance: experiences of a 3-campus health system in Massachusetts. Am J Med Qual 2006 Sep-Oct;21(5):304-6.

Bates, 1997: Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. JAMA 1997 Jan 22-29;277(4):307-11.

Bond, 2002: Bond CA, Raehl CL, Franke T. Clinical pharmacy services, hospital pharmacy staffing and medication errors in United States hospitals. Pharmacotherapy 2002 Feb;22(2):134-47.

Boockvar, 2006: Boockvar KS, Carlson LaCorte H, Giambanco V, et al. Medication reconciliation for reducing drug-discrepancy adverse events. Am J Geriatr Pharmacother 2006 Sep;4(3):236-43.

Classen, 1997: Classen DC, Pestotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. JAMA 1997 Jan 22-29;277(4):301-6.

Cohen, 1998: Cohen J, Wilson C, Ward F. Improve drug history taking. Pharmacy in Practice 1998;1:13-6.

Coleman, 2004: Coleman EA, Min SJ, Chomiak A, et al. Posthospital care transitions: patterns, complications, and risk identification. Health Serv Res 2004 Oct;39(5):1449-65.

Coleman, 2006: Coleman E, Parry C, Chalmers S, et al. The Care Transitions Intervention: Results of a Randomized Controlled Trial. Arch Intern Med. 2006;166:1822-1828

Cornish, 2005: Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. Arch Intern Med 2005 Feb 28;165(4):424-9.

Cutler, 2009: Cutler TW. Medication reconciliation victory after an avoidable error. Rockville (MD): AHRQ Web M&M; 2009 Feb/Mar. Available at http://webmm.ahrq.gov/printview.aspx?caseID=195. Last accessed October 30, 2009.

Dudas, 2001: Dudas V, Bookwalter T, Kerr K, et al.The Impact of Follow-up Telephone Calls to Patients After Hospitalization. Am J Med. 2001 Dec 21;111(9B):26S-30S.

Etchells, 2006: Etchells E. Reconcilable differences: enhancing medication safety at times of transition. Paper. University of Calgary 4th Annual Quality Improvement Forum. Calgary. 2006 Jan 27.

Forster, 2003: Forster AJ, Murff HJ, Peterson JF, et al. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med 2003 Feb 4;138(4):161-7. Available at http://www.annals.org/cgi/reprint/138/3/161.pdf. Last accessed September 29, 2009.

Gardner, 2009: Gardner B, Graner K. Pharmacists' medication reconciliation-related clinical interventions in a children's hospital. Jt Comm J Qual Patient Saf 2009 May;35(5):278-82.

Gleason, 2004: Gleason KM, Groszek JM, Sullivan C, et al. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. Am J Health Syst Pharm 2004 Aug 15;61(16):1689-95.

Groeschen, 2007: Groeschen HM. Electronic system improves medication reconciliation rates. Am J Health Syst Pharm 2007 Sep 15;64(18):1894.

IHI, 2008: Institute for Healthcare Improvement. Prevent Adverse Drug Events (Medication Reconciliation). Available at http://www.ihi.org/IHI/Programs/Campaign/ADEsMedReconciliation.htm. Last accessed September 29, 2009.

IHI, 2009: [No authors listed.] Medical Reconciliation at all Transitions. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=7ce51016-b4f0-423c-9f8b-5e1ea8d7b810. Last accessed October 11, 2009.

ISMP, 2007: [No authors listed.] A Call to Action: Protecting U.S. Citizens from Inappropriate Medicine Use. A White Paper on Medication Safety in the U.S. and the Role of Community Pharmacists. Huntingdon Valley (PA): Institute for Safe Medication Practices (ISMP); 2007. Available at http://www.ismp.org/pressroom/viewpoints/CommunityPharmacy.pdf. Last accessed October 22, 2009.

Jack, 2009: Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009 Feb 3;150(3):178-87. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2738592&blobtype=pdf. Last accessed October 12, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goals. Oak Brook (IL): Joint Commission Resources; 2010.

Kaboli, 2006: Kaboli P., Hoth A., McClimon B., et al. Clinical Pharmacists and Inpatient Medical Care. Arch Intern Med 2006;166:955-964.

Kanjanarat, 2003: Kanjanarat P, Winterstein AG, Johns TE, et al. Nature of preventable adverse drug events in hospitals: a literature review. Am J Health Syst Pharm 2003 Sep 1;60(17):1750-9.

Karapinar-Çarkit, 2009: Karapinar-Çarkit F, Borgsteede SD, Zoer J, et al. Effect of medication reconciliation with and without patient counseling on the number of pharmaceutical interventions among patients discharged from the hospital. Ann Pharmacother 2009 Jun;43(6):1001-10. Epub 2009 Jun 2. Available at http://www.theannals.com/cgi/content/abstract/aph.1L597v1. Last accessed October 30, 2009.

Lawrence, 2007: Lawrence D. Bringing the outside in. Hospital and vendor collaborate on development of a medication reconciliation IT solution. Healthc Inform 2007 Oct;24(10):10, 12-3.

Lazarou, 1998: Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA 1998 Apr 15;279(15):1200-5.

Leape, 1994: Leape LL. Error in medicine. JAMA 1994 Dec 21;272(23):1851-7.

Lesselroth, 2009: Lesselroth B, Adams S, Felder R, et al. Using consumer-based kiosk technology to improve and standardize medication reconciliation in a specialty care setting. Jt Comm J Qual Patient Saf 2009 May;35(5):264-70.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 29, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 29, 2009.

LMMHS, 2004: Luther Midelfort – Mayo Health System. Medication Reconciliation Review. Cambridge (MA): Institute for Healthcare Improvement; 2004. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Medication+Reconciliation+Review.htm. Last accessed October 22, 2009.

MCPME, N.D.: [No authors listed.] Massachusetts Coalition for the Prevention of Medical Errors. Burlington (MA): Massachusetts Coalition for the Prevention of Medical Errors; No Date. Available at http://www.macoalition.org. Last accessed October 22, 2009.

Nickerson, 2005: Nickerson A, MacKinnon NJ, Roberts N, et al. Drug-therapy problems, inconsistencies and omissions identified during a medication reconciliation and seamless care service. Healthc Q 2005;8 Spec No:65-72. Available at http://www.longwoods.com/product.php?productid=17667. Last accessed October 8, 2009.

NQF, 2009: National Quality Forum. National Voluntary Consensus Standards for Medication Management. Washington, DC: National Quality Forum; 2009. Available at http://www.qualityforum.org/Projects/i-m/Medication_Management/Med_Management_Voting_Report.aspx. Last accessed January 14, 2010.

Pippins, 2008: Pippins JR, Gandhi TK, Hamann C, et al. Classifying and predicting errors of inpatient medication reconciliation. J Gen Intern Med 2008 Sep;23(9):1414-22. Epub 2008 Jun 19.

Pronovost, 2003: Pronovost P, Weast B, Schwarz M, et al. Medication reconciliation: a practical tool to reduce the risk of medication errors. J Crit Care 2003 Dec;18(4):201-5.

Rodehaver, 2005: Rodehaver C. Medication reconciliation in acute care: ensuring an accurate drug regimen on admission and discharge. Jt Comm J Qual Patient Saf 2005 Jul;31(7):406-13.

Rogers, 2006: Rogers G, Alper E, Brunelle D, et al. Reconciling medications at admission: safe practice recommendations and implementation strategies. Jt Comm J Qual Patient Saf 2006 Jan;32(1):37-50.

Rozich, 2001: Rozich JD, Resar RK. Medication safety: one organization's approach to the challenge. J Clin Outcomes Manage 2001 Oct;8(10):27-34

Santell, 2006: Santell JP. Reconciliation failures lead to medication errors. Jt Comm J Qual Patient Saf 2006 Apr;32(4):225-9.

Schnipper, 2006: Schnipper JL, Kirwin JL, Cotugno MC, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. Arch Intern Med 2006 Mar 13;166(5):565-71. Available at http://archinte.ama-assn.org/cgi/reprint/166/5/565. Last accessed October 8, 2009.

Schnipper, 2009: Schnipper JL, Hamann C, Ndumele CD, et al. Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: a cluster-randomized trial. Arch Intern Med 2009 Apr 27;169(8):771-80.

SHM, 2008: [No authors listed.] BOOSTing Care Transitions Resource Room. BOOSTing Care Transitions Resource Room Project Team. Philadelphia (PA): Society of Hospital Medicine (SHM); 2008. Available at http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_CareTransitions/html_CC/12ClinicalTools/01_Toolkits.cfm. Last accessed October 22, 2009.

Stock, 2009: Stock R, Scott J, Gurtel S. Using an electronic prescribing system to ensure accurate medication lists in a large multidisciplinary medical group. Jt Comm J Qual Patient Saf 2009 May;35(5):271-7.

Tam, 2005: Tam VC, Knowles SR, Cornish PL, et al. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. CMAJ 2005 Aug 30;173(5):510-5. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=16129874. Last accessed September 29, 2009.

TJC, 2006: The Joint Commission. Using medication reconciliation to prevent errors. Sentinel Event Alert 35. 2006 Jan 25. Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_35.htm Last accessed September 29, 2009.

TJC, 2007: Joint Commission Resources. The Joint Commission on Accreditation of Healthcare Organizations. Medication Reconciliation at Admission. 2007. Jt Commission Perspectives on Patient Safety. 2007 Dec;7(12):1-5.

TJC, 2009: The Joint Commission. Approved: will not score medication reconciliation in 2009. Plans to review, refine NPSG 8 for 2010. Jt Comm Perspect 2009 Mar;29(3):1, 3.

Turchin, 2008: Turchin A, Hamann C, Schnipper JL, et al. Evaluation of an inpatient computerized medication reconciliation system. Am Med Inform Assoc 2008 Jul-Aug;15(4):449-52. Epub 2008 Apr 24. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2442251&blobtype=pdf. Last accessed October 8, 2009.

Van Hessen, 1990: Van Hessen PA, Petri H, Urquhart J. Do prescribed drugs always follow the patients to the hospital? Pharm Weekbl Sci 1990 Apr 27;12(6):66-70.

Varkey, 2007: Varkey P, Cunningham J, Bisping DS. Improving medication reconciliation in the outpatient setting. Jt Comm J Qual Patient Saf 2007 May;33(5):286-92.

Vira, 2006: Vira T, Colquhoun M, Etchells E. Reconcilable differences: correcting medication errors at hospital admission and discharge. Qual Saf Health Care 2006 Apr;15(2):122-6. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2464829&blobtype=pdf. Last accessed October 8, 2009.

Yu, 2007: Yu F, Leising S, Turner S. Development approach to an enterprise-wide medication reconciliation tool in a free-standing pediatric hospital with commercial best-of-breed systems. Paper. American Medical Informatics Association Annual Symposium. Chicago, IL. 2007 Nov 12.

SAFE PRACTICE 18: PHARMACIST LEADERSHIP STRUCTURES AND SYSTEMS

The Objective

Pharmacy leadership is the core of a successful medication safety program. Pharmacy leadership structures and systems ensure a multidisciplinary focus and a streamlined operational approach to achieve organization-wide safe medication use.

The Problem

The frequency of adverse drug events, or ADEs, is at a critical level, and is the most frequently cited significant cause of injury and death among hospital patients. More than 40 percent of Americans take at least one prescription drug, and 16 percent take at least three. Approximately 90 percent of Medicare beneficiaries report taking prescription medicines, and nearly half of those individuals use five or more different medications. [Bedell, 2000] A study of 4,200 charts in community hospitals in Massachusetts revealed a 10.4 percent ADE rate, equating to 1 ADE per 10 inpatients. [Bates, 2008]

The severity of harm has been estimated at a mortality rate of 1.0 to 2.45 percent attributed to ADEs. [Bates, 1995; Classen, 1997; Levinson, 2008a; Levinson, 2008b] Heparin, a high alert medication, remains in the consumer spotlight as a common medication involved in medication errors and ADEs that have led to death. ADEs contribute to 2.5 percent of emergency department visits for unintentional injuries and 0.6 percent for all medical visits. [Budnitz, 2006] Twenty-two percent of hospitalizations have been attributed to patient medication nonadherence. [Stagnitti, 2003] Healthcare systems must learn from one another's mistakes and use proactive risk mitigation strategies to prevent the past from repeating itself.

The Institute of Medicine's (IOM's) Committee on Identifying and Preventing Medication Errors estimated that at least 1.5 million preventable ADEs occur each year in the United States. [Aspden, 2007; Denham, 2008a] A high percentage of preventable ADEs results from a problem in medication ordering. [Kohn, 2000] To achieve a preventability rate in ADEs of between 28 and 95 percent, organizations can reduce medication errors through computerized monitoring systems according to the Agency for Healthcare Research and Quality 2001 report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices.* [AHRQ, 2001] A direct observation study found that medication barcode technology significantly reduced the rate of target dispensing errors leaving the pharmacy by 85 percent and the rate of potential ADEs due to dispensing errors by 63 percent. Therefore, in a 735-bed hospital where 6 million doses of medications are dispensed per year, this technology is expected to prevent approximately 13,000 dispensing errors and 6,000 potential ADEs per year. [Poon, 2005] It has also been demonstrated in inpatient settings that having a pharmacist review medication orders before administration is associated with a significant decrease in preventable ADEs. [Nester, 2002; Slee, 2002; Gleason, 2004] Similar findings have been found in ambulatory settings. [Ellis, 2000; Carmichael, 2004; Knapp, 2005] A recent study showed that pharmacists intercepted or intervened in potential medication errors at a rate of 3 per 100 medication orders in the emergency department. Ninety percent of errors were intercepted before reaching the patient. [Rothschild, 2009] In addition,

including a pharmacist on a clinical team conducting patient rounds resulted in a 66-78 percent reduction in preventable ADEs. [Leape, 1998; Kucukarslan, 2003]

The cost impact of ADEs, as well as of medication expenses, is staggering. The IOM committee estimated that ADEs accounted for $3.5 billion (in 2006 dollars) of additional costs to hospitals. Moreover, the average cost per ADE is estimated to be $2,400 to $7,000. [Senst, 2001; Bates, 1997] In 2000, outpatient prescription medicine spending equated to $102 billion, [WHO, 2001] comprising nearly one-tenth of total U.S. healthcare spending and representing the fastest growing type of medical expenditure. [Haynes, 2001] The 2005 national drug expenditure was $200.7 billion, more than five times the $40.3 billion spent in 1990. The 2005 U.S. prescription drug budget was calculated to be approximately 10 percent of total healthcare expenditure, compared to a U.S. hospital services budget of 31 percent. [Kaiser, 2007] As drug spending continues to rise at double-digit rates for hospital expenditures, hospital leadership must ensure that pharmacists have a central role in medication management strategies.

An increased awareness of the lack of care coordination among providers, an increase in ADEs, the advancements in health information technologies, and the passage of the Medicare Modernization Act of 2003 and the Medicare Prescription Medication Benefit (Part D) have prompted calls for an enhanced role for pharmacists to ensure effective drug use and patient safety. This enhanced role for pharmacists may require some changes in the views of the pharmacists' role, responsibilities, and contributions to the medication management process. Furthermore, there is a need to recognize pharmacists as healthcare providers for the purpose of practice liability and billing.

Senior administrative management and governance leaders must recognize the critical role that pharmacists can play in reducing patient safety risks, optimizing the safe function of medication management systems, and aligning pharmacy services with national initiatives that measure and reward quality performance. [Denham, 2005a; Denham, 2005b; Denham, 2008b] Pharmacy leaders should be included as part of the organizations' leadership team and involved with integral system decisions. Also, pharmacists should take an active role in medication management programs as part of the overall care team. There should be explicit organizational policies and procedures, prepared in accordance with applicable state and federal laws, about the role of pharmacists in medication management systems. Because of the manpower burden of managing this complex integrated system, adequate resources should be allocated to support the comprehensive pharmacy structure and system.

There is recognizable, palpable tension about the lack of rigorous evidence in the realm of medication management solutions; however, these system failures are real and have resulted in human suffering and death. This safe practice attempts to highlight medication management practice gaps that have resulted in patient harm and to encourage proactive risk mitigation and a strong foundation of pharmacist leadership, teamwork, and safety culture. [Denham, 2006a; Denham, 2006b; Denham, 2006c; Frankel, 2006]

Safe Practice Statement

Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. [IHI, 2009a; Burgess, 2010]

Additional Specifications

Leadership and Culture of Safety

A structure should be established and maintained to ensure that pharmacy leaders engage in regular, direct communications with the administrative leaders and the board of directors about medication management systems performance. [NQF, 2006; ASHP, 2003]

Pharmacists should actively participate in medication management processes, structures, and systems, by, at a minimum:

- Working with the interdisciplinary team to ensure safe and effective medication use across the continuum of care as patients move from one setting to another (e.g., from ambulatory care to inpatient to home care). [Chiquette, 1998; Dudas, 2002; Schnipper, 2006; Koshman, 2008; Jack, 2009]
- Establishing pharmacy leadership structures and systems to ensure organization awareness of medication safety gaps; that there is direct accountability of senior leadership for these gaps with adequate budget available for performance improvement; and that action is taken to ensure the safe medication use by every patient. [Manasse, 2000; Mark, 2007a; Mark, 2007b]
- Supporting an organizational culture of safe medication use; measuring pharmacy staff safety culture; providing feedback to leadership and staff; and undertaking interventions that will reduce medication safety risks. [Clarke, 2007; Connor, 2007; ISMP, 2007a; Ashcroft, 2009]
- Establishing a proactive, systematic, and organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable patient harm. [Sehgal, 2008; Clark, 2009; IHI, 2009b]
- Systematically identifying and mitigating medication safety risks and hazards to reduce preventable patient harm. [Benjamin, 2003; Rath, 2008]
- Working with the interdisciplinary team to ensure evidence-based medication regimens for all patients. [Leape, 1999; Scarsi, 2002; Kucukarslan, 2003; Rodgers, 2007]
- Establishing a medication safety committee to review medication errors, adverse drug events (ADEs), and medication near misses, and reporting data and prevention strategies to senior leadership, the Patient Safety Officer, and the interdisciplinary patient safety committee. [Piotrowski, 2002; Kowiatek, 2004; Odwazny, 2005; Denham, 2007; Abramson, 2009]
- Performing medication safety walk-rounds to evaluate medication processes and frontline staff input about medication safe practices. [Frankel, 2005; Thomas, 2005]
- Ensuring that pharmacy staff engage in teamwork and communication, leadership, and safety culture training, at least annually. [Sehgal, 2008; Clark, 2009]
- Establishing a central role in readiness planning for the implementation of CPOE, medication and patient barcoding, and other health information technologies that have an impact on medication management systems and medication use. [McGregor, 2006; Kilbridge, 2006; ASHP, 2003]
- Engaging in public health initiatives on behalf of the pharmacy community, including best practice immunization and vaccination initiatives, smoking cessation, and emergency preparedness. [ASHP, 2003; Hogue, 2006; Terriff, 2008; Dent, 2009]

Selection and Procurement

- Pharmacists work with physicians and other health professionals to select and maintain a formulary of medications chosen for safety, effectiveness, and cost, as well as medication-associated products or devices, medication use policies, important ancillary drug information, decision support tools, and organizational guidelines. The formulary system should have a process for which the medical staff has oversight and approval of the formulary. [Pedersen, 2001; Pedersen, 2008]
- Medication selection should be informed by the best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. [NQF, 2006] The prescriber should document the specific reason, clinical indications, and/or patient preferences, and why a patient is not receiving a recommended medication, based on readily available, current guidelines. [Meyer, 2000; IHI, 2009c]
- Pharmacists are actively involved in the development and implementation of evidence-based drug therapy protocols and/or order sets. [ASHP, 2003; Magee, 2007]

Storage

- Identify and, at least annually, review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs. [AHA, 2005; McCoy, 2005; IHI, 2009a; JCR, 2010a]
- Ensure that the written medication storage policy is implemented. The policy includes safe storage, safe handling, security, and disposition of these medications. [Rich, 2004; JCR, 2010a]
- Ensure that all medications, including pediatric doses, parenteral, and those used during emergencies, are available in unit-dose (single unit), age- and/or weight-appropriate, and ready-to-administer forms, whenever possible. [Rich, 2004; IHI, 2009a; JCR, 2010b]

Ordering and Transcribing

- Ensure with the healthcare team that only the medications needed to treat the patient's condition are ordered, provided, and administered. [TJC, 2008; Gardner, 2009]

Preparing and Dispensing

- Pharmacists should review all medication orders and the patient medication profile for appropriateness and completeness, address any problems and ensure needed change, and document actions taken before medications are dispensed or made available for administration, except in those instances when review would cause a medically unacceptable delay or when a licensed independent practitioner controls the ordering, preparation, and administration of the medication. [JCR, 2010b; Westerlund, 2009]
- Pharmacists should oversee the preparation of medications, including sterile products, and ensure that they are safely prepared. [Kastango, 2005; JCR, 2010b]
- Medications should be labeled in a standardized manner according to hospital policy, applicable law and regulation, and standards of practice. [Jennings, 2007; Shrank, 2007; ISMP, 2008b; Momtahan, 2008; JCR, 2010a]
- Every unit-dose package label should contain a machine-readable code identifying the product name, strength, and manufacturer. Machine-readable coding should be considered in compounding, stocking, and

dispensing procedures to facilitate accuracy. [VHA, 2006; ASHP, 2009; IHI, 2009a]

- When a full-time pharmacist is not available onsite, a pharmacist is available by telephone or accessible at another location that has 24-hour pharmacy services. [Woodall, 2004; Pedersen, 2008; JCR, 2010a]

Medication Administration [IHI, 2009e]

- Organizations should consider the use of medication administration technologies such as barcode-enabled medication administration (BCMA) and "Smart Pump" infusion devices as part of their medication safety strategy. [Johnson, 2002; Wilson, 2004; Larsen, 2005; Rothschild, 2005; Poon, 2006; Cohen, 2007b; Fanikos, 2007; Paoletti, 2007]
- The five rights for medication administration (right patient, right medication, right dose, right time and frequency, and right route of administration) have historically been a guideline for nurses and caregivers; however, this framework is not all inclusive of domains relating to medication adverse events. It does not address all pertinent organizational systems, human factors performance, and human-technology interface issues. The practitioner's duty is to follow the procedural rules designed by the organization to produce optimal outcomes. If system issues negatively affect the adherence to procedural rules and their intended impact, the practitioner also has the duty to report the hindrance so that it can be remedied. [Bechtel, 1993; ISMP, 2007b]

Monitoring

- Pharmacists should monitor patient medication therapy regularly, based on patient needs and best evidence, for effectiveness, adherence, persistence, and avoidance of adverse events. Monitoring information should be communicated to providers, caregivers, and patients. [Bond, 2006; Bond, 2007]
- Medication errors and near miss internal reports should be shared with organizational safety, risk, and senior leadership through the pharmacy leader. A performance improvement and risk mitigation plan should be created, integrated into the organization's improvement strategy, implemented, and documented annually. This plan should be updated as frequently as necessary based on internal data. [Cohen, 2000; Lehmann, 2007; Montesi, 2009]
- Medication error and near miss information is reported through external sources such as Patient Safety Organizations, the Food and Drug Administration (FDA), the United States Pharmacopeia, or the Institute for Safe Medicine Practices (ISMP), as appropriate, in an effort to trend data to prevent future patient harm. [Cohen, 2000; MCPME, 2006]
- Proactive risk mitigation strategies should be demonstrated to prevent errors in the organization. Example: On an ongoing basis,* use external sources for review (such as ISMP, FDA) of reported near-miss/medication errors. [ISMP, 2009]

  **The NQF Maintenance Committee recommends, but does not mandate, quarterly review of published literature and internal organizational data to identify potential harm to patients and implementation of risk mitigation strategies.*

High-Alert Medications [IHI, 2009f]

- Identify high-alert medications within the organization. [ISMP, 2008b]
- Implement institutional processes for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and monitoring high-alert medications. [Runy, 2004; Cohen, 2007a; Federico, 2007; JCR, 2010b]

Evaluation

- Perform a medication safety self-assessment to identify organizational structure, system, and communication opportunities to proactively target harm reduction and risk mitigation strategies. [ISMP, N.D.a; Smetzer, 2003; JCR, 2010b]
- Evaluate the ability of the patient to understand and adhere to medication regimens when in the community setting. Consider patient health literacy, feasible dosing schedules, and affordability, as well as cultural, physical, and environmental barriers. [NQF, 2006; Davis, 2006a; Davis, 2006b]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Seek pharmacists with experience, expertise, and training in management and clinical services to lead and oversee clinical pharmacy operations. Suggested skills include communication, conflict resolution, negotiation, and collaboration.
- In light of the central role that pharmacists play in medication management systems, have the pharmacy director or leader regularly represent the pharmacy at senior leadership and clinical service line meetings as well as medical, surgical, and psychiatric staff meetings.
- Enable pharmacy staff collaboration with medical, nursing, and direct workforce staff in clinical areas to optimize knowledge transfer about medication patient safety issues and to monitor performance of medication management systems (e.g., pharmacist rounding with interdisciplinary teams).
- Patient-specific doses are prepared by the pharmacy to eliminate final preparation of the dose by nurses. [Garrelts, 2001]
- Provide resources to pharmacists to maintain awareness of safe practices literature and have the opportunity to attend the professional organization's continuing education conferences as well as local, state, and national professional meetings.
- Require pharmacists to complete credentialing consistent with their scope of practice.
- Encourage professional development, such as residency training or board certification, and implement a reward system for those pharmacists who seek this further education.
- Provide resources to ensure that space and equipment allocated for pharmacy activities, facility drug storage areas, and sterile product production areas are adequate.

- Provide an organized, well-lit workspace to both decrease errors and allow attention to detail by reducing distractions. [Flynn, 1999; Simmons, 2009]
- Organizational training programs should include extensive education about patient populations with special needs and treatment considerations, such as pediatrics medication use and safety. [Kaushal, 2001]

Strategies of Progressive Organizations

- High-reliability organizations have daily check-in calls/meetings with the primary focus of significant safety or quality issues from the last 24 hours or last shift, anticipated safety or quality issues in the next 24 hours, and follow-up on critical issues for accountability of resolution. These daily meetings are intentional, purposed conversations among the senior leaders and middle managers of the organization with an endpoint of issue prioritization, ownership, and resolution of potential harm to patients or staff. These meetings are limited to 15-30 minutes, with an expected attendance of all department directors, and are facilitated by a senior leader. [Resar, 2006] Similarly, pharmacy leaders should be directly engaged daily with front-line managers and staff to reassess the organizations goals and strategy.
- When physicians and pharmacists partner to provide care, patient outcomes are improved. High-performing clinics and health systems have clinical pharmacists providing direct patient care on interdisciplinary teams. The medical home model for chronic conditions such as hypertension should include pharmacists on the team due to the mounting evidence for their contribution to quality of care. [Carter, 2009]
- Some organizations have created a Chief Pharmacy Officer post as a senior administrative position in recognition of the "system-ness" of medication management and the need for pharmacy oversight of the systems. Regardless of the title, having a pharmacy executive report at a high level of administration has been shown to be effective. [Ivey, 2005]
- Some organizations have developed 24/7/365 pharmacist coverage with combinations of remote order entry, telephony, streaming video, and scanning technologies that enable clear, evidence-based practices, or prospective pharmacist order review and face-to-face patient counseling. [Clifton, 2003; Paré, 2007; Stratton, 2008]
- Establishing conflict resolution guidelines for resolving human conflicts when questions arise about the safety of medication orders. [ISMP, 2008a; ISMP, 2008c]
- High-performing organizations have implemented real-time electronic alert triggers for potential ADEs for the pharmacist to review and intervene early. Example: Laboratory alert triggers for INR, PT, drug plasma levels. [Young, 2001; Humphries, 2007; Griffin, 2009]
- Senior leadership enables appropriate pharmacist staffing levels to sustain pharmacy operational, clinical, and quality improvement activities. [Bond, 2001; Bond, 2002; Malone, 2007; Lyons, 2007]
- Clinical pharmacy interventions are documented in the medical record and cumulatively analyzed for opportunities to improve medication safety organization wide. [Nesbit, 2001; Kopp, 2007]

- Adoption of a pharmacy practice model where pharmacists are put in their best position to promote the safe and effective use of medications, while technologies and technicians are used for preparation and dispensing processes. [Abramowitz, 2009; ASHP PITEComm, 2009]
- Continually reevaluating and redesigning the medication-use system to improve error prone steps through the use of technology. [Neuenschwander, 2009]
- Utilizing pharmacy technicians with standardized training and certification to improve the efficiency and safety of medication preparation and dispensing. [Desselle, 2005a; Desselle, 2005b]
- High-performing organizations understand three critical issues, described in the literature, that impact execution:
  - Execution is integral to strategy, it is a major responsibility of the leader, and it is core to the organization's culture, behavior, and reward system. If the strategy is not achievable, that is, not mapped to skills, resources, and assets of the organization, success is unlikely.
  - The leader must be engaged in the execution of the strategy to adjust goals and priorities or make available additional resources to overcome barriers in a timely manner.
  - The leader has a direct impact on the behaviors of the employees, by joining in the execution of the strategy, clarifying the expected results, and aligning the rewards system. The leader must ensure the right person for the right role, and with execution as part of the expected behavior, it becomes part of the culture. [Collins, 2001; Bossidy, 2002; Covey, 2006; Gladwell, 2008]

Opportunities for Patient and Family Involvement [Burroughs, 2007; IHI, 2009g; Weingart, 2009a; Weingart, 2009b]

- Educate patient and family members about the common incidence of medication errors.
- Encourage patient and family members to ask questions about their medication regimens and to request consultation with a pharmacist when necessary.
- Involve patient and family members on medication safety committees.
- Use teach-back method to ensure patient/family understanding of appropriate medication use. Example: Medication that involve injections or inhalation devices; proper storage and disposal.
- Patient and family members should be instructed how to identify and manage routine side effects and to know when and whom to contact if they believe they are experiencing any serious adverse effects of drug therapy.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures** include reduction of ADEs causing death, disability (permanent or temporary), or preventable harm requiring further treatment; number of self-reported medication errors using the organization's self-reporting system (IHI); pharmacy interventions per 100 admissions (IHI); operational measures including increased staff efficiency and throughput metrics; financial metrics

including reduction in costs of medications, and reduction in indirect and direct costs associated with patient harm and liability. [Denham, 2008b]

- Consider using national taxonomy for medication errors, such as the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors [NCC MERP, 1998] and reporting of medication errors and hazardous conditions related to drug products through the USP-ISMP Medication Errors Reporting System. USP-ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies, including FDA, and manufacturers are automatically notified of medication incidents when safety is of concern. [ISMP, N.D.b]

- **Process Measures** include intercepted errors requiring intervention by a pharmacist; documentation of pharmacist recommendations that promote medication error prevention throughout the organization; recommendations implemented on a system- or patient-specific basis; medication-related errors; and frequency of administration of medications given without pharmacist review.
  - NQF-endorsed® process measures:
    1. These measures can be found in the National Quality Forum's National Voluntary Consensus Standards for Medication Management. [NQF, 2009]

- **Structure Measures** include verification of explicit organizational policies and procedures about the role of pharmacists in the medication management systems and verification of competency of and educational programs for personnel involved in medication management.
  - NQF-endorsed structure measures:
    1. #0486: Adoption of Medication e-Prescribing [Ambulatory Care (office/clinic), Community Healthcare, Other]: Documents whether provider has adopted a qualified e-Prescribing system and the extent of use in the ambulatory setting.
    2. #0487: EHR (electronic health record) with EDI (electronic data interchange) prescribing used in encounters where a prescribing event occurred [Ambulatory Care (office/clinic), Community Healthcare, Other]: Of all patient encounters within the past month that used an EHR with EDI where a prescribing event occurred, how many used EDI for the prescribing event.

- **Patient-Centered Measures** include metrics from surveys of patients about their satisfaction related to medication management and communication by caregivers. The NQF-endorsed HCAHPS survey [HCAHPS, 2008] addresses this through the following questions: "During this hospital stay, were you given any medicine you had not taken before?" (Q.15); "Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?" (Q.16); and "Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?" (Q.17).

Settings of Care Considerations

- **Rural Healthcare Settings:** It is recognized that small and rural healthcare settings are resource constrained; however, using telephone support and other technologies such as Internet systems allows such healthcare settings to comply with the requirements of the practice. Adoption may require new alliances and creative approaches to safe medication management systems. In the absence of full-time pharmacists, small hospitals must rely on good collaboration and use of technologies. [Talbert, 2005; Casey, 2006; Peterson, 2007]
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

It is critical that medication management systems be better understood in order to leverage products, services, and technologies that can enable practices that will reduce preventable harm to patients across the healthcare enterprise. Practices in the adoption of health information technologies must be developed to reduce the risks associated with migration and adoption. For example, methods of notifying the prescriber when filled prescriptions are not picked up by the patient are being explored, including prescriber contact with the patient to discuss treatment alternatives. Exploration of the future role of the global trigger tool for identifying ADEs is also warranted. [Adler, 2008; Griffin, 2009] The creation of standardized metrics, including process and outcome measures to quantify the implementation of the safe practice specifications, are vital to improving medication management systems and medication safety nationally.

Other Relevant Safe Practices

Relevant practices include: Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Cultural Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; Safe Practice 4: Identification and Mitigation of Risks and Hazards; Safe Practice 12: Patient Care Information; Safe Practice 13: Order Read-Back and Abbreviations; Safe Practice 15: Discharge Systems; Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry; Safe Practice 17: Medication Reconciliation; and Safe Practice 29: Anticoagulation Therapy.

Notes

Abramowitz, 2009: Abramowitz PW. The evolution and metamorphosis of the pharmacy practice model. Am J Health Syst Pharm 2009 Aug 15;66(16):1437-46.

Abramson, 2009: Abramson E, Hyman D, Osorio SN, et al. Implementing a patient safety and quality program across two merged pediatric institutions. Jt Comm J Qual Patient Saf 2009 Jan;35(1):43-8.

Adler, 2008 : Adler L, Denham CR, McKeever M, et al. Global Trigger Tool: implementation basics. J Patient Saf 2008 Dec;4(4):245-9.

AHA, 2005: American Hospital Association; American Society of Health-System Pharmacists; Hospitals & Health Networks. Medication safety issue brief, Look-alike, sound-alike drugs. Hosp Health Netw 2005 Oct;79(10):57-8. Available at http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/PatientSafety/MedicationSafetyIssueBriefs_1/LookalikeSoundalikeDrugs.aspx. Last accessed September 10, 2009.

AHRQ, 2001 : Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment: Number 43. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality: 2001 Jul. Available at http://www.ahrq.gov/clinic/ptsafety/. Last accessed October 14, 2009.

Ashcroft, 2009: Ashcroft DM, Parker D. Development of the pharmacy safety climate questionnaire: a principal components analysis. Qual Saf Health Care 2009 Feb;18(1):28-31.

ASHP PITEComm, 2009: ASHP Section of Pharmacy Informatics and Technology Executive Committee, 2008-09. Technology-enabled practice: a vision statement by the ASHP Section of Pharmacy Informatics and Technology. Am J Health Syst Pharm 2009 Sep 1;66(17):1573-7.

ASHP, 2003: American Society of Health-System Pharmacists (ASHP). 2015 ASHP Health-System Pharmacy Initiative. Bethesda (MD): American Society of Health-System Pharmacists; 2003. Available at http://www.ashp.org/s_ashp/cat1c.asp?CID=218&DID=255. Last accessed October 12, 2009.

ASHP, 2009: [No authors listed.] Section of Pharmacy Informatics and Technology, American Society of Health-System Pharmacists. ASHP Statement on bar-code-enabled medication administration technology. Am J Health Syst Pharm 2009 Mar 15;66(6):588-90. Available at http://www.ashp.org/s_ashp/docs/files/BP07/New_St_BPOC.pdf. Last accessed September 11, 2009.

Aspden, 2007 : Committee on Identifying and Preventing Medication Errors, Aspden P, Wolcott J, Bootman JL, et al., eds. Preventing Medication Errors: Quality Chasm Series. Washington, DC: The National Academies Press; 2007. Available at http://www.nap.edu/catalog.php?record_id=11623#toc. Last accessed November 10, 2008.

Bates, 1995 : Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995 Jul 5;274(1):29-34.

Bates, 1997 : Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. JAMA 1997 Jan 2229;277(4):307-11.

Bates, 2008 : Bates DW. Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry in Massachusetts. Massachusetts Technology Collaborative and New England Healthcare Institute. 2008 Feb. Available at http://www.nehi.net/uploads/full_report/cpoe20808_final.pdf. Last accessed October 14, 2009.

Bechtel, 1993: Bechtel GA, Vertrees JL, Swartzberg B. A continuous quality improvement approach to medication administration. J Nurs Care Qual 1993 Apr;7(3):28-34.

Bedell, 2000 : Bedell SE, Jabbour S., Goldberg R, et al. Discrepancies in the use of medications. Arch Intern Med 2000 Jul 24;160(14):2129-34. Available at http://archinte.ama-assn.org/cgi/content/full/160/14/2129. Last accessed October 14, 2009.

Benjamin, 2003: Benjamin DM. Reducing medication errors and increasing patient safety: case studies in clinical pharmacology. J Clin Pharmacol 2003 Jul;43(7):768-83.

Bond, 2001: Bond CA, Raehl CL. Pharmacists' assessment of dispensing errors: risk factors, practice sites, professional functions, and satisfaction. Pharmacotherapy 2001 May;21(5):614-26.

Bond, 2002: Bond CA, Raehl CL, Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. Pharmacotherapy 2002 Feb;22(2):134-47.

Bond, 2006: Bond CA, Raehl CL. Clinical pharmacy services, pharmacy staffing, and adverse drug reactions in United States hospitals. Pharmacotherapy 2006 Jun;26(6):735-47.

Bond, 2007: Bond CA, Raehl CL. Clinical pharmacy services, pharmacy staffing, and hospital mortality rates. Pharmacotherapy 2007 Apr;27(4):481-93.

Bossidy, 2002 : Bossidy L, Charan R. Execution: The Discipline of Getting Things Done. New York (NY): Crown Business; 2002.

Budnitz, 2006 : Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006 Oct 18;296(15):1858-66. Available at http://jama.ama-assn.org/cgi/content/full/296/15/1858. Last accessed October 14, 2009.

Burgess, 2010: Burgess LH, Cohen MR, Denham CR. A new leadership role for pharmacists: a prescription for change. J Patient Saf 2010 Mar;6(1):Pending.

Burroughs, 2007: Burroughs TE, Waterman AD, Gallagher TH, et al. Patients' concerns about medical errors during hospitalization. Jt Comm J Qual Patient Saf 2007 Jan;33(1):5-14.

Carmichael, 2004 : Carmichael JM, Alvarez A, Chaput R, et al. Establishment and outcomes of a model primary care pharmacy service system. Am J Health Syst Pharm 2004 Mar 1;61(5):472-82.

Carter, 2009: Carter BL, Ardery G, Dawson JD, et al. Physician and pharmacist collaboration to improve blood pressure control. Arch Intern Med 2009 Nov 23;169(21):1996-2002.

Casey, 2006: Casey MM, Moscovice IS, Davidson G. Pharmacist staffing, technology use, and implementation of medication safety practices in rural hospitals. J Rural Health 2006 Fall;22(4):321-30.

Chiquette, 1998: Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and health care costs. Arch Intern Med 1998 Aug 10-24;158(15):1641-7. Available at http://archinte.ama-assn.org/cgi/reprint/158/15/1641. Last accessed December 15, 2009.

Clark, 2009: Clark PR. Teamwork: building healthier workplaces and providing safer patient care. Crit Care Nurs Q 2009 Jul-Sep;32(3):221-31.

Clarke, 2007: Clarke JR, Lerner JC, Marella W. The role for leaders of health care organizations in patient safety. Am J Med Qual 2007 Sep-Oct;22(5):311-8.

Classen, 1997 : Classen DC, Pestotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. JAMA 1997 Jan 22-29; 277(4):301-6.

Clifton, 2003: Clifton GD, Byer H, Heaton K, et al. Provision of pharmacy services to underserved populations via remote dispensing and two-way videoconferencing. Am J Health Syst Pharm 2003 Dec 15;60(24):2577-82.

Cohen, 2000: Cohen MR. Why error reporting systems should be voluntary. BMJ 2000 Mar 18;320(7237):728-9. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1117750&blobtype=pdf. Last accessed September 14, 2009.

Cohen, 2007a: Cohen H. Protecting patients from harm: reduce the risks of high-alert drugs. Nursing 2007 Sep;37(9):49-55; quiz 1 p following 55.

Cohen, 2007b: Cohen MR, Schneider P, Niemi K. Effective approaches to standardization and implementation of smart pump technology: a continuing education program for pharmacists and nurses. Huntingdon Valley (PA): Institute for Safe Medication Practices; 2007 May 1. Available at http://www.ismp.org/profdevelopment/SmartPumpTechnologyforwebce.pdf. Last accessed October 8, 2009.

Collins, 2001 : Collins J. Level 5 Leadership: The Triumph of Humility and Fierce Resolve. Harv Bus Rev 2001 Jan;79(1):66-76, 175.

Connor, 2007: Connor M, Duncombe D, Barclay E, et al. Creating a fair and just culture: one institution's path toward organizational change. Jt Comm J Qual Patient Saf 2007 Oct;33(10):617-24.

Covey, 2006 : Covey SMR, Merrill RR. The SPEED of Trust: The One Thing That Changes Everything. New York (NY): Free Press; 2006.

Davis, 2006a: Davis TC, Wolf MS, Bass PF 3rd, et al. Literacy and misunderstanding prescription drug labels. Ann Intern Med 2006 Dec 19;145(12):887-94. Epub 2006 Nov 29. Available at http://www.annals.org/cgi/reprint/145/12/887.pdf. Last accessed September 15, 2009.

Davis, 2006b: Davis TC, Wolf MS, Bass PF 3rd, et al. Low literacy impairs comprehension of prescription drug warning labels. J Gen Intern Med 2006 Aug;21(8):847-51. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1831578&blobtype=pdf. Last accessed September 15, 2009.

Denham, 2005a : Denham CR. Patient safety practices: leaders can turn barriers Into accelerators. J Patient Saf 2005 Mar;1(1):41-55.

Denham, 2005b : Denham CR. The Quality Choir: from warm-up to harmony. J Patient Saf 2005 Sep;1(3):170-5.

Denham, 2006a : Denham CR. Leaders need dashboards, dashboards need leaders. J Patient Saf 2006 Mar;2(1):45-53.

Denham, 2006b : Denham CR. The 3 Ts of leadership engagement: truth, trust and teamwork. J Patient Saf 2006 Sep;2(3): 162-70.

Denham, 2006c: Denham CR. The patient safety battles: put on your armor. J Patient Saf 2006 Jun;2(2):97-101.

Denham, 2007 : Denham CR. The new patient safety officer: a lifeline for patients, a life jacket for CEOs. J Patient Saf 2007 Mar;3(1);43-54.

Denham, 2008a : Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Denham, 2008b : Denham CR. CEOs: Meet your new revenue preservation officer…Your PSO! J Patient Saf 2008 Sep:4(3):201-11.

Denham, 2008c : Denham CR. May I have the envelope please? J Patient Saf 2008 Jun;4(2):119-23.

Dent, 2009: Dent LA, Harris KJ, Noonan CW. Randomized trial assessing the effectiveness of a pharmacist-delivered program for smoking cessation. Ann Pharmacother 2009 Feb;43(2):194-201. Epub 2009 Feb 3.

Desselle, 2005a: Desselle SP. Certified pharmacy technicians' views on their medication preparation errors and educational needs. Am J Health Syst Pharm 2005 Oct 1;62(19):1992-7.

Desselle, 2005b: Desselle SP. Survey of certified pharmacy technicians in the United States: a quality-of-worklife study. J Am Pharm Assoc (2003) 2005 Jul-Aug;45(4):458-65.

Dudas, 2002: Dudas V, Bookwalter T, Kerr KM, et al. The impact of follow-up telephone calls to patients after hospitalization. Am J Med 2001 Dec 21;111(9B):26S-30S.

Ellis, 2000 : Ellis SL, Carter BL, Malone DC, et al. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study. Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. Pharmacotherapy 2000 Dec;20(12):1508-16.

Fanikos, 2007: Fanikos J, Fiumara K, Baroletti S, et al. Impact of smart infusion technology on administration of anticoagulants (unfractionated Heparin, Argatroban, Lepirudin, and Bivalirudin). Am J Cardiol 2007 Apr 1;99(7):1002-5. Epub 2007 Feb 15.

Federico, 2007: Federico F. Preventing harm from high-alert medications. Jt Comm J Qual Patient Saf 2007 Sep;33(9):537-42.

Flynn, 1999: Flynn EA, Barker KN, Gibson JT, et al. Impact of interruptions and distractions on dispensing errors in an ambulatory care pharmacy. Am J Health Syst Pharm 1999 Jul 1;56(13):1319-25.

Frankel, 2005 : Frankel A, Grillo SP, Baker EG, et al. Patient Safety Leadership WalkRounds at Partners Healthcare: learning from implementation. Jt Comm J Qual Patient Saf 2005 Aug;31(8):423-37.

Frankel, 2006 : Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. Health Serv Res. 2006 Aug;41(4 Pt 2):1690-709. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1955339&blobtype=pdf. Last accessed October 30, 2009.

Gardner, 2009: Gardner B, Graner K. Pharmacists' medication reconciliation-related clinical interventions in a children's hospital. Jt Comm J Qual Patient Saf 2009 May;35(5):278-82.

Garrelts, 2001: Garrelts JC, Koehn L, Snyder V, et al. Automated medication distribution systems and compliance with Joint Commission standards. Am J Health Syst Pharm 2001 Dec 1;58(23):2267-72.

Gladwell, 2008 : Gladwell M. Outliers: The Story of Success. Boston (MA): Little, Brown and Company; 2008.

Gleason, 2004 : Gleason KM, Groszek JM, Sullivan C, et al. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. Am J Health Syst Pharm 2004 Aug 15;61(16):1689-95.

Griffin, 2009: Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). White Papers: 13. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/IHI/Results/WhitePapers/IHIGlobalTriggerToolWhitePaper.htm. Last accessed December 15, 2009.

Haynes, 2001 : Haynes RB, Montague P, Oliver T, et al. Interventions for helping patients to follow prescriptions for medications. Cochrane Database Syst Rev 2000;(2):CD000011.

HCAHPS, 2008: HCAHPS. CAHPS (Consumer Assessment of Healthcare Providers and Systems) Hospital Survey. Available at http://www.hcahpsonline.org/default.aspx. Baltimore (MD): Centers for Medicare & Medicaid Services; 2008. Last accessed October 12, 2009.

Hogue, 2006: Hogue MD, Grabenstein JD, Foster SL, et al. Pharmacist involvement with immunizations: a decade of professional advancement. J Am Pharm Assoc (2003) 2006 Mar-Apr;46(2):168-79; quiz 179-82.

Humphries, 2007: Humphries TL, Carroll N, Chester EA, et al. Evaluation of an electronic critical drug interaction program coupled with active pharmacist intervention. Ann Pharmacother 2007 Dec;41(12):1979-85. Epub 2007 Nov 6.

IHI, 2009a: [No authors listed.] Pharmacy Safety and Reliability. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=fcda1db9-4438-4deb-9007-8a2350d1eafc. Last accessed March 9, 2010.

IHI, 2009b: [No authors listed.] Communication & Teamwork. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=54d111e7-9bef-437b-b3c2-27f775b9eb53. Last accessed March 9, 2010.

IHI, 2009c: [No authors listed.] Medication Reconcilliation at All Transitions. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=7ce51016-b4f0-423c-9f8b-5e1ea8d7b810. Last accessed March 9, 2010.

IHI, 2009d: [No authors listed.] Medication Ordering. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=09361f0e-4fd6-4b02-af72-0f662a11282f. Last accessed March 9, 2010.

IHI, 2009e: [No authors listed.] Medication Administration. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=1bec3b88-aa1f-46a5-82ce-841518cb14ee. Last accessed March 9, 2010.

IHI, 2009f: [No authors listed.] High-Alert Medication Safety. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=b8541097-7456-4aab-a885-38c31950e6bf. Last accessed March 9, 2010.

IHI, 2009g: [No authors listed.] Communication with Patients & Families after an Adverse Event. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=e2af2d43-4135-49a2-b145-bbd65d8a2bee. Last accessed March 9, 2010.

ISMP, 2007a: [No authors listed.] If safety is your yardstick, measuring culture from the top down must be a priority. ISMP Newsletter 2007 Mar 22. Huntingdon Valley (PA): Institute for Safe Medication Practices; 2007. Available at http://www.ismp.org/Newsletters/acutecare/articles/20070322.asp. Last accessed October 12, 2009.

ISMP, 2007b : The Five Rights: A Destination Without a Map. Huntingdon Valley (PA): The Institute for Safe Medication Practices; 2007 Jan 25. Available at http://www.ismp.org/Newsletters/acutecare/articles/20070125.asp. Last accessed October 30, 2009.

ISMP, 2008a: [No authors listed.] Resolving human conflicts when questions about the safety of medical orders arise. Horsham (PA): Institute for Safe Medication Practices (ISMP); 2008 Mar 13. Available at http://www.ismp.org/Newsletters/acutecare/articles/20080313.asp. Last accessed September 15, 2009.

ISMP, 2008b: Institute for Safe Medication Practices (ISMP). ISMP's List of High-Alert Medications. 2008. Available at http://www.ismp.org/Tools/highalertmedications.pdf. Last accessed October 12, 2009.

ISMP, 2008c: Institute for Safe Medication Practices (ISMP). Resolving Human Conflicts When Questions about the Safety of Medical Orders Arise. ISMP Newsletter 2008 Mar 13. Available at http://www.ismp.org/Newsletters/acutecare/articles/20080313.asp. Last accessed October 12, 2009.

ISMP, 2009: [No authors listed.] Quarterly Action Agenda: Free CE for nurses. Horsham (PA): Institute for Safe Medication Practices (ISMP); 2009. Available at http://www.ismp.org/Newsletters/acutecare/actionagendas.asp. Last accessed September 14, 2009.

ISMP, N.D.a: Institute for Safe Medication Practices (ISMP). ISMP Medication Errors Reporting Program (MERP). No date. Available at https://www.ismp.org/orderforms/reporterrortoISMP.asp. Last accessed October 12, 2009.

ISMP, N.D.b: Institute for Safe Medication Practices (ISMP). ISMP Medication Safety Self-Assessments. No date. Available at http://www.ismp.org/selfassessments/default.asp. Last accessed October 12, 2009.

Ivey, 2005: Ivey MF. Rationale for having a chief pharmacy officer in a health care organization. Am J Health Syst Pharm 2005 May 1;62(9):975-8.

Jack, 2009: Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009 Feb 3;150(3):178-87. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2738592&blobtype=pdf. Last accessed October 12, 2009.

JCR, 2010a: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.03.04.01. Oak Brook (IL): Joint Commission Resources; 2010.

JCR, 2010b: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards MM.01.01.03; MM.03.01.01; MM.03.01.03; MM.05.01.01; and MM.08.01.0. Oak Brook (IL): Joint Commission Resources; 2010.

Jennings, 2007: Jennings J, Foster J. Medication safety: just a label away. AORN J 2007 Oct;86(4):618-25.

Johnson, 2002: Johnson CL, Carlson RA, Tucker CL, et al. Using BCMA software to improve patient safety in Veterans Administration Medical Centers. J Healthc Inf Manag 2002 Winter;16(1):46-51.

Kaiser, 2007 : Kaiser Family Foundation. Prescription Drug Trends. 2007 May. Available at http://www.kff.org/rxdrugs/upload/3057_06.pdf. Last accessed October 30, 2009.

Kastango, 2005: Kastango ES; American Society of Health-System Pharmacists (ASHP). Blueprint for implementing USP chapter 797 for compounding sterile preparations. Am J Health Syst Pharm 2005 Jun 15;62(12):1271-88.

Kaushal, 2001: Kaushal R, Bates DW, Landrigan C, et al. (2001). Medication errors and adverse events in pediatric inpatients. JAMA 2001 Apr 25;285(16):2114-20. Available at http://jama.ama-assn.org/cgi/reprint/285/16/2114. Last accessed September 15, 2009.

Kilbridge, 2006 : Kilbridge, PM, Classen D, Bates DW, Denham CR, et al. The National Quality Forum Safe Practice Standard for computerized physician order entry: updating a critical patient safety practice. J Patient Saf 2006 Dec;(2)4:183-190.

Knapp, 2005 : Knapp KK. Pharmacy and medicine: different workforce strategies driving expansion in educational systems. J Am Pharm Assoc (2003) 2005 Jul-Aug;45(4):430-2.

Kohn, 2000: Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health System, Washington, DC: The National Academies Press; 2000. Available at http://www.nap.edu/catalog.php?record_id=9728#toc. Last accessed October 14, 2009.

Kopp, 2007: Kopp BJ, Mrsan M, Erstad BL, et al. Cost implications of and potential adverse events prevented by interventions of a critical care pharmacist. Am J Health Syst Pharm 2007 Dec 1;64(23):2483-7.

Koshman, 2008: Koshman SL, Charrois TL, Simpson SH, et al. Pharmacist care of patients with heart failure: a systematic review of randomized trials. Arch Intern Med 2008 Apr 14;168(7):687-94. Available at http://archinte.ama-assn.org/cgi/reprint/168/7/687. Last accessed October 12, 2009.

Kowiatek, 2004: Kowiatek JG, Weber RJ, Skledar SJ, et al. Medication safety manager in an academic medical center. Am J Health Syst Pharm 2004 Jan 1;61(1):58-64.

Kucukarslan, 2003 : Kucukarslan SN, Peters M, Mlynarek M, et al. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. Arch Intern Med 2003 Sep 22;163(17):2014-8. Available at http://archinte.ama-assn.org/cgi/reprint/163/17/2014. Last accessed December 15, 2009.

Larsen, 2005: Larsen GY, Parker HB, Cash J, et al. Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients. Pediatrics 2005 Jul;116(1):e21-5. Available at http://pediatrics.aappublications.org/cgi/reprint/116/1/e21. Last accessed September 14, 2009.

Leape, 1998 : Leape LL, Woods DD, Hatlie MJ, et al. Promoting patient safety by preventing medical error. JAMA 1998 Oct 28;280(16):1444-7. Available at http://jama.ama-assn.org/cgi/content/full/280/16/1444. Last accessed October 30, 2009.

Leape, 1999: Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. JAMA 1999 Jul 21;282(3):267-70. Available at http://jama.ama-assn.org/cgi/reprint/282/3/267. Last accessed October 12, 2009.

Lehmann, 2007: Lehmann DF, Page N, Kirschman K, et al. Every error a treasure: improving medication use with a nonpunitive reporting system. Jt Comm J Qual Patient Saf 2007 Jul;33(7):401-7.

Levinson, 2008a : Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed October 30, 2009.

Levinson, 2008b : Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 30, 2009.

Lyons, 2007: Lyons TJ, Hola ET, Patel M, et al. Effects of 16-hour shifts on order-verification medication errors by hospital pharmacists. Am J Health Syst Pharm 2007 Jul 15;64(14):1467-8.

Magee, 2007: Magee MF. Hospital protocols for targeted glycemic control: Development, implementation, and models for cost justification. Am J Health Syst Pharm 2007 May 15;64(10 Suppl 6):S15-20; quiz S21-3.

Malone, 2007: Malone DC, Abarca J, Skrepnek GH, et al. Pharmacist workload and pharmacy characteristics associated with the dispensing of potentially clinically important drug-drug interactions. Med Care 2007 May;45(5):456-62.

Manasse, 2000: Manasse HR Jr. Pharmacists and the quality-of-care imperative. Am J Health Syst Pharm 2000 Jun 15;57(12):1170-2.

Mark, 2007a: Mark S, Weber RJ. Developing a medication patient safety program, Part 2: process and implementation. Hosp Pharm 2007 Mar;42(3):249-54. Available at http://www.factsandcomparisons.com/assets/hpdatenamed/20070301_mar2007_dirform.pdf. Last accessed October 12, 2009.

Mark, 2007b: Mark SM, Weber RJ. Developing a medication patient safety program – infrastructure and strategy. Hosp Pharm 2007 Feb;42(2):149-56. Available at http://www.factsandcomparisons.com/assets/hpdatenamed/20070201_feb2007_dirform.pdf. Last accessed October 12, 2009.

McCoy, 2005: McCoy LK. Look-alike, sound-alike drugs review: include look-alike packaging as an additional safety check. Jt Comm J Qual Patient Saf 2005 Jan;31(1):47-53.

McGregor, 2006 : McGregor JC, Weekes E, Forrest GN, et al. Impact of a computerized clinical decision support system on reducing inappropriate antimicrobial use: a randomized controlled trial. J Am Med Inform Assoc 2006 Jul-Aug;13(4):378-84. Epub 2006 Apr 18. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1513678&blobtype=pdf. Last accessed October 12, 2009.

MCPME, 2006: [No authors listed.] When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals. Burlington (MA): Massachusetts Coalition for the Prevention of Medical Errors; 2006 March. Available at http://www.macoalition.org/documents/respondingToAdverseEvents.pdf. Last accessed September 14, 2009.

Meyer, 2000: Meyer TA. Improving the quality of the order-writing process for inpatient orders and outpatient prescriptions. Am J Health Syst Pharm 2000 Dec 15;57 Suppl 4:S18-22.

Momtahan, 2008: Momtahan K, Burns CM, Jeon J, et al. Using human factors methods to evaluate the labelling of injectable drugs. Healthc Q 2008;11(3 Spec No.):122-8. Available at http://www.longwoods.com/view.php?aid=19598&cat=538. Last accessed September 11, 2009.

Montesi, 2009: Montesi G, Lechi A. Prevention of medication errors: detection and audit. Br J Clin Pharmacol 2009 Jun;67(6):651-5.

NCC MERP, 1998: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). TNCC MERP Taxonomy of Medication Errors. 1998. Available at http://www.nccmerp.org/pdf/taxo2001-07-31.pdf. Last accessed October 12, 2009.

Nesbit, 2001: Nesbit TW, Shermock KM, Bobek MB, et al. Implementation and pharmacoeconomic analysis of a clinical staff pharmacist practice model. Am J Health Syst Pharm 2001 May 1;58(9):784-90.

Nester, 2002 : Nester TM, Hale LS. Effectiveness of a pharmacist-acquired medication history in promoting patient safety. Am J Health Syst Pharm 2002 Nov 15;59(22):2221-5.

Neuenschwander, 2009: Neuenschwander M, Nessim D, Cassano A, et al. Improving medication safety in health systems through innovations in automation technology. Proceedings of educational symposia and educational sessions. Orlando (FL): 39th ASHP Midyear Clinical Meeting; 2004 Dec 5-9. Available at http://www.hospitalrx.com/pdf/ASHP%20Smart%20Pumps.pdf. Last accessed October 8, 2009.

NQF, 2006: National Quality Forum. National Voluntary Consensus Standards for the Reporting of Therapeutic Drug Management Quality. Washington, DC: National Quality Forum; 2006. Available at http://www.qualityforum.org/Projects/s-z/Therapeutic_Drug_Management_%282008%29/Therapeutic_Drug_Management.aspx. Last accessed October 12, 2009.

NQF, 2009: National Quality Forum. National Voluntary Consensus Standards for Medication Management. Washington, DC: National Quality Forum; 2009. Available at http://www.qualityforum.org/Projects/i-m/Medication_Management/Med_Management_Voting_Report.aspx. Last accessed January 14, 2010.

Odwazny, 2005: Odwazny R, Hasler S, Abrams R, et al. Organizational and cultural changes for providing safe patient care. Qual Manag Health Care 2005 Jul-Sep;14(3):132-43.

Paoletti, 2007: Paoletti RD, Suess TM, Lesko MG, et al. Using bar-code technology and medication observation methodology for safer medication administration. Am J Health Syst Pharm 2007 Mar 1;64(5):536-43.

Paré, 2007: Paré G, Jaana M, Sicotte C. Systematic review of home telemonitoring for chronic diseases: the evidence base. J Am Med Inform Assoc 2007 May-Jun;14(3):269-77. Epub 2007 Feb 28. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2244878&blobtype=pdf. Last accessed September 15, 2009.

Pedersen, 2001: Pedersen C, Schneider P, Santell J. ASHP national survey of pharmacy practice in hospital settings: prescribing and transcribing – 2001. Am J Health-Syst Pharm 2001 Dec 1;58(23):2251-66.

Pedersen, 2008: Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: prescribing and transcribing – 2007. Am J Health Syst Pharm 2008 May 1;65(9):827-43.

Peterson, 2007: Peterson CD, Rathke A, Skwiera J, et al. Hospital telepharmacy network: delivering pharmacy services to rural hospitals. J Pharm Technol 2007;23:158-65.

Piotrowski, 2002: Piotrowski MM, Saint S, Hinshaw DB. The Safety Case Management Committee: expanding the avenues for addressing patient safety. Jt Comm J Qual Improv 2002 Jun;28(6):296-305.

Poon, 2005 : Poon EG, Cina JL, Churchill WW, et al. Effect of bar-code technology on the incidence of medication dispensing errors and potential adverse drug events in a hospital pharmacy. AMIA Annu Symp Proc 2005:1085. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=16779372. Last accessed October 30, 2009.

Poon, 2006: Poon EG, Cina JL, Churchill W, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. Ann Intern Med 2006 Sep 19;145(6):426-34. Available at http://www.annals.org/cgi/reprint/145/6/426.pdf. Last accessed September 14, 2009.

Rath, 2008: Rath F. Tools for developing a quality management program: proactive tools (process mapping, value stream mapping, fault tree analysis, and failure mode and effects analysis). Int J Radiat Oncol Biol Phys 2008;71(1 Suppl): S187-90.

Resar, 2006: Resar RK. Making noncatastrophic health care processes reliable: Learning to walk before running in creating high-reliability organizations. Health Serv Res 2006 Aug;41(4 Pt 2):1677-89. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955343/pdf/hesr0041-1677.pdf. Last accessed December 2, 2009.

Rich, 2004: Rich DS. New JCAHO medication management standards for 2004. Am J Health Syst Pharm 2004 Jul 1;61(13):1349-58.

Rodgers, 2007: Rodgers JE, Stough WG. Underutilization of evidence-based therapies in heart failure: the pharmacist's role. Pharmacotherapy 2007 Apr;27(4 Pt 2):18S-28S.

Rothschild, 2005: Rothschild JM, Keohane CA, Cook EF, et al. A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. Crit Care Med 2005 Mar;33(3):533-40.

Rothschild, 2009: Rothschild JM, Churchill W, Erickson A, et al. Medication errors recovered by emergency department pharmacists. Ann Emerg Med Article in press;doi:10.1016/j.annemergmed.2009.10.012. Available online 2009 Dec 11.

Runy, 2004: Runy LA. A guide to the safer use of dangerous medications. High-Alert medications. Hosp Health Netw 2004 Sep;78(9):67-73, 2.

Scarsi, 2002: Scarsi KK, Fotis MA, Noskin GA. Pharmacist participation in medical rounds reduces medication errors. Am J Health Syst Pharm 2002 Nov 1;59(21):2089-92.

Schnipper, 2006: Schnipper JL, Kirwin JL, Cotugno MC, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. Arch Intern Med 2006 Mar 13;166(5):565-71. Available at http://archinte.ama-assn.org/cgi/reprint/166/5/565. Last accessed October 12, 2009.

Sehgal, 2008 : Sehgal NL, Fox M, Vidyarthi AR, et al. A multidisciplinary teamwork training program: the Triad for Optimal Patient Safety (TOPS) experience. J Gen Intern Med 2008 Dec;23(12):2053-7. Epub 2008 Oct 2.

Senst, 2001 : Senst BL, Achusim LE, Genest RP, et al. Practical approach to determining costs and frequency of adverse drug events in a health care network. Am J Health Syst Pharm 2001 Jun 15;58(12):1126-32.

Shrank, 2007: Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. Arch Intern Med 2007 Sep 10;167(16):1760-5. Available at http://archinte.ama-assn.org/cgi/reprint/167/16/1760. Last accessed September 11, 2009.

Simmons, 2009: Simmons D, Graves K, Flynn EA. Threading needles in the dark: the effect of the physical work environment on nursing practice. Crit Care Nurs Q 2009 Apr-Jun;32(2):71-4; quiz 75-6.

Slee, 2002 : Slee A, Farrar K, Hughes D. Implementing an automated dispensing system. Pharmaceutical Journal 2002 Mar 30;268(7191):437-8. Available at http://www.pharmj.com/pdf/articles/pj_20020330_automated.pdf. Last accessed October 30, 2009.

Smetzer, 2003: Smetzer JL, Vaida AJ, Cohen MR, et al. Findings from the ISMP Medication Safety Self-Assessment for hospitals. Jt Comm J Qual Saf 2003 Nov;29(11):586-97.

Stagnitti, 2003 : Stagnitti MN. Statistical Brief #21: Trends in Outpatient Prescription Drug Utilization and Expenditures: 1997-2000. Rockville (MD): Agency for Healthcare Research and Quality; N.D. Available at http://www.meps.ahrq.gov/mepsweb/data_files/publications/st21/stat21.pdf. Last accessed October 30, 2009.

Stratton, 2008: Stratton TP, Worley MM, Schmidt M, et al. Implementing after-hours pharmacy coverage for critical access hospitals in northeast Minnesota. Am J Health Syst Pharm 2008 Sep 15;65(18):1727-34.

Talbert, 2005: Talbert DA, Roush E, Velazco L, et al. An incremental pharmacy informatics model for use in a rural hospital. AMIA Annu Symp Proc 2005:1131. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1560496&blobtype=pdf. Last accessed September 15, 2009.

Terriff, 2008: Terriff CM, Newton S. Pharmacist role in emergency preparedness. J Am Pharm Assoc (2003) 2008 Nov-Dec;48(6):702, 707.

Thomas, 2005: Thomas EJ, Sexton JB, Neilands TB, et al. The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical units[ISRCTN85147255] [corrected]. BMC Health Serv Res. 2005 Apr 11;5(1):28. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1097728&blobtype=pdf. Last accessed October 12, 2009.

TJC, 2008: The Joint Commission (TJC). Preventing pediatric medication errors. Sentinel Event Alert. 2008 Apr 11. Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_39.htm. Last accessed October 12, 2009.

VHA, 2006: [No authors listed.] Department of Veterans Affairs. Veterans Health Administration. Quality directive for unit-dose packaging and barcode labeling. VHA Directive 2006-008. 2006 Feb 9. Available at http://www.ashp.org/DocLibrary/VABarcodeLabeling.aspx. Last accessed September 14, 2009.

Weingart, 2009a: Weingart SN, Morway L, Brouillard D, et al. Rating recommendations for consumers about patient safety: sense, common sense, or nonsense? Jt Comm J Qual Patient Saf 2009 Apr;35(4):206-15.

Weingart, 2009b: Weingart SN, Simchowitz B, Eng TK, et al. The You CAN campaign: teamwork training for patients and families in ambulatory oncology. Jt Comm J Qual Patient Saf 2009 Feb;35(2):63-71.

Westerlund, 2009: Westerlund T, Marklund B. Assessment of the clinical and economic outcomes of pharmacy interventions in drug-related problems. J Clin Pharm Ther 2009 Jun;34(3):319-27.

WHO, 2001 : World Health Organization (WHO). Adherence to Long-Term Therapies: Policy for Action (Meeting Report). Geneva (Switzerland): WHO; 2001 June 4-5.

Wilson, 2004: Wilson K, Sullivan M. Preventing medication errors with smart infusion technology. Am J Health Syst Pharm 2004 Jan 15;61(2):177-83.

Woodall, 2004: Woodall SC. Remote order entry and video verification: reducing after-hours medication errors in a rural hospital. Jt Comm J Qual Saf 2004 Aug;30(8):442-7.

Young, 2001: Young D. Electronic system alerts pharmacists to potential adverse drug events. Am J Health Syst Pharm 2001 Dec 15;58(24):2362, 2365.

Chapter 7: Improving Patient Safety Through the Prevention of Healthcare-Associated Infections

Background

WITH THE ANNOUNCEMENT from the Centers for Disease Control and Prevention (CDC) that as many as 100,000 lives are lost due to healthcare-associated infections (HAIs), the cause of death from medical-related harm in America rose from the eighth leading cause in 1999 to the third leading cause. [Kohn, 2000; Starfield, 2000; Klevens, 2007] Traditional infection control programs are a focus of considerable attention. The entire marketplace needs to move from an infection control mentality to one of infection prevention. This will demand structural, functional, and environmental changes to meet existing and future needs. [Denham, 2009a; Denham, 2009b]

HAIs are the most common complication affecting hospitalized patients, with between 5 and 10 percent of inpatients acquiring one or more infections during their hospitalization. The Centers for Disease Control and Prevention estimates that nearly 2 million patients experience an HAI each year; these infections lead to nearly 100,000 deaths and $4.5 billion to $6.5 billion in extra costs. [Yokoe, 2008] Of these infections, 32 percent (562,000) are urinary tract infections, 22 percent (290,000) are surgical-site infections (SSIs), 15 percent (250,000) are lung infections, and 14 percent (249,000) are blood-stream infections. Infection prevention begins with the most basic of infection control: hand hygiene. Experts generally believe that at least 20 percent of such infections are preventable.

The risk of acquiring an infection while hospitalized appears to be rising, and the occurrence of HAIs has been of increasing concern to healthcare purchasers, consumers, and providers in recent years. Fortunately, some practices have been shown to reduce the potential for HAIs and the harm to patients, as well as the costs incurred by all stakeholders.

Explicit organizational policies and procedures should be in place with respect to hand hygiene and the prevention of ventilator-associated pneumonia, central venous catheter-associated bloodstream infections, SSIs, catheter-associated urinary tract infections, and multidrug-resistant organisms and influenza. Compliance with these practices highlights the importance of teamwork to ensure that every patient receives safe, efficient, and effective care. All clinical staff and practitioners need to be aware of the need for teamwork and continued communication to increase the adoption of these practices and sustain their use.

Although intensive research is in progress on HAIs, it will take time to understand the absolute magnitude of preventability and the value of risk-assessment methods; however, there is full consensus that actions need to be taken now to reduce HAIs with what is currently known.

Notes

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: can reality meet the rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4):210-5.

Klevens, 2007: Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep 2007 Mar-Apr;122(2): 160-6.

Kohn, 2000: Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000. Available at http://www.nap.edu/catalog.php?record_id=9728. Last accessed November 11, 2009.

Starfield, 2000: Starfield B. Is US health really the best in the world? JAMA 2000 Jul 26;284(4):483-5. Available at http://jama.ama-assn.org/cgi/reprint/284/4/483. Last accessed December 14, 2009.

Yokoe, 2008: Yokoe DS, Mermel LA, Anderson DJ, et al. A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals. Infect Control Hosp Epidemiol 2008 Oct;29 Suppl 1:S12-21.

SAFE PRACTICE 19: HAND HYGIENE

The Objective

Prevent person-to-person transmission of infections.

The Problem

Many healthcare-associated infections (HAIs) are caused by pathogens transmitted from one patient to another via the contaminated hands of healthcare workers. [CDC, 2002; IHI, 2007] Pathogens may be recovered from wounds as well as intact skin, and they may be easily transmitted. [Sanderson, 1992; Sanford, 1994] The Centers for Disease Control (CDC) estimates that approximately 2 million patients acquire an HAI, and nearly 90,000 patients die as a result, annually. [CDC, 2002b; Klevens, 2007] Hand hygiene is one of the most important and effective interventions in preventing the transmission of pathogens in healthcare facilities. [Whitby, 2007] However, a compliance rate of less than 50 percent was observed in studies. [Pittet, 1999; IHI, 2009]

Traditional infection control programs are directionally correct but insufficient to enable organizations to "chase zero" and reduce the harm of preventable healthcare-associated infections (HAIs). [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c]

The frequency of infections caused by drug-resistant organisms is increasing. The Centers for Disease Control and Prevention (CDC) reports that methicillin-resistant *Staphylococcus aureus* (MRSA) accounts for more than 50 percent of hospital-acquired *S. aureus* infections and for 63 percent of *S. aureus* infections acquired in intensive care units in the United States in 2004. [NNIS, 2004] In one study, 100 to 1,000 CFUs of *Klebsiella* species were recovered on nurses' hands after "clean" activities, such as lifting a patient or taking vital signs. [Casewell, 1977] Other organisms such as gram-negative bacilli, *Enterococcus, Clostridium difficile,* and respiratory syncytial virus could potentially be transmitted on healthcare workers' hands if proper hygienic measures are not followed. [CDC, 2002a]

The severity of infections caused by healthcare-associated transmission varies among the organisms. [Levinson, 2008] More than 126,000 hospitalized persons are infected with MRSA annually (approximately 3.95 per 1,000 hospital discharges). More than 5,000 deaths each year are attributable to MRSA. *Clostridium difficile* infection has recently been associated with an attributable mortality rate of 6.9 percent at 30 days, and 16.7 percent at 1 year. [Pepin, 2005]

Proper hand hygiene greatly improves the preventability of many HAIs. [Denham, 2008] In one study, implementation of a hand hygiene improvement program, using an alcohol-based hand sanitizer, demonstrated enhanced compliance rates and was associated with a decrease in HAIs and in new infections caused by MRSA. [Pittet, 2000] Healthcare facilities should educate and train staff and patients on proper techniques for hand sanitation and their importance. [Denham, 2008b; Cantrell, 2009; Erasmus, 2009; Laustsen, 2009] Hand sanitation with alcohol-based hand rubs should be utilized and provided at points of patient care. Washing hands with antimicrobial soap and water should be the primary route of hand hygiene if hands are visibly dirty or contaminated with proteinaceous material

or are visibly soiled with blood or other body fluids, or before eating and after using a restroom. [CDC, 2002; WHO, 2005]

According to a World Health Organization report, the cost of HAIs in the United States has been estimated to be $4.5 billion to $5.7 billion annually [WHO, 2005]. The material cost of hand antiseptic is generally minimal and has been estimated to be as little as 34 cents per patient day. In the United Kingdom, the administration, education, and implementation costs of its "Clean Your Hands" campaign was less than 0.1 percent of the national cost of treating HAIs. The campaign organizers estimated the potential savings to reach 140 million pounds each year. [NHS, 2008]

Safe Practice Statement

Comply with current Centers for Disease Control and Prevention Hand Hygiene Guidelines. [CDC, 2002a; WHO, 2009, JCR, 2010]

Additional Specifications

At a minimum, this practice should include all of the following elements:

- Implement all Centers for Disease Control and Prevention (CDC) guidelines with category IA, IB, or IC evidence and/or WHO Guidelines on Hand Hygiene in Health Care. [CDC, 2002a; Braun, 2009; Stevenson, 2009; WHO, 2009]
- Encourage compliance with CDC guidelines with category II evidence.
- Ensure that all staff know what is expected of them with regard to hand hygiene, and ensure compliance. [Boyce, 2008; Creedon, 2008; Kohli, 2009; McGuckin, 2009; JCR, 2010]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility. [Aiello, 2008]

Example Implementation Approaches

[CDC, 2002; WHO, 2005]

- Undertake religiously sensitive and culturally appropriate ongoing campaigns to reinforce proper and frequent hand hygiene for caregivers [Allegranzi, 2008] in such a way that workers have a consistent view and practice of hand hygiene in and outside of the healthcare environment, and involve patients and families. [Whitby, 2007] Develop tools, provide resources, and encourage creative strategies to motivate and re-energize staff around this critical practice. [Day, 2009; Magiorakos, 2009] Signs can be strategically placed around the facility as reminders and flyers can be made available for visitors. [APIC, N.D.b]
- Ensure that physicians and senior staff practice quality hand hygiene, as their example greatly influences the actions of all the healthcare staff. [Duggan, 2008; Mody, 2008; Chatzizacharias, 2009; Erasmus, 2009]
- Provide alcohol-based hand rub in pump dispensers, as appropriate, in locations that are easily accessible for staff, [Thomas, 2009] after engaging them in determining the most convenient and logical placement. Establish a program of random observation techniques to recognize staff who exhibit excellent transmission prevention.

- Utilize a user-centered hand hygiene concept that has minimal complexity, integrates into the natural workflow, and has maximum preventive effect. [Lautenbach, 2001; Sax, 2007; Day, 2009; IHI, 2009; AHRQ, N.D.]
- Expand hand hygiene implementation to both before and after patient contact.
- Emphasize hand hygiene after the healthcare worker's gloves are removed.
- Use hand hygiene before insertion of all invasive devices, regardless of glove use.
- Use alcohol rub or soap and water before handling medications.
- Do not add soap to a partially filled soap dispenser. If dispensers must be reused, clean them thoroughly externally and internally, and refill them in a timely manner.

Strategies of Progressive Organizations

- Some organizations have developed internal studies aimed at continuously educating caregivers on appropriate and effective hand hygiene, including digital images of hand prints (blinded random sampling) and the use of agar culture plates to provide an easily understood visual aid. [Stevenson, 2009; van der Vegt, 2009]
- Some organizations have explored increasing the vigilance of environmental cleaning of high contact surfaces in patient rooms, such as television remote control devices, and operating room equipment and devices, such as pulse oximeters that are shared or used across multiple patients to prevent the spread of infectious diseases
- High-performing organizations have created placards for patients and families to hold up that ask caregivers if they have washed their hands upon entry into their room. This empowers the patient to become part of their care while minimizing intimidation and allowing a "stop the line" concept for patients.

Opportunities for Patient and Family Involvement [WHO, 2009]

- Teach patients and families the proper method for hand hygiene, as well as precautions for preventing infection. Visitor and patient handouts, videos, etc., in multiple languages, such as English and Spanish, should be employed. [APIC, N.D.a]
- Encourage patients and families to use hand hygiene dispensers placed throughout the facility.
- Teach patients and families to recognize the signs and symptoms of infection.
- Invite patients to ask staff whether they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions about infection control activities.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures** include HAI rates and rates of compliance with hand hygiene. Consider monitoring hand hygiene failure rate (number of failed performances per number of opportunities). [Eveillard, 2009; WHO, 2009]

- **Process Measures** include compliance with CDC guidelines, stratified by unit, department, or service, with evidence of feedback to staff. Monitor barriers to hand hygiene compliance: inconveniently located dispensers, dispensers that do not work or are not filled, lack of paper towels, and lack of access to hand creams and/or lotions. Monitor individual hand hygiene technique. [WHO, 2009] Hand hygiene monitoring should be performed by using a facility-approved monitoring tool measuring opportunities for hand hygiene interventions. [Arias, 2006]
- **Structure Measures** include verification of the existence of policies and documentation related to hand hygiene and adherence to the practice as part of a quality dashboard for administrative leadership and governance. [Cookson, 2009]
- **Patient-Centered Measures** include surveying patients to ascertain whether they noticed their caregiver(s) performing hand hygiene before providing care.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings.
- **Specialty Hospitals:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Research into methods for optimizing the adoption of the practice will be critical, because adoption rates are far too low and HAIs pose a serious threat to patients. [Boyce, 2008; Vaughan, 2009] A comprehensive standard of practice that can be used across various healthcare settings is needed to measure hand hygiene effectiveness. [Braun, 2009] Also, new behavioral modification techniques, such as hospital video sampling and reinforcement methods, are being explored. [Dierks, 2008; WHO, 2009]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Hand hygiene is the cornerstone of an organization's infection control program and directly affects Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention; Safe Practice 22: Surgical-Site Infection Prevention; and Safe Practice 23: Care of the Ventilated Patient.

Notes

Aboelela, 2007: Aboelela SW, Stone PW, Larson EL. Effectiveness of bundled behavioural interventions to control healthcare-associated infections: a systematic review of the literature. J Hosp Infect 2007 Jun;66(2):101-8. Epub 2007 Feb 21. Review.

AHRQ, N.D.: [No authors listed.] Patient Safety Primer: Health Care-Associated Infections. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=7. Last accessed October 22, 2009.

Aiello, 2008: Aiello AE, Coulborn RM, Perez V, et al. Effect of hand hygiene on infectious disease risk in the community setting: a meta-analysis. Am J Public Health 2008 Aug;98(8):1372-81. Epub 2008 Jun 12.

Allegranzi, 2008: Allegranzi B, Memish ZA, Donaldson L, et al. Religion and culture: potential undercurrents influencing hand hygiene promotion in health care. Am J Infect Control 2009 Feb;37(1):28-34. Epub 2008 Oct 3.

APIC, N.D.a: [No authors listed.] Protect Our Patients: Visitor Education Program. Washington, DC: Association for Professionals in Infection Control and Epidemiology (APIC); No Date. Available at http://www.apic.org/AM/Template.cfm?Section=Protect_Our_Patients&Template=/CM/HTMLDisplay.cfm&ContentID=11254. Last accessed October 22, 2009.

APIC, N.D.b: [No authors listed.] Clean Hands Save Lives poster. Washington, DC: Association for Professionals in Infection Control and Epidemiology (APIC); No Date. Available at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/HandHygiene/Clean_Hands_Save_Lives.pdf. Last accessed October 22, 2009.

Archibald, 1997: Archibald LK, Corl A, Shah B, et al. Serratia marcescens outbreak associated with extrinsic contamination of 1% chlorxylenol soap. Infect Control Hosp Epidemiol 1997 Oct;18(10):704-9.

Arias, 2006: Arias KM, Soule BM, eds. The APIC/JCAHO Infection Control Workbook. Oak Brook (IL): Joint Commission Resources; 2006.

Boyce, 2008: Boyce JM. Hand hygiene compliance monitoring: current perspectives from the USA. J Hosp Infect 2008 Oct;70 Suppl 1:2-7.

Braun, 2009: Braun BI, Kusek L, Larson E. Measuring adherence to hand hygiene guidelines: a field survey for examples of effective practices. Am J Infect Control 2009 May;37(4):282-8. Epub 2008 Dec 31.

Cantrell, 2009: Cantrell D, Shamriz O, Cohen MJ, et al. Hand hygiene compliance by physicians: marked heterogeneity due to local culture? Am J Infect Control 2009 May;37(4):301-5. Epub 2008 Oct 3.

Casewell, 1977: Casewell M, Phillips I. Hands as route of transmission for Klebsiella species. Br Med J 1977 Nov 19;2(6098):1315-7. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=589166. Last accessed September 24, 2009.

CDC, 2002a: [No authors listed.] Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Atlanta (GA): Centers for Disease Control and Prevention; 2002. MMWR 2002;51(RR-16):1-45. Available at http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf. Last accessed September 2, 2009.

CDC, 2002b: CDC Media Relations. Hand Hygiene in Healthcare Settings: CDC releases new hand-hygiene guidelines. Press release. Atlanta (GA): Centers for Disease Control and Prevention; 2002 Oct 25. Available at http://www.cdc.gov/handhygiene/pressrelease.htm. Last accessed October 22, 2009.

Chatzizacharias, 2009: Chatzizacharias NA, Chapple K. Doctors' compliance with hand hygiene guidelines in the surgical ward. Infect Control Hosp Epidemiol 2009 Mar;30(3):308-9.

Cookson, 2009: Cookson B, Mathai E, Allegranzi B, et al. Comparison of national and subnational guidelines for hand hygiene. J Hosp Infect 2009 Jul;72(3):202-10. Epub 2009 May 29.

Creedon, 2008: Creedon SA. Hand hygiene compliance: exploring variations in practice between hospitals. Creedon SA. Nurs Times 2008 Dec 9-15;104(49):32-5.

Day, 2009: Day C. Engaging the nursing workforce: an evidence-based tool kit. Nurs Adm Q 2009 Jul-Sep;33(3):239-44.

Denham, 2008a: Denham CR. A growing national chorus: the 2009 Safe Practices for Better Healthcare. J Patient Saf 2008 Dec;4(4):253-60.

Denham, 2008b: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: Can Reality Meet the Rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: Making Idealized Design a Reality. J Patient Saf 2009 Dec;5(4):210-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Dierks, 2008: Dierks M. Arrowsight Impact (newsletter). Perspective on healthcare: video monitoring saves lives. Mt. Kisco (NY): Arrowsight, Inc.; 2008 Mar. Available at http://www.arrowsight.com/public/as/pdf/Arrowsight_Newsletter_031108.pdf [pg. 6]. Last accessed September 24, 2009.

Duggan, 2008: Duggan JM, Hensley S, Khuder S, et al. Inverse correlation between level of professional education and rate of handwashing compliance in a teaching hospital. Infect Control Hosp Epidemiol 2008 Jun;29(6):534-8. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/588164?cookieSet=1. Last accessed October 14, 2009.

Erasmus, 2009: Erasmus V, Brouwer W, van Beeck EF, et al. A qualitative exploration of reasons for poor hand hygiene among hospital workers: lack of positive role models and of convincing evidence that hand hygiene prevents cross-infection. Infect Control Hosp Epidemiol 2009 May;30(5):415-9.

Eveillard, 2009: Eveillard M, Hitoto H, Raymond F, et al. Measurement and interpretation of hand hygiene compliance rates: importance of monitoring entire care episodes. J Hosp Infect 2009 Jul;72(3):211-7. Epub 2009 May 29.

Grohskopf, 2001: Grohskopf LA, Roth VR, Feikin DR, et al. Serratia liquefaciens bloodstream infections from contamination of epoetin alfa at a hemodialysis center. N Engl J Med. 2001 May 17;344(20):1491-7. Available at

IHI, 2008: [No authors listed.] 5 Million Lives Campaign. Getting Started Kit: Reduce Methicillin-Resistant Staphylococcus aureus (MRSA) Infection: How-to Guide. Cambridge (MA): Institute for Healthcare Improvement; 2008. Available at http://www.ihi.org/nr/rdonlyres/f4d9de7a-3952-4ae7-bbac-4e4222084a03/0/mrsahowtoguide.doc. Last accessed October 30, 2009.

IHI, 2009: [No authors listed.] Hand Hygiene. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=f0e22d9b-e08d-4d96-9f5b-181fe63743d8. Last accessed October 22, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.07.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

Klevens, 2007: Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep. 2007 Mar-Apr;122(2):160-6.

Kohli, 2009: Kohli E, Ptak J, Smith R, et al. Variability in the Hawthorne effect with regard to hand hygiene performance in high- and low-performing inpatient care units. Infect Control Hosp Epidemiol 2009 Mar;30(3):222-5.

Laustsen, 2009: Laustsen S, Lund E, Bibby BM, et al. Cohort study of adherence to correct hand antisepsis before and after performance of clinical procedures. Infect Control Hosp Epidemiol 2009 Feb;30(2):172-8.

Lautenbach, 2001: Lautenbach E. Practices to improve handwashing compliance. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058, Ch. 12. Rockville (MD): Agency for Healthcare Research and Quality; 2001 Jul. Available at http://www.ahrq.gov/clinic/ptsafety/chap12.htm. Last accessed October 22, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 24, 2009.

Magiorakos, 2009: Magiorakos AP, Suetens C, Boyd L, et al. National hand hygiene campaigns in Europe, 2000-2009. Euro Surveill. 2009 Apr 30;14(17). pii: 19190.

McGuckin, 2009: McGuckin M, Waterman R, Govednik J. Hand hygiene compliance rates in the United States – a one-year multicenter collaboration using product/volume usage measurement and feedback. Am J Med Qual 2009 May/June;24(3):205-13.

Mody, 2008: Mody L, Saint S, Kaufman SR, et al. Adoption of alcohol-based handrub by United States hospitals: a national survey. Infect Control Hosp Epidemiol 2008 Dec;29(12): 1177-80. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2666622&blobtype=pdf. Last accessed October 14, 2009.

NHS, 2008: National Health Service, United Kingdom. Clean Your Hands Campaign, 2008. Available at http://www.npsa.nhs.uk/cleanyourhands. Last accessed September 24, 2009.

NNIS, 2004: [No authors listed.] National Nosocomial Infections Surveillance (NNIS) System Report, data summary from January 1992 through June 2004, issued October 2004. Atlanta (GA): National Nosocomial Infections Surveillance (NNIS) System [Division of Healthcare Quality Promotion, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Public Health Service, US Department of Health and Human Services]. Am J Infect Control 2004;32:470-85. Available at http://www.cdc.gov/ncidod/dhqp/pdf/nnis/2004NNISreport.pdf. Last accessed September 24, 2009.

Pepin, 2005: Pepin J, Saheb N, Coulombe MA, et al. Emergence of fluoroquinolones as the predominant risk factor for Clostridium difficile-associated diarrhea: a cohort study during an epidemic in Quebec. Clin Infect Dis 2005 Nov 1;41(9):1254-60. Epub 2005 Sep 20.

Pittet, 1999: Pittet D, Mourouga P, Perneger TV. Compliance with handwashing in a teaching hospital. Ann Intern Med 1999 Jan 19;130(2):126-30. Available at http://www.annals.org/cgi/reprint/130/2/126.pdf. Last accessed September 24, 2009.

Pittet, 2000: Pittet D, Hugonnet S, et al. Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Lancet 2000 Oct 14;356(9238):1307-12.

Sanderson, 1992: Sanderson PJ, Weissler S. Recovery of coliforms from the hands of nurses and patients: activities leading to contamination. J Hosp Infect 1992 Jun;21(2):85-93.

Sanford, 1994: Sanford MD, Widmer AF, Bale MJ, et al. Efficient detection and long-term persistence of the carriage of methicillin-resistant Staphylococcus aureus. Clin Infect Dis 1994 Dec;19(6):1123-8.

Sax, 2007: Sax H, Allegranzi B, Uçkay I, et al. "My five moments for hand hygiene": a user-centred design approach to understand, train, monitor and report hand hygiene. J Hosp Infect 2007 Sep;67(1):9-21. Epub 2007 Aug 27. Review.

Stevenson, 2009: Stevenson RJ, Case TI, Hodgson D, et al. A scale for measuring hygiene behavior: Development, reliability and validity. Am J Infect Control 2009 Apr 9. [Epub ahead of print]

Thomas, 2009: Thomas BW, Berg-Copas GM, Vasquez DG, et al. Conspicuous vs customary location of hand hygiene agent dispensers on alcohol-based hand hygiene product usage in an intensive care unit. J Am Osteopath Assoc 2009 May;109(5):263-7; quiz 280-1. Available at http://www.jaoa.org/cgi/reprint/109/5/263. Last accessed October 11, 2009.

van der Vegt, 2009: van der Vegt DS, Voss A. Are hospitals too clean to trigger good hand hygiene? J Hosp Infect 2009 Jul;72(3):218-20. Epub 2009 May 14.

Vaughan, 2009: Vaughan C. Technology offers real-time monitoring of hand washing. HealthLeaders Media 2009 Jun 9. Available at http://www.healthleadersmedia.com/content/234235/page/2/topic/WS_HLM2_TEC/Technology-Offers-RealTime-Monitoring-of-Hand-Washing.html. Last accessed October 14, 2009.

Whitby, 2007: Whitby M, Pessoa-Silva CL, McLaws ML, et al. Behavioural considerations for hand hygiene practices: the basic building blocks. J Hosp Infect 2007 Jan;65(1):1-8. Epub 2006 Dec 4. Review.

WHO, 2009: [No authors listed.] WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge. Clean Care is Safer Care. Geneva (Switzerland): World Health Organization/Patient Safety: A World Alliance for Safer Health Care; 2009. Available at http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Last accessed October 14, 2009.

SAFE PRACTICE 20: INFLUENZA PREVENTION

The Objective

Prevent person-to-person transmission of influenza through appropriate vaccination.

The Problem

Influenza is a contagious respiratory infection caused by the influenza virus. It is primarily transmitted from person to person via respiratory droplets produced by the infected person. Those at greatest risk for influenza-related complications include individuals older than 65 years [Gavazzi, 2009] or younger than 2 years; residents of nursing homes and other chronic care facilities; and persons of any age who have medical conditions that place them at increased risk for complications from influenza. [Fiore, 2009] Healthcare workers are at an increased risk of acquiring influenza and can transmit the virus to patients or other healthcare professionals. Evidence suggests that 13 to 23 percent of healthcare professionals experience influenza each year. [Ofstead, 2008] However, approximately 64 percent of healthcare workers do not receive annual influenza vaccinations. [APIC, N.D.] Various studies have attempted to estimate the incidence of influenza among healthcare workers. In one cross-sectional survey, 37 percent of healthcare workers reported having influenza or influenza-like illness during one influenza season (September to April). [Lester, 2003] In another study, conducted during 1993-1994, 23.2 percent of healthcare workers had serological evidence of influenza during that influenza season. [Elder, 1996]

The frequency of influenza is variable from year to year, because of seasonal variation in the circulating influenza virus and antigenic drift. Each year, approximately 226,000 people are hospitalized for influenza or its complications. [Greene, 2008] During 1990-1999, influenza-associated pulmonary and circulatory deaths were estimated to be 0.4 to 0.6 per 100,000 persons between 0 and 49 years of age, 7.5 per 100,000 persons between 50 and 64 years of age, and 98.3 per 100,000 persons older than 65 years. [Thompson, 2003]

The severity of the clinical consequences of influenza is high, especially in at-risk patients. Approximately 36,000 people die from influenza or its complications annually. [Thompson, 2003; Thompson, 2004; Smith, 2006] Patients 85 years or older are 100 times more likely to suffer mortality than younger adults (65 years or older). [Gavazzi, 2009] Secondary infection after or co-infection during influenza is a common complication. An increase in *Staphylococcus aureus* (including methicillin-resistant *S. aureus* [MRSA]) infections during and after influenza has been observed and reported by the Centers for Disease Control and Prevention (CDC). Mortality associated with *S. aureus* co-infection in pediatric patients has increased during the preceding four influenza seasons, [Fiore, 2009] with a five-fold increase during the 2006-2007 season. [CDC, 2008]

Preventing influenza outbreaks requires proper immunization and infection control practices. The CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) recommend annual influenza vaccination for all healthcare workers who work at acute care hospitals, nursing homes, skilled nursing facilities, physician's offices, urgent care centers, and outpatient clinics, and to persons who provide home healthcare and emergency medical services. [Pearson, 2006; Gavazzi, 2009] Influenza vaccine was found to be effective in preventing influenza in healthcare workers and in reducing absenteeism and febrile respiratory illness. [Wilde, 1999]

During an outbreak in an institution, chemoprophylaxis with a neuraminidase inhibitor should be offered to residents or patients. [Hota, 2007; Fiore, 2008; Fiore, 2009; WHO, 2009]

Chemoprophylaxis should also be considered for unvaccinated healthcare workers who care for persons at high risk for complications. [Fiore, 2008 Fiore, 2009] Prudent infection control measures, such as limiting contact of ill workers with patients and instituting droplet precautions for patients with confirmed or suspected influenza, are critical in preventing transmission of the influenza virus.

The direct and indirect costs of influenza are significant. Three outbreaks of influenza among Thai healthcare professionals in intensive care units led to costs more than 10 times what it would have cost had they received the influenza vaccine. [Apisarnthanarak, 2008] In 2003, the total direct medical costs of influenza-related illness were estimated to be $10.4 billion in the United States. In one study utilizing a health insurance claims database, the mean direct medical costs of hospitalized, high-risk patients with influenza were calculated to be $41,309 for those ages 50 to 64 years and $16,750 for those older than 64 years (in 2003 dollars). [Molinari, 2007] In a review of pediatric influenza-related hospitalizations during 2000-2004, the mean cost of each hospitalization was $13,159, and the cost of hospitalization for children admitted to intensive care units averaged $39,792. [Keren, 2006]

Safe Practice Statement

Comply with current Centers for Disease Control and Prevention (CDC) recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control. [Pearson, 2006; Fiore, 2008; CDC, 2009b; CDC, 2009c; CMS, 2009; JCR, 2010]

Additional Specifications

- *Healthcare workers* are individuals currently employed in a healthcare occupation or in a healthcare-industry setting who come in direct contact with patients. Healthcare workers with contraindications to immunization or who refuse immunization are exempted.
- Patients who should be immunized are specified by current CDC recommendations.
- Explicit organizational policies and procedures, as well as a robust voluntary healthcare worker and patient influenza immunization program, should be in place. [MMC, 2006]
- Document the immunization status of all employees, subject to collective bargaining, labor law, and privacy law.
- At a minimum, this practice should include all of the following elements: [Pearson, 2006; Fiore, 2008; Fiore, 2009]
  - Implement the CDC Advisory Committee on Immunization Practices annual recommendations for influenza prevention and control.
  - Implement all CDC guidelines with category IA, IB, or IC evidence.
    - Educate healthcare personnel (HCP) on the benefits of influenza vaccination and the potential health consequences of influenza illness for themselves and their patients, the epidemiology and modes of transmission, diagnosis, treatment, and nonvaccine infection control strategies, in accordance with their level of responsibility in preventing healthcare-associated influenza (category IB).

  - Offer influenza vaccine annually to all eligible HCP to protect staff, patients, and family members, and to decrease HCP absenteeism. Use of either available vaccine (inactivated or live, attenuated influenza vaccine [LAIV]) is recommended for eligible persons. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged, when feasible, for eligible HCP (category IA).
  - Provide influenza vaccination to HCP at the work site and at no cost as one component of employee health programs. Use strategies that have been demonstrated to increase influenza vaccine acceptance, including vaccination clinics, mobile carts, vaccination access during all work shifts, and modeling and support by institutional leaders (category IB).
  - Monitor HCP influenza vaccination coverage and declination at regular intervals during the influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration (category IB).
- Encourage compliance with CDC guidelines with category II evidence.
  - Use the level of HCP influenza vaccination coverage as one measure of a patient safety quality program (category II).

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Encourage compliance with CDC guidelines with category II evidence:
  - Obtain a signed declination from HCP who decline influenza vaccination for reasons other than medical contraindications (category II). [Talbot, 2009]
- Consider incorporating influenza vaccination status as part of patients' admission assessment, and develop a hospital-wide process to ensure that eligible patients who have not been vaccinated are offered the opportunity. [AHRQ, 2009a; AHRQ, 2009b; ASHP, 2009]
- Influenza and pneumococcal polysaccharide vaccines are administered according to a physician order, or, as permitted by law and regulation, according to physician-approved, organization-specific protocol(s). [OSHA, 2007]
- Offer influenza vaccine as part of an employee and medical staff wellness program. Reward individuals for compliance as part of the organization's incentives focused on wellness; this could include competitive rewards for areas achieving the highest rates of vaccination. [Anikeeva, 2009]
- Educate healthcare workers and patients about the importance of vaccination as a line of defense in the prevention and spread of influenza. [Ofstead, 2008; ASHP REF, 2009]

Strategies of Progressive Organizations

- Some organizations have developed extensive community outreach programs to identify at-risk patients and offer them options for immunization. Setting the expectation that healthcare workers, in the absence of contraindications, should be immunized

[Polgreen, 2009] and making immunization convenient and accessible to workers (e.g., influenza immunization clinics provided outside the employee cafeteria) have boosted the rate of healthcare worker immunization. [ASHP, 2003; Kaplan, 2009; Primus, 2009]

- High-performing organizations have implemented influenza vaccination requirements for healthcare professionals. [Wicker, 2009]. In 2005, Virginia Mason Medical Center (VMMC) mandated that staff members receive the influenza vaccination or wear a mask for the duration of the flu season. In 2007, staff vaccination rates soared to 98.5 percent, from 55 percent a few years before. However, as a result of VMMC's action, WSNA filed an Unfair Labor Practice with the National Labor Relations Board (NLRB) against the hospital on behalf of the registered nurses who were forced to wear face masks. [US, 2006; VMMC, 2006; Smith, 2007]
- Some organizations have explored increasing the vigilance of environmental cleaning of high-contact surfaces in patient rooms, such as television remote control devices, and operating room equipment and devices, such as pulse oximeters that are shared or used across multiple patients to prevent the spread of infectious diseases.

Opportunities for Patient and Family Involvement [Denham, 2008]

- Educate patient and family members about the importance of influenza vaccinations, addressing common misconceptions about this vaccination "inducing the flu." [HHS, 2006]
- Encourage patient and family members to ask questions about their risk for influenza.
- Consider offering noninjection influenza vaccinations for appropriate patient populations.
- Consider including patients or families of patients who have experienced the influenza infection to serve on appropriate patient safety or performance improvement committees.
- Provide hand sanitizing and respiratory etiquette information for patients, family, and visitors (brochures and posters). [CDC, 2009a]

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Process Measures** include compliance with documentation of patient or healthcare worker acceptance or refusal of influenza immunization, in order to monitor vaccination rates among healthcare workers and vaccine offered to patients.
  - National Quality Forum-endorsed® process measures:
    1. #0149: Influenza Vaccination (Hospital): Percentage of patients discharged during October, November, December, January, or February with pneumonia, age 50 and older, who were screened for influenza vaccine status and were vaccinated prior to discharge, if indicated.

2. #0432: Influenza Vaccination (Nursing Home/Skilled Nursing Facility): Percentage of nursing home/skilled nursing facility residents given the influenza vaccination during the flu season.
3. #0226: Influenza Vaccination in the ESRD (End-Stage Renal Disease) Population – Facilities: Percentage of all ESRD patients aged 18 years and older receiving hemodialysis and peritoneal dialysis during the flu season (October 1 - March 31) who receive an influenza vaccination during the October 1 - March 31 reporting period.
4. #0227: Influenza Immunization: Percentage of patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis who received the influenza immunization during the flu season (September through February).
5. #0431: Influenza Vaccination Coverage among Healthcare Personnel: Percentage of healthcare professionals who receive the influenza vaccination.
6. #0522: Influenza Immunization Received for Current Flu Season: Percent of patients who received influenza immunization for the current flu season from this home health agency.

- **Structure Measures** include rate of vaccination, excluding exempt healthcare workers/medical staff, as a seasonal indicator in the organization's dashboard.
- **Patient-Centered Measures** include surveys of improved patient awareness of immunization options, and the receipt of immunization-related information.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Areas for research in this safe practice include best practices for healthcare worker immunization programs; the role of live attenuated vaccine; and the continued evolution of the identification of patients who are most likely to benefit from immunization. Additionally, research focused on the development of practicable and robust outcome measures, related to the role of vaccination in person-to-person transmission of influenza in the healthcare setting, is needed.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Compliance with Safe Practice 19: Hand Hygiene, along with immunization of patients and healthcare workers, is a solid tactic of an organization's HAI prevention program.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Anikeeva, 2009: Anikeeva O, Braunack-Mayer A, Rogers W. Requiring influenza vaccination for health care workers. Am J Public Health 2009 Jan;99(1):24-9. Epub 2008 Nov 13. Available at http://www.ajph.org/cgi/reprint/99/1/24. Last accessed October 6, 2009.

APIC, N.D.: Association for Professionals in Infection Control and Epidemiology (APIC). Healthcare Worker Role in Infection Prevention: Influenza. Available at http://www.apic.org/AM/Template.cfm?Section=Healthcare_Workers_and_Infection_Prevention&Template=/CM/HTMLDisplay.cfm&ContentID=12448. Last accessed September 24, 2009.

Apisarnthanarak, 2008: Apisarnthanarak A, Puthavathana P, Kitphati R, et al. Outbreaks of influenza A among nonvaccinated healthcare workers: implications for resource-limited settings. Infect Control Hosp Epidemiol 2008 Aug;29(8):777-80. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/588162. Last accessed October 6, 2009.

ASHP REF, 2009: ASHP Research and Education Foundation. Pandemic Influenza Assessment Tool for Health-System Pharmacy Departments™ and Planning Resources. Bethesda (MD): ASHP Research and Education Foundation; 2009. Available at http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/PandemicInfluenzaAssessmentToolforHealthSystemPharmacyDepartments.aspx. Last accessed October 22, 2009.

ASHP, 2003: American Society of Health-System Pharmacists. ASHP guidelines on the pharmacist's role in immunization. Am J Health-Syst Pharm 2003;60:1371–7. Available at http://www.ashp.org/s_ashp/docs/files/BP07/Specific_Gdl_Immun.pdf. Last accessed October 6, 2009.

ASHP, 2009: [No authors listed.] Stop the flu – it starts with you! Pharmacists as Advocates for Immunizing Health Care Workers against Influenza. ASHP Resource Center. Bethesda (MD): American Society of Health-System Pharmacists (ASHP); 2009. Available at http://www.youcanstoptheflu.com/index.html. Last accessed October 22, 2009.

CDC, 2008: Centers for Disease Control and Prevention. Health Advisory: Influenza-Associated Pediatric Mortality and Staphylococcus aureus co-infection. Issued January 30, 2008. Available at http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00268. Last accessed September 24, 2009.

CDC, 2009a: [No authors listed.] Seasonal Influenza (Flu): Free Resources. Atlanta (GA): Centers for Disease Control and Prevention; 2009 Jul 1. Available at http://www.cdc.gov/flu/freeresources/index.htm. Last accessed October 22, 2009.

CDC, 2009b: [No authors listed.] Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season. Atlanta (GA): Centers for Disease Control and Prevention; 2009 Oct 16. Available at http://www.cdc.gov/h1n1flu/recommendations.htm. Last accessed October 22, 2009.

CDC, 2009c: Centers for Disease Control and Prevention. 2009-2010 Flu Season. Recommendations. Available at http://www.cdc.gov/flu/about/season/index.htm. Last accessed October 12, 2009.

CMS, 2009: [No authors listed.] CMS Initiatives on prevention of influenza. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2009 Aug 31. Available at http://www.cms.hhs.gov/AdultImmunizations/05_CMSInitiatives.asp. Last accessed October 22, 2009.

Denham, 2008: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Elder, 1996: Elder AG, O'Donnell B, McCruden EA, et al. Incidence and recall of influenza in a cohort of Glasgow healthcare workers during the 1993-4 epidemic: results of serum testing and questionnaire. BMJ 1996 Nov 16;313(7067):1241-2. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2352563&blobtype=pdf. Last accessed September 24, 2009.

Fiore, 2008: Fiore AE, Shay DK, Broder K, et al. Advisory Committee on Immunization Practices. Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2008 Aug 8;57(RR-7):1-60. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm. Last accessed September 24, 2009.

Fiore, 2009: Fiore A, Shay D, Broder K, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Issued July 31, 2009. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm. Last accessed October 5, 2009.

Gavazzi, 2009: Gavazzi G. Influenza vaccination for healthcare workers: from a simple concept to a resistant issue? Aging Clin Exp Res 2009 Jun;21(3):216-21.

Greene, 2008: Greene LR, Cain TA, Dolan SA, et al. APIC Position Paper: Influenza Immunization of Healthcare Personnel. 2008 APIC Public Policy Committee. 2008 Nov 7. Available at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf. Last accessed September 2, 2009.

HHS, 2006: [No authors listed.] Flu.gov: A family guide to preventing flu. Washington, DC: U.S. Department of Health and Human Services; 2006 May. Available at http://www.flu.gov/individualfamily/familyguide.html. Last accessed October 22, 2009.

Hota, 2007: Hota S, McGeer A. Antivirals and the control of influenza outbreaks. Clin Infect Dis 2007 Nov 15;45(10):1362-8. Epub 2007 Oct 11.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goals. Oak Brook (IL): Joint Commission Resources; 2010.

Kaplan, 2009: Kaplan S, Bisgaard S, Truesdell D, et al. Design for Six Sigma in healthcare: developing an employee influenza vaccination process. J Healthc Qual 2009 May-Jun;31(3):36-43.

Keren, 2006: Keren R, Zaoutis TE, Saddlemire S, et al. Direct medical cost of influenza-related hospitalizations in children. Pediatrics 2006 Nov;118(5):e1321-7.

Lester, 2003: Lester RT, McGeer A, Tomlinson G, et al. Use of, effectiveness of, and attitudes regarding influenza vaccine among house staff. Infect Control Hosp Epidemiol 2003 Nov;24(11):839-44.

MMC, 2006: Maine Medical Center (Portland). Improvement Report: An Institutional Strategy for Inpatient Immunization. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2006. Available at http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/ImprovementStories/AnInstitutionalStrategyforInpatientImmunization.htm. Last accessed October 22, 2009.

Molinari, 2007: Molinari NA, Ortega-Sanchez IR, Messonnier ML, et al. The annual impact of seasonal influenza in the US: measuring disease burden and costs. Vaccine 2007 Jun 28;25(27):5086-96. Epub 2007 Apr 20.

Ofstead, 2008: Ofstead CL, Tucker SJ, Beebe TJ, et al. Influenza vaccination among registered nurses: information receipt, knowledge, and decision-making at an institution with a multifaceted educational program. Infect Control Hosp Epidemiol 2008 Feb;29(2):99-106. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/526431. Last accessed November 2, 2009.

OSHA, 2007: Occupational Safety and Health Administration. Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers. OSHA Document 33328-05, 2007. Accessed at http://www.osha.gov/Publications/OSHA_pandemic_health.pdf. Last accessed September 24, 2009.

Pearson, 2006: Pearson ML, Bridges CB, Harper SA; Advisory Committee on Immunization Practices. Influenza Vaccination of Health-care Personnel. Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2006 Feb 24;55(RR-2):1-16. Erratum in: MMWR Recomm Rep 2006 Mar 10;55(9):252. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm. Last accessed September 24, 2009.

Polgreen, 2009: Polgreen PM, Polgreen LA, Evans T, et al. A statewide system for improving influenza vaccination rates in hospital employees. Infect Control Hosp Epidemiol 2009 May;30(5):474-8.

Primus, 2009: Primus L. Improving influenza vaccination to health care workers. Am J Infect Control 2009 Jun;37(5):430-1.

Smith, 2006: Smith N, Bresee J, Shay D, et al; Advisory Committee on Immunization Practices. Prevention and control of influenza. recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2006 Jul 28;55 (RR-10):1-42.

Smith, 2007: Smith S. For the Sake of Patients, Doctors Need Flu Shots. October 8, 2007. Available at http://www.boston.com/yourlife/health/articles/2007/10/08/for_the_sake_of_patients_doctors_need_flu_shots/. Last accessed September 24, 2009.

Talbot, 2009: Talbot TR. Do declination statements increase health care worker influenza vaccination rates? Clin Infect Dis 2009 Sep 1;49(5):773-9.

Thompson, 2003: Thompson WW, Shay DK, Weintraub E, et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003 Jan 8;289(2):179-86. Available at http://jama.ama-assn.org/cgi/content/full/289/2/179. Last accessed September 24, 2009.

Thompson, 2004: Thompson WW, Shay DK, Weintraub E, et al. Influenza-associated hospitalizations in the United States. JAMA 2004 Sep 15;292(11):1333-40.

US, 2006: U.S. Court of Appeals 0635073. Virginia Mason Hosp. v. Washington State Nurses 16585. 2006. Summer 2006. Available at http://caselaw.findlaw.com/data2/circs/9th/0635073P.pdf. Last accessed September 24, 2009.

VMMC, 2006: [No authors listed.] Nurses Prevail: The Ongoing Saga at Virginia Mason Medical Center. The Washington Nurse 2006 Summer:36(1);19-21. Available at http://www.wsna.org/washingtonnurse/PDFS/WaNurse-2.pdf. Last accessed September 24, 2009.

WHO, 2009: [No authors listed.] Global Alert and Response (GAR). WHO Guidelines for Pharmacological Management of Pandemic (H1N1) 2009 Influenza and other Influenza Viruses. Geneva (Switzerland): World Health Organization (WHO); 2009 Aug 20. Available at http://www.who.int/csr/resources/publications/swineflu/h1n1_use_antivirals_20090820/en/index.html. Last accessed October 22, 2009.

Wicker, 2009: Wicker S. Unvaccinated health care workers must wear masks during flu season – a possibility to improve influenza vaccination rates? Vaccine 2009 May 5;27(20):2631-2. Epub 2009 Feb 13.

Wilde, 1999: Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in health care professionals: a randomized trial. JAMA 1999 Mar 10;281(10):908-13. Available at http://jama.ama-assn.org/cgi/content/full/281/10/908. Last accessed September 24, 2009.

SAFE PRACTICE 21: CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTION PREVENTION

The Objective

Prevent central line-associated bloodstream infections (CLABSIs).

The Problem

It is estimated that nearly 2 million patients experience a healthcare-associated infection (HAI) each year; of these, 14 percent are bloodstream infections. [Klevens, 2007] Central venous catheters (CVCs), including peripherally inserted central catheters, are being used with increased frequency to provide long-term venous access to patients who need extended or repeated infusion therapy. [AHRQ, 2009a] While these lines are essential and appropriate for many patients, they increase the risk for infection by disrupting skin integrity. [McKibben, 2005] CLABSIs are bloodstream infections that occur in patients with CVCs when other sources of infection have been excluded. From 2004 to 2006, the percentage of CVC placements resulting in CLABSIs and mechanical adverse events increased significantly. [AHRQ, 2009b] Migration of skin organisms at the insertion site into the cutaneous catheter tract with colonization of the catheter tip is the most common route of infection for peripherally inserted, short-term catheters. Contamination of the catheter hub can contribute to intraluminal colonization of long-term catheters. Occasionally, catheters might become hematogenously seeded from another focus of infection.

The frequency of CLABSIs has been estimated to be 5.3 infections per 1,000 catheter days in intensive care units (ICUs). At least 48 percent of ICU patients have CVCs, accounting for about 15 million CVC-days per year in ICUs alone. [Pronovost, 2006] Therefore, an estimated 79,500 CLABSIs occur each year in U.S. ICUs. Approximately 90 percent of catheter-associated bloodstream infections occur with CVCs. [Mermel, 2000] Historically, ICU patients were considered to be at highest risk for CLABSIs. [Maki, 2006] However, recent data reveal that CVCs are increasingly used outside the ICUs, putting more patients at risk for CLABSIs. [Vonberg, 2006; Marschall, 2007]

The severity of CLABSIs varies; up to 35 percent mortality has been associated with CLABSIs. [Dimick, 2001; Levinson, 2008; Pittet, 1994; Renaud, 2001] Bloodstream infections may spread, resulting in hemodynamic changes, organ dysfunction, and, ultimately, sepsis. [Mermel, 2000] Studies report approximately 14,000 to 28,000 deaths each year occur due to CLABSIs. [Pittet, 1994; Berenholtz, 2004] An excess length of ICU stay of about eight days was associated with CLABSIs. [Pittet, 1994]

To prevent and reduce the incidence of CLABSIs, a comprehensive, multifaceted approach should be employed. [Marschall, 2008a] Healthcare personnel should be educated on the proper insertion, care, and maintenance of CVCs and on CLABSI prevention before they perform the insertion. [Marschall, 2008a; Zingg, 2009] An all-inclusive cart or kit, available at point of care, and a checklist should be employed at the time of insertion. [Berenholtz, 2004; Tsuchida, 2007] Femoral veins should be avoided in adults, because venipuncture in those veins is associated with greater risk of infection and deep venous thrombosis in adults. [Goetz, 1998; Merrer, 2001; Gowardman, 2008; Ishizuka, 2009] Maximal sterile barriers

should be used during CVC insertion. Skin should be prepared using a chlorhexidine-based antiseptic, which should be allowed to dry before line insertion, in patients older than two months of age. [Maki, 1991; Raad, 1994; Humar, 2000; Hu, 2004; Marschall, 2008a] After insertion, transparent dressings should be changed and site care should be performed with a chlorhexidine-based antiseptic every five to seven days, or more frequently if the dressing is soiled, loose, or damp for nontunneled CVCs in adults and adolescents. Gauze dressings should be changed every two days or more frequently as necessary. [Maki, 1994; Rasero, 2000; Marschall, 2008] For patients undergoing hemodialysis with a history of recurrent *Staphylococcus aureus* CLABSIs, use antimicrobial ointment such as povidone-iodine or polysporin at the hemodialysis catheter site. [Levin, 1991; Lok, 2003] Administration sets not used for blood, blood products, or lipids should be replaced at least every 96 hours. [Gillies, 2005] Ultimately, the risk of CLABSIs can be minimized by removing catheters when they are no longer necessary. The continued need for central vascular access should be assessed daily. [Lederle, 1992; Marschall, 2008a; Marschall, 2008b]

The total direct financial cost of CLABSIs in the United States is estimated to be more than $9 billion annually. [Stone, 2005; Klevens, 2007] The excess direct hospitalization costs of CLABSIs, documented in various studies, range from $12,000 to $56,000 per incident. [Dimick, 2001; Digiovine, 1999; Pittet, 1994; Warren, 2006] Using the consumer price index for inpatient hospital services, the aggregate attributable hospital costs due to CLABSI range from $7,288 to $29,156 in 2007 dollars. [Scott, 2009] While the direct medical costs documented in these studies vary, researchers consistently found longer length of hospitali-zation and ICU stay in patients with CLABSIs; and three of the studies demonstrated an association between CLABSIs and significantly higher mortality rates. CMS has selected vascular catheter-associated infections as a hospital-acquired condition that will no longer receive a higher reimbursement when not present on admission, beginning October 1, 2008. [CMS/HAC, 2008]

There is intense research of healthcare-associated infections (HAIs), and it will take time to understand the absolute magnitude of preventability and value of risk assessment methods; however, there is full consensus that actions need to be taken now to reduce CLABSIs with what is currently known. [Denham, 2005: Denham, 2009d] Traditional infection control programs are directionally correct but insufficient to enable organizations to "chase zero" and reduce the harm of preventable HAIs. [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c]

Safe Practice Statement

Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices. [O'Grady, 2002; Marschall, 2008a; IHI, 2009; Mermel, 2009; JCR, 2010]

Additional Specifications

Before insertion:

- Educate healthcare personnel involved in the insertion, care, and maintenance of central venous catheters (CVCs) about central line-associated bloodstream infection (CLABSI) prevention. [Sherertz, 2000; Eggimann, 2000; Coopersmith, 2002; Warren, 2003; VMMC, 2004; Warren, 2004; Marschall, 2008a; TMIT, 2008b]

At insertion:

- Use a catheter checklist to ensure adherence with infection prevention practices at the time of CVC insertion. [Berenholtz, 2004; Tsuchida, 2007]
- Perform hand hygiene prior to catheter insertion or manipulation. [Boyce, 2002; Rosenthal, 2005; Yilmaz, 2007; Smith, 2008; OSHA, N.D.]
- Avoid using the femoral vein for central venous access in adult patients. [Goetz, 1998; Merrer, 2001] (Subclavian or internal jugular are the preferred sites, unless contraindicated.)
- Make available and easily accessible for use a catheter cart or kit that contains all necessary components for aseptic catheter insertion. [Berenholtz, 2004]
- Use maximal sterile barrier precautions during CVC insertion to include a mask, cap, sterile gown, and sterile gloves worn by all healthcare personnel involved in the procedure. The patient is to be covered with a large sterile drape during catheter insertion. [Mermel, 1991; Raad, 1994; Hu, 2004; Young, 2006; Smith, 2008]
- Use chlorhexidine gluconate 2% and isopropyl alcohol solution as skin antiseptic preparation in patients more than two months of age and allow appropriate drying time per product guidelines. [Maki, 1991; Garland, 1995; Humar, 2000; O'Grady, 2002; Chaiyakunapruk, 2002; Darouiche, 2008; Pronovost, 2008; Ruschulte, 2009; Smith, 2008; Darouiche, 2010]

After insertion:

- Use a standardized protocol to disinfect catheter hubs, needleless connectors, and injection ports before accessing the ports. [Salzman, 1993; Luebke, 1998; Casey, 2003; Shapey, 2009]
- Remove nonessential catheters. [Lederle, 1992; Parenti, 1994; Garnacho-Montero, 2008]
- Use a standardized protocol for nontunneled CVCs in adults and adolescents for dressing care, such as changing transparent dressings and performing site care with a chlorhexidine-based antiseptic every five to seven days, or earlier if the dressing is soiled, loose, or damp; change gauze dressings every two days, or earlier if the dressing is soiled, loose, or damp. [Maki, 1994; Rasero, 2000; Ruschulte, 2009]
- Perform surveillance for CLABSI and report the data on a regular basis to the units, physician and nursing leadership, and hospital administrators overseeing the units. [Marschall, 2008a; Marschall, 2008b; Rosenthal, 2008]

Pediatric Specificity: Chlorhexidine may be contraindicated for use in very low birth-weight (VLBW) infants. Optimal catheter site selection is specific to the size and condition of the infant or child and accessibility factors.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Empower clinical staff to stop the insertion procedure if protocol elements are not followed, and to resume only when corrective action has been taken.

- Replace administrative sets not used for blood, blood products, or lipids at intervals no longer than 96 hours. [Gillies, 2005; Labeau, 2009]
- Perform a CLABSI risk assessment, and consider special approaches for use in locations and/or populations within the organization with unacceptably high CLABSI rates, despite implementation of the basic CLABSI prevention strategies. [Bonello, 2008]
  - Bathe ICU patients over two months of age daily with a chlorhexidine preparation. [Bleasdale, 2007]
- Consider use of antiseptic- or antimicrobial-impregnated CVCs in defined adult populations. [Maki, 1997; Raad, 1997; Darouiche, 1999; Veenstra, 1999; Hanna, 2003; McConnell, 2003; Hanna, 2004; Rupp, 2005; Halton, 2009]
- Use chlorhexidine-containing sponge dressings for CVCs in patients older than two months of age. [Garland, 2001; Levy, 2005; Ho, 2006]
- Use antimicrobial locks for CVCs. [Carratalà, 1999; Henrickson, 2000; Safdar, 2006; Labriola, 2007]
- Use antimicrobial ointments for hemodialysis catheter insertion sites. [Levin, 1991; Zakrzewska, 1995; Riu, 1998; Lok, 2003; Fong, 1993]
- Disinfection of needleless access ports is important to the maintenance of central lines. Scrubbing the port hub for 15 seconds with alcohol alone or with chlorhexidine/alcohol combinations have been shown to be effective for disinfection. [Kaler, 2007] For example, certain organizations have created a "scrub the hub" awareness campaign to improve compliance.

Strategies of Progressive Organizations

- Empower clinical staff to "stop the line" to make sure that the practice is followed for every patient.

Opportunities for Patient and Family Involvement [Denham, 2008; SHEA, N.D.]

- Teach patients and families the proper care of the CVC, as well as precautions for preventing infection.
- Teach patients and families to recognize signs and symptoms of infection.
- Encourage patients to report changes in their catheter site or any new discomfort.
- Encourage patients and family members to make sure that doctors and nurses check the line every day for signs of infection.
- Invite patients to ask staff if they have washed their hands prior to treatment, if culturally appropriate.
- Encourage patients and family members to ask questions before a central line is placed.
- Consider including patients or families of patients who have experienced a CLABSI to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include trending the rate of CLABSI over time and report as part of a multicenter registry, for example, the

National Healthcare Safety Network (NHSN), as well as the operational and financial outcomes associated with reduction in sepsis. [Marschall, 2008b]

- National Quality Forum (NQF)-endorsed® outcome measure:
  1. #0139: Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients: Percentage of ICU and high-risk nursery patients, who over a certain amount of days acquired a central line catheter-associated blood stream infections over a specified amount of line-days.

- **Process Measures** include periodic assessment of compliance with all components of the prevention bundle, with actions to mitigate performance gaps.
- Compliance with documentation of daily assessment of the need for continuing CVC access. Measure the percentage of patients with a CVC where there is documentation of daily assessment.
- Compliance with cleaning of catheter hubs and injection ports before they are accessed. Assess compliance through observations of practice. [Bezzio, 2009; Buchman, 2009; Franzetti, 2009]
- Compliance with avoiding the femoral site for CVC insertion in adult patients. Perform point prevalence surveys or utilize information collected as part of the central line insertion checklist to determine the percentage of patients whose CVCs are in the femoral vein vs. in the subclavian or internal jugular vein.
  - NQF-endorsed process measure:
    1. #0298: Central Line Bundle Compliance [Hospital]: Percentage of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place. The central line bundle elements include: Hand hygiene; maximal barrier precautions upon insertion; chlorhexidine skin antisepsis; optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters in patients 18 years and older; daily review of line necessity with prompt removal of unnecessary lines.
    2. #0464: Anesthesiology and Critical Care: Prevention of Catheter-Related Bloodstream Infections (CRBSI) [Hospital, Other] – Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique (cap, mask, sterile gown, sterile gloves, a large sterile sheet, hand hygiene, and 2% chlorhexidine for cutaneous antisepsis) followed.
- **Structure Measures** include the identification, stratification, and trending of specific risk factors of patients who have developed central venous line bloodstream infections to determine the success of mitigation strategies and reporting the CLABSI rate to senior leadership and clinical staff.
- **Patient-Centered Measures** include surveying patients about organization staff adherence to hand hygiene upon entering the patient area and surveying patients about education on infection prevention strategies associated with CVCs. [Worth, 2009]

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural settings where central venous catheters are used.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings where central venous catheters are used. (See the additional specifications section for details.)
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty settings where central venous catheters are used.

New Horizons and Areas for Research

Research in this area needs to continue until this patient safety problem has been eliminated. Explore the optimal use of antimicrobial/coated catheters [Casey, 2008; Hagau, 2009; Halton, 2009; Smith, 2008] and the impact of specific CVC insertion teams, nurse-to-patient ratio, and the use of float nurses in the ICU on the reduction of CLABSIs. [Marschall, 2008a; Bezzio, 2009] Furthermore, examining the optimal place for catheter insertion and strategies for estimating catheter days for determining incidence density of CLABSIs should be considered. [Gowardman, 2008] Some organizations have explored increasing the vigilance of environmental cleaning of high-contact surfaces in patient rooms, such as television remote control devices, and operating room equipment and devices, such as pulse oximeters, that are shared or used across multiple patients.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Prevention of HAIs, in compliance with Safe Practice 19: Hand Hygiene, is critical to the success of this safe practice.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Berenholtz, 2004: Berenholtz SM, Pronovost PF, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. Crit Care Med 2004 Oct;32(10):2014-20.

Bezzio, 2009: Bezzio S, Scolfaro C, Broglia R, et al. Prospective incidence study of bloodstream infection in infants and children with central venous catheters after cardiac surgery in Italy. Infect Control Hosp Epidemiol 2009 Jul;30(7):698-701.

Bleasdale, 2007: Bleasdale SC, Trick WE, Gonzales IM, et al. Effectiveness of chlorhexidine bathing to reduce catheter-associated bloodstream infections in medical intensive care unit patients. Arch Intern Med 2007 Oct 22;167(19):2073-9. Available at http://archinte.ama-assn.org/cgi/content/full/167/19/2073. Last accessed September 24, 2009.

Bonello, 2008: Bonello RS, Fletcher CE, Becker WK, et al. An intensive care unit quality improvement collaborative in nine Department of Veterans Affairs hospitals: reducing ventilator-associated pneumonia and catheter-related bloodstream infection rates. Jt Comm J Qual Patient Saf 2008 Nov;34(11):639-45.

Boyce, 2002: Boyce JM, Pittet D; Healthcare Infection Control Practices Advisory Committee. Guideline for hand hygiene in health-care settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Society for Healthcare Epidemiology of America/Association for Professionals in Infection Control/Infectious Diseases Society of America. MMWR Recomm Rep 2002 Oct 25;51(RR-16):1-45, quiz CE1-4.

Buchman, 2009: Buchman AL, Spapperi J, Leopold P. A new central venous catheter cap: decreased microbial growth and risk for catheter-related bloodstream infection. J Vasc Access 2009 Jan-Mar;10(1):11-21.

Carratalà , 1999: Carratalà J, Niubo J, Fernandez-Sevilla A, et al. Randomized, double-blind trial of an antibiotic-lock technique for prevention of gram-positive central venous catheter-related infection in neutropenic patients with cancer. Antimicrob Agents Chemother 1999 Sep;43(9):2200-4. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=10471564. Last accessed September 24, 2009.

Casey, 2003: Casey AL, Worthington T, Lambert PA, et al. A randomized, prospective clinical trial to assess the potential infection risk associated with the PosiFlow needleless connector. J Hosp Infect 2003 Aug;54(4):288-93.

Casey, 2008: Casey AL, Mermel LA, Nightingale P, et al. Antimicrobial central venous catheters in adults: a systematic review and meta-analysis. Lancet Infect Dis 2008 Dec;8(12):763-76. Review.

Chaiyakunapruk, 2002: Chaiyakunapruk N, Veenstra DL, Lipsky BA, et al. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site care: a meta-analysis. Ann Intern Med 2002 Jun 4;136(11):792-801. Available at http://www.annals.org/cgi/reprint/136/11/792.pdf. Last accessed September 24 2009.

CMS/HAC, 2008: Centers for Medicare & Medicaid Services. Hospital-acquired conditions (Present on Admission Indicator). Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed October 30, 2009.

Coopersmith, 2002: Coopersmith CM, Rebmann TL, Zack JE, et al. Effect of an education program on decreasing catheter-related bloodstream infections in the surgical intensive care unit. Crit Care Med 2002 Jan;30(1):59-64.

Darouiche, 1999: Darouiche RO, Raad II, Heard SO, et al. A comparison of two antimicrobial-impregnated central venous catheters: Catheter Study Group. N Engl J Med 1999 Jan 7;340(1):1-8. Available at http://content.nejm.org/cgi/content/full/340/1/1. Last accessed October 30, 2009.

Darouiche, 2008: Darouiche R, Wall M, Itani K, et al. A comparison of two antiseptic preparations for prevention of surgical site infections. Abstract #K-601a. Washington, DC: The 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the 46th Annual Meeting of the Infectious Disease Society of America (IDSA); 2008.

Darouiche, 2010: Darouiche RO, Wall MJ, Itani KMF, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. N Engl J Med 2010 Jan 7;362(1):18-26.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2008: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: can reality meet the rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4):210-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Denham, 2009d: Denham CR. Are you infected? J Patient Saf 2009 Sep;5(3):188-96.

Digiovine, 1999: Digiovine B, Chenoweth C, Watts C, et al. The attributable mortality and costs of primary nosocomial bloodstream infections in the intensive care unit. Am J Respir Crit Care Med 1999 Sep;160(3):976-81.

Dimick, 2001: Dimick JB, Pelz RK, Consunji R, et al. Increased resource use associated with catheter-related bloodstream infection in the surgical intensive care unit. Arch Surg 2001 Feb;136(2):229-34.

Eggimann, 2000: Eggimann P, Harbarth S, Constantin MN, et al. Impact of a prevention strategy targeted at vascular-access care on incidence of infections acquired in intensive care. Lancet 2000 May 27;355(9218):1864-8.

Fong, 1993: Fong IW. Prevention of haemodialysis and peritoneal dialysis catheter related infection by topical povidone-iodine. Postgrad Med J 1993;69 Suppl 3:S15-7.

Franzetti, 2009: Franzetti F, Borghi B, Raimondi F, et al. Impact on rates and time to first central vascular-associated bloodstream infection when switching from open to closed intravenous infusion containers in a hospital setting. Epidemiol Infect 2009 Jul;137(7):1041-8. Epub 2009 Jan 15.

Garland, 1995: Garland JS, Buck RK, Maloney P, et al. Comparison of 10% povidone-iodine and 0.5% chlorhexidine gluconate for the prevention of peripheral intravenous catheter colonization in neonates: a prospective trial. Pediatr Infect Dis J 1995 Jun;14(6):510-6.

Garland, 2001: Garland JS, Alex CP, Mueller CD, et al. A randomized trial comparing povidone-iodine to a chlorhexidine gluconate-impregnated dressing for prevention of central venous catheter infections in neonates. Pediatrics 2001 Jun;107(6):1431-6. Available at http://pediatrics.aappublications.org/cgi/content/full/107/6/1431. Last accesssed September 24, 2009.

Garnacho-Montero, 2008: Garnacho-Montero J, Aldabó-Pallás T, Palomar-Martínez M, et al. Risk factors and prognosis of catheter-related bloodstream infection in critically ill patients: a multicenter study. Intensive Care Med 2008 Dec;34(12):2185-93. Epub 2008 Jul 12.

Gillies, 2005: Gillies D, O'Riordan L, Wallen M, et al. Optimal timing for intravenous administration set replacement. Cochrane Database Syst Rev 2005 Oct 19;(4):CD003588.

Goetz, 1998: Goetz AM, Wagener MM, Miller JM, et al. Risk of infection due to central venous catheters: effect of site of placement and catheter type. Infect Control Hosp Epidemiol 1998 Nov;19(11):842-5.

Gowardman, 2008: Gowardman JR, Robertson IK, Parkes S, et al. Influence of insertion site on central venous catheter colonization and bloodstream infection rates. Intensive Care Med 2008 Jun;34(6):1038-45. Epub 2008 Mar 4.

Hagau, 2009: Hagau N, Studnicska D, Gavrus RL, et al. Central venous catheter colonization and catheter-related bloodstream infections in critically ill patients: a comparison between standard and silver-integrated catheters. Eur J Anaesthesiol 2009 Apr 20. [Epub ahead of print]

Halton, 2009: Halton KA, Cook DA, Whitby M, et al. Cost effectiveness of antimicrobial catheters in the intensive care unit: addressing uncertainty in the decision. Crit Care 2009;13(2): R35. Epub 2009 Mar 11. Available at http://ccforum.com/content/pdf/cc7744.pdf. Last accessed July 21, 2009.

Hanna, 2003: Hanna HA, Raad II, Hackett B, et al.; M.D. Anderson Catheter Study Group. Antibiotic-impregnated catheters associated with significant decrease in nosocomial and multidrug-resistant bacteremias in critically ill patients. Chest 2003 Sep;124(3):1030-8.

Hanna, 2004: Hanna H, Benjamin R, Chatzinikolaou I, et al. Long-term silicone central venous catheters impregnated with minocycline and rifampin decrease rates of catheter-related bloodstream infection in cancer patients: a prospective randomized clinical trial. J Clin Oncol 2004 Aug 1;22(15):3163-71.

Henrickson, 2000: Henrickson KJ, Axtell RA, Hoover SM, et al. Prevention of central venous catheter-related infections and thrombotic events in immunocompromised children by the use of vancomycin/ciprofloxacin/heparin flush solution: a randomized, multicenter, double-blind trial. J Clin Oncol 2000 Mar;18(6):1269-78.

Ho, 2006: Ho KM, Litton E. Use of chlorhexidine-impregnated dressing to prevent vascular and epidural catheter colonization and infection: a meta-analysis. J Antimicrob Chemother 2006 Aug;58(2):281-7. Epub 2006 Jun 6. Available at http://jac.oxfordjournals.org/cgi/reprint/58/2/281. Last accessed September 24, 2009.

Hu, 2004: Hu KK, Lipsky BA, Veenstra DL, et al. Using maximal sterile barriers to prevent central venous catheter-related infection: a systematic evidence-based review. Am J Infect Control 2004 May;32(3):142-6.

Humar, 2000: Humar A, Ostromecki A, Direnfeld J, et al. Prospective randomized trial of 10% povidone-iodine versus 0.5% tincture of chlorhexidine as cutaneous antisepsis for prevention of central venous catheter infection. Clin Infect Dis 2000 Oct;31(4):1001-7. Epub 2000 Oct 25.

IHI, 2009: [No authors listed.] Central Line Bundle. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=e876565d-fd43-42ce-8340-8643b7e675c7. Last accessed October 26, 2009.

Ishizuka, 2009: Ishizuka M, Nagata H, Takagi K, et al. Femoral venous catheterization is a major risk factor for central venous catheter-related bloodstream infection. J Invest Surg 2009 Jan-Feb;22(1):16-21.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.07.04.01. Oak Brook (IL): Joint Commission Resources; 2010.

Kaler, 2007: Kaler W, Chinn R. Successful disinfection of needleless access ports: a matter of time and friction. Journal of the Association for Vascular Access 2007;12(3);140.

Klevens, 2007: Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep 2007 Mar-Apr;122(2): 160-6.

Labeau, 2009: Labeau S, Vandijck D, Lizy C, et al. Replacement of administration sets used to administer blood, blood products, or lipid emulsions for the prevention of central line-associated bloodstream infection. Infect Control Hosp Epidemiol 2009 May;30(5):494.

Labriola, 2007: Labriola L, Crott R, Jadoul M. Preventing haemodialysis catheter-related bacteraemia with an antimicrobial lock solution: a meta-analysis of prospective randomized trials. Nephrol Dial Transplant 2008 May;23(5):1666-72. Epub 2007 Dec 8.

Lederle, 1992: Lederle FA, Parenti CM, Berskow LC, et al. The idle intravenous catheter. Ann Intern Med 1992 May 1;116(9):737-8.

Levin, 1991: Levin A, Mason AJ, Jindal KK, et al. Prevention of hemodialysis subclavian vein catheter infections by topical povidone-iodine. Kidney Int 1991 Nov;40(5):934-8.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 24, 2009.

Levy, 2005: Levy I, Katz J, Solter E, et al. Chlorhexidine-impregnated dressing for prevention of colonization of central venous catheters in infants and children: a randomized controlled study. Pediatr Infect Dis J 2005 Aug;24(8):676-9.

Lok, 2003: Lok CE, Stanley KE, Hux JE, et al. Hemodialysis infection prevention with polysporin ointment. J Am Soc Nephrol 2003 Jan;14(1):169-79. Available at http://jasn.asnjournals.org/cgi/content/full/14/1/169. Last accessed September 24, 2009.

Luebke, 1998: Luebke MA, Arduino MJ, Duda DL, et al. Comparison of the microbial barrier properties of a needleless and a conventional needle-based intravenous access system. Am J Infect Control 1998 Aug;26(4):437-41.

Maki, 1991: Maki DG, Ringer M, Alvarado CJ. Prospective randomised trial of povidone-iodine, alcohol, and chlorhexidine for prevention of infection associated with central venous and arterial catheters. Lancet 1991 Aug 10;338(8763):339-43.

Maki, 1994: Maki DG, Stolz SS, Wheeler S, et al. A prospective, randomized trial of gauze and two polyurethane dressings for site care of pulmonary artery catheters: implications for catheter management. Crit Care Med 1994;22:1729-37.

Maki, 1997: Maki DG, Stolz SM, Wheeler S, et al. Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter. A randomized, controlled trial. Ann Intern Med 1997 Aug 15;127(4):257-66.

Maki, 2006: Maki DG, Kluger DM, Crnich CJ. The risk of bloodstream infection in adults with different intravascular devices: a systematic review of 200 published prospective studies. Mayo Clin Proc 2006 Sep;81(9):1159-71.

Marschall, 2007: Marschall J, Leone C, Jones M, et al. Catheter-associated bloodstream infections in general medical patients outside the intensive care unit: a surveillance study. Infect Control Hosp Epidemiol 2007 Aug;28(8):905-9. Epub 2007 Jun 27.

Marschall, 2008a: Marschall J, Mermel LA, Classen D, et al. Strategies to prevent central line-associated bloodstream infections in acute care hospitals. Infect Control Hosp Epidemiol 2008 Oct;29 Suppl 1:S22-30. Available at http://www.journals.uchicago.edu/doi/full/10.1086/591059. Last accessed November 17, 2009.

Marschall, 2008b: Marschall J. Catheter-associated bloodstream infections: looking outside of the ICU. Am J Infect Control 2008 Dec;36(10):S172.e5-8.

McConnell, 2003: McConnell SA, Gubbins PO, Anaissie EJ. Do antimicrobial-impregnated central venous catheters prevent catheter-related bloodstream infection? Clin Infect Dis 2003 Jul 1;37(1):65-72. Epub 2003 Jun 24.

McKibben, 2005: McKibben L, Horan T, Tokars JI, et al; Heathcare Infection Control Practices Advisory Committee.(HICPAC) Guidance on public reporting of healthcare-associated infections: recommendations of the healthcare infection control practices advisory committee. Am J Infect Control 2005 May;33(4):217-26.

Mermel, 1991: Mermel LA, McCormick RD, Springman SR, et al. The pathogenesis and epidemiology of catheter-related infection with pulmonary artery Swan-Ganz catheters: a prospective study utilizing molecular subtyping. Am J Med 1991 Sep 16;91(3B):197S-205S.

Mermel, 2000: Mermel LA. Prevention of intravascular catheter-related infections. Ann Intern Med 2000;132(5):391-402.

Mermel, 2009: Mermel LA, Allon M, Bouza E, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis 2009 Jul 1;49(1):1-45. Available at http://www.journals.uchicago.edu/doi/full/10.1086/599376 Last accessed October 8, 2009.

Merrer, 2001: Merrer J, De Jonghe B, Golliot F, et al. Complications of femoral and subclavian venous catheterization in critically ill patients: a randomized controlled trial. JAMA 2001 Aug 8;286(6):700-7. Available at http://jama.ama-assn.org/cgi/content/full/286/6/700. Last accessed September 24, 2009.

O'Grady, 2002 : O'Grady NP, Alexander M, Dellinger EP, et al. Guidelines for the prevention of intravascular catheter-related infections. CDC MMWR August 9, 2002/51(RR10);1-26. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm. Last accessed September 24, 2009.

OSHA, N.D.: Occupational Health & Safety Administration, U.S. Department of Labor. Available at http://www.osha.gov. Last accessed September 24, 2009.

Parenti, 1994: Parenti CM, Lederle FA, Impola CL, et al. Reduction of unnecessary intravenous catheter use. Internal medicine house staff participate in a successful quality improvement project. Arch Intern Med 1994 Aug 22;154(16):1829-32.

Pittet, 1994: Pittet D, Tarara D. Wenzel RP. Nosocomial bloodstream infection in critically ill patients. Excess length of stay, extra costs, and attributable mortality. JAMA 1994 May 25;271(20):1598-601.

Pronovost, 2006: Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med 2006 Dec 28;355(26):2725-32. Erratum in: N Engl J Med 2007 Jun 21;356(25):2660. Available at http://content.nejm.org/cgi/content/full/355/26/2725. Last accessed September 24, 2009.

Pronovost, 2008: Pronovost P. Interventions to decrease catheter-related bloodstream infections in the ICU: the Keystone Intensive Care Unit Project. Am J Infect Control 2008 Dec;36(10):S171.e1-5.

Raad, 1994: Raad II, Hohn DC, Gilbreath BJ, et al. Prevention of central venous catheter-related infections by using maximal sterile barrier precautions during insertion. Infect Control Hosp Epidemiol 1994 Apr;15(4 Pt 1):231-8.

Raad, 1997: Raad I, Darouiche R, Dupuis J. Central venous catheters coated with minocycline and rifampin for the prevention of catheter-related colonization and bloodstream infections. A randomized, double-blind trial. The Texas Medical Center Catheter Study Group. Ann Intern Med 1997 Aug 15;127(4):267-74.

Rasero, 2000: Rasero L, Degl'Innocenti M, Mocali M, et al. Comparison of two different time interval protocols for central venous catheter dressing in bone marrow transplant patients: results of a randomized, multicenter study. Haematologica 2000;85:275-9.

Renaud, 2001: Renaud B, Brun-Buisson C; ICU-Bacteremia Study Group. Outcomes of primary and catheter-related bacteremia. A cohort and case-control study in critically ill patients. Am J Respir Crit Care Med 2001 Jun;163(7):1584-90.

Riu, 1998: Riu S, Ruiz CG, Martinez-Vea A, et al. Spontaneous rupture of polyurethane peritoneal catheter: a possible deleterious effect of mupirocin ointment. Nephrol Dial Transplant 1998 Jul;13(7):1870-1. Available at http://ndt.oxfordjournals.org/cgi/reprint/13/7/1870. Last accessed September 24, 2009.

Rosenthal, 2005: Rosenthal VD, Guzman S, Safdar N. Reduction in nosocomial infection with improved hand hygiene in intensive care units of a tertiary care hospital in Argentina. Am J Infect Control 2005 Sep;33(7):392-7.

Rosenthal, 2008: Rosenthal VD, Maki DG, Mehta A, et al. International Nosocomial Infection Control Consortium report, data summary for 2002-2007, issued January 2008. Am J Infect Control 2008 Nov;36(9):627-37. Epub 2008 Oct 3.

Rupp, 2005: Rupp ME, Lisco SJ, Lipsett PA, et al. Effect of a second-generation venous catheter impregnated with chlorhexidine and silver sulfadiazine on central catheter-related infections: a randomized, controlled trial. Ann Intern Med 2005 Oct 18;143(8):570-80.

Ruschulte, 2009: Ruschulte H, Franke M, Gastmeier P, et al. Prevention of central venous catheter related infections with chlorhexidine gluconate impregnated wound dressings: a randomized controlled trial. Ann Hematol 2009 Mar;88(3):267-72. Epub 2008 Aug 5.

Safdar, 2006: Safdar N, Maki DG. Use of vancomycin-containing lock or flush solutions for prevention of bloodstream infection associated with central venous access devices: a meta-analysis of prospective, randomized trials. Clin Infect Dis 2006 Aug 15;43(4):474-84. Epub 2006 Jul 11.

Salzman, 1993: Salzman MB, Isenberg HD, Rubin LG. Use of disinfectants to reduce microbial contamination of hubs of vascular catheters. J Clin Microbiol 1993 Mar;31(3):475-9.

Scott, 2009: Scott RD. The direct medical costs of healthcare-associated infections in US hospitals and the benefits of prevention. Atlanta (GA):Centers for Disease Control and Prevention (CDC); 2009 March. Available at www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf. Last accessed September 24, 2009.

Shapey, 2009: Shapey IM, Foster MA, Whitehouse T, et al. Central venous catheter-related bloodstream infections: improving post-insertion catheter care. J Hosp Infect 2009 Feb;71(2):117-22. Epub 2008 Nov 14.

SHEA, N.D.: [No authors listed.] FAQs (Frequently Asked Questions) about "Catheter-Associated Bloodstream Infections" (also known as "Central-Line Bloodstream Infections"). Arlington (VA): Society for Healthcare Epidemiology of America [SHEA]; No Date. Available at http://www.shea-online.org/Assets/files/patient%20guides/NNL_CA-BSI.pdf. Last accessed October 26, 2009.

Sherertz, 2000: Sherertz RJ, Ely EW, Westbrook DM, et al. Education of physicians-in-training can decrease the risk for vascular catheter infection. Ann Intern Med 2000 Apr 18;132(8):641-8. Available at http://www.annals.org/cgi/reprint/132/8/641.pdf. Last accessed September 24, 2009.

Smith, 2008: Smith MJ. Catheter-related bloodstream infections in children. Am J Infect Control 2008 Dec;36(10):S173.e1-3.

Stone, 2005: Stone PW, Braccia D, Larson E. Systematic review of economic analyses of health care-associated infections. Am J Infect Control 2005 Nov;33(9):501-9.

TMIT, 2008a: [No authors listed.] Nursing Checklist: Central Venous Catheter Insertion. From TMIT High Performer Webinar ["Safer Critical Care: Resources to Prevent Ventilator-Associated Pneumonia (VAP) and Central Venous Catheter-Associated Bloodstream Infections (CVC-BSI)"] presented 2008 May 14. Available at http://www.safetyleaders.org/downloads/CVCInsertionChecklist.pdf. Last accessed October 26, 2009.

TMIT, 2008b: TMIT. Safer Critical Care: Resources to Prevent Ventilator-Associated Pneumonia (VAP) and Central Venous Catheter-Associated Bloodstream Infections (CVC-BSI). TMIT High Performer Webinar presented 2008 May 14. Available at http://www.safetyleaders.org/pages/idPage.jsp?ID=4878. Last accessed October 26, 2009.

Tsuchida, 2007: Tsuchida T, Makimoto K, Toki M, et al. The effectiveness of a nurse-initiated intervention to reduce catheter-associated bloodstream infections in an urban acute hospital: An intervention study with before and after comparison. Int J Nurs Stud 2007 Nov;44(8):1324-33. Epub 2006 Sep 25.

Veenstra, 1999: Veenstra DL, Saint S, Saha S, et al. Efficacy of antiseptic-impregnated central venous catheters in preventing catheter-related bloodstream infections: a meta-analysis. JAMA 1999 Jan 20;281(3):261-7. Available at http://jama.ama-assn.org/cgi/content/full/281/3/261. Last accessed September 24, 2009.

VMMC, 2004: Virginia Mason Medical Center. Central Line Insertion Checklist. Cambridge (MA): Institute for Healthcare Improvement; 2004 Dec 21. Available at http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Tools/CentralLineInsertionChecklist.htm. Last accessed October 26, 2009.

Vonberg, 2006: Vonberg RP, Behnke M, Geffers C, et al. Device-associated infection rates for non-intensive care unit patients. Infect Control Hosp Epidemiol 2006 Apr;27(4):357-61. Epub 2006 Mar 17.

Warren, 2003: Warren DK, Zack JE, Cox MJ, et al. An educational intervention to prevent catheter-associated bloodstream infections in a nonteaching, community medical center. Crit Care Med 2003 Jul;31(7):1959-63.

Warren, 2004: Warren DK, Zack JE, Mayfield JL, et al. The effect of an education program on the incidence of central venous catheter-associated bloodstream infection in a medical ICU. Chest 2004 Nov;126(5):1612-8. Available at http://www.chestjournal.org/cgi/content/full/126/5/1612. Last accessed September 24, 2009.

Warren, 2006: Warren DK, Quadir WW, Hollenbeak CS, et al. Attributable cost of catheter-associated bloodstream infection among intensive care patients in a nonteaching hospital. Crit Care Med 2006 Aug;34(8):2084-9.

Worth, 2009: Worth LJ, Brett J, Bull AL, et al. Impact of revising the National Nosocomial Infection Surveillance System definition for catheter-related bloodstream infection in ICU: reproducibility of the National Healthcare Safety Network case definition in an Australian cohort of infection control professionals. Am J Infect Control 2009 Jul 7. [Epub ahead of print]

Yilmaz, 2007: Yilmaz G, Koksal I, Aydin K, Caylan R, Sucu N, Aksoy F. Risk factors of catheter-related bloodstream infections in parenteral nutrition catheterization. J Parenter Enteral Nutr 2007 Jul-Aug;31(4):284-7.

Young, 2006: Young EM, Commiskey ML, Wilson SJ. Translating evidence into practice to prevent central venous catheter-associated bloodstream infections: a systems-based intervention. Am J Infect Control 2006 Oct;34(8):503-6.

Zakrzewska, 1995: Zakrzewska-Bode A, Muytjens HL, Liem KD, et al. Mupirocin resistance in coagulase-negative staphylococci, after topical prophylaxis for the reduction of colonization of central venous catheters. J Hosp Infect 1995 Nov;31(3): 189-93.

Zingg, 2009: Zingg W, Imhof A, Maggiorini M, et al. Impact of a prevention strategy targeting hand hygiene and catheter care on the incidence of catheter-related bloodstream infections. Crit Care Med 2009 Jul;37(7):2167-73; quiz 2180.

SAFE PRACTICE 22: SURGICAL-SITE INFECTION PREVENTION

The Objective

Prevent healthcare-associated surgical-site infections (SSIs).

The Problem

Traditional infection control programs are directionally correct, but insufficient to enable organizations to "chase zero" and reduce the harm of preventable healthcare-associated infections (HAIs). [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c] It is estimated that nearly 2 million patients experience a healthcare-associated infection each year; of these infections, 22 percent are SSIs. [Klevens, 2007]

SSIs are infections that occur within 30 days after an operation and can involve the skin, subcutaneous tissue of incision, fascia, muscular layer, or the organ or surrounding space.

SSIs have the second highest frequency of any adverse event occurring in hospitalized patients and are the third most common healthcare-associated infection (HAI). Approximately 500,000 SSIs occur each year in 2 to 5 percent of patients undergoing inpatient surgeries. [Anderson, 2008] Estimated rates for operative wound classifications are as follows: clean contaminated cases 3.3 percent, contaminated cases 6 percent, and dirty cases 7.1 percent. The national rate of SSI averages between 2 and 3 percent for clean cases, and an estimated 40 to 60 percent of these infections are preventable. [Kirkland, 1999; de Lissovoy, 2009]

The severity of SSI harm to patients is significant, resulting in increased mortality, readmission rate, length of hospital stay, and cost for patients who incur them. [Levinson, 2008] Each SSI is associated with an average of 9.7 additional postoperative hospital days. [Cruse, 1980; Cruse, 1981; de Lissovoy, 2009] According to the American Heart Association, approximately 700,000 open-heart procedures are performed each year in the United States; more than 67 percent of those are coronary artery bypass grafts (CABG). Mediastinitis can occur after an open-heart surgical procedure with rates of between 0.5 and 5.0 percent, with a mortality rate as high as 40 percent. In 2006, 2.7 percent of Medicare patients acquired postoperative pneumonia or a thromboembolic event. [AHRQ, 2009b] Patients with SSI have a 2 to 11 times higher risk of death compared to operative patients without SSI. [Kirkland, 1999; Engemann, 2003] Approximately 8,205 patients die from an SSI each year. [Klevens, 2007] Seventy-seven percent of deaths in patients with an SSI are directly attributable to the infection. [Mangram, 1999]

The preventability of SSIs has been studied, and guidelines and recommendations for their prevention have been published by multiple professional organizations; the key recommended practices are consistent among them. [Anderson, 2008; WHO, 2008; WHO, 2009] These include: 1) proper selection and administration of antimicrobial prophylaxis, as well as timely discontinuation postoperatively; [Mangram, 1999; Bratzler, 2004; Bratzler, 2006; Kirby, 2009; Pan, 2009; Quinn, 2009] 2) avoidance of hair removal at the operative site, unless the presence of hair will interfere with the operation; [Mangram, 1999] and

3) maintaining blood glucose level at less than 200 mg/dL in patients undergoing cardiac surgeries. [Bratzler, 2006] Surveillance for SSI should be performed, and ongoing findings and feedback should be communicated to surgical personnel and organizational leadership. [Anderson, 2008]

Costs of SSIs vary depending on the type of operative procedure and the type of infecting pathogen; published estimates range from $3,000 to $29,000. [Coello, 1993; Vegas, 1993; Kirkland, 1999; Hollenbeak, 2000] However, the recent Pennsylvania Health Care Cost Containment Council found that the median cost of an SSI was $153,132, compared to a hospital stay with no infection of $33,260, resulting in an increased cost per patient of $119,872. [PHC4, 2008] Using the consumer price index for inpatient hospital services, the aggregate attributable hospital costs due to SSI range from $11,874 to $34,670 in 2007 dollars. [Scott, 2009] Using the 2005 Healthcare Cost and Utilization Project National Inpatient Sample (HCUP NIS) database, 6,891 cases of SSI were identified. On average, SSI extended the length of stay by 9.7 days, with an increase in cost of $20,842 per admission. Nationally, these SSI cases contributed to an additional 406,730 hospital days and hospital costs exceeding $900 million. Readmissions of 91,613 patients for treatment of SSI accounted for 521,933 days at a cost of nearly $700 million. [de Lissovoy, 2009] Sub-classifying analysis of SSIs into superficial incisional, deep incisional, and organ/space categories will provide better precision in cost forecasting and a reality check to performance improvement cost-benefit assessments. [Anderson, 2008]

Beginning October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) has selected SSIs, including mediastinitis after CABG; certain orthopedic procedures (spine, neck, shoulder, elbow); and bariatric surgery for obesity (laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery); as hospital-acquired conditions that will no longer receive a higher reimbursement when not present on admission. [CMS/HAC, 2008]

There is intense research of HAIs, and it will take time to understand the absolute magnitude of preventability and the value of risk assessment methods; however, there is full consensus that actions need to be taken now to reduce SSIs with what is currently known. [Denham, 2005; Denham, 2009d]

Safe Practice Statement

Take actions to prevent surgical-site infections by implementing evidence-based intervention practices. [Mangram, 1999; WHO, 2008; IHI, 2009b; JCR, 2010]

Additional Specifications

- Document the education of healthcare professionals, including nurses and physicians, involved in surgical procedures about healthcare-acquired infections, surgical-site infections (SSIs), and the importance of prevention. Education occurs upon hire and annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities. [Bratzler, 2004; Bratzler, 2006; TMIT, 2008; Chatzizacharias, 2009; Rosenthal, 2009]
- Prior to all surgical procedures, educate the patient and his or her family as appropriate about SSI prevention. [Torpy, 2005; Schweon, 2006]
- Implement policies and practices that are aimed at reducing the risk of SSI that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines).

[Mangram, 1999; Dellinger, 2005; Bratzler, 2006; Anderson, 2008; WHO, 2009]

- Conduct periodic risk assessments for SSI, select SSI measures using best practices or evidence-based guidelines, monitor compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts. [Bratzler, 2006]
- Ensure that measurement strategies follow evidence-based guidelines, and that SSI rates are measured for the first 30 days following procedures that do not involve the insertion of implantable devices, and for the first year following procedures that involve the insertion of implantable devices. [Horan, 1992; Biscione, 2009]
- Provide SSI rate data and prevention outcome measures to key stakeholders, including senior leadership, licensed independent practitioners, nursing staff, and other clinicians. [Mangram, 1999]
- Administer antimicrobial agents for prophylaxis with a particular procedure or disease according to evidence-based standards and guidelines for best practices. [ASHP, 1999; Mangram, 1999; Antimicrobial, 2001; IHI, 2009a]
  - Administer intravenous antimicrobial prophylaxis within one hour before incision to maximize tissue concentration (two hours are allowed for the administration of vancomycin and fluoroquinolones). [Bratzler, 2004; Bratzler, 2006]
  - Discontinue the prophylactic antimicrobial agent within 24 hours after surgery (within 48 hours is allowable for cardiothoracic procedures). [Bratzler, 2004; Bratzler, 2006]
- When hair removal is necessary, use clippers or depilatories. Note: Shaving is an inappropriate hair removal method. [Mangram, 1999]
- Maintain normothermia (temperature >36.0°C) immediately following colorectal surgery. [Kurz, 1996]
- Control blood glucose during the immediate postoperative period for cardiac surgery patients. [Bratzler, 2006; Dronge, 2006; Kao, 2009]
- Preoperatively, use solutions that contain isopropyl alcohol as skin antiseptic preparation until other alternatives have been proven as safe and effective, and allow appropriate drying time per product guidelines.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include ambulatory surgical center and inpatient service/hospital.

Example Implementation Approaches

- Perform expanded SSI surveillance to determine the source and extent of high SSI rates despite implementation of basic SSI prevention strategies. Consider expanding surveillance to include additional procedures, and possibly all National Healthcare Safety Network (NHSN) procedures. [Mangram, 1999]
- Implementation of the WHO 19-item surgical safety checklist has been estimated to save the lives of 1 in 144 surgical patients. [Haynes, 2009]
- Hospitals that have been successful in reducing SSIs have incorporated some, if not all, of the following elements as part of their prevention strategies and approaches: [Graf, 2009]
  - Appropriate and timely use of prophylactic antibiotics. [AHRQ, 2009a; AHRQ, 2009b; Pan, 2009; Ryckman, 2009]

- Identify and treat all infections remote to the surgical site before elective surgery, and postpone elective surgeries until the infection has resolved.
- Utilize mechanical and intraluminal antibiotic bowel preparation for patients undergoing elective colorectal surgery, as appropriate per patient clinical case. The literature is evolving and patients should be treated according to the latest evidence based practices. [Wille-Jørgensen, 2005; Guenaga, 2009; Howard, 2009; Slim, 2009]
- Administer a prophylactic antimicrobial agent to patients, based on published guidelines and recommendations targeting the most common pathogens for the planned procedure.
- Give appropriate weight-based guideline antibiotic dosing.
- Ensure optimal antibiotic concentration by redosing based on antimicrobial agent half-life and length of procedure.
- Utilize an intravenous route to administer prophylactic antimicrobial agents and antibiotics so that a bactericidal concentration is established in serum and tissues when the incision is made (except for cesarean delivery, when antibiotics should be administered after cord clamp).
  1. Give an intraoperative dose of antibiotic as indicated based on pharmacokinetics of the antibiotic and length of the surgical procedure.
  2. If a cuff or tourniquet is used, fully infuse the antibiotic prior to inflation.
  3. Use preprinted or computerized standing orders that specify antibiotic, timing, dose, and discontinuation.
  4. Change operating room drug stocks to include only standard doses and standard drugs that reflect national guidelines.
  5. Assign antibiotic dosing responsibilities to the anesthesia or holding area nurse to improve timeliness.
  6. Use visible reminders, checklists, and stickers.
  7. Involve pharmacy, infection control, and infectious disease staff to ensure appropriate selection, timing, and duration.

- Appropriate hair removal:
  - Remove hair from the incision site only if the hair interferes with the operation.
  - Educate patients not to shave themselves preoperatively. [Pan, 2009]
- Maintenance of postoperative glucose control:
  - Implement a glucose control protocol.
  - Regularly check preoperative blood glucose levels on all patients.
  - Assign responsibility and accountability for blood glucose monitoring and control.
- Establish postoperative normothermia, and maintain perioperative euthermia, based on the constellation of benefits beyond SSI for colorectal surgery patients.
  - Use warmed forced-air blankets preoperatively, during surgery, and in the post-anesthesia care unit (PACU).
  - Increase the ambient temperature in the operating room.
  - Use warming blankets under patients on the operating table.
  - Use hats and booties on patients perioperatively.

Strategies of Progressive Organizations

- Some organizations advocate maintaining perioperative glucose at specific target levels for patients with Type 1 Diabetes and for those who have Type 2 Diabetes with insulin deficiency.
- Establish implementation of perioperative supplemental oxygen therapy. [Casey, 2009; Qadan, 2009]

Opportunities for Patient and Family Involvement [Denham, 2008; SHEA, N.D.]

- Consider including patients or families of patients who have experienced an SSI to serve on appropriate patient safety or performance improvement committees.
- Teach patients and families the proper care of the surgical site, as well as precautions for preventing infection.
- Teach patients and families to recognize the signs and symptoms of infection.
- Encourage patients to report changes in their surgical site or any new discomfort.
- Encourage patients and family members to make sure that doctors and nurses check the site every day for signs of infection.
- Invite patients to ask staff if they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions before a surgical procedure is performed.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts, and may not necessarily all address external reporting needs.

- **Outcome Measures** include trending the rate of SSIs per procedure over time and reporting SSIs as part of a multicenter registry, for example, NHSN. [NHSN, N.D.] Also consider trending operational and financial outcomes associated with reduction in SSI patient complications. Use NHSN definitions where appropriate. [NHSN, N.D.]
  - National Quality Forum (NQF)-endorsed® outcome measures:
    1. #0130: Deep Sternal Wound Infection Rate [Hospital]: Percent of patients undergoing isolated CABG who developed deep sternal wound infection within 30 days post-operatively.
    2. #0299: Surgical-site infection rate [Hospital]: Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.
    3. #0450: Postoperative DVT or PE: Percent of adult surgical discharges with a secondary diagnosis code of deep vein thrombosis or pulmonary embolism.

- **Process Measures** include periodic assessment of compliance with all components of the prevention bundle, with actions to mitigate performance gaps.
  - NQF-endorsed® process measures:
    1. #0125: Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery who received prophylactic antibiotics within one hour prior to of surgical incision (two hours if receiving vancomycin).
    2. #0126: Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery who received prophylactic antibiotics recommended for the operation.
    3. #0128: Duration of Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery whose prophylactic antibiotics were discontinued within 24 hours after surgery end time.
    4. #0264: Prophylactic Intravenous (IV) Antibiotic Timing [Hospital, Ambulatory Surgical Centers]: Percentage of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time.
    5. #0269: Timing of Prophylactic Antibiotics - Administering Physician [Hospital, Ambulatory Surgical Centers]: Percentage of surgical patients aged > 18 years with indications for prophylactic parenteral antibiotics for whom administration of the antibiotic has been initiated within one hour (if vancomycin, two hours) prior to the surgical incision or start of procedure when no incision is required.
    6. #0270: Timing of Antibiotic Prophylaxis: Ordering Physician [Hospital, Ambulatory Surgical Centers]: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required).
    7. #0271: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures) [Hospital, Ambulatory Surgical Centers]: Percentage of non- cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 24 hours of surgical end time.
    8. #0472: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision or at the Time of Delivery – Cesarean section [Hospital]: Percentage of patients undergoing cesarean section who receive prophylactic antibiotics within one hour prior to surgical incision or at the time of delivery.
    9. #0527: Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-Inf-2.
    10. #0528: Prophylactic antibiotic selection for surgical patients.
    11. #0529: Prophylactic antibiotics discontinued within 24 hours after surgery end time.

12. #0301: Surgery patients with appropriate hair removal [Hospital]: Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal.
13. #0515: Ambulatory surgery patients with appropriate method of hair removal [Ambulatory Care (office/clinic)]: Percentage of ASC admissions with appropriate surgical site hair removal.
14. #0300: Cardiac surgery patients with controlled 6 A.M. postoperative serum glucose: Percentage of cardiac surgery patients with controlled 6 A.M. serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.
15. #0452: Surgery patients with perioperative temperature management: Surgery patients for whom either active warming was used intraoperatively for the purpose of maintaining normothermia, or who had at least one body temperature equal to or greater than 96.8° F/36° C recorded within the 30 minutes immediately prior to or the 15 minutes immediately after anesthesia end time.
16. #0218: Surgery patients who received appropriate VTE prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time: Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) Prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time.
17. #0239: Venous Thromboembolism (VTE) Prophylaxis [Hospital]: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
18. #0371: Venous Thromboembolism (VTE) Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
19. #0372: Intensive Care Unit (ICU) VTE Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).
20. #0376: Incidence of Potentially Preventable VTE [Hospital]: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

- **Structure Measures** include verification that monitoring documentation incorporates the identification, stratification, and trending of specific risk factors of patients who have developed a SSI to determine the success of mitigation strategies.
- **Patient-Centered Measures** include evidence of education about the patient's role in perioperative infection risk reduction.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural settings where invasive procedures are performed.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings where invasive procedures are performed.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty settings where invasive procedures are performed.

New Horizons and Areas for Research

Further research is required to discern the optimal timing and use of antibiotics for specific patient profiles; the effectiveness of preoperative bathing with chlorhexidine-containing products; [Miller, 1996; Perl, 2002; Wilcox, 2003; Kallen, 2005; Nicholson, 2005] the effectiveness of routine screening for MRSA [Gould, 2009; Yano, 2009] and routine attempts to decolonize surgical patients with an antistaphylococcal agent in the preoperative setting; best strategies and evidence for maintaining oxygenation with supplemental oxygen during and following colorectal procedures; [Al-Niaimi, 2009; Casey, 2009; Qadan, 2009] and the validity of preoperative intranasal and pharyngeal chlorhexidine treatment for patients undergoing cardiothoracic procedures. [Segers, 2006] Some organizations have learned from other industries, such as the food industry, and explored increasing the vigilance of environmental cleaning of high-contact surfaces in patient rooms, such as television remote control devices, and operating room equipment and devices, such as pulse oximeters that are shared or used across multiple patients. Other environmental design issues may have real importance to reducing preventable infections in the future. National harmonization efforts are being undertaken to optimize safety during the pre-operative, intra-operative, and post-operative periods, broadening the scope of a systematic approach to safe care of the surgical patient. [NPP, 2009]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 19: Hand Hygiene, is the cornerstone of an organization's infection control program. Implementing Safe Practice 24: Multidrug-Resistant Organism Prevention, will also reduce infections by using standard evidence-based practice prevention.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Al-Niaimi, 2009: Al-Niaimi A, Safdar N. Supplemental perioperative oxygen for reducing surgical site infection: a meta-analysis. J Eval Clin Pract 2009 Apr;15(2):360-5.

Anderson, 2008: Anderson DJ, Kaye KS, Classen D, et al. Strategies to prevent surgical site infections in acute care hospitals. Infect Control Hosp Epidemiol 2008 Oct;29 Suppl 1:S51-61. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/591064. Last accessed October 7, 2009.

Antimicrobial, 2001: [No authors listed.] Antimicrobial prophylaxis in surgery. Med Lett Drugs Ther 2001 Oct 29;43(1116-1117):92-7.

ASHP, 1999: ASHP Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999;56(18):1839-88.

Biscione, 2009: Biscione FM, Couto RC, Pedrosa TM. Accounting for incomplete postdischarge follow-up during surveillance of surgical site infection by use of the National Nosocomial Infections Surveillance system's risk index. Infect Control Hosp Epidemiol 2009 May;30(5):433-9.

Bratzler, 2004: Bratzler DW, Houck PM, et al. Antimicrobial prophylaxis for surgery: an advisory statement from the National Surgical Infection Prevention Project. Clin Infect Dis 2004 Jun 15;38(12):1706-15. Epub 2004 May 26. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/421095. Last accessed October 7, 2009.

Bratzler, 2006: Bratzler DW, Hunt DR. The surgical infection prevention and surgical care improvement projects: national initiatives to improve outcomes for patients having surgery. Clin Infect Dis 2006 Aug 1;43(3):322-30. Epub 2006 Jun 16. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/505220. Last accessed October 7, 2009.

Casey, 2009: Casey AL, Elliott TS. Progress in the prevention of surgical site infection. Curr Opin Infect Dis 2009 Aug;22(4):370-5.

Chatzizacharias, 2009: Chatzizacharias NA, Chapple K. Doctors' compliance with hand hygiene guidelines in the surgical ward. Infect Control Hosp Epidemiol 2009 Mar;30(3):308-9.

CMS/HAC, 2008: Centers for Medicare & Medicaid Services. Hospital-Acquired Conditions (Present on Admission Indicator) Overview. Available at http://www.cms.hhs.gov/hospitalacq-cond/. Last accessed October 30, 2009.

Coello, 1993: Coello R, Glenister H, Fereres J, et al. The cost of infection in surgical patients: a case-control study. J Hosp Infect 1993 Dec;25(4):239-50.

Cruse, 1980: Cruse PJ, Foord R. The epidemiology of wound infection. A 10-year prospective study of 62,939 wounds. Surg Clin North Am 1980 Feb;60(1):27-40.

Cruse, 1981: Cruse P. Wound infection surveillance. Rev Infect Dis 1981 Jul-Aug;3(4):734-7.

de Lissovoy, 2009: de Lissovoy G, Fraeman K, Hutchins V, et al. Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control 2009 Jun;37(5):387-97. Epub 2009 Apr 23.

Dellinger, 2005: Dellinger EP, Hausmann SM, Bratzler DW, et al. Hospitals collaborate to decrease surgical site infections. Am J Surg 2005 Jul;190(1):9-15.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2008: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: can reality meet the rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4):210-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Denham, 2009d: Denham CR. Are you infected? J Patient Saf 2009 Sep;5(3):188-96.

Dronge, 2006: Dronge AS, Perkal MF, Kancir S, et al. Long-term glycemic control and postoperative infectious complications. Arch Surg 2006 Apr;141(4):375-80; discussion 380.

Engemann, 2003: Engemann JJ, Carmeli Y, Cosgrove SE, et al. Adverse clinical and economic outcomes attributable to methicillin resistance among patients with Staphylococcus aureus surgical site infection. Clin Infect Dis 2003 Mar 1; 36(5): 592-8. Epub 2003 Feb 7. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/367653. Last accessed October 7, 2009.

Gould, 2009: Gould FK, Brindle R, Chadwick PR, et al. Guidelines (2008) for the prophylaxis and treatment of methicillin-resistant Staphylococcus aureus (MRSA) infections in the United Kingdom. J Antimicrob Chemother 2009 May;63(5):849-61. Epub 2009 Mar 12.

Graf, 2009: Graf K, Sohr D, Haverich A, et al. Decrease of deep sternal surgical site infection rates after cardiac surgery by a comprehensive infection control program. Interact Cardiovasc Thorac Surg 2009 Aug;9(2):282-6. Epub 2009 May 5. Available at http://icvts.ctsnetjournals.org/cgi/reprint/9/2/282. Last accessed October 7, 2009.

Guenaga, 2009: Guenaga KK, Matos D, Wille-Jørgensen P. Mechanical bowel preparation for elective colorectal surgery. Cochrane Database Syst Rev 2009 Jan 21;(1):CD001544.

Haynes, 2009: Haynes HR, Weiser TG, Berry WR, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med 2009;360:491-9. Epub 2009 Jan 14. Available at http://content.nejm.org/cgi/reprint/360/5/491.pdf. Last accessed September 28, 2009.

Hollenbeak, 2000: Hollenbeak CS, Murphy DM, Koenig S, et al. The clinical and economic impact of deep chest surgical site infections following coronary artery bypass graft surgery. Chest 2000 Aug;118(2):397-402. Available at http://www.chestjournal.org/cgi/content/full/118/2/397. Last accessed October 7, 2009.

Horan, 1992: Horan TC, Gaynes RP, Martone WJ, et al. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992 Oct;13(10):606-8.

Howard, 2009: Howard DD, White CQ, Harden TR, et al. Incidence of surgical site infections postcolorectal resections without preoperative mechanical or antibiotic bowel preparation. Am Surg 2009 Aug;75(8):659-63; discussion 663-4.

IHI, 2009a: [No authors listed.] Antibiotic Stewardship. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=584d97d9-d698-478f-8a10-ee60362d7462. Last accessed October 26, 2009.

IHI, 2009b: [No authors listed.] Surgical Complications Core Processes (SCIP). IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=9102c77f-e32e-4677-be9f-a5dbf8329940. Last accessed October 26, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.07.05.01. Oak Brook (IL): Joint Commission Resources; 2010.

Kallen, 2005: Kallen AJ, Wilson CT, Larson RJ. Perioperative intranasal mupirocin for the prevention of surgical-site infections: systematic review of the literature and meta-analysis. Infect Control Hosp Epidemiol 2005 Dec;26(12):916-22. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/505453. Last accessed October 7, 2009.

Kao, 2009: Kao LS, Meeks D, Moyer VA, et al. Peri-operative glycaemic control regimens for preventing surgical site infections in adults. Cochrane Database Syst Rev 2009 Jul 8;(3):CD006806.

Kirby, 2009: Kirby JP, Mazuski JE. Prevention of surgical site infection. Surg Clin North Am 2009 Apr;89(2):365-89, viii.

Kirkland, 1999: Kirkland KB, Briggs JP, Trivette SL, et al. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol 1999 Nov;20(11):725-30. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/501572. Last accessed October 7, 2009.

Klevens, 2007: Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep 2007 Mar-Apr;122(2):160-72.

Kurz, 1996: Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. Study of Wound Infection and Temperature Group. N Engl J Med 1996 May 9;334(19): 1209-15. Available at http://content.nejm.org/cgi/reprint/334/19/1209.pdf. Last accessed October 7, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 7, 2009.

Mangram, 1999: Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 1999 Apr;20(4):250-78; quiz 279-80. Atlanta (GA):Centers for Disease Control and Prevention; 1999. Available at http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html. Last accessed October 26, 2009.

Miller, 1996: Miller MA, Dascal A, Portnoy J, et al. Development of mupirocin resistance among methicillin-resistant Staphylococcus aureus after widespread use of nasal mupirocin ointment. Infect Control Hosp Epidemiol 1996 Dec;17(12):811-3.

NHSN, N.D.: National Healthcare Safety Network (NHSN). Available at http://www.cdc.gov/nhsn/index.html. Last accessed October 7, 2009.

Nicholson, 2005: Nicholson MR, Huesman LA. Controlling the usage of intranasal mupirocin does impact the rate of Staphylococcus aureus deep sternal wound infections in cardiac surgery patients. Am J Infect Control 2006 Feb;34(1):44-8.

NPP, 2009: National Priorities Partnership. National Quality Forum. Available at http://www.nationalprioritiespartnership.org/Home.aspx. Last accessed October 15, 2009.

Pan, 2009: Pan A, Ambrosini L, Patroni A, et al. Adherence to surgical site infection guidelines in Italian cardiac surgery units. Infection 2009 Apr;37(2):148-52. Epub 2009 Mar 23.

Perl, 2002: Perl TM, Cullen JJ, Wenzel RP, et al. Intranasal mupirocin to prevent postoperative Staphylococcus aureus infections. N Engl J Med 2002 Jun 13;346(24):1871-7. Available at http://content.nejm.org/cgi/reprint/346/24/1871.pdf. Last accessed October 7, 2009.

PHC4, 2008: Pennsylvania Health Care Cost Containment Council. Statewide Summary Data -- Calendar Year 2006. Available at http://www.phc4.org/reports/hai/06/docs/hai2006statewidesummary.pdf. Last accessed October 7, 2009.

Qadan, 2009: Qadan M, Akça O, Mahid SS, et al. Perioperative supplemental oxygen therapy and surgical site infection: a meta-analysis of randomized controlled trials. Arch Surg 2009 Apr;144(4):359-66; discussion 366-7.

Quinn, 2009: Quinn A, Hill AD, Humphreys H. Evolving issues in the prevention of surgical site infections. Surgeon 2009 Jun;7(3):170-2.

Rosenthal, 2009: Rosenthal R, Weber WP, Zwahlen M, et al. Impact of surgical training on incidence of surgical site infection. World J Surg 2009 Jun;33(6):1165-73.

Ryckman, 2009: Ryckman FC, Schoettker PJ, Hays KR, et al. Reducing surgical site infections at a pediatric academic medical center. Jt Comm J Qual Patient Saf 2009 Apr;35(4):192-8.

Schweon, 2006: Schweon S. Stamping out surgical site infections. RN 2006 Aug;69(8):36-40; quiz 41. Available at http://rn.modernmedicine.com/rnweb/article/articleDetail.jsp?id=362478. Last accessed October 7, 2009.

Scott, 2009: Scott RD. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention. Atlanta (GA):Centers for Disease Control and Prevention (CDC); 2009 March. Available at http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf. Last accessed October 28, 2009.

Segers, 2006: Segers P, Speekenbrink RG, Ubbink DT, et al. Prevention of nosocomial infection in cardiac surgery by decontamination of the nasopharynx and oropharynx with chlorhexidine gluconate: a randomized controlled trial. JAMA 2006 Nov 22;296(20):2460-6. Available at http://jama.ama-assn.org/cgi/content/full/296/20/2460. Last accessed October 7, 2009.

SHEA, N.D.: [No authors listed.] FAQs (Frequently Asked Questions) about "Surgical Site Infections". Arlington (VA): Society for Healthcare Epidemiology of America [SHEA]; No Date. Available at http://www.shea-online.org/Assets/files/patient%20guides/NNL_SSI.pdf. Last accessed October 26, 2009.

Slim, 2009: Slim K, Vicaut E, Launay-Savary MV, et al. Updated systematic review and meta-analysis of randomized clinical trials on the role of mechanical bowel preparation before colorectal surgery. Ann Surg 2009 Feb;249(2):203-9.

TMIT, 2008: TMIT. Are You Preventing Surgical-Site Infections? No Outcome, No Income. TMIT High Performer Webinar presented 2008 Feb 25. Available at http://www.safetyleaders.org/pages/idPage.jsp?ID=4872. Last accessed October 26, 2009.

Torpy, 2005: Torpy JM, Burke A, Glass RM. JAMA patient page. Wound infections. JAMA 2005 Oct 26;294(16):2122. Available at http://jama.ama-assn.org/cgi/content/full/294/16/2122. Last accessed October 7, 2009.

Vegas, 1993: Vegas AA, Jodra VM, García ML. Nosocomial infection in surgery wards: a controlled study of increased duration of hospital stays and direct cost of hospitalization. Eur J Epidemiol 1993 Sep;9(5):504-10.

WHO, 2008: [No authors listed.] WHO surgical safety checklist and implementation manual. Geneva (Switzerland): World Health Organization (WHO)/World Alliance for Patient Safety; 2008. Available at http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html. Last accessed October 7, 2009.

WHO, 2009: [No authors listed.] WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge. Clean Care is Safer Care. Geneva (Switzerland): World Health Organization/Patient Safety: A World Alliance for Safer Health Care; 2009. Available at http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Last accessed October 12, 2009.

Wilcox, 2003: Wilcox MH, Hall J, Pike H, et al. Use of perioperative mupirocin to prevent methicillin-resistant Staphylococcus aureus (MRSA) orthopaedic surgical site infections. J Hosp Infect 2003 Jul;54(3):196-201.

Wille-Jørgensen, 2005: Wille-Jørgensen P, Guenaga KF, Matos D, et al. Pre-operative mechanical bowel cleansing or not? an updated meta-analysis. Colorectal Dis 2005 Jul;7(4):304-10.

Yano, 2009: Yano K, Minoda Y, Sakawa A, et al. Positive nasal culture of methicillin-resistant Staphylococcus aureus (MRSA) is a risk factor for surgical site infection in orthopedics. Acta Orthop 2009 Jan 1:1-5. [Epub ahead of print] Available at http://pdfserve.informaworld.com/251334__913080445.pdf. Last accessed October 26, 2009.

SAFE PRACTICE 23: DAILY CARE OF THE VENTILATED PATIENT

The Objective

Prevent healthcare-associated complications in ventilated patients.

The Problem

Ventilator-associated pneumonia (VAP) is one of the most common healthcare-associated infections (HAIs). [AHRQ, N.D.] VAP is precipitated by a bacterial invasion of the pulmonary parenchyma in a mechanically ventilated patient. [Koulenti, 2009] Absence of adequate salivary flow in intubated intensive care unit patients causes severe xerostomia, which may contribute to the development of mucositis and oropharyngeal colonization with gram-negative bacteria. [Dennesen, 2003] Oral bacteria, poor oral hygiene, and periodontitis seem to influence the incidence of pulmonary infections, especially nosocomial pneumonia episodes in high-risk subjects. Improved oral hygiene has been shown to reduce the occurrence of nosocomial pneumonia, both in mechanically ventilated hospital patients and nonventilated nursing home residents. [Paju, 2007]

The frequency of VAP has been reported to range from 1 to 4 cases per 1,000 ventilator days, and may exceed 10 cases per 1,000 ventilator days in special populations, such as pediatric and surgical patients. [NNIS, 2004; Edwards, 2007] VAP occurs in 8 percent to 28 percent of mechanically ventilated patients.

The severity of the consequences of VAP to the patient is not inconsiderable. Based on 2002 Centers for Disease Control and Prevention (CDC) data, there were 250,205 VAPs reported, and of those, 35,969 were fatal, resulting in a mortality rate of 14.4 percent. [Klevens, 2007; Levinson, 2008] Recently, the Pennsylvania Health Care Cost Containment Council reported that mortality rates for patients with VAP were as high as 23.8 percent, compared to a mortality rate of 2.1 percent for patients who did not have an HAI. [PHC4, 2008] One study among ICU patients showed that the presence of nosocomial pneumonia significantly prolonged the mean length of mechanical ventilation by 10.3 days and mean ICU unit length of stay by 12.2 days. [Koulenti, 2009]

Adopting care practices that have been demonstrated to reduce the risk of VAP greatly increases the preventability of VAP. The first strategy is to reduce the duration of mechanical ventilation by assessing patients daily for continual need of mechanical ventilation, interrupting sedation daily, and utilizing weaning protocols. [ATS/IDSA, 2005; Resar, 2005; Brook, 1999; Dellinger, 2005; Kress, 2000; Marelich, 2000] To prevent aspiration in adults, maintain patients in semi-recumbent position, with a 30- to 45-degree elevation of the head of the bed (unless medically contraindicated). [Resar, 2005; Tablan, 2004; Kollef, 2004; Dellinger, 2005; Drakulovic, 1999; Helman, 2003; Orozco-Levi, 1995] For pediatric patients, elevate airway opening between 15 to 30 degrees for neonates, and 30 to 45 degrees for infants through pediatric ages, unless clinically inappropriate for the patient. To reduce bacterial colonization in the aerodigestive tract, provide oral care with an antiseptic agent, such as chlorhexidine. [DeRiso, 1996; Yoneyama, 2002; Kollef, 2004; Mori, 2006; Halm, 2009; Panchabhai, 2009; Segers, 2009; Sona, 2009] Other strategies that should be employed to minimize the risk of VAP include avoiding gastric

overdistention, using prophylactic inhaled antimicrobials, avoiding unplanned extubation and reintubation, and using a cuffed endotracheal tube with in-line or subglottic suctioning. [Coffin, 2008; Rodvold, 2009; Sergers, 2009; Siempos, 2009]

The total annual cost of VAP to U.S. hospitals approaches $2.5 billion (in 2002 dollars). [Klevens, 2007; Stone, 2005] In a single center study conducted in 1998-1999, hospitalization costs were $48,948 higher in patients with VAP than those ventilated patients without VAP, and length of hospitalization was found to be 25 days longer. [Warren, 2003] Using the consumer price index for inpatient hospital services, the aggregate attributable hospital costs due to VAP range from $19,633 to $28,508 in 2007 dollars. [Scott, 2009] In a study of pediatric patients admitted to PICU, those patients with VAP had a mean additional hospitalization cost of $30,932. [Foglia, 2007]

There is intense research on HAIs, and it will take time to understand the absolute magnitude of preventability and the value of risk-assessment methods; however, there is full consensus that actions need to be taken now to reduce VAPs with what is currently known. [Denham, 2005; Anderson, 2007; CMS, 2008; Coffin, 2008; Denham, 2009d; Zaccard, 2009] Traditional infection control programs are directionally correct but insufficient to enable organizations to "chase zero" and reduce the harm of preventable healthcare-associated infections (HAIs). [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c] It is estimated that nearly 2 million patients experience an HAI each year; of these infections, 15 percent are pneumonia. [Klevens, 2007]

Safe Practice Statement

Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers. [IHI, 2009]

Additional Specifications [Coffin, 2008]

- Educate healthcare workers about the daily care of ventilated patients and the necessity for the prevention of associated complications such as ventilator-associated pneumonia (VAP), venous thromboembolism (VTE), peptic ulcer disease (PUD), dental complications, and pressure ulcers. [TMIT, 2008; Bloos, 2009]
- Implement policies and practices for disinfection, sterilization, and maintenance of respiratory equipment that are aligned with evidence-based standards (e.g., CDC and professional organization guidelines). [Tablan, 2004; CDC, 2005; Brito, 2009]
- Conduct active surveillance for VAP and associated process measures in units that care for ventilated patients that are known or suspected to be at high risk for VAP based on risk assessment. [Erhart, 2004; Tablan, 2004; Hortal, 2009a; Hortal, 2009b]
- Provide ventilated patient data on VAP, VAP-related process measures, and general care process measures to key stakeholders, including senior leadership, LIPS, nursing staff, and other clinicians.
- Educate patients, as appropriate, and their families about prevention measures involved in the care of ventilated patients.
- For adult patients, institute a ventilated patient checklist and a standardized protocol for the following prevention measures:
  - Adhere to hand hygiene guidelines. [Tablan, 2004; Erhart, 2004]

- Perform regular antiseptic oral care according to product guidelines. [Panchabhai, 2009; Prendergast, 2009]
- Maintain patients in semi-recumbent position: 30- to 45-degree elevation of head of bed (unless medically contraindicated). [Torres, 1992; Kollef, 1993; Orozco-Levi, 1995; Drakulovic, 1999; Collard, 2003; Helman, 2003; Erhart, 2004; Kollef, 2004; Tablan, 2004; Dellinger, 2005; Resar, 2005]
- Perform daily assessment of readiness to wean and sedation interruption. [ATS/IDSA, 2005; Resar, 2005; Girard, 2008]
- Use weaning protocols. [Thorens, 1995; Brook, 1999; Kress, 2000; Marelich, 2000; Needleman, 2002; Burns, 2003; Kollef, 2004; Dellinger, 2005; Girard, 2008; Burns, 2009]
- Implement PUD prophylaxis based on patient risk assessment. (PUD prophylaxis data remain controversial. Clinical judgment should be used based on individual patient needs.) [Prod'hom, 1994; Bonten, 1997]
- Provide VTE prophylaxis unless contraindicated (refer to Safe Practice 28).
- Implement a pressure ulcer prevention program based on patient risk assessment (refer to Safe Practice 27).

- For pediatric patients (less than 18 years of age), institute a ventilated patient checklist and a standardized protocol for the following prevention measures:
  - Elevate airway opening between 15 and 30 degrees for neonates and 30 and 45 degrees for infants through pediatric ages, unless clinically inappropriate for the patient.
  - Assess readiness to extubate daily.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include emergency room, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Prolonged immobilization reduces passive range-of-motion of joints, creating joint contractures. Organizations are encouraged to incorporate range-of-motion as daily care for ventilated patients per the organization's protocol. [Clavet, 2008; Trudel, 2008]
- Use antibiotic de-escalation therapy with critically ill patients who acquire a VAP. [ASHP, 1998; Eachempati, 2009]
- Perform regular oral care [Rumbak, 1995; DeRiso, 1996; Yoneyama, 2002; Kollef, 2004; Mori, 2006] with an antiseptic solution; [DeRiso, 1996; Bergmans, 2001; Houston, 2002; Segers, 2006; Chan, 2007; Silvestri, 2007] consider a chlorhexidine agent. Remove oral secretion before changing the patient's position. [Chao, 2009] The optimal frequency for oral care is unresolved. [Chan, 2007]
  - A comprehensive oral hygiene program, including an antiseptic agent, oral suctioning, and tooth brushing, will augment the removal of plaque and reduce bacterial growth.
- Consider the use of the direct antibiogram using E-test strips. [Bouza, 2009]

- General strategies found to influence the risk of VAP:
  - Provide easy access to noninvasive ventilation equipment and institute protocols to promote the use of noninvasive ventilation. [Brochard, 1995; Antonelli, 1998; Nava, 1998; Nourdine, 1999; Girou, 2000; Brochard, 2003; Girou, 2003; Kollef, 2004; Burns, 2009]
  - Strategies to prevent aspiration:
    - Consider ICU beds used for ventilated patients to have a built-in tool to provide continuous monitoring for the angle of incline.
    - Avoid gastric overdistention. [Niederman, 1997; Heyland, 2001; Ibrahim, 2002; Kollef, 2004]
    - Avoid unplanned extubation and reintubation. [Torres, 1995; Elward, 2002; Erhart, 2004]
    - Consider a cuffed endotracheal tube with in-line and subglottic suctioning for all eligible patients. [Mahul, 1992; Vallés, 1995; Rello, 1996; Cook, 1998b; Kollef, 1999; Kollef, 2004; Tablan, 2004; Dezfulian, 2005]
  - Strategies to reduce colonization of the aerodigestive tract:
    - Orotracheal intubation is preferable to nasotracheal intubation. [Salord, 1990; Holzapfel, 1993; Rouby, 1994; Holzapfel, 1999]
    - Evaluate the use of histamine receptor-2 blocking agents and proton-pump inhibitors in patients who are not at high risk of developing a stress ulcer or stress gastritis. [Erhart, 2004; Kollef, 2004; Collard, 2003; Saint, 1998]
  - Strategies to minimize contamination of equipment used to care for patients receiving mechanical ventilation:
    - Use sterile water to rinse reusable respiratory equipment. [Tablan, 2004]
    - Remove condensate from ventilatory circuit. Keep the ventilatory circuit closed during condensate removal. [Dreyfuss, 1991; Kollef, 1995; Kollef, 1998; Stamm, 1998; Markowicz, 2000; Hess, 2003; Tablan, 2004]
    - Change ventilatory circuit only when visibly soiled or malfunctioning. [Kollef, 1998; Tablan, 2004; Stamm, 1998; Kollef, 1995; Hess, 2003; Dreyfuss, 1991; Markowicz, 2000]
    - Store and disinfect respiratory therapy equipment properly. [Tablan, 2004]

Strategies of Progressive Organizations

- Many organizations have set a goal of zero VAPS and visually display their successes in patient care areas (such as a graph of months with zero VAP rates).

Opportunities for Patient and Family Involvement [SHEA, N.D.; Denham, 2008]

- Teach patients and families the proper care of the ventilated patient, as well as precautions for preventing infection.
- Involve families in the process by educating them about the importance of head-of-the-bed elevation, and encourage them to notify clinical personnel when the bed does not appear to be in the proper position.
- Teach patients and families to recognize the signs and symptoms of infection.
- Encourage patients and family members to make sure that doctors and nurses perform the ventilated bundle every day.

- Invite patients to ask staff if they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions.
- Consider including patients or families of patients who have experienced a complication related to mechanical ventilation to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome measures** include trending the rate of VAP, VTE, and PUD for ventilated patients over time, and reporting VAP as part of a multicenter registry (e.g., National Healthcare Safety Network [NHSN]). [NHSN, 2008] Also include the trending of operational and financial outcomes associated with a reduction in ventilated-patient complications. Use NHSN definitions as appropriate.
  - National Quality Forum (NQF)-endorsed® outcome measure:
    1. #0140: Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients [Hospital]: Percentage of ICU and HRN patients who, over a certain number of days, have ventilator-associated pneumonia.
- **Process Measures** include periodic assessment of compliance with all components of the prevention bundle, [Blamoun, 2009; Bloos, 2009; Brito, 2009; Marwick, 2009; Weireter, 2009; Wip, 2009; Zilberberg, 2009] with actions to mitigate performance gaps.
  - Compliance with hand hygiene guidelines for all clinicians who deliver care to ventilated patients. This is assessed by observation of hand hygiene episodes performed by healthcare workers.
  - Compliance with daily sedation interruption and assessment of readiness-to-wean. This is assessed by number of ventilated patients with daily documentation of consideration of sedation interruption and assessment of readiness-to-wean or contraindication.
  - Compliance with regular antiseptic oral care. Measured by number of ventilated patients with daily documentation of regular oral care according to product instructions.
  - Compliance with semi-recumbent positioning for all eligible patients. Measured by number of ventilated patients who are in semi-recumbent position (30- to 45-degree elevation of head of bed) at the time of observation. [Alexiou, 2009]
  - NQF-endorsed process measure:
    1. #0302: Ventilator Bundle [Hospital]: Percentage of intensive care unit patients on mechanical ventilation at time of survey for whom all four elements of the ventilator bundle are documented and in place. The ventilator bundle elements are: 1) head of bed (HOB) elevation 30 degrees or greater (unless medically contraindicated); noted on 2 different shifts within a 24-hour period; 2) daily "sedation interruption" and daily assessment of readiness to extubate; process includes

interrupting sedation until patient follows commands and patient is assessed for discontinuation of mechanical ventilation; parameters of discontinuation include: resolution of reason for intubation; inspired oxygen content roughly 40 percent; assessment of patients ability to defend airway after extubation due to heavy sedation; minute ventilation less than equal to 15 liters/minute; and respiratory rate/tidal volume less than or equal to 105/min/L(RR/TV< 105); 3) SUD (peptic ulcer disease) prophylaxis; and 4) DVT (deep venous thrombosis) prophylaxis. [Hawe, 2009]

- **Structure Measures** include dashboard of measures with results of outcomes and process measures specific to VAP prevention; trending should include the percentage of adverse outcomes compared to other findings.
- **Patient-Centered Measures** include evidence of education of patients and families about the importance of the practice elements and their compliance with the interventions and patient and family satisfaction with communication about the importance of the practice.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings. [AHRQ Innovation Profile, 2008]
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Research in the area of accelerated, reliable, and sustainable adoption of the interventions embodied in this practice, and evaluation of methods of noninvasive ventilatory assistance, reducing the need for endotracheal intubation and mechanical ventilation, hold promise for reducing VAP. [Burns, 2009; Zilberberg, 2009] Establishing balanced therapies for avoiding PUD is vital to the protection of ventilated patients. This includes the evaluation of the best method for identification of patients at low risk of developing gastrointestinal bleeding. [Cook, 1995; Cook, 1996; Levy, 1997; Cook, 1998a; Yildizdas, 2002; Collard, 2003; Kantorova, 2004; Kahn, 2006] Further research is needed to establish the best use of antiseptic-impregnated endotracheal tubes. [Berra, 2004; Pacheco-Fowler, 2004; Shorr, 2009] Establishing guidance for intensive glycemic control will provide further insights to the safety of the ventilated patient. [van den Berghe, 2001; Collier, 2005; Toschlog, 2007; Brunkhorst, 2008] The diagnosis of VAP is well debated by infectious diseases experts, and an optimal, reliable method for result benchmarking is imperative. [Coffin, 2008; Bouza, 2009; Morris, 2009] New technology horizons include development of Automated Infection Identification Mitigation Systems (AIIMS) [Denham, 2009b] and pattern recognition Health Information Technologies that integrate ventilator settings with other clinical factors.

Other Relevant Safe Practices

Safe Practice 4: Identification and Mitigation of Risks and Hazards is aligned with this practice. Safe Practice 19: Hand Hygiene; Safe Practice 27: Pressure Ulcer Prevention; and Safe Practice 28: Venous Thromboembolism Prevention are also aligned with this safe practice.

Notes

AHRQ Innovation Profile, 2008: Agency for Healthcare Research and Quality. Innovation Profile. Evidence-Based Bundle for Adults Is Adapted by Pediatric Intensive Care Units, Reducing Ventilator-Acquired Pneumonia and Lowering Costs. Available at http://www.innovations.ahrq.gov/content.aspx?id=1888. Last accessed September 24, 2009.

AHRQ, N.D.: [No authors listed.] Patient Safety Primer: Health Care-Associated Infections. AHRQ PSNet Patient Safety Network. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); No Date. Available at http://www.psnet.ahrq.gov/primer.aspx?primerID=7. Last accessed October 26, 2009.

Alexiou, 2009: Alexiou VG, Ierodiakonou V, Dimopoulos G, et al. Impact of patient position on the incidence of ventilator-associated pneumonia: A meta-analysis of randomized controlled trials. J Crit Care 2009 Feb 12. [Epub ahead of print]

Anderson, 2007: Anderson DJ, Kirkland KB, Kaye KS, et al. Underresourced hospital infection control and prevention programs: penny wise, pound foolish? Infect Control Hosp Epidemiol 2007 Jul;28(7):767-73. Epub 2007 May 31. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/518518. Last accessed September 24, 2009.

Antonelli, 1998: Antonelli M, Conti G, Rocco M, et al. A comparison of noninvasive positive-pressure ventilation and conventional mechanical ventilation in patients with acute respiratory failure. N Engl J Med 1998 Aug 13;339(7):429-35. Available at http://content.nejm.org/cgi/reprint/339/7/429.pdf. Last accessed September 24, 2009.

ASHP, 1998: American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in infection control. Am J Health-Syst Pharm 1998; 55:1724-6. Available at http://www.ashp.org/s_ashp/docs/files/BP07/Specific_St_Infection.pdf. Last accessed October 26, 2009.

ATS/IDSA, 2005: American Thoracic Society; Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am J Respir Crit Care Med 2005 Feb 15;171(4):388-416. Available at http://ajrccm.atsjournals.org/cgi/content/full/171/4/388. Last accessed September 24, 2009.

Bergmans, 2001: Bergmans DC, Bonten MJ, Gaillard CA, et al. Prevention of ventilator-associated pneumonia by oral decontamination: a prospective, randomized, double-blind, placebo-controlled study. Am J Respir Crit Care Med 2001 Aug 1;164(3):382-8. Available at http://ajrccm.atsjournals.org/cgi/content/full/164/3/382. Last accessed September 24, 2009.

Berra, 2004: Berra L, De Marchi L, Yu ZX, et al. Endotracheal tubes coated with antiseptics decrease bacterial colonization of the ventilator circuits, lungs, and endotracheal tube. Anesthesiology 2004 Jun;100(6):1446-56.

Blamoun, 2009: Blamoun J, Alfakir M, Rella ME, et al. Efficacy of an expanded ventilator bundle for the reduction of ventilator-associated pneumonia in the medical intensive care unit. Am J Infect Control 2009 Mar;37(2):172-5. Epub 2008 Oct 22.

Bloos, 2009: Bloos F, Müller S, Harz A, et al. Effects of staff training on the care of mechanically ventilated patients: a prospective cohort study. Br J Anaesth 2009 Aug;103(2):232-7. Epub 2009 May 20.

Bonten, 1997: Bonten MJ, Gaillard CA, de Leeuw PW, et al. Role of colonization of the upper intestinal tract in the pathogenesis of ventilator-associated pneumonia. Clin Infect Dis 1997 Mar;24(3):309-19.

Bouza, 2009: Bouza E, Burillo A. Advances in the prevention and management of ventilator-associated pneumonia. Curr Opin Infect Dis 2009 Aug;22(4):345-51.

Brito, 2009: Brito V, Niederman MS. Standardized care for nosocomial pneumonia is a valuable tool to improve patient outcomes: how do we get intensivists to listen? Crit Care Med 2009 Jan;37(1):350-2.

Brochard, 1995: Brochard L, Mancebo J, Wysocki M, et al. Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. N Engl J Med 1995 Sep 28;333(13):817-22. Available at http://content.nejm.org/cgi/reprint/333/13/817.pdf. Last accessed September 24, 2009.

Brochard, 2003: Brochard L. Mechanical ventilation: invasive versus noninvasive. Eur Respir J Suppl 2003 Nov;47:31s-37s. Available at http://erj.ersjournals.com/cgi/reprint/22/47_suppl/31s. Last accessed September 24, 2009.

Brook, 1999: Brook AD, Ahrens TS, Schaiff R, et al. Effect of a nursing-implemented sedation protocol on the duration of mechanical ventilation. Crit Care Med 1999 Dec;27(12): 2609-15.

Brunkhorst, 2008: Brunkhorst FM, Engel C, Bloos F, et al. Intensive insulin therapy and pentastarch resuscitation in severe sepsis. N Engl J Med 2008 Jan 10;358(2):125-39. Available at http://content.nejm.org/cgi/reprint/358/2/125.pdf. Last accessed September 24, 2009.

Burns, 2003: Burns KE, Adhikari NK, Meade MO. Noninvasive positive pressure ventilation as a weaning strategy for intubated adults with respiratory failure. Cochrane Database Syst Rev 2003;(4):CD004127.

Burns, 2009: Burns KE, Adhikari NK, Keenan SP, et al. Use of non-invasive ventilation to wean critically ill adults off invasive ventilation: meta-analysis and systematic review. BMJ 2009 May 21;338:b1574. Available at http://www.bmj.com/cgi/reprint/338/may21_1/b1574. Last accessed October 6, 2009

CDC, 2005: [No authors listed.] An Overview of Ventilator-Associated Pneumonia. Atlanta (GA): Centers for Disease Control and Prevention; 2005 Sep 27. Available at http://www.cdc.gov/ncidod/dhqp/dpac_ventilate.html. Last accessed October 26, 2009.

Chan, 2007: Chan EY, Ruest A, Meade MO, et al. Oral decontamination for prevention of pneumonia in mechanically ventilated adults: systematic review and meta-analysis. BMJ 2007 Apr 28;334(7599):889. Epub 2007 Mar 26. Available at http://www.bmj.com/cgi/content/full/334/7599/889. Last accessed October 6, 2009.

Chao, 2009: Chao YF, Chen YY, Wang KW, et al. Removal of oral secretion prior to position change can reduce the incidence of ventilator-associated pneumonia for adult ICU patients: a clinical controlled trial study. J Clin Nurs 2009 Jan;18(1):22-8. Epub 2008 May 8.

Clavet, 2008: Clavet H, Hébert PC, Fergusson D, et al. Joint contracture following prolonged stay in the intensive care unit. CMAJ 2008 Mar 11;178(6):691-7. Available at http://www.cmaj.ca/cgi/content/full/178/6/691. Last accessed September 24, 2009.

CMS, 2008: CMS Office of Public Affairs. CMS Proposes Additions to List of Hospital-Acquired Conditions for Fiscal Year 2009. Baltimore (MD): Centers for Medicare & Medicare Services; 2008 Apr 14. Available at http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3042&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date. Last accessed October 26, 2009.

Coffin, 2008: Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. Infect Control Hosp Epidemiol. 2008 Oct;29 Suppl 1:S31-40. http://www.journals.uchicago.edu/doi/pdf/10.1086/591062. Last accessed October 7, 2009.

Collard, 2003: Collard HR, Saint S, Matthay MA. Prevention of ventilator-associated pneumonia: an evidence-based systematic review. Ann Intern Med 2003 Mar 18;138(6):494-501. Available at http://www.annals.org/cgi/content/full/138/6/494. Last accessed September 24, 2009.

Collier, 2005: Collier B, Diaz J, Jr., Forbes R, et al. The impact of a normoglycemic management protocol on clinical outcomes in the trauma intensive care unit. JPEN J Parenter Enteral Nutr 2005 Sep-Oct;29(5):353-8; discussion 359.

Cook, 1995: Cook DJ. Stress ulcer prophylaxis: gastrointestinal bleeding and nosocomial pneumonia. Best evidence synthesis. Scand J Gastroenterol Suppl 1995;210:48-52.

Cook, 1996: Cook DJ, Reeve BK, Guyatt GH, et al. Stress ulcer prophylaxis in critically ill patients. Resolving discordant meta-analyses. JAMA 1996 Jan 24-31;275(4):308-14.

Cook, 1998a: Cook D, Guyatt G, Marshall J, et al. A comparison of sucralfate and ranitidine for the prevention of upper gastrointestinal bleeding in patients requiring mechanical ventilation. Canadian Critical Care Trials Group. N Engl J Med 1998 Mar 19;338(12):791-7. Available at http://content.nejm.org/cgi/reprint/338/12/791.pdf. Last accessed September 24, 2009.

Cook, 1998b: Cook DJ, Kollef MH. Risk factors for ICU-acquired pneumonia. JAMA 1998 May 27;279(20):1605-6. Available at http://jama.ama-assn.org/cgi/content/full/279/20/1605. Last accessed September 24, 2009.

Dellinger, 2005: Dellinger RP, Vincent JL. The Surviving Sepsis Campaign sepsis change bundles and clinical practice. Crit Care Med 2005;9(6):653-4. Epub 2005 Nov 25. Available at http://ccforum.com/content/9/6/653. Last accessed September 24, 2009.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2008: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: can reality meet the rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4):210-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Denham, 2009d: Denham CR. Are you infected? J Patient Saf 2009 Sep;5(3):188-96.

Dennesen, 2003: Dennesen P, van der Ven A, Vlasveld M, et al. Inadequate salivary flow and poor oral mucosal status in intubated intensive care unit patients. Crit Care Med 2003 Mar;31(3):781-6.

DeRiso, 1996: DeRiso AJ 2nd, Ladowski JS, Dillon TA, et al. Chlorhexidine gluconate 0.12% oral rinse reduces the incidence of total nosocomial respiratory infection and nonprophylactic systemic antibiotic use in patients undergoing heart surgery. Chest 1996 Jun;109(6):1556-61. Available at http://www.chestjournal.org/cgi/reprint/109/6/1556. Last accessed September 24, 2009.

Dezfulian, 2005: Dezfulian C, Shojania K, Collard HR, et al. Subglottic secretion drainage for preventing ventilator-associated pneumonia: a meta-analysis. Am J Med 2005 Jan;118(1):11-8.

Drakulovic, 1999: Drakulovic MB, Torres A, Bauer TT, et al. Supine body position as a risk factor for nosocomial pneumonia in mechanically ventilated patients: a randomised trial. Lancet 1999 Nov 27;354(9193):1851-8.

Dreyfuss, 1991: Dreyfuss D, Djedaini K, Weber P, et al. Prospective study of nosocomial pneumonia and of patient and circuit colonization during mechanical ventilation with circuit changes every 48 hours versus no change. Am Rev Respir Dis 1991 Apr;143(4 Pt 1):738-43.

Eachempati, 2009: Eachempati SR, Hydo LJ, Shou J, et al. Does de-escalation of antibiotic therapy for ventilator-associated pneumonia affect the likelihood of recurrent pneumonia or mortality in critically ill surgical patients? J Trauma 2009 May;66(5):1343-8.

Edwards, 2007: Edwards JR, Peterson KD, Andrus ML, et al. National Healthcare Safety Network (NHSN) Report, data summary for 2006, issued June 2007. Am J Infect Control 2007 Jun;35(5):290-301. Available at http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/2006_NHSN_Report.pdf. Last accessed September 24, 2009.

Elward, 2002: Elward AM, Warren DK, Fraser VJ. Ventilator-associated pneumonia in pediatric intensive care unit patients: risk factors and outcomes. Pediatrics 2002 May;109(5):758-64. Available at http://pediatrics.aappublications.org/cgi/content/full/109/5/758. Last accessed September 24, 2009.

Erhart, 2004: Erhart LM, Rangel MC, Lu PJ, et al. Prevalence and characteristics of children at increased risk for complications from influenza, United States, 2000. J Pediatr 2004 Feb;144(2):191-5.

Foglia, 2007: Foglia E, Meier MD, Elward A. Ventilator-associated pneumonia in neonatal and pediatric intensive care unit patients. Clin Microbiol Rev 2007 Jul;20(3):409-25, table of contents. Available at http://cmr.asm.org/cgi/reprint/20/3/409. Last accessed September 24, 2009.

Girard, 2008: Girard TD, Kress JP, Fuchs BD, et al. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomised controlled trial. Lancet 2008 Jan 12;371(9607):126-34.

Girou, 2000: Girou E, Schortgen F, Delclaux C, et al. Association of noninvasive ventilation with nosocomial infections and survival in critically ill patients. JAMA 2000 Nov 8;284(18):2361-7. Available at http://jama.ama-assn.org/cgi/content/full/284/18/2361. Last accessed September 24, 2009.

Girou, 2003: Girou E, Brun-Buisson C, Taillé S, et al. Secular trends in nosocomial infections and mortality associated with noninvasive ventilation in patients with exacerbation of COPD and pulmonary edema. JAMA 2003 Dec 10;290(22):2985-91. Available at http://jama.ama-assn.org/cgi/content/full/290/22/2985. Last accessed September 24, 2008.

Halm, 2009: Halm MA, Armola R. Effect of oral care on bacterial colonization and ventilator-associated pneumonia. Am J Crit Care 2009 May;18(3):275-8.

Hawe, 2009: Hawe CS, Ellis KS, Cairns CJ, et al. Reduction of ventilator-associated pneumonia: active versus passive guideline implementation. Intensive Care Med 2009 Jul;35(7):1180-6. Epub 2009 Mar 24.

Helman, 2003: Helman DL Jr, Sherner JH 3rd, Fitzpatrick TM, et al. Effect of standardized orders and provider education on head-of-bed positioning in mechanically ventilated patients. Crit Care Med 2003 Sep;31(9):2285-90.

Hess, 2003: Hess DR, Kallstrom TJ, Mottram CD, et al. Care of the ventilator circuit and its relation to ventilator-associated pneumonia. Respir Care 2003 Sep;48(9):869-79. Available at http://www.rcjournal.com/contents/09.03/09.03.0869.pdf. Last accessed September 24, 2009.

Heyland, 2001: Heyland DK, Drover JW, MacDonald S, et al. Effect of postpyloric feeding on gastroesophageal regurgitation and pulmonary microaspiration: results of a randomized controlled trial. Crit Care Med 2001 Aug;29(8):1495-501.

Holzapfel, 1993: Holzapfel L, Chevret S, Madinier G, et al. Influence of long-term oro- or nasotracheal intubation on nosocomial maxillary sinusitis and pneumonia: results of a prospective, randomized, clinical trial. Crit Care Med 1993 Aug;21(8):1132-8.

Holzapfel, 1999: Holzapfel L, Chastang C, Demingeon G, et al. A randomized study assessing the systematic search for maxillary sinusitis in nasotracheally mechanically ventilated patients. Influence of nosocomial maxillary sinusitis on the occurrence of ventilator-associated pneumonia. Am J Respir Crit Care Med 1999 Mar;159(3):695-701. Available at http://ajrccm.atsjournals.org/cgi/content/full/159/3/695. Last accessed September 24, 2009.

Hortal, 2009a: Hortal J, Giannella M, Pérez MJ, et al. Incidence and risk factors for ventilator-associated pneumonia after major heart surgery. Intensive Care Med 2009 Jun 26. [Epub ahead of print]

Hortal, 2009b: Hortal J, Muñoz P, Cuerpo G, et al. Ventilator-associated pneumonia in patients undergoing major heart surgery: an incidence study in Europe. Crit Care 2009;13(3):R80. Epub 2009 May 22. Available at http://ccforum.com/content/pdf/cc7896.pdf. Last accessed October 6, 2009.

Houston, 2002: Houston S, Hougland P, Anderson JJ, et al. Effectiveness of 0.12% chlorhexidine gluconate oral rinse in reducing prevalence of nosocomial pneumonia in patients undergoing heart surgery. Am J Crit Care 2002 Nov;11(6):567-70. Available at http://ajcc.aacnjournals.org/cgi/content/full/11/6/567. Last accessed September 24, 2009.

Ibrahim, 2002: Ibrahim E, Mehringer L, Prentice D, et al. Early versus late enteral feeding of mechanically ventilated patients: results of a clinical trial. JPEN J Parenter Enteral Nutr 2002 May-Jun;26(3):174-81.

IHI, 2009: [No authors listed.] Ventilator Bundle. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=0f029d21-a307-4663-9d64-07da43f3f857. Last accessed October 26, 2009.

Kahn, 2006: Kahn JM, Doctor JN, Rubenfeld GD. Stress ulcer prophylaxis in mechanically ventilated patients: integrating evidence and judgment using a decision analysis. Intensive Care Med 2006 Aug;32(8):1151-8. Epub 2006 Jun 21. Available at http://www.springerlink.com/content/h10288x4v44250l2/fulltext.pdf. Last accessed September 24, 2009.

Kantorova, 2004: Kantorova I, Svoboda P, Scheer P, et al. Stress ulcer prophylaxis in critically ill patients: a randomized controlled trial. Hepatogastroenterology 2004 May-Jun;51(57):757-61.

Klevens, 2007: Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep 2007 Mar-Apr;122(2):160-6.

Kollef, 1993: Kollef MH. Ventilator-associated pneumonia. A multivariate analysis. JAMA 1993 Oct 27;270(16):1965-70.

Kollef, 1995: Kollef MH, Shapiro SD, Fraser VJ, et al. Mechanical ventilation with or without 7-day circuit changes. A randomized controlled trial. Ann Intern Med 1995 Aug 1;123(3):168-74. Available at http://www.annals.org/cgi/content/full/123/3/168. Last accessed September 24, 2009.

Kollef, 1998: Kollef MH. Prolonged use of ventilator circuits and ventilator-associated pneumonia: a model for identifying the optimal clinical practice. Chest 1998 Feb;113(2):267-9. Available at http://www.chestjournal.org/cgi/reprint/113/2/267. Last accessed September 24, 2009.

Kollef, 1999: Kollef MH, Skubas NJ, Sundt TM. A randomized clinical trial of continuous aspiration of subglottic secretions in cardiac surgery patients. Chest 1999 Nov;116(5):1339-46. Available at http://www.chestjournal.org/cgi/content/full/116/5/1339. Last accessed September 24, 2009.

Kollef, 2004: Kollef MH. Prevention of hospital-associated pneumonia and ventilator-associated pneumonia. Crit Care Med 2004 Jun;32(6):1396-405.

Koulenti, 2009: Koulenti D, Lisboa T, Brun-Buisson C, et al. Spectrum of practice in the diagnosis of nosocomial pneumonia in patients requiring mechanical ventilation in European intensive care units. Crit Care Med 2009 Aug;37(8):2360-8.

Kress, 2000: Kress JP, Pohlman AS, O'Connor MF, et al. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. N Engl J Med 2000 May 18;342(20):1471-7. Available at http://content.nejm.org/cgi/reprint/342/20/1471.pdf. Last accessed September 24, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 24, 2009.

Levy, 1997: Levy MJ, Seelig CB, Robinson NJ, et al. Comparison of omeprazole and ranitidine for stress ulcer prophylaxis. Dig Dis Sci 1997 Jun;42(6):1255-9.

Liberati, 2004: Liberati A, D'Amico R, Pifferi, et al. Antibiotic prophylaxis to reduce respiratory tract infections and mortality in adults receiving intensive care. Cochrane Database Syst Rev 2004;(1):CD000022.

Mahul, 1992: Mahul P, Auboyer C, Jospe R, et al. Prevention of nosocomial pneumonia in intubated patients: respective role of mechanical subglottic secretions drainage and stress ulcer prophylaxis. Intensive Care Med 1992;18(1):20-5. Available at http://www.springerlink.com/content/m7h88n348302110w/fulltext.pdf. Last accessed September 24, 2009.

Marelich, 2000: Marelich GP, Murin S, Battistella F, et al. Protocol weaning of mechanical ventilation in medical and surgical patients by respiratory care practitioners and nurses: effect on weaning time and incidence of ventilator-associated pneumonia. Chest 2000 Aug;118(2):459-67. Available at http://www.chestjournal.org/cgi/content/full/118/2/459. Last accessed September 24, 2009.

Markowicz, 2000: Markowicz P, Ricard JD, Dreyfuss D, et al. Safety, efficacy, and cost-effectiveness of mechanical ventilation with humidifying filters changed every 48 hours: a prospective, randomized study. Crit Care Med 2000 Mar;28(3):665-71.

Marwick, 2009: Marwick C, Davey P. Care bundles: the holy grail of infectious risk management in hospital? Curr Opin Infect Dis 2009 Aug;22(4):364-9.

Mori, 2006: Mori H, Hirasawa H, Oda S, et al. Oral care reduces incidence of ventilator-associated pneumonia in ICU populations. Intensive Care Med 2006 Feb;32(2):230-6. Epub 2006 Jan 25. Available at http://www.springerlink.com/content/y7647557747781p4/fulltext.pdf. Last accessed September 24, 2009.

Morris, 2009: Morris AC, Kefala K, Simpson AJ, et al. Evaluation of the effect of diagnostic methodology on the reported incidence of ventilator-associated pneumonia. Thorax 2009 Jun;64(6):516-22. Epub 2009 Feb 12.

Nava, 1998: Nava S, Ambrosino N, Clini E, et al. Noninvasive mechanical ventilation in the weaning of patients with respiratory failure due to chronic obstructive pulmonary disease. A randomized, controlled trial. Ann Intern Med 1998 May 1;128(9):721-8. Available at http://www.annals.org/cgi/content/full/128/9/721. Last accessed September 24, 2009.

Needleman, 2002: Needleman J, Buerhaus P, Mattke S, et al. Nurse-staffing levels and the quality of care in hospitals. N Engl J Med 2002 May 30;346(22):1715-22. Available at http://content.nejm.org/cgi/reprint/346/22/1715.pdf. Last accessed September 24, 2009.

NHSN, 2008: The National Healthcare Safety Network (NHSN) Manual Patient Safety Component Protocol. Update 2008 Jan. Division of Healthcare Quality Promotion. National Center for Infectious Diseases. Centers for Disease Control and Prevention (CDC). Available at http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/NHSN_Manual_PatientSafetyProtocol_CURRENT.pdf. Last accessed September 24, 2009.

Niederman, 1997: Niederman MS, Craven DE. Devising strategies for preventing nosocomial pneumonia – should we ignore the stomach? Clin Infect Dis 1997 Mar;24(3):320-3.

NNIS, 2004: National Nosocomial Infections Surveillance (NNIS) System. National Nosocomial Infections Surveillance (NNIS) System Report, data summary from January 1992 through June 2004, issued October 2004. Am J Infect Control 2004 Dec;32(8):470-85.

Nourdine, 1999: Nourdine K, Combes P, Carton MJ, et al. Does noninvasive ventilation reduce the ICU nosocomial infection risk? A prospective clinical survey. Intensive Care Med 1999 Jun;25(6):567-73. Available at http://www.springerlink.com/content/56d115qvwrrh11fn/fulltext.pdf. Last accessed September 24, 2009.

Orozco-Levi, 1995: Orozco-Levi M, Torres A, Ferrer M, et al. Semirecumbent position protects from pulmonary aspiration but not completely from gastroesophageal reflux in mechanically ventilated patients. Am J Respir Crit Care Med 1995 Oct;152(4 Pt 1):1387-90.

Pacheco-Fowler, 2004: Pacheco-Fowler V, Gaonkar T, Wyer PC, et al. Antiseptic impregnated endotracheal tubes for the prevention of bacterial colonization. J Hosp Infect 2004 Jun;57(2):170-4.

Paju, 2007: Paju S, Scannapieco FA. Oral biofilms, periodontitis, and pulmonary infections. Oral Dis 2007 Nov;13(6):508-12. Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=17944664. Last accessed September 24, 2009.

Panchabhai, 2009: Panchabhai TS, Dangayach NS, Krishnan A, et al. Oropharyngeal cleansing with 0.2% chlorhexidine for prevention of nosocomial pneumonia in critically ill patients: an open-label randomized trial with 0.01% potassium permanganate as control. Chest 2009 May;135(5):1150-6.

PHC4, 2008: Pennsylvania Health Care Cost Containment Council (PHC4). Hospital-acquired Infections in Pennsylvania – Calendar Year 2006. Harrisburg, PA: Pennsylvania Health Care Cost Containment Council, April 2008. Available at http://www.phc4.org/reports/hai/06/docs/hai2006report.pdf. Last accessed September 24, 2009.

Prendergast, 2009: Prendergast V, Hallberg IR, Jahnke H, et al. Oral health, ventilator-associated pneumonia, and intracranial pressure in intubated patients in a neuroscience intensive care unit. Am J Crit Care 2009 Jul;18(4):368-7.

Prod'hom, 1994: Prod'hom G, Leuenberger P, Koerfer J, et al. Nosocomial pneumonia in mechanically ventilated patients receiving antacid, ranitidine, or sucralfate as prophylaxis for stress ulcer. A randomized controlled trial. Ann Intern Med 1994 Apr 15;120(8):653-62. Available at http://www.annals.org/cgi/content/full/120/8/653. Last accessed September 24, 2009.

Rello, 1996: Rello J, Torres A. Microbial causes of ventilator-associated pneumonia. Semin Respir Infect 1996 Mar;11(1):24-31.

Resar, 2005: Resar R, Pronovost P, Haraden C, et al. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. Jt Comm J Qual Patient Saf 2005 May;31(5):243-8.

Rodvold, 2009: Rodvold KA. Collaborative strategies for improving clinical resource utilization: how pharmacists can make a difference. J Manag Care Pharm 2009 Jun;15(5 Suppl):S10-4. Available at http://www.amcp.org/data/jmcp/S10-S14.pdf. Last accessed October 28, 2009.

Rouby, 1994: Rouby JJ, Laurent P, Gosnach M, et al. Risk factors and clinical relevance of nosocomial maxillary sinusitis in the critically ill. Am J Respir Crit Care Med 1994 Sep;150(3):776-83.

Rumbak, 1995: Rumbak MJ, Cancio MR. Significant reduction in methicillin-resistant Staphylococcus aureus ventilator-associated pneumonia associated with the institution of a prevention protocol. Crit Care Med 1995 Jul;23(7):1200-3.

Saint, 1998: Saint S, Matthay MA. Risk reduction in the intensive care unit. Am J Med 1998 Dec;105(6):515-23.

Salord, 1990: Salord F, Gaussorgues P, Marti-Flich J, et al. Nosocomial maxillary sinusitis during mechanical ventilation: a prospective comparison of orotracheal versus the nasotracheal route for intubation. Intensive Care Med 1990;16(6):390-3. Available at http://www.springerlink.com/content/u156545186402163/fulltext.pdf. Last accessed September 24, 2009.

Scott, 2009: Scott RD. The direct medical costs of healthcare-associated infections in US hospitals and the benefits of prevention. Atlanta (GA):Centers for Disease Control and Prevention (CDC); 2009 March. Available at www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf. Last accessed September 24, 2009.

Segers, 2006: Segers P, Speekenbrink RG, Ubbink DT, et al. Prevention of nosocomial infection in cardiac surgery by decontamination of the nasopharynx and oropharynx with chlorhexidine gluconate: a randomized controlled trial. JAMA 2006 Nov22;296(20):2460-6. Available at http://jama.ama-assn.org/cgi/content/full/296/20/2460. Last accessed October 6, 2009.

Segers, 2009: Segers P, de Mol BA. Prevention of ventilator-associated pneumonia after cardiac surgery: prepare and defend! Intensive Care Med 2009 Jun 26. [Epub ahead of print]

SHEA, N.D.: [No authors listed.] FAQs (Frequently Asked Questions) about "Ventilator-Associated Pneumonia." Arlington (VA): Society for Healthcare Epidemiology of America (SHEA); No Date. Available at http://www.shea-online.org/Assets/files/patient%20guides/NNL_VAP.pdf. Last accessed October 26, 2009.

Shorr, 2009: Shorr AF, Zilberberg MD, Kollef M. Cost-effectiveness analysis of a silver-coated endotracheal tube to reduce the incidence of ventilator-associated pneumonia. Infect Control Hosp Epidemiol 2009 Aug;30(8):759-63.

Siempos, 2009: Siempos II, Dimopoulos G, Falagas ME. Meta-analyses on the prevention and treatment of respiratory tract infections. Infect Dis Clin North Am 2009 Jun;23(2):331-53.

Silvestri, 2007: Silvestri L, van Saene JJ, van Saene HK, et al. Topical chlorhexidine and ventilator-associated pneumonia. Crit Care Med 2007 Oct;35(10):2468.

Sona, 2009: Sona CS, Zack JE, Schallom ME, et al. The impact of a simple, low-cost oral care protocol on ventilator-associated pneumonia rates in a surgical intensive care unit. J Intensive Care Med 2009 Jan-Feb;24(1):54-62.

Stamm, 1998: Stamm AM. Ventilator-associated pneumonia and frequency of circuit changes. Am J Infect Control 1998 Feb;26(1):71-3.

Stone, 2005: Stone PW, Braccia D, Larson E. Systematic review of economic analysis of health care-associated infections. Am J Infect Control 2005;33:501-9.

Tablan, 2004: Tablan OC, Anderson LJ, Besser R, et al.; CDC; Healthcare Infection Control Practices Advisory Committee. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR Recomm Rep 2004 Mar 26;53(RR-3):1-36. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm. Last accessed September 24, 2009.

Thorens, 1995: Thorens JB, Kaelin RM, Jolliet P, et al. Influence of the quality of nursing on the duration of weaning from mechanical ventilation in patients with chronic obstructive pulmonary disease. Crit Care Med 1995 Nov;23(11):1807-15.

TMIT, 2008: TMIT. Safer Critical Care: Resources to Prevent Ventilator-Associated Pneumonia (VAP) and Central Venous Catheter-Associated Bloodstream Infections (CVC-BSI). TMIT High Performer Webinar presented 2008 May 14. Available at http://www.safetyleaders.org/pages/idPage.jsp?ID=4878. Last accessed October 26, 2009.

Torres, 1992: Torres A, Serra-Batlles J, Ros E, et al. Pulmonary aspiration of gastric contents in patients receiving mechanical ventilation: the effect of body position. Ann Intern Med 1992 Apr 1;116(7):540-3.

Torres, 1995: Torres A, Gatell JM, Aznar E, et al. Re-intubation increases the risk of nosocomial pneumonia in patients needing mechanical ventilation. Am J Respir Crit Care Med 1995 Jul;152(1):137-41.

Toschlog, 2007: Toschlog EA, Newton C, Allen N, et al. Morbidity reduction in critically ill trauma patients through use of a computerized insulin infusion protocol: a preliminary study. J Trauma 2007 Jun;62(6):1370-5; discussion 1375-6.

Trudel, 2008: Trudel G, Zhou J, Uhthoff HK, et al. Four weeks of mobility after 8 weeks of immobility fails to restore normal motion: a preliminary study. Clin Orthop Relat Res 2008 May;466(5):1239-44. Epub 2008 Feb 26. Available at http://www.springerlink.com/content/60893452w776v012/fulltext.pdf. Last accessed September 24, 2009.

Vallés, 1995: Vallés J, Artigas A, Rello J, et al. Continuous aspiration of subglottic secretions in preventing ventilator-associated pneumonia. Ann Intern Med 1995 Feb 1;122(3):179-86. Available at http://www.annals.org/cgi/content/full/122/3/179. Last accessed September 24, 2009.

van den Berghe, 2001: van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in the critically ill patients. N Engl J Med 2001 Nov 8;345(19):1359-67. Available at http://content.nejm.org/cgi/reprint/345/19/1359.pdf. Last accessed September 24, 2009.

Warren, 2003: Warren, DK, Shukla SJ, Olsen MA, et al. Outcome and attributable cost of ventilator-associated pneumonia among intensive care unit patients in a suburban medical center. Crit Care Med 2003; 31: 1312-7.

Weireter, 2009: Weireter LJ Jr, Collins JN, Britt RC, et al. Impact of a monitored program of care on incidence of ventilator-associated pneumonia: results of a longterm performance-improvement project. J Am Coll Surg 2009 May;208(5):700-4; discussion 704-5.

Wip, 2009: Wip C, Napolitano L. Bundles to prevent ventilator-associated pneumonia: how valuable are they? Curr Opin Infect Dis 2009 Apr;22(2):159-66.

Yildizdas, 2002: Yildizdas D, Yapicioglu H, Yilmaz HL. Occurrence of ventilator-associated pneumonia in mechanically ventilated pediatric intensive care patients during stress ulcer prophylaxis with sucralfate, ranitidine, and omeprazole. J Crit Care 2002 Dec;17(4):240-5.

Yoneyama, 2002: Yoneyama T, Yoshida M, Ohrui T, et al. Oral care reduces pneumonia in older patients in nursing homes. J Am Geriatr Soc 2002 Mar;50(3):430-3.

Zaccard, 2009: Zaccard CR, Schell RF, Spiegel CA. Efficacy of bilateral bronchoalveolar lavage for the diagnosis of ventilator-associated pneumonia. J Clin Microbiol 2009 Jul 15. [Epub ahead of print]

Zilberberg, 2009: Zilberberg MD, Shorr AF, Kollef MH. Implementing quality improvements in the intensive care unit: ventilator bundle as an example. Crit Care Med 2009 Jan;37(1):305-9.

SAFE PRACTICE 24: MULTIDRUG-RESISTANT ORGANISM PREVENTION

The Objective

Prevent healthcare-associated multidrug-resistant organism (MDRO) infections, including methicillin-resistant *Staphylococcus aureus (S. aureus)* (MRSA), vancomycin-resistant *enterococci* (VRE), and *Clostridium difficile* infections (CDIs).

The Problem

The incidence rate of invasive MRSA is estimated to be 31.8 per 100,000; the standardized mortality rate is 6.3 per 100,000. [Klevens, 2007] MDROs are microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Common MDROs include MRSA, VRE, *Clostridium difficile,* and certain drug-resistant gram-negative bacilli such as *Pseudomonas aeruginosa,* and *Acinetobacter* species. [Harrison, 1998; Siegel, 2006; APIC, N.D.a; APIC, N.D.b] Patients infected or colonized with MDROs may readily contaminate their environment, and healthcare workers coming into contact with these patients or their surrounding environments may contaminate their own hands, clothing, and equipment, and transmit the MDROs to other persons. [Muto, 2003; Bhalla, 2004] Prevention and control of infections caused by MDROs are critical, because treatment options are often limited for patients infected by these organisms.

The frequency of infections caused by MDROs is increasing. The Centers for Disease Control and Prevention (CDC) reports that MRSA accounts for more than 50 percent of hospital-acquired *S. aureus* infections and for more than 63 percent of *S. aureus* infections acquired in intensive care units in the United States in 2004. [NNIS, 2004] More than 126,000 hospitalized persons are infected with MRSA annually—approximately 3.95 per 1,000 hospital discharges. [IHI, 2008] One study found that 82 percent of hospitals had not seen their CDI rate decrease in the past three years. [Jarvis, 2009] Recent statistics show that the number of hospital discharges with CDIs more than doubled from 2001 to 2005 and that there was an increase from approximately 149,000 cases in 2001 to more than 300,000 cases in 2005. [Carrico, 2008] The prevalence of vancomycin resistance in *Enterococcus* species isolated in hospitalized patients increased from 1 percent in 1990 to 15 percent in 1997. [Fridkin, 2001] In 2003, 25 percent of *Enterococcus* species isolated in intensive care units were resistant to vancomycin. [Jones, 2001]

The severity of infections caused by MDROs varies among the organisms. More than 5,000 deaths each year are attributable to MRSA. [IHI, 2008; Levinson, 2008] CDIs have recently been associated with an attributable mortality rate of 6.9 percent at 30 days and 16.7 percent at 1 year. [Loo, 2005; Muto, 2005; Pépin, 2005]

The burdens of MDROs can be reduced in the first place by increasing the preventability of healthcare-associated infections (HAIs). [Siegel, 2006] Support from the organization's leadership is imperative to ensure that adequate resources are provided to prevent the transmissions of MDROs within the healthcare facility. [Siegel, 2006] One study showed a 40 percent reduction in MDROs by implementing a checklist for hospital interventions. [Abbett, 2009] Education of healthcare workers about MDROs, proper hand hygiene, and proper environmental cleaning techniques all are important in preventing the transmission

of MDROs. [Seto, 1995; Boyce, 2002; Wright, 2004; Johnson, 2005; Johnston, 2009; Kaier, 2009] A notification system to inform infection control personnel of patients colonized or infected with MDROs should be established so that contact precautions may be instituted in a timely manner. [Siegel, 2006; Siegel, 2007; Dubberke, 2009] Active surveillance programs have demonstrated effectiveness in reducing the incidence of MDRO isolations in healthcare facilities; however, other studies did not show similar benefits of such programs. [Ostrowsky, 2001; Muto, 2003; Nijssen, 2005; Troché, 2005] The decrease in MDROs, through infection control activities, will also lead to the decline in other infections. [O'Dowd, 2009]

Excess costs and mortality are well recognized in patients infected with MDROs. An additional cost of more than $39,000 per case was reported in patients with an MRSA surgical-site infection. [Engemann, 2003] Mortality rates were approximately 13 percent higher in patients with MRSA infection in the aforementioned study and in a large claims review of patients discharged from New York City hospitals in 1995. [Rubin, 1999; Engemann, 2003] In one prospective surveillance study, CDIs increased the average length of stay by 3.6 days. [Kyne, 2002] Using the consumer price index for inpatient hospital services, the aggregate attributable hospital costs due to CDI range from $6,408 to $9,124 in 2007 dollars. [Scott, 2009] In a 4-year study involving more than 800 patients in 1993-1997, patients with VRE isolated or cultured during hospitalization were associated with an additional mean attributable cost of $12,766, and an increase in length of stay of 6.2 days. [Carmeli, 2002]

There is intense research of healthcare-associated infections (HAIs), and it will take time to understand the absolute magnitude of preventability and value of risk-assessment methods; [Wilcox, 2009] however, there is full consensus that actions need to be taken now to reduce MDROs with what is currently known. [Denham, 2005; Calfee, 2008; Dubberke, 2008; Denham, 2009d; NQF, 2009] Traditional infection control programs are directionally correct but insufficient to enable organizations to "chase zero" and reduce the harm of preventable HAIs. [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c]

Safe Practice Statement

Implement a systematic multidrug-resistant organism (MDRO) eradication program built upon the fundamental elements of infection control, an evidence-based approach, assurance of the hospital staff and independent practitioner readiness, and a re-engineered identification and care process for those patients with or at risk for MDRO infections.

Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *enterococci,* and *Clostridium difficile.* Multidrug-resistant gram-negative bacilli, such as *Enterobacter* species, *Klebsiella* species, *Pseudomonas* species, and *Escherichia coli,* and vancomycin-resistant *Staphylococcus aureus,* should be evaluated for inclusion on a local system level based on organizational risk assessments.

Additional Specifications [Siegel, 2006; Calfee 2008; Dubberke, 2008; JCR, 2010]

- The organization's leadership has assigned responsibility for oversight and coordination of the development, testing, and implementation of an MDRO prevention program. [IHI, N.D.; IHI, 2009b
- Conduct a risk assessment for MDRO acquisition and transmission.
- Upon hire and annually thereafter, educate staff and licensed independent practitioners about MDROs, including risk factors, routes of transmission, outcomes associated with infection, prevention measures, and local epidemiology. [Seto, 1995; TMIT, 2008]
- Educate patients who are infected with methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *enterococci*, or *Clostridium difficile,* or who are colonized with MRSA, and their families, as needed, about healthcare-associated infections and infection prevention strategies. [Lewis, 1999]
- Implement a surveillance program for MDROs based on risk assessment. [NHSN, 2009]
- Measure and monitor MDRO prevention processes and outcomes, including:
  - Infection rates using evidence-based metrics.
  - Compliance with evidence-based guidelines or best practices. [Calfee, 2008]
  - Evaluation of the education program provided to staff and licensed independent practitioners.
- Provide MDRO surveillance data, prevention processes, and outcome measures to key stakeholders, including senior hospital leadership, physicians, nursing staff, and other clinicians. [Calfee, 2008]
- Implement a laboratory-based alert system to provide immediate notification to infection control and clinical personnel about newly diagnosed MDRO-colonized or -infected patients.
- Implement an alert system that identifies readmitted or transferred MRSA-colonized or -infected patients.
- Promote compliance with hand hygiene recommendations. [Boyce, 2002; Gopal Rao, 2002; Johnson, 2005; D'Agata, 2009; Lederer, 2009]
- Use contact precautions for MDRO-colonized or -infected patients. [Siegel, 2006; CDC, 2007; Siegel, 2007; Salgado, 2009]
- Ensure cleaning and disinfection of equipment and environment. [Rampling, 2001; de Gialluly, 2006; Hardy, 2006; Huang, 2006; Boyce, 2009; IHI, 2009c; Salgado, 2009]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Place patients with MDRO on contact precautions to reduce patient-to-patient spread of the organism within the hospital.
  - Place the patient in a single or private room when available. Cohorting of MDRO-positive patients is acceptable when a single or private room is not available.

- Use appropriate hand hygiene upon entering and exiting the patient's room. [Humphreys, 2009; Mears, 2009] Wearing gloves does not eliminate the need for hand hygiene.
- Organizations that have created an opportunity for cleaning staff to have a leadership role in infection prevention have been rewarded by new energy and discipline at the frontline.

- Ensure cleaning and disinfection of equipment and the environment.
  - MDRO contaminates the patient's environment (e.g., overbed tables, bedrails, furniture, sinks, floors, television remote controls) and patient care equipment (e.g., stethoscopes, blood pressure cuffs, pulse oximeters).
  - Deploy specific environmental cleaning instructions to cleaning staff, including visual diagrams and checklists based on cleaning protocols.
  - Ensure adequate environmental cleaning staff on all shifts for successful compliance with cleaning requirements.
  - Perform environmental tracers to highlight skipped surfaces during cleaning process.
  - Ensure dedicated equipment for patients with known MDRO infection or colonization (such as thermometers, blood pressure cuffs, stethoscopes).
- Implement an MRSA active surveillance program. [Calfee, 2008; AHRQ, 2009]
  - Implement an MRSA active surveillance testing program as part of a multifaceted strategy to control and prevent MRSA when evidence suggests that there is ongoing transmission of MRSA despite effective implementation of basic practices.
  - Use the MRSA risk assessment as the basis for determining if, when, and where active surveillance testing is to be implemented at an individual hospital. Performance of a facility-specific MRSA risk assessment will result in the baseline description of MRSA incidence, prevalence, and transmission. [APIC, N.D.c ; APIC, N.D.d]
  - Convene a multidisciplinary team to review the MRSA risk assessment and to plan and oversee the active surveillance testing program.
- Initiate an antimicrobial stewardship program: [IHI, 2009a; Weber, 2009]
  - Assess the appropriateness of antimicrobial prescribing practices.
  - Construct an antibiogram considering the Clinical and Laboratory Standards Institute guideline document. [Hindler, 2005]
  - Restrict antimicrobials strongly associated with CDI, in addition to promoting appropriate antimicrobial use. [Weiss, 2009]

Strategies of Progressive Organizations

- Readiness of hospital staff and independent practitioners:
  - For program success, there must be a culture change. [Humphreys, 2009; Mears, 2009] The initiation of a systematic MDRO eradication program will require upfront allocation of additional resources. Increasing evidence for the "business case" shows that the initial investment is more than offset by cost savings in antibiotic therapy, length of stay, and pay-for-performance losses. [PHC4, 2008] Accountability of leaders

and their staff is absolutely necessary in order to decrease MDRO infections and prevent needless morbidity and mortality.

- One organization implemented an educational campaign and introduced a prevention bundle to include a series of specific processes aimed at preventing the transmission of C. *difficile* among hospitalized patients, with enhanced isolation practices, laboratory notification procedures, and steps coordinating infection control and environmental services activities. Also incorporated was a treatment bundle with a set of hospital-wide evidence based practices aimed at minimizing the risk of serious CDI complications. Quarterly incidence rates and case-fatality rates for health-care-associated CDI cases were tracked quarterly. [Abbett, 2009]

- Hospital leadership performs tracers:
  - Staff clearly witnesses leadership members utilizing hand sanitizers between patient encounters. Hands are the most likely source of the spread of HAIs. [Calfee, 2008]
  - Staff and physicians are consistently practicing hand hygiene before and after each patient encounter. [D'Agata, 2009]
  - Ancillary departments (dietary, respiratory, PT) appropriately use hand sanitizers between patient rooms.
  - Signs are clearly posted outside of MDRO patient rooms indicating contact precautions.
  - Barrier supplies are readily accessible outside an MDRO patient room (gown, gloves), and staff members are utilizing them. [Johnston, 2009]

Opportunities for Patient and Family Involvement [Denham, 2008; SHEA, N.D.a; SHEA, N.D.b]

- Teach patients and families the proper care of patients with MDROs, as well as precautions for preventing infection.
- Teach patients and families to recognize the signs and symptoms of infection.
- Encourage patients and family members to make sure that doctors and nurses utilize the barrier precautions upon entry into an MDRO patient room.
- Invite patients to ask staff whether they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions about MDRO transmission and prevention.
- Invite patients and families who have experienced MDRO-related illnesses to become members of appropriate patient safety and quality committees that address this issue.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs. [Calfee, 2008]

- **Outcome Measures**
  - Hospital onset bacteremia incidence or incidence density rate:
    - Numerator: Number of bloodstream MDRO isolates (separated by 14 days) for each unit or facility >3 calendar days after admission to unit or facility.

  - Denominator: 100 patient admissions (incidence); 1,000 patient days (incidence density).
- Nosocomial organism-specific infection incidence or incidence density rate:
  - Numerator: Number of hospital-onset MDRO infections meeting standard infection criteria (e.g., CDC NHSN-defined infection).
  - Denominator: 100 patient admissions (incidence); 1,000 patient days (incidence density).
- Point prevalence rate:
  - Numerator: Number of MDRO colonization or infection isolates, regardless of specimen source, per patient for each unit or facility.
  - Denominator: 100 patient admissions.
- Incidence or incidence density rate of hospital-onset MDRO based on clinical cultures:
  - Number of first MDRO colonization or infection isolates from only clinical specimens, regardless of specimen source, per patient for each unit or facility >3 calendar days after admission to unit or facility, excluding historically positive patients.
  - 100 patient admissions (incidence); 1,000 patient days (incidence density).

Process Measures

- Compliance with hand hygiene guidelines:
  - Monitor healthcare personnel compliance with hand hygiene guidelines both before and after contact with the MDRO patient or environment.
  - Numerator: number of observed adequate hand hygiene episodes performed by healthcare personnel.
  - Denominator: number of observed opportunities for hand hygiene.
  - Multiply by 100 so that the measure is expressed as a percentage.
- Compliance with contact precautions:
  - Numerator: number of observed patient care episodes in which contact precautions are appropriately implemented.
  - Denominator: number of observed patient care episodes in which contact precautions are indicated.
  - Multiply by 100 so that the measure is expressed as a percentage.
- Compliance with environmental cleaning:
  - One specific measure of compliance for use in all hospitals cannot be recommended. However, many hospitals use checklists and environmental rounds to assess the cleaning process and the cleanliness of the equipment and the environment.

Structure Measures include the verification of oversight or operational structures and documentation of readiness plans, including care re-engineering and workflow design. They also include the identification, stratification, and trending of specific risk factors of patients who have developed a MDRO infection to determine the success of mitigation strategies and the reporting of MDRO infections to leadership and staff.

Patient-Centered Measures include surveying patients to ascertain whether they noticed caregivers performing hand hygiene and contact precautions for MDRO patients.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Pediatric Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings, with the understanding that there are special considerations for pediatrics.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Further research is needed to establish criteria for active surveillance testing for MRSA among patient populations and healthcare personnel and for the implementation of MRSA-decolonization/eradication therapy for colonization or infection. [Boyce, 2009; Fraser, 2009; Otter, 2009] Developing better methods of testing for MDROs, such as CDI, is needed. [Wilcox, 2009] Evaluation of unintended consequences of care provided to patients receiving contact precautions also requires further consideration.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 19: Hand Hygiene is the cornerstone of an organization's infection control program. Implementing Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention; Safe Practice 22: Surgical-Site Infection Prevention; and Safe Practice 23: Care of the Ventilated Patient will also reduce MRSA infections by using standard evidence-based bundles prevention.

Notes

Abbett, 2009: Abbett SK, Yokoe DS, Lipsitz SR, et al. Proposed checklist of hospital interventions to decrease the incidence of healthcare-associated Clostridium difficile infection. Infect Control Hosp Epidemiol 2009 Nov;30(11):1062-9.

AHRQ, 2009: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed September 23, 2009.

APIC, N.D.a: Association for Professionals in Infection Control and Epidemiology (APIC). Multiple Drug Resistant Organisms (MDROs). Available at http://www.apic.org/AM/Template.cfm?Section=Multi_Drug_Resistance_Organisms&Template=/CM/HTMLDisplay.cfm&ContentID=11527. Last accessed September 24, 2009.

APIC, N.D.b: Association for Professionals in Infection Control and Epidemiology (APIC). National U.S. Inpatient Healthcare Facility: Clostridium difficile Survey. Available at http://www.apic.org/AM/Template.cfm?Section=National_C_Diff_Prevalance_Study&Template=/CM/HTMLDisplay.cfm&ContentID=12412. Last accessed September 24, 2009.

APIC, N.D.c: Association for Professionals in Infection Control and Epidemiology (APIC). Guide to the Elimination of Methicillin-Resistant Staphylococcus aureus (MRSA) Transmission in Hospital Settings. Available at http://www.ihatoday.org/issues/quality/apicguide.pdf. Last accessed October 7, 2009.

APIC, N.D.d: Association for Professionals in Infection Control and Epidemiology (APIC). Guide to the Elimination of Methicillin-Resistant Staphylococcus aureus (MRSA) Transmission in Hospital Settings 2009 Supplement. Available at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/MRSA-CA.pdf. Last accessed October 7, 2009.

Bhalla, 2004: Bhalla A, Pultz NJ, Gries DM, et al. Acquisition of nosocomial pathogens on hands after contact with environmental surfaces near hospitalized patients. Infect Control Hosp Epidemiol 2004 Feb;25(2):164-7. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/502369. Last accessed September 24, 2009.

Boyce, 2002: Boyce JM, Pittet D; Healthcare Infection Control Practices Advisory Committee; HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002 Oct 25;51(RR-16):1-45, quiz CE1-4. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm. Last accessed September 24, 2009.

Boyce, 2009: Boyce JM. New approaches to decontamination of rooms after patients are discharged. Infect Control Hosp Epidemiol 2009 Jun;30(6):515-7.

Calfee, 2008: Calfee DP, Salgado CD, Classen D, et al. Strategies to prevent transmission of methicillin-resistant Staphylococcus aureus in acute care hospitals. Infect Control Hosp Epidemiol 2008 Oct;29 Suppl 1:S62-80.

Carmeli, 2002: Carmeli Y, Eliopoulos G, Mozaffari E, et al. Health and economic outcomes of vancomycin-resistant enterococci. Arch Intern Med 2002 Oct 28;162(19):2223-8. Available at http://archinte.ama-assn.org/cgi/content/full/162/19/2223. Last accessed September 24, 2009.

Carrico, 2008: Carrico R. Guide to the Elimination of Clostridium difficile in Healthcare Settings. Washington, DC: Association for Professionals in Infection Control and Epidemiology (APIC); 2008.

CDC, 2007: Centers for Disease Control and Prevention. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. Available at http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf. Last accessed September 24, 2009.

D'Agata, 2009: D'Agata EM, Webb GF, Horn MA, et al. Modeling the invasion of community-acquired methicillin-resistant Staphylococcus aureus into hospitals. Clin Infect Dis 2009 Feb 1;48(3):274-84. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2666259&blobtype=pdf. Last accessed October 7, 2009.

de Gialluly, 2006: de Gialluly D, Morange V, de Gialluly E, et al. Blood pressure cuff as a potential vector of pathogenic microorganisms: a prospective study in a teaching hospital. Infect Control Hosp Epidemiol 2006 Sep;27(9):940-3. Epub 2006 Aug 21. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/507284. Last accessed September 24, 2009.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2008: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: can reality meet the rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4): 201-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Denham, 2009d: Denham CR. Are you infected? J Patient Saf 2009 Sep;5(3):188-96.

Dubberke, 2008: Dubberke ER, Gerding DN, Classen D, et al. Strategies to prevent clostridium difficile infections in acute care hospitals. Infect Control Hosp Epidemiol 2008 Oct;29 Suppl 1:S81-92.

Dubberke, 2009: Dubberke ER, Butler AM, Hota B, et al. Multicenter study of the impact of community-onset Clostridium difficile infection on surveillance for C. difficile infection. Infect Control Hosp Epidemiol 2009 Jun;30(6):518-25.

Engemann, 2003: Engemann JJ, Carmeli Y, Cosgrove SE, et al. Adverse clinical and economic outcomes attributable to methicillin resistance among patients with Staphylococcus aureus surgical site infection. Clin Infect Dis 2003 Mar 1;36(5):592-8. Epub 2003 Feb 7. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/367653. Last accessed September 24, 2009.

Fraser, 2009: Fraser TG, Fatica C, Gordon SM. Necessary but not sufficient: a comparison of surveillance definitions of Clostridium difficile-associated diarrhea. Infect Control Hosp Epidemiol 2009 Apr;30(4):377-9.

Fridkin, 2001: Fridkin SK, Edwards JR, Courval JM, et al. The effect of vancomycin and third-generation cephalosporins on prevalence of vancomycin-resistant enterococci in 126 U.S. adult intensive care units. Ann Intern Med 2001 Aug 7;135(3):175-83. Available at http://www.annals.org/cgi/content/full/135/3/175. Last accessed September 24, 2009.

Gopal Rao, 2002: Gopal Rao G, Jeanes A, Osman M, et al. Marketing hand hygiene in hospitals – a case study. J Hosp Infect 2002 Jan;50(1):42-7.

Hardy, 2006: Hardy KJ, Oppenheim BA, Gossain S, et al. A study of the relationship between environmental contamination with methicillin-resistant Staphylococcus aureus (MRSA) and patients' acquisition of MRSA. Infect Control Hosp Epidemiol 2006 Feb;27(2):127-32. Epub 2006 Feb 8. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/500622. Last accessed September 24, 2009.

Harrison, 1998: Harrison PF, Lederberg J, eds. Antimicrobial Resistance: Issues and Options. Forum on Emerging Infections. Washington, DC: Institute of Medicine; 1998. Available at http://books.nap.edu/catalog.php?record_id=6121. Last accessed September 24, 2009.

Hindler, 2005: Hindler JF, Evangelista AT, Jenkins SG, et al. Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline – Second Edition. CLSI document M39-A2 (ISBN 1-56238-585-2). Wayne (PA): Clinical and Laboratory Standards Institute (CLSI); 2005.

Huang, 2006: Huang SS, Datta R, Platt R. Risk of acquiring antibiotic-resistant bacteria from prior room occupants. Arch Intern Med 2006 Oct 9;166(18):1945-51. Available at http://archinte.ama-assn.org/cgi/content/full/166/18/1945. Last accessed September 24, 2009.

Humphreys, 2009: Humphreys H, Grundmann H, Skov R, et al. Prevention and control of methicillin-resistant Staphylococcus aureus. Clin Microbiol Infect 2009 Feb;15(2):120-4.

IHI, 2008: Institute for Healthcare Improvement. 5 Million Lives Campaign. Getting Started Kit: Reduce Methicillin-Resistant Staphylococcus aureus (MRSA) Infection: How-to Guide. Cambridge (MA): Institute for Healthcare Improvement; 2008. Available at http://www.ihi.org/nr/rdonlyres/f4d9de7a-3952-4ae7-bbac-4e4222084a03/0/mrsahowtoguide.doc. Last accessed September 24, 2009.

IHI, 2009a: [No authors listed.] Antibiotic Stewardship. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=584d97d9-d698-478f-8a10-ee60362d7462. Last accessed October 26, 2009.

IHI, 2009b: [No authors listed.] Infection Prevention. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI): 2009. Available at http://www.ihi.org/imap/tool/#Process=33ad5993-cbdb-47c1-8013-35c6d4f1f9d7. Last accessed October 26, 2009.

IHI, 2009c: [No authors listed.] Standard Precautions. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=a0fec1a5-373b-43cc-802a-037151e416ef. Last accessed October 11, 2009.

IHI, N.D.: [No authors listed.] Reduce Methicillin-Resistant Staphylococcus aureus (MRSA) Infection. Cambridge (MA): Institute for Healthcare Improvement (IHI); No Date. Available at http://www.ihi.org/IHI/Programs/Campaign/MRSAInfection.htm. Last accessed October 26, 2009.

Jarvis, 2009: Jarvis WR, Schlosser J, Jarvis AA, et al. National point prevalence of Clostridium difficile in US health care facility inpatients, 2008. Am J Infect Control 2009 May;37(4):263-70. Epub 2009 Mar 10.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.07.03.01.Oak Brook (IL): Joint Commission Resources; 2010.

Johnson, 2005: Johnson PD, Martin R, Burrell LJ, et al. Efficacy of an alcohol/chlorhexidine hand hygiene program in a hospital with high rates of nosocomial methicillin-resistant Staphylococcus aureus (MRSA) infection. Med J Aust 2005 Nov 21;183(10):509-14. Available at http://www.mja.com.au/public/issues/183_10_211105/joh10507_fm.html. Last accessed September 24, 2009.

Johnston, 2009: Johnston BL, Bryce E. Hospital infection control strategies for vancomycin-resistant Enterococcus, methicillin-resistant Staphylococcus aureus and Clostridium difficile. CMAJ 2009 Mar 17;180(6):627-31. Available at http://www.pubmedcentral.nih.gov.ezp-prod1.hul.harvard.edu/picrender.fcgi?artid=2653571&blobtype=pdf. Last accessed September 8, 2009.

Jones, 2001: Jones RN. Resistance patterns among nosocomial pathogens: trends over the past few years. Chest 2001 Feb;119(2 Suppl):397S-404S. Available at http://www.chestjournal.org/cgi/content/full/119/2_suppl/397S. Last accessed September 24, 2009.

Kaier, 2009: Kaier K, Hagist C, Frank U, et al. Two time-series analyses of the impact of antibiotic consumption and alcohol-based hand disinfection on the incidences of nosocomial methicillin-resistant Staphylococcus aureus infection and Clostridium difficile infection. Infect Control Hosp Epidemiol 2009 Apr;30(4):346-53.

Klevens, 2007: Klevens RM, Morrison MA, Nadle J, et al. Invasive methicillin-resistant Staphylococcus aureus infections in the United States. JAMA 2007 Oct 17;298(15):1763-71. Available at http://jama.ama-assn.org/cgi/reprint/298/15/1763. Last accessed October 29, 2009.

Kyne, 2002: Kyne L, Hamel MB, Polavaram R, et al. Health care costs and mortality associated with nosocomial diarrhea due to Clostridium difficile. Clin Infect Dis 2002 Feb 1;34(3):346-53. Epub 2001 Dec 17. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/338260. Last accessed September 24, 2009.

Lederer, 2009: Lederer JW Jr, Best D, Hendrix V. A comprehensive hand hygiene approach to reducing MRSA health care-associated infections. Jt Comm J Qual Patient Saf 2009 Apr;35(4):180-5.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 24, 2009.

Lewis, 1999: Lewis AM, Gammon J, Hosein I. The pros and cons of isolation and containment. J Hosp Infect 1999 Sep;43(1):19-23.

Loo, 2005: Loo VG, Poirier L, Miller MA, et al. A predominantly clonal multi-institutional outbreak of Clostridium difficile-associated diarrhea with high morbidity and mortality. N Engl J Med 2005 Dec 8;353(23):2442-9. Epub 2005 Dec 1. Available at http://content.nejm.org/cgi/reprint/353/23/2442.pdf. Last accessed September 24, 2009.

Mears, 2009: Mears A, White A, Cookson B, et al. Healthcare-associated infection in acute hospitals: which interventions are effective? J Hosp Infect 2009 Apr;71(4):307-13. Epub 2009 Feb 6.

Muto, 2003: Muto CA, Jernigan JA, Ostrowsky BE, et al. SHEA guideline for preventing nosocomial transmission of multidrug-resistant strains of Staphylococcus aureus and enterococcus. Infect Control Hosp Epidemiol. 2003 May;24(5):362-86. Review.

Muto, 2005: Muto CA, Pokrywka M, Shutt K, et al. A large outbreak of Clostridium difficile-associated disease with an unexpected proportion of deaths and colectomies at a teaching hospital following increased fluoroquinolone use. Infect Control Hosp Epidemiol 2005 Mar;26(3):273-80. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/502539. Last accessed September 24, 2009.

NHSN, 2009: National Healthcare Safety Network (NHSN). Multidrug-resistant Organism (MDRO) and Clostridium difficile-Associated Disease (CDAD) Module. Atlanta (GA): Centers for Disease Control and Prevention; 2009. Available at http://www.cdc.gov/nhsn/mdro_cdad.html. Last accessed October 26, 2009.

Nijssen, 2005: Nijssen S, Bonten MJ, Weinstein RA. Are active microbiological surveillance and subsequent isolation needed to prevent the spread of methicillin-resistant Staphylococcus aureus? Clin Infect Dis 2005 Feb 1;40(3):405-9. EWpub 2005 Jan 10. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/427281. Last accessed September 24, 2009.

NNIS, 2004: National Nosocomial Infections Surveillance (NNIS) System. National Nosocomial Infections Surveillance (NNIS) System Report, data summary from January 1992 through June 2004, issued October 2004. Am J Infect Control 2004 Dec;32(8):470-85. Available at http://www.cdc.gov/ncidod/dhqp/pdf/nnis/2004NNISreport.pdf. Last accessed September 24, 2009.

NQF, 2009: [No authors listed.] Patient Safety: Healthcare Acquired Conditions and Serious Reportable Events in Healthcare. Washington, DC: National Quality Forum; 2009. Available at http://www.qualityforum.org/projects/hacs_and_sres.aspx. Last accessed October 26, 2009.

O'Dowd, 2009: O'Dowd A. Government claims measures to cut MRSA and C difficile rates will help reduce other infections. BMJ 2009 Jun 26;338:b2580.

Ostrowsky, 2001: Ostrowsky BE, Trick WE, Sohn AH, et al. Control of vancomycin-resistant Enterococcus in health care facilities in a region. N Engl J Med. 2001 May 10;344(19):1427-33. Available at http://content.nejm.org/cgi/reprint/344/19/1427.pdf. Last accessed September 24, 2009.

Otter, 2009: Otter JA, Puchowicz M, Ryan D, et al. Feasibility of routinely using hydrogen peroxide vapor to decontaminate rooms in a busy United States hospital. Infect Control Hosp Epidemiol 2009 Jun;30(6):574-7.

Pépin, 2005: Pépin J, Saheb N, Coulombe MA, et al. Emergence of fluoroquinolones as the predominant risk factor for Clostridium difficile-associated diarrhea: a cohort study during an epidemic in Quebec. Clin Infect Dis 2005 Nov 1;41(9):1254-60. Epub 2005 Sep 20. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/496986. Last accessed September 24, 2009

PHC4, 2008: Pennsylvania Health Care Cost Containment Council (PHC4). Hospital-acquired Infections in Pennsylvania – Calendar Year 2006. Harrisburg, PA: Pennsylvania Health Care Cost Containment Council; 2008 Apr. Available at http://www.phc4.org/reports/hai/06/docs/hai2006report.pdf. Last accessed September 24, 2009.

Rampling, 2001: Rampling A, Wiseman S, Davis L, et al. Evidence that hospital hygiene is important in the control of methicillin-resistant Staphylococcus aureus. J Hosp Infect 2001 Oct;49(2):109-16.

Rubin, 1999: Rubin RJ, Harrington CA, Poon A, et al. The economic impact of Staphylococcus aureus infection in New York City hospitals. Emerg Infect Dis 1999 Jan-Feb;5(1):9-17. Available at http://www.cdc.gov/ncidod/eid/vol5no1/rubin.htm. Last accessed September 24, 2009.

Salgado, 2009: Salgado CD, Mauldin PD, Fogle PJ, et al. Analysis of an outbreak of Clostridium difficile infection controlled with enhanced infection control measures. Am J Infect Control 2009 Feb 23. [Epub ahead of print]

Scott, 2009: Scott RD. The direct medical costs of healthcare-associated infections in US hospitals and the benefits of prevention. Atlanta (GA):Centers for Disease Control and Prevention (CDC); 2009 March. Available at www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf. Last accessed September 24, 2009.

Seto, 1995: Seto WH. Training the work force – models for effective education in infection control. J Hosp Infect 1995 Jun;30 Suppl:241-7.

SHEA, N.D.a: [No authors listed.] FAQs (Frequently Asked Questions) about "Clostridium Difficile." Arlington (VA): Society for Healthcare Epidemiology of America (SHEA); No Date. Available at http://www.shea-online.org/Assets/files/patient%20guides/NNL_C-Diff.pdf. Last accessed October 26, 2009.

SHEA, N.D.b: [No authors listed.] FAQs (Frequently Asked Questions) about "MRSA" (Methicillin-Resistant Staphylococcus aureus). Arlington (VA): Society for Healthcare Epidemiology of America (SHEA); No Date. Available at http://www.shea-online.org/Assets/files/patient%20guides/NNL_MRSA.pdf. Last accessed October 26, 2009.

Siegel, 2006: Siegel JD, Rhinehart E, Jackson M, et al.; the Healthcare Infection Control Practices Advisory Committee. Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006. Centers for Disease Control and Prevention. Available at http://www.cdc.gov/ncidod/dhqp/pdf/ar/MDROGuideline2006.pdf. Last accessed September 24, 2009.

Siegel, 2007: Siegel JD, Rhinehart E, Jackson M, et al.; the Healthcare Infection Control Practices Advisory Committee. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007. Available at http://www.cdc.gov/ncidod/dhqp/gl_isolation.html. Last accessed September 24, 2009.

TMIT, 2008: TMIT. MRSA: For the Birds, or Pandemic Potential? TMIT High Performer Webinar presented 2008 Apr 8. Available at http://www.safetyleaders.org/pages/idPage.jsp?ID=4877. Last accessed October 26, 2009.

Troché, 2005: Troché G, Joly LM, Guibert M, et al. Detection and treatment of antibiotic-resistant bacterial carriage in a surgical intensive care unit: a 6-year prospective survey. Infect Control Hosp Epidemiol 2005 Feb;26(2):161-5. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/502521. Last accessed September 24, 2009.

Weber, 2009: Weber S, Soule BM, eds. What Every Health Care Executive Should Know: The Cost of Antibiotic Resistance. Oak Brook (IL): Joint Commission Resources; 2009. Available at http://www.jcrinc.com/MDRO-Toolkit/. Last accessed October 26, 2009.

Weiss, 2009: Weiss K, Boisvert A, Chagnon M, et al. Multipronged intervention strategy to control an outbreak of Clostridium difficile infection (CDI) and its impact on the rates of CDI from 2002 to 2007. Infect Control Hosp Epidemiol 2009 Feb;30(2):156-62.

Wilcox, 2009: Wilcox MH, Planche T. Clostridium difficile infection. BMJ 2009 Jun 23;338:b2528.

Wright, 2004: Wright MO, Hebden JN, Harris AD, et al. Aggressive control measures for resistant Acinetobacter baumannii and the impact on acquisition of methicillin-resistant Staphylococcus aureus and vancomycin-resistant Enterococcus in a medical intensive care unit. Infect Control Hosp Epidemiol 2004 Feb;25(2);167-8. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/502370. Last accessed September 24, 2009.

SAFE PRACTICE 25: CATHETER-ASSOCIATED URINARY TRACT INFECTION PREVENTION

The Objective

Prevent healthcare-acquired catheter-associated urinary tract infections (CAUTIs).

The Problem

It is estimated that nearly 2 million patients experience a healthcare-associated infection each year; of these infections, 32 percent are CAUTIs. [Klevens, 2007; Kanouff, 2008; AHRQ, 2009a; AHRQ, 2009b] CAUTIs are the most frequent healthcare-associated infections in acute care hospitals. Of these, 80 percent were attributable to an indwelling urethral catheter. [Saint, 2003] CAUTIs have been associated with increased morbidity, mortality, hospital cost, and length of stay. [Saint, 2000] Bacteremia and sepsis are infrequent but serious adverse events. [Tambya, 2000; Saint, 2006] Outbreaks of resistant gram-negative organisms attributable to bacteriuria in catheterized patients have been reported. [Jarvis, 1985; Yoon, 2005]

Because of the high frequency of catheter use in hospitalized patients, the burden of CAUTIs is substantial. [Saint, 2003; Saint, 2002; Tambya, 2002] National data from NHSN acute care hospitals in 2006 reported mean CAUTI rates of 3.1 to 7.5 infections per 1,000 catheter days. [Weinstein, 1999] Between 15 and 25 percent of hospitalized patients may receive short-term indwelling urinary catheters. [Warren, 2001; Weinstein, 1999] In 2002, the Centers for Disease Control and Prevention (CDC) estimated that 561,667 CAUTIs occurred in the United States, contributing to 13,088 deaths. [Klevens, 2007]

The morbidity attributable to any single episode of catheterization is limited, [Tambya, 2000] but due to the high incidence in hospitals, the cumulative severity of harm caused by CAUTIs is considerable. [Levinson, 2008] About 5 percent of bacteriuric cases develop bacteremia, making CAUTI the leading cause of secondary nosocomial bloodstream infection. About 17 percent of hospital-acquired bacteremias are from a urinary source, with an associated mortality of approximately 10 percent. [Weinstein, 1999]

The preventability of CAUTIs is estimated to be 17 to 69 percent with recommended infection control measures; this would translate into estimates of up to 380,000 preventable infections and 9,000 preventable deaths related to CAUTI per year. Strategies for the prevention of CAUTIs focus primarily on minimizing modifiable risk factors. The most significant risk factor for development of CAUTI is duration of catheterization. [Saint, 2003] Therefore, limiting catheter use and, when a catheter is indicated, minimizing the duration the catheter remains in situ are principal strategies for CAUTI prevention. [Kanouff, 2008] Institutions should provide and implement written guidelines for appropriate catheter use, insertion, and maintenance, including a system for documenting indication, as well as the date and time of insertion and the removal of the catheter. Institutions must ensure that the supplies necessary for aseptic-technique catheter insertion are readily available and must provide education to the personnel who are responsible for inserting catheters. [Lo, 2008; Barford, 2008; Willson, 2009] Evolving evidence also shows the use of an antimicrobial or silver alloy-coated catheter reduce the risk of CAUTIs. [Ciavarella, 2009; Parker, 2009]

The annual direct medical cost of CAUTI is estimated to be $565 million in the United States. Using the consumer price index for

inpatient hospital services, the aggregate attributable hospital costs per CAUTI case range from $862 to $1,007 in 2007 dollars. [Scott, 2009]

The National Quality Forum (NQF) report *National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data* recommends the immediate need for quality improvement in CAUTI prevention. The incorporation of best practices for urinary catheter care is recommended, in addition to using computer-based or written reminder systems for catheter assessment and removal and obtaining a urine culture before initiating antimicrobial therapy for urinary tract infection (UTI) in a patient with a urinary catheter. [NQF, N.D.]

Beginning October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) selected CAUTI as a hospital-acquired condition that will no longer receive higher reimbursement when not present on admission. [CMS/HAC, 2008; Saint, 2009]

Intense research is ongoing on healthcare-association infections, and it will take time to understand the absolute magnitude of its preventability and the value of risk-assessment methods; however, there is full consensus that actions need to be taken now to reduce CAUTIs with what is currently known. [Denham, 2005; Anderson, 2007; Lo, 2008; Denham, 2009d] Traditional infection control programs are directionally correct but insufficient to enable organizations to "chase zero" and reduce the harm of preventable healthcare-associated infections (HAIs). [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c]

Safe Practice Statement

Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices. [Lo, 2008; Gould, 2009]

Additional Specifications

- Document the education of healthcare personnel involved in the insertion, care, and maintenance of urinary catheters about catheter-associated urinary tract infection (CAUTI) prevention, including alternatives to indwelling catheters and procedures for catheter insertion, management, and removal. [Willson, 2009] Education should occur upon hire and annually thereafter, and when involvement in these procedures is added to an individual's job responsibilities. [Kanouff, 2008]
- Prior to insertion of a urinary catheter, educate the patient, and his or her family, as appropriate, about CAUTI prevention.
- Identify the patient groups or units on which surveillance should be conducted, using risk assessments that consider frequency of catheter use and potential risk.
- Implement policies and practices that are aimed at reducing the risk of CAUTI, that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). [Smith, 2008] Evidence-based practices include, but are not limited to, the following: [Greene, 2008; IHI, 2009; JCR, 2010]
  - Perform hand hygiene immediately before and after catheter insertion and any manipulation of the catheter site or apparatus. [Barford, 2008]

  - Ensure that the supplies necessary for aseptic technique for catheter insertion are readily available.
  - Insert catheters following an aseptic technique and using sterile equipment.
  - Insert urinary catheters only for appropriate indications, and leave them in place only as long as indications remain.
  - Obtain a urine culture before initiating antimicrobial therapy for urinary tract infection in a patient with a urinary catheter.
- Measure compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts for internal performance improvement.
- Provide CAUTI surveillance data, including process and outcome measures, to key stakeholders within the organization, including senior hospital leadership, physicians, nursing staff, and other clinicians.

Applicable Clinical Care Settings

This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Implement a system for documenting the following in the patient record: indications for catheter insertion; date and time of catheter insertion; individual who inserted catheter; and date and time of catheter removal.
- Develop and implement facility criteria for acceptable indications for indwelling urinary catheter use. [Gokula, 2004; Marklew, 2004]
- Suggested indications for indwelling urethral catheter use include:
  - Perioperative use for selected surgical procedures.
  - Accurate measurement of urine output in critically ill patients.
  - Management of acute urinary retention and urinary obstruction.
  - To assist in pressure ulcer healing for incontinent residents.
  - As an exception, at patient request to improve comfort.
  - Relief of bladder outlet obstruction or congenital urologic abnormalities.
- Following aseptic insertion of the urinary catheter, maintain a closed drainage system.
- Maintain unobstructed urine flow. [Gould, 2009]
- Implement an organization-wide program to identify and remove catheters that are no longer necessary, using one or more methods documented to be effective. Some examples include:
  - Automatic stop orders requiring renewal of order for continuation of the indwelling catheter.
  - Standardized reminders placed into patient charts or the electronic patient record.
  - The implementation of daily ward rounds by nursing and physician staff to review all patients with urinary catheters and ascertain continuing necessity.

Strategies of Progressive Organizations

- High-performing organizations have protocols for the management of post-operative urinary retention, including nurse-directed use of intermittent catheterization and use of bladder scanners.
- Innovations include direct visualization of the urethra during insertion of catheters, with the recognition that damage to the urethra can occur with blind insertion, leading to risk of infection. [Chapple, 2004; Fenton, 2005]
- Implement a system for analyzing and reporting data on catheter use and adverse events from catheter use. [AHRQ, 2009a; AHRQ, 2009b]
  - Define and monitor adverse outcomes, in addition to CAUTI, including catheter obstruction, unintended removal, catheter trauma, or reinsertion within 24 hours of removal.
  - For analysis, stratify measurements of catheter use and adverse outcomes by relevant risk factors (e.g., sex, age, ward, duration). Review data in a timely fashion and report to appropriate stakeholders.

Opportunities for Patient and Family Involvement [Denham, 2008; SHEA, N.D.]

- Teach patients and families the proper care of the urinary catheters, as well as precautions for preventing infection.
- Teach patients and families to recognize signs and symptoms of infection.
- Encourage patients to report changes in their catheter site, or any new discomfort.
- Encourage patients and family members to make sure that doctors and nurses check the catheter site every day for necessity and for signs of infection.
- Invite patients to ask staff if they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions before a urinary catheter is placed.
- Consider including patients or families of patients who have experienced a urinary catheter-related adverse event to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily all address external reporting needs.

- **Outcome Measures**
  - Rates of symptomatic catheter-associated urinary tract infection, stratified by risk factors (age, gender, ward, indication, catheter days): **Although the validity of the current CDC/NHSN definition for symptomatic CAUTI for comparison of facility-to-facility outcomes is not established, measurement of rates allows an individual facility to gauge the longitudinal impact of implementation of prevention strategies.**
    - Numerator: number of symptomatic CAUTI in each location monitored.
    - Denominator: total number of urinary catheter days for all patients in each location monitored who have an indwelling urinary catheter.

  - Multiply by 1000 so that measure is expressed as cases per 1000 catheter days.
- Rates of bacteremia attributable to CAUTI.
- Use NHSN definitions for laboratory-confirmed bloodstream infection. [NHSN, 2008]
  - Numerator: number of episodes of bloodstream infections attributable to CAUTI.
  - Denominator: total number of urinary catheter days for all patients in each location monitored who have an indwelling urinary catheter.
  - Multiply by 1000 so that measure is expressed as cases per 1000 catheter days.
- NQF-endorsed® outcome measures:
  1. #0138: Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients (Hospital): Percentage of intensive care unit patients with urinary catheter-associated urinary tract infections.
  2. #0281: Urinary infections (Hospital): This measure is used to assess the number of admissions for urinary tract infection per 100,000 population. [AHRQ, 2009b]
  3. #0196: Residents with a urinary tract infection: Percentage of residents on most recent assessment with a urinary tract infection.

Process Measures

- Compliance with documentation of catheter insertion and removal dates:
  - Conduct random audits of selected units and calculate compliance rate:
    - Numerator: number of patients with urinary catheters on the unit with proper documentation of insertion and removal dates.
    - Denominator: number of patients on the unit with a urinary catheter in place.
    - Multiply by 100 so that the measure is expressed as a percentage.
- Compliance with documentation of indication for catheter placement:
  - Conduct random audits of selected units and calculate compliance rate:
    - Numerator: number of patients with urinary catheters on the unit with proper documentation of indication.
    - Denominator: number of patients on the unit with a urinary catheter in place.
    - Multiply by 100 so that the measure is expressed as a percentage.
- NQF-endorsed process measure:
  1. #0453: Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero (Hospital): Surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero.

Structure Measures include the verification of oversight or operational structures and documentation of readiness plans, including care re-engineering and workflow design. Also include the identification, stratification, and trending of specific risk factors of patients who have developed a CAUTI to determine the success of mitigation strategies, and the reporting of CAUTI infections to leadership and staff.

- **Patient-Centered Measures** include surveying patients/families to ascertain whether they noticed caregivers performing hand hygiene.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Pediatric Healthcare Settings:** The NQF Pediatric Technical Advisory Panel concluded that healthcare-associated UTI is not a priority for measurement in pediatrics because of the low frequency of catheter use, and the difficulty of attributing UTIs to the receipt of healthcare.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.

New Horizons and Areas for Research

Further research will help define the use of antiseptic solution versus sterile saline for metal cleaning prior to catheter insertion and appropriate use of antimicrobial-coated catheters for selected patients at high risk of infection. [Drekonja, 2008] Also needed is valid measure development to align and support the safe practices of CAUTI. Any measure development would include supporting research on risk adjustment and stratification methods to account for patient populations, comorbidities, unit type, and catheter type.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 19: Hand Hygiene is the cornerstone of an organization's infection control program.

Notes

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Anderson, 2007: Anderson DJ, Kirkland KB, Kaye KS, et al. Underresourced hospital infection control and prevention programs: penny wise, pound foolish? Infect Control Hosp Epidemiol 2007 Jul;28(7):767–73. Epub 2007 May 31. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/518518. Last accessed September 23, 2009.

Barford, 2008: Barford JM, Anson K, Hu Y, et al. A model of catheter-associated urinary tract infection initiated by bacterial contamination of the catheter tip. BJU Int 2008 Jul;102(1):67-74. Epub 2008 Feb 18.

Chapple, 2004: Chapple C, Barbagli G, Jordan G, et al. Consensus on Genitourinary Trauma: Consensus statement on urethral trauma. 2004 June;93(9)1195-1202.

Ciavarella, 2009: Ciavarella DJ, Ritter J. Strategies to prevent catheter-associated urinary tract infection. Infect Control Hosp Epidemiol 2009 Apr;30(4):404-5; author reply 405-6.

CMS/HAC, 2008: Centers for Medicare & Medicaid Services. Hospital-Acquired Conditions (Present on Admission Indicator) Overview. 2008 Sep 4. Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed October 30, 2009.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2008: Denham CR. SBAR for patients. J Patient Saf 2008 Mar;4(1):38-48.

Denham, 2009a: Denham CR, Angood P, Berwick D, et al. Chasing Zero: can reality meet the rhetoric? J Patient Saf 2009 Dec;5(4):216-22.

Denham, 2009b: Denham CR, Angood P, Berwick D, et al. The Chasing Zero Department: making idealized design a reality. J Patient Saf 2009 Dec;5(4):201-5.

Denham, 2009c: Denham CR. Green light issues for the CFO: investing in patient safety. J Patient Saf 2010 Mar;6(1):Pending.

Denham, 2009d: Denham CR. Are you infected? J Patient Saf 2009 Sep;5(3):188-96.

Drekonja, 2008: Drekonja DM, Kuskowski MA, Wilt TJ, et al. Antimicrobial urinary catheters: a systematic review. Expert Rev Med Devices 2008 Jul;5(4):495-506.

Fenton, 2005: Fenton AS, Morey AF, Aviles R, et al. Anterior urethral strictures: etiology and characteristics. Urology 2005 Jun;65(6):1055-8.

Gokula, 2004: Gokula RRM, Hickner JA, Smith MA. Inappropriate use of urinary catheters in elderly patients at a midwestern community teaching hospital. Am J Infect Control 2004 Jun;32(4):196-9.

Gould, 2009: Gould CV, Umscheid CA, Agarwal RK, et al.; Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for prevention of catheter-associated urinary tract infections 2009. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2009.

Greene, 2008: Greene L, Marx J, Oriola S. Guide to the Elimination of Catheter-Associated Urinary Tract Infections (CAUTIs). Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc. (APIC); 2008. Available at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/CAUTI_Guide1.htm. Last accessed October 26, 2009.

IHI, 2009: [No authors listed.] Catheter-Associated Urinary Tract Infection (CA UTI) Prevention. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI): 2009. Available at http://www.ihi.org/imap/tool/#Process=2e1ead62-c0c8-41f2-96f6-884d5702f374. Last accessed October 26, 2009.

Jarvis, 1985: Jarvis WR, Munn VP, Highsmith AK, et al. The epidemiology of nosocomial infections caused by Klebsiella pneumoniae. Infect Control 1985 Feb;6(2):68-74.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goals. Oak Brook (IL): Joint Commission Resources; 2010.

Kanouff, 2008: Kanouff AJ, DeHaven KD, Kaplan PD. Prevention of nosocomial infections in the intensive care unit. Crit Care Nurs Q 2008 Oct-Dec;31(4):302-8.

Klevens, 2007: Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep 2007 Mar-Apr;122(2):160-6.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 23, 2009.

Lo, 2008: Lo E, Nicolle L, Classen D, et al. Strategies to prevent catheter-associated urinary tract infections in acute care hospitals. Infect Control Hosp Epidemiol 2008 Oct;29 Suppl 1:S41-50. http://www.journals.uchicago.edu/doi/pdf/10.1086/591066 Last accessed October 6, 2009.

Marklew, 2004: Marklew A. Urinary catheter care in the intensive care unit. Nurs Crit Care 2004 Jan-Feb;9(1):21-7.

NHSN, 2008: National Healthcare Safety Network (NHSN). Department of Health and Human Services. Centers for Disease Control and Prevention. NHSN Members Page. Available at http://www.cdc.gov/nhsn/. Last accessed September 23, 2009.

NQF, N.D.: National Quality Forum. National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data. Available at http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_the_Reporting_of_Healthcare-Associated_Infection_Data.aspx. Last accessed September 23, 2009.

Parker, 2009: Parker D, Callan L, Harwood J, et al. Nursing interventions to reduce the risk of catheter-associated urinary tract infection. Part 1: Catheter selection. J Wound Ostomy Continence Nurs 2009 Jan-Feb;36(1):23-34.

Saint, 2000: Saint S, Veenstra DL, Lipsky BA. Infect Control Hosp Epidemiol 2000 Jun;21(6):375-80. Review.

Saint, 2002: Saint S, Savel RH, Matthay MA. Am J Respir Crit Care Med. 2002 Jun 1;165(11):1475-9. Review. No abstract available.

Saint, 2003: Saint S, Chenoweth CE. Biofilms and catheter-associated urinary tract infections. Infect Dis Clin North Am 2003 Jun;17(2):411-32.

Saint, 2006: Saint S, Kaufman SR, Rogers MA, et al. Risk factors for nosocomial urinary tract related bacteremia: a case-control study. Am J Infect Control 2006 Sep;34(7):401-7.

Saint, 2009: Saint S, Meddings JA, Calfee D, et al. Catheter-associated urinary tract infection and the Medicare rule changes. Ann Intern Med 2009 Jun 16;150(12):877-84.

Scott, 2009: Scott RD. The direct medical costs of healthcare-associated infections in US hospitals and the benefits of prevention. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2009 March. Available at www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf. Last accessed October 30, 2009.

SHEA, N.D.: [No authors listed.] FAQs (Frequently Asked Questions) about "Catheter-Associated Urinary Tract Infection." Arlington (VA): Society for Healthcare Epidemiology of America (SHEA); No Date. Available at http://www.shea-online.org/Assets/files/patient%20guides/NNL_CA-UTI.pdf. Last accessed October 26, 2009.

Smith, 2008: Smith PW, Bennett G, Bradley S, et al. SHEA/APIC Guideline: Infection prevention and control in the long-term care facility. Am J Infect Control 2008 Sep;36(7):504-35. Available at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APIC-SHEA_Guideline.pdf. Last accessed September 23, 2009.

Tambyah, 2000: Tambyah PA, Maki DG. Catheter-associated urinary tract infection is rarely symptomatic: a prospective study of 1,497 catheterized patients. Arch Intern Med 2000 Mar 13;160(5):678-82. Available at http://archinte.ama-assn.org/cgi/content/full/160/5/678. Last accessed September 23, 2009.

Warren, 2001: Warren JW. Catheter-associated urinary tract infections. Int J Antimicrob Agents 2001 Apr;17(4):299-303.

Weinstein, 1999: Weinstein JW, Mazon D, Pantelick E, et al. A decade of prevalence surveys in a tertiary-care center: trends in nosocomial infection rates, device utilization, and patient acuity. Infect Control Hosp Epidemiol 1999 Aug;20(8):543-8. Available at http://www.journals.uchicago.edu/doi/pdf/10.1086/501675. Last accessed September 23, 2009.

Willson, 2009: Willson M, Wilde M, Webb ML, et al. Nursing interventions to reduce the risk of catheter-associated urinary tract infection: part 2: staff education, monitoring, and care techniques. J Wound Ostomy Continence Nurs 2009 Mar-Apr;36(2):137-54.

Yoon, 2005: Yoon HJ, Choi JY, Park YS, et al. Outbreaks of Serratia marcescens bacteriuria in a neurosurgical intensive care unit of a tertiary care teaching hospital: a clinical, epidemiologic, and laboratory perspective. Am J Infect Control 2005 Dec;33(10):595-601.

Chapter 8: Improving Patient Safety Through Condition- and Site-Specific Practices

Background

PEOPLE WHO ARE ADMITTED to inpatient care facilities (e.g., acute care hospitals, nursing homes) are often at increased risk of suffering an adverse event simply by virtue of being an inpatient. Risk factors include experiencing decreased mobility or stress, being exposed to unusual pathogens, and being subjected to various invasive interventions.

Patients who are cared for in outpatient settings also have an increased risk of suffering adverse events, due to the fragmentation of care delivered by multiple caregivers and the inherent interruption of full care information flow about conditions and therapies. Coalitions such as the National Priorities Partnership have recognized enormous opportunities for improving care through patient safety and care coordination. These are two of the National Priorities Partnership's six major Priorities. [NPP, 2009]

The organization of patient care processes and the commitment of resources for care and care improvement have a significant impact on outcomes for some types of patients. It also is increasingly evident, as the collection and reporting of data related to adverse events increase, that organizations that strive for quality and safety improvement (e.g., by participating in condition- and procedure-related registries, actively measuring performance and addressing performance gaps, and encouraging team building and teamwork that actively include all staff and patients) show significant improvement in healthcare quality and safety.

The following nine practices, if fully implemented, could significantly reduce the risks of adverse events for patients with specific types of care needs. Existing practices have been updated in light of evolving patient safety risks.

Note

NPP, 2009: National Priorities Partnership. National Quality Forum. Available at http://www.nationalprioritiespartnership.org/Home.aspx. Last accessed October 15, 2009.

SAFE PRACTICE 26: WRONG-SITE, WRONG-PROCEDURE, WRONG-PERSON SURGERY PREVENTION

The Objective

Prevention of wrong-site, wrong-procedure, and wrong-person surgeries.

The Problem

Wrong-site surgery involves all surgical procedures performed on the wrong patient, wrong body part, wrong side of the body, or wrong level of a correctly identified anatomic site. [Kwaan, 2006] Wrong-patient surgery may include patients who were never scheduled for a procedure but who received one; procedures performed that were not scheduled; and procedures that were scheduled correctly, but for which the wrong procedure was performed. Because wrong-site surgery is preventable, the National Quality Forum (NQF) has designated it as one of its serious reportable events. [NQF, 2002; NQF 2007; Levinson, 2008b]

The true frequency of wrong-site surgery is not known, and current estimations of the incidence of wrong-site surgeries vary. Based on their analysis of wrong-site surgeries reported to a large malpractice insurer, Kwaan et al. concluded that nonspine wrong-site surgeries are rare, occurring only once in 112,994 operations. [Kwaan, 2006] However, for spine surgeons there was one wrong-site surgery for every 3,110 operations, and it is estimated that 50 percent of spine surgeons will perform a wrong-site surgery at least once in their career. [Mody, 2008] Seiden and Barach estimated, after analyzing 5 major incident reporting and claims databases, that the incidence of wrong-site surgeries may be as high as 1,300 to 2,700 per year. [Seiden, 2006] Data reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS) indicate that, on average, 1 wrong-site surgery occurs in every 300-bed hospital each year. [PA-PSRS, 2007] Forty percent of PA-PSRS-reported events reached the patient, and 20 percent actually involved the completion of a wrong-site procedure. Wrong-site surgeries were the most reported sentinel events (13 percent of 5,208 events) to The Joint Commission between January 1995 and July 2008. [TJC, 2008a] Wrong-surgery sentinel events were distributed among the following types: wrong-side surgeries (59 percent); wrong-patient (12 percent); wrong-procedure (10 percent); and other wrong-site surgeries (19 percent). The surgical specialties most commonly involved were orthopedic (41 percent); general surgery (20 percent); neurosurgery (14 percent); and urology (11 percent). [TJC, 2009]

Because wrong-site surgeries are believed to significantly under-reported, it is not currently possible to estimate the severity of harm caused by these sentinel events. [Seiden, 2006; Levinson, 2008a] Only one major study has attempted to evaluate the severity of harm associated with wrong-site studies. That study concluded that wrong-site studies were rare and that major injury from these errors is even rarer. [Kwaan, 2006] Additional research is needed before this conclusion can be accepted or refuted.

The preventability of wrong-site, wrong-procedure, and wrong-person surgeries cannot be overstated. Analyses performed by hospitals on 126 cases of wrong-site surgery identified the following root causes: communication failures among the surgical team, patient, and family; breakdowns during the preoperative assessment of the patient; and inadequate policies or procedures related to site marking

and verification procedures by the surgical team. [Clarke, 2008; Blanco, 2009] Other factors related to staffing, culture, and distractions were also cited as root causes. [TJC, 2001] In July 2003, The Joint Commission's Board of Commissioners approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. The Universal Protocol is applicable to all operative and other invasive procedures. [JCR, 2010b]

Relatively speaking, the cost of wrong-site surgeries is low. According to the Physician Insurers Association of America, the likelihood for paid claims on wrong-site cases is small. Between 1998 and 2007, the overall average indemnity (in 2008 dollars) paid for a claim was $146,201. Neurosurgeons ($425,677) and urologists ($306,460) paid the highest average indemnities, while orthopedic surgeons were the most likely to have or pay a claim against them. [PA-PSRS, 2008]

Safe Practice Statement

Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ for all invasive procedures. [AHRQ, 2001; IHI, 2009]

Additional Specifications

Specifications of Universal Protocol: [Angle, 2008; JCR, 2010a; JCR, 2010b]

- Create and use a preoperative verification process to ensure that relevant preoperative tasks are completed and that information is available and correct. [WAPS, 2008; Haynes, 2009; Henrickson, 2009; HPR, 2009]
- Mark the surgical site and involve the patient in the marking process, at a minimum, for cases involving right/left distinction, multiple structures (e.g., fingers, toes) or multiple levels (e.g., spinal procedures). [Robinson, 2009]
- Immediately before the start of any invasive procedure, conduct a "time out" to confirm the correct patient, procedure, site, and any required implants or special equipment. [VMMC, 2006; Dillon, 2008]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory surgical center, emergency room, inpatient service/hospital, and outpatient hospital.

Example Implementation Approaches

- Empower the entire healthcare team to "stop the line" at any point in the process and to resume only when all elements of the protocol are in place/verified.
- Implement the WHO 19-item surgical safety checklist, which has been estimated to save the lives of 1 in 144 surgical patients. [Haynes, 2009]
- Raise awareness of wrong-site surgery through system-wide patient safety alerts. [Rhodes, 2008]

Strategies of Progressive Organizations

- Some organizations include the patient's own words into the health record. This includes the patient confirming his or her full name and birth date.

Opportunities for Patient and Family Involvement

- Educate the patient and family members about the common incidence of wrong-site surgical procedures.
- Actively involve the patient, and family whenever appropriate, in all steps of presurgery preparation.
- Include the patient during time-out procedure to verify correct surgical site.
- Encourage the patient to ask questions and "stop the line" before sedation if he or she is not included in the time-out.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include change in rates of incidence of the NQF-endorsed® serious reportable events and The Joint Commission sentinel events related to surgery performed on the wrong site, wrong side, or wrong person.
  - Percentage of Ambulatory Surgical Center admissions experiencing a wrong-site, wrong-side, wrong-patient, wrong-procedure, or wrong-implant surgery.
  - NQF-endorsed® outcome measure:
    1. #0267: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant [Hospital, Ambulatory Surgical Centers]: Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.
- **Process Measures** include monitoring to identify actual or aborted gaps in performance of all steps of the Universal Protocol.
- **Structure Measures** include compliance with the Universal Protocol as part of the leadership dashboard and evidence of ongoing education and training for all caregivers, including medical staff who participate in operative and invasive procedures. This should include the percentage of individuals completing initial and refresher sessions.
- **Patient-Centered Measures** include surveys of patient involvement in surgical-site identification and communication with the entire team.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

Opportunities for further improvement exist in the area of patient identification that include the use of technology-enabled best practices.

Other Relevant Safe Practices

See Safe Practice 1: Leadership Structures and Systems and Safe Practice 4: Identification and Mitigation of Risks and Hazards.

Notes

AHRQ, 2001: [No authors listed.] Strategies to Avoid Wrong-Site Surgery. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality; 2001 Jul: Ch. 43, Subchapter 43.2. Available at http://www.ahrq.gov/clinic/ptsafety/chap43b.htm#43.2. Last accessed October 27, 2009.

Angle, 2008: Angle JF, Nemcek AA Jr, Cohen AM, et al. Quality improvement guidelines for preventing wrong site, wrong procedure, and wrong person errors: application of the joint commission "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" to the practice of interventional radiology. J Vasc Interv Radiol 2008 Aug;19(8):1145-51.

Blanco, 2009: Blanco M, Clarke JR, Martindell D. Wrong site surgery near misses and actual occurrences. AORN J 2009 Aug;90(2):215-22.

Clarke, 2008: Clarke JR, Johnston J, Blanco M, et al. Wrong-site surgery: can we prevent it? Adv Surg 2008;42:13-31.

Dillon, 2008: Dillon KA. Time out: an analysis. AORN J 2008 Sep;88(3):437-42.

Haynes, 2009: Haynes HR, Weiser TG, Berry WR, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med 2009;360:491-9. Epub 2009 Jan 14. Available at http://content.nejm.org/cgi/reprint/360/5/491.pdf. Last accessed September 28, 2009.

Henrickson, 2009: Henrickson SE, Wadhera RK, Elbardissi AW, et al. Development and pilot evaluation of a preoperative briefing protocol for cardiovascular surgery. J Am Coll Surg 2009 Jun;208(6):1115-23. Epub 2009 Apr 17.

HPR, 2009: [No authors listed.] TJC still focusing on NPSGs, universal protocol. Hosp Peer Rev 2009 Apr;34(4):45-7.

IHI, 2009: [No authors listed.] Surgical Checklist. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=f4638151-91d3-4329-99dc-3e9372511afa. Last accessed October 27, 2009.

JCR, 2010a: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goals. Oak Brook (IL): Joint Commission Resources; 2010.

JCR, 2010b: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goals. Universal Protocol. Oak Brook (IL); Joint Commission Resources; 2010.

Kwaan, 2006: Kwaan MR, Studdert DM, Zinner MJ, et al. Incidence, patterns, and prevention of wrong-site surgery. Arch Surg 2006 Apr;141(4):353-7; discussion 357-8. Available at http://archsurg.ama-assn.org/cgi/content/full/141/4/353. Last accessed September 28, 2009.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 28, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 28, 2009.

Mody, 2008: Mody MG, Nourbakhsh A, Stahl DL, et al. The prevalence of wrong level surgery among spine surgeons. Spine (Phila Pa 1976) 2008 Jan 15;33(2):194-8.

NQF, 2002 : National Quality Forum (NQF). Serious Reportable Events in Healthcare: A Consensus Report. Washington, DC: NQF; 2002 Mar.

NQF, 2007: NQF. Safe Practices for Better Healthcare 2006 Update – A Consensus Report. Washington, DC: National Quality Forum; 2006. Available at http://www.qualityforum.org/pdf/projects/safe-practices/SafePractices2006UpdateFINAL.pdf. Last accessed September 28, 2009.

PA-PSRS, 2007: Pennsylvania Patient Safety Reporting System. Pennsylvania Patient Safety Advisory. Doing the "Right" Things to Correct Wrong-Site Surgery. 2007 Jun;4(2). Available at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/jun4(2)/Pages/29b.aspx. Last accessed September 28, 2009.

PA-PSRS, 2008: Pennsylvania Patient Safety Reporting System. Pennsylvania Patient Safety Advisory. Quarterly Update on the Preventing Wrong-Site Surgery Project. 2008 Sep;5(3):103-5. Available at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/103.aspx. Last accessed September 28, 2009.

Rhodes, 2008: Rhodes P, Giles SJ, Cook GA, et al. Assessment of the implementation of a national patient safety alert to reduce wrong site surgery. Qual Saf Health Care 2008 Dec;17(6):409-15.

Robinson, 2009: Robinson PM, Muir LT. Transfer of a pre-operative surgical site mark to the opposite side increases the risk of wrong site surgery. Ann R Coll Surg Engl 2009 Jul;91(5):444-5.

Seiden, 2006: Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: are they preventable? Arch Surg 2006 Sep;141(9):931-9. Available at http://archsurg.ama-assn.org/cgi/content/full/141/9/931. Last accessed September 28, 2009.

TJC, 2001: The Joint Commission (TJC). A follow up review of wrong-site surgery. Sentinel Event Alert. 2001;24:1-3. Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm. Last accessed September 28, 2009.

TJC, 2009: The Joint Commission. Sentinel Event Statistics – Updated through September 30, 2009. Oakbrook Terrace (IL): The Joint Commission (TJC); 2009 Sep 30. Available at http://www.jointcommission.org/SentinelEvents/Statistics/. Last accessed October 29, 2009.

VMMC, 2006: [No authors listed.] Procedural Pause Audit Tool. Seattle (WA): Virginia Mason Medical Center; 2006. Available at http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/ProceduralPauseAuditTool.htm. Last accessed October 27, 2009.

WAPS, 2008: World Alliance for Patient Safety. WHO surgical safety checklist and implementation manual. Geneva (Switzerland): World Health Organization; 2008. Available at http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html. Last accessed October 27, 2009.

SAFE PRACTICE 27: PRESSURE ULCER PREVENTION

The Objective

Prevent healthcare-associated pressure ulcers.

The Problem

Pressure ulcers (also known as bedsores, pressure sores, and decubitus ulcers) are areas of localized damage to the skin and underlying tissue that are the result of pressure. Patients who are acutely ill, cognitively impaired, malnourished, and unable to adjust themselves easily are at risk for developing pressure ulcers as they develop over a short period of time. [Dorner, 2009] Pressure ulcers are staged from I through IV to classify the degree of damage. [NPUAP, 2009] Pressure ulcers continue to be problematic in all healthcare settings.

Pressure ulcers occur in more than 2.5 million patients in the United States; [JCR, 2008] however, the frequency of pressure ulcers varies considerably by clinical setting. In acute care settings, the incidence ranges from 0.4 percent to 38 percent, with 48 percent to 53 percent occurring while the patient is hospitalized. [Lyder, 2003] It is estimated that 2.5 million patients are treated for pressure ulcers in U.S. acute care facilities each year. [Lyder, 2003; Reddy, 2006] Approximately 60,000 U.S. hospital patients die each year from healthcare-acquired pressure ulcer complications. [Redelings, 2005] The 2005 International Pressure Ulcer Prevalence Study, sponsored by Hill-Rom, reported a pressure ulcer prevalence of 15.2 percent and a hospital-acquired pressure ulcer prevalence of 7.3 percent. [Hill-Rom, 2005]

The severity of harm caused by healthcare-acquired pressure ulcers goes beyond the statistics. [Levinson, 2008a] Pressure ulcers are painful, expensive, and largely a preventable harmful event. [AHRQ, 2009a; AHRQ, 2009b; NQF, 2009] A retrospective analysis of nosocomial pressure ulcer data showed a 67 percent, 180-day mortality rate for patients who developed full-thickness pressure ulcers during acute hospitalizations. [Brown, 2003] Pressure ulcers can cause significant pain, prolonged infections, and decreased quality of life. Patients with pressure ulcers often have longer lengths of stay and slower recoveries and are at a higher risk for developing future ulcers. Pressure ulcers can lead to amputations and death. Stage III and IV under the previous system of measurement, pressure ulcers heal by contraction and the replacement of the lost muscle with connective tissue. [AHCPR, 1994] But Stage III and Stage IV ulcers are slower to heal than earlier stage ulcers, and often the muscle does not regenerate. The difficulty in dealing with pressure ulcers in healthcare settings results from the complexity of the patients and of the environment. Risk factors of the patient, such as age and concomitant conditions, are compounded with environmental factors (friction and shear, moisture), and may be further complicated by the reason the patient is hospitalized (acute illness, surgical procedures). [Harrison, 2008]

The preventability of pressure ulcers has been well established. Through evidence-based practices, most pressure ulcers can be prevented, and deterioration at Stage I can be halted. Appropriate prevention methods are widely known and available, yet underutilized. Prevention methods, such as minimizing skin friction and pressure while also managing related risk factors (such as incontinence and inadequate nutrition), are key. Close monitoring is imperative; there are several scoring

systems that can be used to reliably assess the risk for pressure ulcer development. [Benbow, 2008] Effective identification of patients and early intervention are the first steps in preventing healthcare-associated pressure ulcers. [Brandeis, 2001] Healthcare systems have been successful in eliminating Stage III and IV healthcare-acquired pressure ulcers. A 528-bed acute care facility was able to reduce and eliminate pressure ulcers by implementing a comprehensive education and monitoring program. [Gibbons, 2006]

An estimated $3.6 billion per year of the national burden can be attributed to the cost of medical care for pressure ulcers. There were 322,946 reported cases of pressure ulcers in 2006, with each one costing on average $40,381 to treat, leading to an aggregate cost of $13 billion annually. [AORN, 2008] The estimated cost of managing a single full-thickness pressure ulcer is as high as $70,000 per case. [Reddy, 2006] The mean cost per hospital admission for patients who develop a pressure ulcer has been reported to be $37,288. [Reddy, 2006] The financial costs do not take into account the total cost of pressure ulcers. The human cost can be painful, debilitating, and even life-threatening. The prevention of pressure ulcers is an intervention that is not new and not expensive, and it has the potential to save millions of patients from unnecessary harm. [Duncan, 2007]

Beginning October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) changed the way it reimburses hospitals for complications sustained during hospital treatment by Medicare beneficiaries. CMS has published a list of conditions—or events—considered to be "reasonably preventable" during a hospital stay and for which Medicare may refuse payment. CMS has selected Stage III and IV pressure ulcers as hospital-acquired conditions that will no longer receive reimbursement. The National Quality Forum (NQF) also has also deemed Stage III and IV pressure ulcers as serious reportable events when acquired after admission to a healthcare facility. [NQF, 2008; Levinson, 2008b; CMS/HAC, 2009]

Safe Practice Statement

Take actions to prevent pressure ulcers by implementing evidence-based intervention practices.

Additional Specifications

- Explicit organizational policies and procedures should be in place about the prevention of pressure ulcers. [IHI, 2009; NPUAP, 2009; JCR, 2010]
- Plans are in place for the risk assessment, prevention, and early treatment of pressure ulcers, which address the following:
  - During patient admission, identify individuals at risk of requiring pressure ulcer prevention using a pressure ulcer risk-assessment plan/guide to identify the specific risks. [Braden, 1998; Norton, 2008; JCR, 2010]
  - Document the pressure ulcer risk assessment and prevention plan as indicated in the patient's record.
  - Assess and periodically reassess each patient's skin and risk for developing a pressure ulcer, and take action to address any identified risks. [AHRQ, 2009a; AHRQ, 2009b; NQF, 2009; JCR, 2010]
  - Maintain and improve tissue tolerance to pressure in order to prevent injury.
  - Protect against the adverse effects of external mechanical forces.

- Reduce the incidence of pressure ulcers through staff educational programs. [NQF, 2009]
- Perform quarterly prevalence studies to evaluate the effectiveness of the pressure ulcer prevention program, and implement a performance improvement initiative as indicated, including the following elements:
  - education about the pertinent pressure ulcer frequency and severity;
  - skill building in the use of pressure ulcer prevention interventions;
  - implementation of process improvement interventions;
  - measurement of process or outcomes indicators; and
  - internal reporting of performance outcomes.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Use as preventive methods fire code-compliant pads or plastic polymer pressure-relieving pads; regular changes in the position of an immobile patient; nutritional assessments and supplements when indicated; and incontinence prevention and management programs.
- Implement a comprehensive skin assessment [NQF, 2009] and a "bundle" of pressure ulcer preventive care measures (inspect skin daily, manage moisture, optimize nutrition, reposition, use pressure-relieving surfaces), especially for high-risk patients. [Defloor, 2005; NQF, 2009]
- Institute a protocol incorporating specific scores (e.g., Braden, Norton scales) during which specific nursing preventive interventions are initiated without a physician order. [Braden, N.D.; Norton, N.D.]
- Reposition any individual in bed who is assessed to be at risk for developing pressure ulcers at least every two hours, or per institutional policy. [Defloor, 2005]
- Stratify and act on patient-specific incidence of pressure ulcer and use of restraints.
- Incorporate educational tools and competencies in nursing education specifically based on aggregate trends from pressure ulcer, restraint use, and preventive foot health prevalence studies.
- Didactic elements of training about pressure ulcer prevention may be delivered through multimedia or distance learning strategies that can be updated with the latest evidence. Documentation of participation can be kept to verify compliance and ensure that new and temporary staff members receive such training. This also provides an opportunity to provide continuing education credits.

Strategies of Progressive Organizations

- Connecting with a nationwide pressure ulcer collaborative to research and understand the causes and preventive steps for the elimination pressure ulcers. [NJHA, 2009]
- Using a comprehensive and systematic approach, organizations have incorporated nutritional consultations with a dietitian for patients assessed to be at risk for developing a pressure ulcer. Patients and their caregivers

are being instructed on causes, risk factors, and ways in which they can minimize risk as part of the care team.

Opportunities for Patient and Family Involvement

- Inform patients and families about any potential risks and or complications of having a pressure ulcer. [NQF, 2009]
- Discuss plans for preventing pressure ulcers with patients and family members and involve them in shared decisionmaking about the prevention and management of pressure ulcers.
- Teach patients and family members:
  - Why the patient may be vulnerable to pressure ulcers.
  - Areas of skin that are most vulnerable to pressure ulcers.
  - How to assess skin and recognize skin changes or pressure ulcers.
  - How to relieve or reduce skin pressure.
- Consider including patients or families of patients who have experienced pressure ulcer-related adverse events to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include tracking complications of pressure ulcers; and operational and financial impact of pressure ulcer prevention.
  - NQF-endorsed® outcome measures:
    1. #0181: Increase in Number of Pressure Ulcers (Home Health): Patients for whom there are more pressure ulcers (all stages 1I-6VI) at the end of care than there were at the beginning time point (summed across all 6 six stages at each time point) Percentage of patients who had an increase in the number of pressure ulcers.
    2. #0187: Recently Hospitalized Residents with Pressure Ulcers – risk adjusted [Nursing home]: Recently hospitalized residents with pressure ulcers.
    3. #0201: Pressure Ulcer Prevalence (Hospital): The total number of patients who have hospital-acquired (nosocomial) stage II or greater pressure ulcers on the day of the prevalence study.
- **Process Measures** include the association of the use of restraints and the occurrence of pressure ulcers; compliance with policies and procedures, including assessment of patients at risk and actions taken based on risk scores. Percentage of at-risk patients receiving "bundle" of pressure ulcer preventive care (inspect skin daily, manage moisture, optimize nutrition, reposition, use pressure-relieving surfaces). [IHI, 2008; NQF, 2009]
  - NQF-endorsed process measures:
    1. #0198: High-risk residents with pressure ulcers: Percentage of residents with a valid target assessment and one of the following inclusion criteria: 1. Impaired in mobility or transfer on the target assessment; 2. Comatose on the target assessment; 3. Suffer malnutrition on the target assessment who have pressure ulcers.

2. #0199: Average-risk residents with pressure ulcers: Percentage of residents with a valid target assessment and not qualifying as high risk with pressure ulcers.
3. #0337: Decubitus Ulcer (PDI 2) (Hospital): Percentage of surgical and medical discharges under 18 years with ICD-9-CM code for decubitus ulcer in secondary diagnosis field.
4. #0538: Pressure Ulcer Prevention Included in Plan of Care [Home Health]: Percentage of patients with assessed risk for Pressure pressure Ulcers ulcers whose physician-ordered plan of care includes intervention(s) to prevent them.
5. #0539: Pressure Ulcer Prevention Plans Implemented [Home Health]: Percentage of patients with assessed risk for Pressure pressure Ulcers ulcers for whom interventions for pressure ulcer prevention were implemented during their episode of care.
6. #0540: Pressure Ulcer Risk Assessment Conducted [Home Health]: Percentage of patients who were assessed for risk of Pressure pressure Ulcers ulcers at start/resumption of home health care.

- **Structure Measures** include verification of the existence of processes/policies/reporting structures to administrative and governance leadership, and pressure ulcer and restraint prevalence as part of an organization dashboard.
- **Patient-Centered Measures** include the effectiveness of communication to patients and families about the prevention of pressure ulcers.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice apply to rural healthcare settings specified as applicable clinical care settings.
- **Children's Healthcare Settings:** All requirements of the practice apply to children's healthcare settings for pressure ulcer "high-risk" children.
- **Specialty Healthcare Settings:** All requirements of the practice apply to specialty healthcare settings specified as applicable clinical care settings.

New Horizons and Areas for Research

Continued research in this area, including research related to the association of pressure ulcers with use of restraints, will be important, especially in the area of the adoption of best practices.

Evaluate use of high-resolution, high-frequency diagnostic ultrasound to detect early indication of skin breakdown before clinical signs of pressure ulcers are visible. [Quintavalle, 2006]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Other relevant practices include Safe Practice 9: Nursing Workforce and Safe Practice 10: Direct Caregivers.

Notes

AHCPR, 1994: [No authors listed.] Treatment of pressure ulcers. Clinical Guideline Number 15. AHCPR Publication No. 95-0652. Rockville (MD): Agency for Healthcare Policy and Research (AHCPR) [now known as Agency for Healthcare Research and Quality (AHRQ)]; 1994 Dec. Available at http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=hsahcpr&part=A5124. Last accessed October 27, 2009.

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

AORN, 2008: [No authors listed.] Skin Integrity: Association of periOperative Registered Nurses Recommended Practices. Acton (MA): Allen Medical Systems; 2008. Available at http://www.skinintegrity.com/pdf/WhyItMatters.pdf. Last accessed October 27, 2009.

Benbow, 2008: Benbow M. Pressure ulcer prevention and pressure-relieving surfaces. Br J Nurs 2008 Jul 10-23;17(13):830-5.

Braden, 1998: Braden B, Bergstrom N. Braden Scale for Predicting Pressure Sore Risk. 1998. Available at http://www.braden-scale.com/images/bradenscale.pdf. Last accessed October 27, 2009.

Brandeis, 2001: Brandeis GH, Berlowitz DR, Katz P. Are pressure ulcers preventable? A survey of experts. Adv Skin Wound Care 2001;14(5):244-8.

Brown, 2003: Brown G. Long-term outcomes of full-thickness pressure ulcers: healing and mortality. Ostomy Wound Manage 2003 Oct;49(10):42-50.

CMS/HAC, 2009: Centers for Medicare & Medicaid Services. Hospital-Acquired Conditions (Present on Admission Indicator). Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed October 30, 2009.

Defloor, 2005: Defloor T, De Bacquer D, Grypdonck MH. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. Int J Nurs Stud 2005 Jan;42(1):37-46.

Dorner, 2009: Dorner B, Posthauer ME, Thomas D; National Pressure Ulcer Advisory Panel. The role of nutrition in pressure ulcer prevention and treatment: National Pressure Ulcer Advisory Panel white paper. Adv Skin Wound Care 2009 May;22(5):212-21.

Duncan, 2007: Duncan KD. Preventing pressure ulcers: the goal is zero. Jt Comm J Qual Patient Saf 2007 Oct;33(10):605-10.

Gibbons, 2006: Gibbons W, Shanks HT, Kleinhelter P, Jones P. Eliminating facility-acquired pressure ulcers at Ascension Health. Jt Comm J Qual Patient Saf 2006 Sep;32(9):488-96.

Harrison, 2008: Harrison MB, Mackey M, Friedberg E. Jt Comm J Qual Patient Saf 2008 Jun;34(6):355-9.

Hill-Rom, 2005: Hill-Rom. Hill-Rom International Pressure Ulcer Prevalence Study. Batesville (IN): Hill-Rom; 2005.

IHI, 2009: [No authors listed.] Pressure Ulcer Prevention. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=cbe9c419-f6ae-49ed-8bb5-5d17844796e2. Last accessed October 27, 2009.

JCR, 2008: [No authors listed.] Strategies for Preventing Pressure Ulcers. Joint Commission Resources. Jt Comm Perspect 2008 Jan;8(1):5-7(3).

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMLTC for Long Term Care. National Patient Safety Goal NPSG.14.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

Levinson, 2008a: Levinson DR. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed October 27, 2009.

Levinson, 2008b: Levinson DR. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed October 27, 2009.

Lyder, 2003: Lyder CH. Pressure ulcer prevention and management. JAMA 2003 Jan 8;289(2):223-6.

NJHA, 2009: Quality, Patient Safety and Clinical Affairs. NJHA (New Jersey Hospital Association) Institute for Quality and Patient Safety For Pressure Ulcer Collaborative Members. Available at http://www.njha.com/qualityinstitute/ulcer.aspx. Last accessed October 27, 2009.

Norton, 2008: [No authors listed.] The Norton Scale for Predicting Pressure Sore Risk. AT: Pressure Ulcers (Pressure sores; Bedsores; Decubitus Ulcers; Decubiti). The Merck Manuals Online Medical Library. Whitehouse Station (NJ): Merck and Co., Inc.; 2008. Available at http://www.merck.com/mmpe/sec10/ch126/ch126a.html. Last accessed October 27, 2009.

NPUAP, 2009: National Pressure Ulcer Advisory Panel. Pressure Ulcer Treatment Guideline. The Guideline Project. Available at http://www.pressureulcerguidelines.org/therapy/. Last accessed October 27, 2009.

NQF, 2008: [No authors listed.] Serious Reportable Events Fact Sheets. Washington, DC: National Quality Forum (NQF); 2008 Oct. Available at http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp. Last accessed October 27, 2009.

NQF, 2009: NQF [National Quality Forum] Staff. Draft Environmental Scan for National Voluntary Consensus Standards for Developing a Framework for Measuring Quality for Prevention and Management of Pressure Ulcers. Sent to Centers for Medicare & Medicaid Services [CMS]. 2009 Feb 20. Available at http://www.qualityforum.org/Projects/n-r/Pressure_Ulcer/enviromentalscan_background_draft_posting.aspx. Last accessed October 27, 2009.

Quintavalle, 2006: Quintavalle PR, et al. Use of High-Resolution, High-Frequency Diagnostic Ultrasound to Investigate the Pathogenesis of Pressure Ulcer Development. Adv Skin Wound Care 2006 Nov-Dec;19(9):498-505.

Reddy, 2006: Reddy M, Gill SS, Rochon PA. Preventing pressure ulcers: a systematic review. JAMA 2006 Aug 23;296(8):974-84.

Redelings, 2005: Redelings MD, Lee NE, Sorvillo F. Pressure ulcers: More lethal than we thought? Adv Skin Wound Care 2005 Sep;18(7):367-72.

SAFE PRACTICE 28: VENOUS THROMBOEMBOLISM PREVENTION

The Objective

Prevent the occurrence of venous thromboembolism (VTE).

The Problem

Deep vein thrombosis (DVT) is a common and extremely dangerous condition in which a blood clot forms in a large vein, usually in the leg, that partially or completely blocks circulation. If the clot breaks free and travels through the bloodstream, it can reach the lungs and block a blood vessel there. This blockage is called a pulmonary embolism (PE), which can be fatal within hours. On September 15, 2008, the U.S. Surgeon General issued a call to action to prevent deep vein thrombosis and pulmonary embolism because it is a growing problem. [Rathbun, 2009]

The frequency of VTE is estimated to include approximately 900,000 Americans who suffer from this condition each year. Of these, roughly 400,000 are DVTs and 500,000 are PEs. [Heit, 2005] VTE is the third most common cause of hospital-related deaths in the United States and the most common preventable cause of hospital death. [Geerts, 2001; Heit, 2002; Tapson, 2005] About two-thirds of all VTE events are related to hospitalization.

VTE is devastating to patients and their families. [Levinson, 2008a; Levinson, 2008b] In as many as 30 percent of affected individuals, PE proves to be fatal. VTE increases the hospital and intensive care unit (ICU) length of stay. VTE is an adverse event that can be caused by other situations, such as a patient having a central venous catheter. One study reports that patients undergoing major orthopedic surgery who develop a VTE incur an increased length of hospital stay of 11 to 12 days versus 5 days for those without a VTE diagnosis. The average time in the ICU is roughly 10 times greater (1.7 days for DVT only and 2.7 days for PE, versus 0.2 day for no VTE). [Ollendorf, 2002] The long-term morbidity associated with VTE should not be underestimated. DVT is associated with significant long-term complications, such as post-thrombotic syndrome.

Despite widespread education about preventing VTE and the need for intervention and the publication of clinical guidelines for VTE prevention, appropriate prophylaxis continues to be substantially underused, especially in patients at low or moderate risk of venous thrombosis. Current estimates suggest that less than 50 percent of patients diagnosed and hospitalized with DVT had received prophylaxis. [Ollendorf, 2002; Goldhaber, 2004] Studies have shown that improved VTE prophylaxis resulted in a substantial reduction in hospital-acquired VTE. [Maynard, 2009]

Recent studies have demonstrated that VTE can be prevented when appropriate VTE prophylaxis is provided. [Masroujeh, 2008; Rathbun, 2009] Hospitalized acutely ill medical patients are at high risk for VTE, and clinical trials clearly demonstrate that pharmacologic prophylaxis of VTE for up to 14 days significantly reduces its incidence in this population. [Jaffer, 2008; Becker, 2009] Several clinical interventions are known to be effective in preventing VTE, including but not limited to mechanical interventions, such as intermittent leg compression devices and graduated compression stockings. [McKenna, 2009] Also effective is pharmacologic prophylaxis, including subcutaneous administration of heparin (e.g., unfractionated heparin, low

molecular weight heparin [LMWH]) or Factor Xa inhibitors (e.g., fondaparinux), or oral administration of vitamin K inhibitors (e.g., warfarin). The most appropriate specific intervention depends on the thrombotic risk, the clinical setting, and other factors. Use of evidence-based order sets can improve deep vein thrombosis prophylaxis rates, as well as other outcomes. [O'Connor, 2009]

The financial impact of VTE in direct medical cost is substantial, resulting from not only the initial hospitalization, but also from the high rate of hospital readmission (5 percent to 14 percent), over half of which occur within 90 days of discharge. One study estimated that the cost for a primary diagnosis of VTE would result in the average total annual provider payments made by a health plan of $10,804 for DVT and $16,644 for PE. [Spyropoulos, 2007]

The Centers for Medicare & Medicaid Services (CMS) has selected DVT and PE after total knee or hip replacements as a hospital-acquired condition that will no longer receive a higher reimbursement when not present on admission, beginning October 1, 2008. [NQF, 2006; CMS, 2009; CMS/HAC, 2009]

Safe Practice Statement

Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis.

Additional Specifications

- Ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established, evidence-based protocols. [NQF, 2006; Geerts, 2008; IHI, 2009]
- Have in place a system for ongoing quality improvement that demonstrates that evidence-based guidelines/practices are acted upon (rationale for departing from guidelines should be documented unless documentation itself is for some reason contraindicated).
- Include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment. [Hairon, 2008]
- Include appropriate quality improvement activity/monitoring for all phases of care with periodic (as defined by institutional policy) assessment of compliance with policies and measures. [TMIT, 2008; CFMC, N.D.]
- Provide for a system of provider education that encompasses all aspects of venous thromboembolism (VTE) prevention and care, including primary and secondary prevention, risk assessment and stratification, prophylaxis, diagnosis, and treatment. [IHA, 2007]
- Provide for the risk assessment of all patients based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified). [Kleinbart, 2001; Caprini, 2009; Patel, 2009]
- Document in the patient's health record that VTE risk assessment/stratification was completed.
- Provide and explain to VTE patients or their caregivers, at the patient-appropriate reading and health literacy level, written discharge instructions, or other educational material, addressing all of the following: 1) follow-up/monitoring; 2) compliance issues; 3) dietary restrictions; 4) potential for adverse drug reactions/interactions; and 5) VTE prophylaxis issues related to that patient.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include ambulatory, ambulatory surgical center, emergency room, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Strategies used to increase thromboprophylaxis adherence include the use of computer decision support systems, preprinted orders, and periodic audit and feedback. [Maynard, 2009; O'Connor, 2009; Piazza, 2009a; Piazza, 2009b] Passive methods of education distribution or educational meetings are not recommended as sole strategies to increase adherence to thromboprophylaxis. [Kucher, 2005; Hamieh, 2009]
- Depending on the level of risk, different specific methods may be more appropriate or more effective than other methods. [Goldhaber, 2009] For example, in major orthopedic surgery or trauma patients, LMWH is preferred over low-dose heparin, because LMWH is more effective; while for postoperative patients at high risk for bleeding, mechanical prophylaxis methods, such as graduated compression stockings or intermittent calf compression, may be preferred over anticoagulant-based prophylaxis. [Holten, 2009; Spencer, 2009; JCR, 2010]

Strategies of Progressive Organizations

- Key strategies that have been implemented include documentation of a VTE risk assessment and prevention plans in the patient's record, approved through the medical staff leadership. This should be focused on those patients found to be at high risk for developing VTE. [SHM, 2008] Examples include:
- Medical: congestive heart failure, obesity, cancer. [Monreal, 2009]
- Surgical: thromboembolism in last 30 days, previous risk of DVT, orthopedics, immediate postoperative window switching from intravenous to oral anticoagulants.

Opportunities for Patient and Family Involvement

- Educate patient and family members about the incidence of DVT and PE.
- Engage patient and family members in the prevention of DVT and PE; if intermittent pneumatic compression devices are used as part of the prevention regimen, ensure that they are used appropriately.
- Educate patients on strategies such as early ambulation and encourage self-assessment and self-reporting of VTE signs and symptoms. [Le Sage, 2008]
- Provide written, patient-directed information on VTE. [Le Sage, 2008]
- Encourage patients to be as mobile as appropriate; if they are unable to walk, then encourage arm and leg movements/exercises in bed.

- Consider including patients or families of patients who have experienced VTE adverse events to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures:** [TJC, 2009; SHM, N.D.]
  - National Quality Forum (NQF)-endorsed® outcome measures:
    1. #0376: Incidence of Potentially Preventable VTE: This measure assesses the number of patients who were diagnosed with VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis.
    2. #0450: Postoperative DVT or PE: Percentage of adult surgical discharges with a secondary diagnosis code of deep vein thrombosis or pulmonary embolism.
- **Process Measures:**
  - NQF-endorsed process measures:
    1. #0217: Surgery Patients with Recommended VTE Prophylaxis Ordered: Percentage of surgery patients with recommended VTE prophylaxis ordered during admission.
    2. #0218: Surgery Patients Who Received Appropriate VTE Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery-End Time: Percentage of surgery patients who received appropriate VTE prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time.
    3. #0239: VTE Prophylaxis [Hospital]: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
    4. #0371: VTE Prophylaxis [Hospital]: This measure assesses the number of patients who receive VTE prophylaxis or have documentation of why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
    5. #0372: Intensive Care Unit (ICU) VTE Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation of why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the ICU or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).
    6. #0373: VTE Patients with Overlap of Anticoagulation Therapy: This measure assesses the number of patients diagnosed with VTE who received parenteral and warfarin therapy for at least five days with an international normalized

ratio (INR) greater than or equal to 2 prior to discontinuation of parenteral therapy, or discharged in less than five days on both medications.

7. #0374: VTE Patients Receiving Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) Receiving UFH with Dosages/Platelet Count Monitored by Protocol (or Nomogram): This measure assesses the number of patients receiving intravenous UFH therapy with documentation that the dosages and platelet counts are monitored by protocol or nomogram.
8. #0375: VTE Discharge Instructions [Hospital]: This measure assesses the number of VTE patients who are discharged to home, to home with home health, or home hospice on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.
9. #0555: Monthly INR Monitoring for Beneficiaries on Warfarin: Average percentage of monthly intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period.
10. #0556: INR for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications: Percentage of episodes with an INR test performed three to seven days after a newly started interacting anti-infective medication for Part D beneficiaries receiving warfarin.
11. #0612: Warfarin – INR Monitoring: Percentage of patients taking warfarin with PT/INR monitoring.

- **Structure Measures** include identification, stratification, and trending of specific risk factors of patients who have developed VTE/DVT or PE to determine the success of mitigation strategies; and documentation of risk assessment during admission evaluation. [Millar, 2008]
- **Patient-Centered Measures** include evidence that patient preferences are being respected. The HCAHPS survey addresses this with respect to prophylaxis/treatment through the following questions: "During your hospital stay, were you given any medicine you had not taken before?" (Q15); "Before giving you any new medicine, how often did the hospital staff tell you what the medicine was for?" (Q16); and "Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?" (Q17).

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice apply to rural healthcare settings, as specified in applicable clinical care settings.
- **Children's Healthcare Settings:** The development of VTE/DVT is a rare occurrence in the patient population under 18 years of age.
- **Specialty Healthcare Settings:** All requirements of the practice apply to specialty healthcare settings, other than psychiatric facilities, as specified in applicable clinical care settings.

New Horizons and Areas for Research

The role of newer agents in VTE prophylaxis is the subject of ongoing research, as is the extension of these practices to select settings and populations (e.g., long-term care). [Roberts, 2010] Consideration of "opt-out" VTE programs as a potential solution for poor VTE prophylaxis should be further researched.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 17: Medication Reconciliation and Safe Practice 18: Pharmacist Leadership Structures and Systems are vitally important to a successful VTE program. This safe practice has direct relevance to Safe Practice 29: Anticoagulation Therapy.

Notes

Becker, 2009: Becker RC. The importance of VTE prevention after orthopaedic surgery. Lancet 2009 May 16;373(9676):1661-2. Epub 2009 May 4.

Caprini, 2009: Caprini JA. Implications of thromboprophylaxis registry data on clinical practice. Am J Med Sci 2009 Jul;338(1):58-63.

CFMC, N.D.: [No authors listed.] Surgical Care Improvement Project (SCIP). Englewood (CO): Colorado Foundation for Medical Care; No Date. Available at http://www.cfmc.org/hospital/hospital_scip.htm. Last accessed October 27, 2009.

CMS, 2009: [No authors listed.] Hospital-Acquired Conditions (Present on Admission Indicator). Educational Resources. Baltimore (MD): Centers for Medicare & Medicaid Services; 2009. Available at http://www.cms.hhs.gov/HospitalAcqCond/07_EducationalResources.asp. Last accessed October 27, 2009.

CMS/HAC, 2009: Centers for Medicare & Medicaid Services. Hospital-Acquired Conditions (Present on Admission Indicator) Overview. Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed October 30, 2009.

Geerts, 2001: Geerts WH, Clagett GP, Heit JA, et al. Prevention of venous thromboembolism. Chest 2001 Jan;119(1 Suppl): 132S-175S.

Geerts, 2008: Geerts WH, Bergqvist D, Pineo GF, et al. Prevention of venous thromboembolism: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008 Jun;133(6 Suppl):381S-453S.

Goldhaber, 2004: Goldhaber SZ, Tapson VF; DVT FREE Steering Committee. A prospective registry of 5451 patients with ultrasound-confirmed deep vein thrombosis. Am J Cardiol 2004 Jan 15;93(2):259-62.

Goldhaber, 2009: Goldhaber SZ. Optimal duration of anticoagulation after venous thromboembolism: fixed and evidence-based, or flexible and personalized? Ann Intern Med 2009 May 5;150(9):644-6.

Hairon, 2008: Hairon N. New risk assessment tool aims to help nurses prevent VTE. Nurs Times 2008 Sep 30-Oct 6;104(39): 23-5.

Hamieh, 2009: Hamieh T, Michota F. Educational interventions alone are not sufficient to change outcomes in venous thromboembolism. J Hosp Med 2009 Feb;4(2):142-3.

Heit, 2002: Heit JA, O'Fallon WM, Petterson TM, et al. Relative impact of risk factors for deep vein thrombosis and pulmonary embolism: a population-based study. Arch Intern Med 2002 Jun 10;162(11):1245-8.

Heit, 2005: Heit JA, Cohen AT, Anderson FA Jr. Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US. Blood (ASH Annual Meeting Abstracts)2005 Nov; 106: abstract #910. Available at http://abstracts.hematologylibrary.org/cgi/content/abstract/106/11/910?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=%22Estimated+annual+number%22&searchid=1&FIRSTINDEX=0&volume=106&issue=11&resourcetype=HWCIT. Last accessed September 23, 2009.

Holten, 2009: Holten KB, Merok J. Guideline update. VTE disease: which agents, and when. J Fam Pract 2009 Mar;58(3):E1.

IHA, 2007: [No authors listed.]. Venous Thromboembolism Prophylaxis and Treatment for Surgical Patients – Achieving the Standard of Care: Tools and Resources for Hospital Performance Measurement Improvement Activities. Naperville (IL): Illinois Hospital Association; 2007 Jan 19. Available at http://www.ihatoday.org/issues/quality/venous.pdf. Last accessed October 27, 2009.

IHI, 2009: [No authors listed.] Venous Thromboembolus Prevention & Treatment. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=5b9bfd5a-1e17-433b-a9d4-602fafef73c8. Last accessed October 27, 2009.

Jaffer, 2008: Jaffer AK, Amin AN, Brotman DJ, et al. Prevention of venous thromboembolism in the hospitalized medical patient. Cleve Clin J Med 2008 Apr;75 Suppl 3:S7-16.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.03.05.01. Oak Brook (IL): Joint Commission Resources; 2010.

Kleinbart, 2001: Kleinbart J, Williams MV, Rask K. Prevalence and severity of venous thromboembolism. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2001 Jul: Ch. 31. Available at http://www.ahrq.gov/clinic/ptsafety/chap31a.htm. Last accessed October 27, 2009.

Kucher, 2005: Kucher N, Koo S, Quiroz R, et al. Electronic alerts to prevent venous thromboembolism among hospitalized patients. N Engl J Med 2005 Mar 10;352(10):969-77.

Le Sage, 2008: Le Sage S, McGee M, Emed JD. Knowledge of venous thromboembolism (VTE) prevention among hospitalized patients. J Vasc Nurs 2008 Dec;26(4):109-17.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 23, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 23, 2009.

Masroujeh, 2008: Masroujeh R, Shamseddeen W, Isma'eel H, et al. Underutilization of venous thromboemoblism prophylaxis in medical patients in a tertiary care center. J Thromb Thrombolysis 2008 Oct;26(2):138-41. Epub 2007 Aug 15.

Maynard, 2009: Maynard GA. Medical admission order sets to improve deep vein thrombosis prevention: a model for others or a prescription for mediocrity? J Hosp Med 2009 Feb;4(2):77-80.

McKenna, 2009: McKenna GS, Karthikesalingam A, Walsh SR, et al. Prevention of venous thromboembolism: improving practice in surgical patients. Int J Surg 2009 Feb;7(1):50-3. Epub 2008 Oct 22.

Millar, 2008: Millar JA. Rational thromboprophylaxis in medical inpatients: not quite there yet. Med J Aust 2008 Nov 3;189(9):504-6. Available at http://www.mja.com.au/public/issues/189_09_031108/mil10283_fm.pdf. Last accessed September 8, 2009.

Monreal, 2009: Monreal M, Trujillo-Santos J. Lessons from VTE registries: the RIETE experience. Best Pract Res Clin Haematol 2009 Mar;22(1):25-33.

NQF, 2006: National Quality Forum. National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Additional Performance Measures. A Consensus Report. Washington, DC: National Quality Forum; 2008 Oct. Available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1259. Last accessed November 4, 2009.

NQF, 2009: National Quality Forum. National Voluntary Consensus Standards for Medication Management. Washington, DC: National Quality Forum; 2009. Available at http://www.qualityforum.org/Projects/i-m/Medication_Management/Med_Management_Voting_Report.aspx. Last accessed January 14, 2010.

O'Connor, 2009: O'Connor C, Adhikari NK, DeCaire K, et al. Medical admission order sets to improve deep vein thrombosis prophylaxis rates and other outcomes. J Hosp Med 2009 Feb;4(2):81-9.

Ollendorf, 2002: Ollendorf DA, Vera-Llonch M, Oster G. Cost of venous thromboembolism following major orthopedic surgery in hospitalized patients. Am J Health-Syst Pharm 2002 Sep 15; 59(18):1750-4.

Patel, 2009: Patel J, Reade H, Sultanzadeh J, et al. Reminders: a simple measure to ensure the mandatory venous thromboembolism risk assessment of hospitalised patients. Int J Clin Pract 2009 Jan;63(1):173-4.

Piazza, 2009a: Piazza G, Goldhaber SZ. Improving clinical effectiveness in thromboprophylaxis for hospitalized medical patients. Am J Med 2009 Mar;122(3):230-2.

Piazza, 2009b: Piazza G, Rosenbaum EJ, Pendergast W, et al. Physician alerts to prevent symptomatic venous thromboembolism in hospitalized patients. Circulation 2009 Apr 28;119(16):2196-201. Epub 2009 Apr 13.

Rathbun, 2009: Rathbun S. Cardiology patient pages. The Surgeon General's call to action to prevent deep vein thrombosis and pulmonary embolism. Circulation 2009 Apr 21;119(15): e480-2.

Roberts, 2010: Roberts LN, Arya R. New anticoagulants for prevention and treatment of venous thromboembolism. Curr Vasc Pharmacol 2010 Jan 1. [Epub ahead of print]

SHM, 2008: Venous Thromboembolism Resource Room Project Team. Venous Thromboembolism Resource Room. Philadelphia (PA): Society of Hospital Medicine; 2008. Available at http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_VTE/VTE_Home.cfm. Last accessed October 27, 2009.

SHM, N.D.: [No authors listed.] Hospital-Acquired Venous Thromboembolism (VTE) Incidence Calculator. Philadelphia (PA): Society of Hospital Medicine; No Date. Available at http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/HospitalAcquiredVTEIncidenceCalculator.htm. Last accessed October 27, 2009.

Spencer, 2009: Spencer FA, Gore JM, Reed G, et al. Venous thromboembolism and bleeding in a community setting. The Worcester Venous Thromboembolism Study. Thromb Haemost 2009 May;101(5):878-85.

Spyropoulos, 2007: Spyropoulos AC, Lin J. Direct medical costs of venous thromboembolism and subsequent hospital readmission rates: an administrative claims analysis from 30 managed care organizations. J Manag Care Pharm 2007 Jul-Aug;13(6): 475-86.

Tapson, 2005: Tapson VF, Hyers TM, Waldo AL, et al. Antithrombotic therapy practices in US hospitals in an era of practice guidelines. Arch Intern Med 2005 Jul 11;165(13): 1458-64.

TJC, 2009: [No authors listed.] Performance Measurement Initiatives: Venous Thromboembolism (VTE) Core Measure Set. Oakbrook Terrace (IL): The Joint Commission; 2009 Apr. Available at http://www.jointcommission.org/Performance Measurement/PerformanceMeasurement/VTE.htm. Last accessed October 27, 2009.

TMIT, 2008: TMIT. Preventing VTE and Improving the Safety of Anticoagulant Therapy. TMIT High Performer Webinar presented 2008 Mar 5. Available at http://www.safety leaders.org/pages/idPage.jsp?ID=4875. Last accessed October 27, 2009.

SAFE PRACTICE 29: ANTICOAGULATION THERAPY

The Objective

Ensure that anticoagulation therapy is effective and safe.

The Problem

Anticoagulants are medications that can be used both prophylactically and therapeutically to prevent thrombosis. Medication errors and adverse events related to anticoagulation therapy occur frequently. The Institute for Safe Medication Practices (ISMP) has identified anticoagulants, including unfractionated heparin (UFH), low-molecular weight heparin (LMWH), fondaparinux, and warfarin, as high alert medications secondary to their propensity to cause harm when used in error. [ISMP, 2008]

The frequency of errors associated with anticoagulants is alarming. As a medication category, anticoagulants are one of the top five medication types associated with patient safety incidents. [NPSA, 2007] Several anticoagulants rank in the top 10 reported medications involved in harmful errors: Heparin ranks third, warfarin ranks sixth, and enoxaparin ranks ninth. [MEDMARX, 2005] Enoxaparin alone was involved in 4 of the 17 medication-related deaths reported to MEDMARX in 2005. [MEDMARX, 2005] Anticoagulants are responsible for 5.1 percent of all adverse drug reactions requiring emergency care. [Budnitz, 2006] An estimated 68,545 cases of bleeding (9.8 percent of all adverse events) were treated in U.S. emergency departments in 2004. In the elderly, insulin, warfarin, and digoxin were implicated in one in every three estimated adverse drug events treated in emergency departments, and in 41.5 percent of estimated hospitalizations. [Budnitz, 2006] In patients with acute cardiac illness, 28.5 percent of adverse drug reactions and 20.1 percent of medication errors were associated with anticoagulants. [Fanikos, 2007]

Many studies have described the severity of harm resulting from errors and adverse events associated with anticoagulants. [Levinson, 2008a; Levinson, 2008b] A lack of standardized dosing guidelines and appropriate monitoring can lead to serious harm associated with this class of medications. [Hull, 1986] In 2004, Fanikos and colleagues found that 7.2 percent of medication errors reported by hospitals were due to anticoagulants, and 6.2 percent of these required medical intervention. [Fanikos, 2004] Medication errors related to anticoagulant therapy have been associated with stroke, myocardial infarction, and death. [Koo, 2004] During the period from January 1, 2001, through December 31, 2006, a total of 59,316 medication errors related to anticoagulants were reported to USP's MEDMARX program. The percentage of harmful errors associated with anticoagulants (2.9 percent) was nearly twice the percentage of harm seen for all errors (1.5 percent) reported to MEDMARX. Wrong administration technique accounted for only 1.7 percent of the total error types, but it accounted for 6.1 percent of all harmful anticoagulant errors. Wrong administration technique includes failure to follow the five basic rights in medication administration (right patient, right drug, right dose, right time, and right route). [MEDMARX, 2005]

The preventability of anticoagulation errors has been further explored in multiple studies. In one study, anticoagulants were responsible for 121 of 1,523 adverse drug events, a third of which were preventable. [Gurwitz, 2003] Another study found that 32.2 percent of preventable adverse drug events in a teaching hospital involved anticoagulants. This was

double the amount caused by any other medication. [Winterstein, 2002] In a study by Bates et al., anticoagulants accounted for 4 percent of preventable adverse drug events (ADEs) and 10 percent of potential ADEs. [Bates, 1995] Prevention of anticoagulation errors and reduction of adverse events can occur in hospital settings. Optimal anticoagulation management occurs when a systematic and coordinated process is used that includes dedicated management by a qualified healthcare professional who ensures reliable patient scheduling and tracking; accessible, accurate, and frequent monitoring; patient-specific decision support and interaction; and ongoing patient education. [ISMP, 2008; Pengo, 2009] As part of its National Patient Safety Goals, The Joint Commission has included anticoagulants, in order to reduce the likelihood of patient harm and to promote the safe use of these medications. The Joint Commission has recommended implementing a pharmacist-managed antico-agulation service, as well as implementing or using computerized physician order entry and barcoding technology. [TJC, 2008] Other studies found that the implementation of evidence-based guidelines resulted in significant increase in the appropriate utilization of anticoagulants, fewer anticoagulant-associated adverse events, and lower costs (savings of 56.15 per day). [Schumock, 2004; Hirsh, 2008] Bringing together an interdisciplinary team to develop evidence-based practices not only improves the safety and efficacy of anticoagulant therapy, but can also minimize costs associated with errors and adverse events.

The total cost impact of errors and adverse events related to anticoagulants has not been well established. It is known that the failure to maintain optimal anticoagulation places patients at risk of complications, which are expensive. In 1998, it was estimated that the cost of an inpatient major anticoagulation-related bleed ranged from $3,000 to $12,000. [Eckman, 1998] Establishing an inpatient anticoagulation service can reduce medication errors, reduce hospital costs, and improve patient care. Studies have attempted to capture the cost savings associated with inpatient anticoagulation programs. By establishing an interdisciplinary team and implementing process improvement, including pharmacist-managed inpatient anticoagulation services, a healthcare company showed an annual savings of up to $9.8 million in avoidable costs. [Jennings, 2008]

Anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring, and inconsistent patient compliance. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with the use UFH, LMWH, and warfarin. [TJC, 2008] Protocols to ensure appropriate dosing, especially for heparin, when multiple agents are used should also be emphasized. This practice has evolved over time, and the focus has narrowed specifically to anticoagulation therapies now tightly linked with The Joint Commission's National Patient Safety Goal NPSG.03.05.01.

Safe Practice Statement

Organizations should implement practices to prevent patient harm due to anticoagulant therapy.

Additional Specifications

- The organization implements a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulant therapy, and

the patient's medication plan is documented in the medication record. Robert-Ebadi, 2009; JCR, 2010; ASHP, N.D.]

- Clinical pharmacy medication review is conducted to ensure safe anticoagulant selection and avoidance of drug-drug interactions. [TMIT, 2008]
- To reduce compounding and labeling errors, the organization uses only oral unit-dose products, prefilled syringes, or premixed infusion bags, when these types of products are available.
- The organization uses approved, standardized protocols for the initiation and maintenance of anticoagulation therapy that is appropriate to the medication used, the condition being treated, and the potential for medication interactions. [Airee, 2009; IHI, 2009]
- For patients starting on warfarin, a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust therapy. [Merli, 2009]
- When dietary services are provided by the hospital, the service is notified of all patients receiving warfarin and responds according to its established food/medication interaction program.
- When heparin is administered intravenously and continuously, the hospital uses programmable infusion pumps in order to provide consistent and accurate dosing.
- The organization has a written policy that addresses baseline and ongoing laboratory tests that are required for heparin and low molecular weight heparin therapies.
- The organization provides education on anticoagulation therapy to prescribers, staff, patients, and families.
- The organization evaluates its anticoagulation safety practices, takes appropriate action to improve its practices, and measures the effectiveness of those actions on a regular basis. [Zhan, 2008]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Clinical studies have demonstrated that problems arise with overdosing as well as underdosing of these agents. Evidence-based protocols should be developed to encourage the use of the fewest, most appropriate agents to achieve the desired therapeutic intent and to minimize adverse events. Facilities should review existing procedures and protocols with special attention to UFH, LMWH and warfarin, and ensure appropriate dosing for all the agents, used alone or in combination, or to identify other, and potentially safer, anticoagulant medications. [Gage, 2008; Denas, 2009]
- Put in place explicit evidence-based organizational policies, practices, and procedures, developed under the direction of multidisciplinary teams that include prescribers, nurses, and pharmacists, that outline the scope of service and accountability with respect to anticoagulation services. [ISMP, 2008; HBQI, 2009]

- Decrease variation in practice through the implementation of evidence-based guidelines and performance outcome measures.
- Include in discharge planning: 1) specific verbal and written patient education material appropriate for each patient's language and reading level with assessment of understanding and 2) a process for ongoing outpatient management with a specific provider who will monitor and manage the patient's anticoagulation needs, including bridging therapy across care-setting transitions.
- Ensure that staff members are experienced in monitoring anticoagulant therapy. There is a growing body of evidence suggesting that heparin-induced thrombocytopenia is underestimated. Consider platelet monitoring according to ACCP guidelines. [Ansell, 2008; Hirsh, 2008; Warkentin, 2008]
- Implement reliable patient scheduling and tracking.
- Utilize patient-specific decision support and interaction.
- Implement ongoing patient education.
- Consider conducting an interdisciplinary failure mode and effects analysis (FMEA) within the facility to identify organization-specific sources of failure with the use of anticoagulants and to individualize the key improvements needed to reduce the risk of harmful errors with these medications. [ISMP, 2007]

Strategies of Progressive Organizations

- Organizational models are in place to ensure that staff is trained/certified and experienced in monitoring and managing anticoagulant therapy, coupled with the implementation of reliable patient scheduling and tracking. [Huber, 2008]
- Many organizations are using web INR tracking and monitoring systems to ensure accessibility to accurate and frequent INR testing and results. Organizations have also implemented programs that establish a continuum of care to manage anticoagulation care through the inpatient and outpatient settings. This involves utilizing patient-specific decision support and ongoing interaction.

Opportunities for Patient and Family Involvement

- Involve patient and family members on medication safety committees and implementation teams about anticoagulation programs. Those who have experienced preventable adverse events related to anticoagulation may provide rich insight for performance improvement.
- Educate patient and family members on the common incidence of medication errors and anticoagulants as high alert medications.
- Encourage patient and family members to carry accurate medication lists and to share those lists with healthcare professionals during office visits, hospitalizations, and community pharmacy encounters.
- Use "teach-back" method to ensure patient/family understanding of appropriate medication use.
- Encourage patient and family members to ask questions about their medication regimens and to request consultations by a pharmacist.
- Standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with the use of heparin, UFH, LMWH, and warfarin.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures:** Adverse drug events related to anticoagulation therapy can be trended in relation to other medication classes, and patient compliance with prescribed medications and follow-up appointments can be tracked.
  - National Quality Forum (NQF)-endorsed® outcome measures:
    1. #0376: Incidence of Potentially Preventable VTE: This measure assesses the number of patients who were diagnosed with VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis.
    2. #0450: Postoperative DVT or PE: Percentage of adult surgical discharges with a secondary diagnosis code of deep vein thrombosis or pulmonary embolism.
- **Process Measures** include recommended VTE prophylaxis ordered for surgery patients (e.g., SCIP VTE 1) and surgery patients who received appropriate VTE prophylaxis within 24 hours prior to surgery to 24 hours after surgery (e.g., SCIP VTE 2); out-of-range INR (>5).
  - NQF-endorsed process measures:
    1. #0239: VTE Prophylaxis [Hospital]: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux, or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
    2. #0371: VTE Prophylaxis [Hospital]: This measure assesses the number of patients who receive VTE prophylaxis or have documentation of why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
    3. #0372: Intensive Care Unit (ICU) VTE Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation of why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the ICU or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).
    4. #0373: VTE Patients with Overlap of Anticoagulation Therapy: This measure assesses the number of patients diagnosed with VTE who received parenteral and warfarin therapy for at least five days with an international normalized ratio (INR) greater than or equal to two prior to discontinuation of parenteral therapy, or discharged in less than five days on both medications.
    5. #0374: VTE Patients Receiving Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) Receiving UFH with Dosages/Platelet Count Monitored by Protocol (or Nomogram): This measure assesses the number of patients receiving intravenous UFH therapy with documentation that the dosages and platelet counts are monitored by protocol or nomogram.

6. #0375: VTE Discharge Instructions [Hospital]: This measure assesses the number of VTE patients who are discharged to home, to home with home health, or home hospice on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/ interactions.
7. #0503: Anticoagulation for acute pulmonary embolus patients [Emergency Department]: Anticoagulation ordered for acute pulmonary embolus patients.
8. #0555: Monthly INR Monitoring for Beneficiaries on Warfarin: Average percentage of monthly intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period.
9. #0556: INR for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications: Percentage of episodes with an INR test performed three to seven days after a newly-started interacting anti-infective medication for Part D beneficiaries receiving warfarin.
10. #0612: Warfarin – INR Monitoring: Percentage of patients taking warfarin with PT/INR monitoring.

- **Structure Measures** include the existence of an anticoagulation clinic or a service that cares for a majority of patients receiving such treatment. Structures and systems that provide the identification, stratification, and trending of specific risk factors of patients who have developed VTE to determine the success of mitigation strategies may also be verified.
- **Patient-Centered Measures** include surveys of patients about their satisfaction related to anticoagulation medication management and communication by caregivers. The HCAHPS survey addresses this through the following questions: "During your hospital stay, were you given any medicine you had not taken before?" (Q15); "Before giving you any new medicine, how often did the hospital staff tell you what the medicine was for?" (Q16); and "Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?" (Q17).

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings for applicable populations at risk. Development of DVT in the younger pediatric population is rare.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings.

New Horizons and Areas for Research

The role of newer anticoagulation agents is the subject of ongoing research, as is the use of newer implementation methods for anticoagulation monitoring, such as web-based tools. [Gulseth, 2009; Mazza, 2009; Poller, 2009; Roberts, 2010]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 17: Medication Reconciliation and Safe Practice 18: Pharmacist Leadership Structures and Systems are vitally important to a successful anticoagulation program. Safe Practice 29: Anticoagulation Therapy has direct relevance to Safe Practice 28: Venous Thromboembolism Prevention.

Notes

Airee, 2009: Airee A, Guirguis AB, Mohammad RA. Clinical outcomes and pharmacists' acceptance of a community hospital's anticoagulation management service utilizing decentralized clinical staff pharmacists. Ann Pharmacother 2009 Apr;43(4):621-8. Epub 2009 Mar 24.

Ansell, 2008: Ansell J, Hirsh J, Hylek E, et al. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008 Jun;133(6 Suppl):160S-198S.

ASHP, N.D.: Section of Clinical Specialists and Scientists. Anticoagulation Resource Center. Bethesda (MD): American Society of Health-System Pharmacists (ASHP); No Date. Available at http://www.ashp.org/Import/PRACTICEAND POLICY/PracticeResourceCenters/Anticoagulation.aspx. Last accessed October 28, 2009.

Bates, 1995: Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995 Jul 5;274(1):29-34.

Budnitz, 2006: Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006 Oct 18;296(15): 1858-66.

Denas, 2009: Denas G, Marzot F, Offelli P, et al. Effectiveness and safety of a management protocol to correct over-anticoagulation with oral vitamin K: a retrospective study of 1,043 cases. J Thromb Thrombolysis 2009 Apr;27(3):340-7. Epub 2008 Mar 13.

Eckman, 1998: Eckman MH, Levine HJ, Salem DN, et al. Making decisions about antithrombotic therapy in heart disease: decision analytic and cost-effectiveness issues. Chest 1998 Nov;114(5 Suppl):699S-714S.

Fanikos, 2004: Fanikos J, Stapinski C, Koo S, et al. Medication errors associated with anticoagulant therapy in the hospital. Am J Cardiol 2004 Aug 15;94(4):532-5.

Fanikos, 2007: Fanikos J, Cina JL, Baroletti S, et al. Adverse drug events in hospitalized cardiac patients. Am J Cardiol 2007 Nov 1;100(9):1465-9. Epub 2007 Aug 21.

Gage, 2008: Gage BF, Eby C, Johnson JA, et al. Use of pharmacogenetic and clinical factors to predict the therapeutic dose of warfarin. Clin Pharmacol Ther 2008 Sep;84(3):326-31. Epub 2008 Feb 27.

Gulseth, 2009: Gulseth MP, Grice GR, Dager WE. Pharmacogenomics of warfarin: uncovering a piece of the warfarin mystery. Am J Health Syst Pharm 2009 Jan 15;66(2):123-33.

Gurwitz, 2003: Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003 Mar 5;289(9):1107-16.

HBQI, 2009: [No authors listed.] Hospital pharmacies meet TJC anticoagulant rules. Healthcare Benchmarks Qual Improv 2009 Feb;16(2):18-20.

Hirsh, 2008: Hirsh J, Guyatt G, Albers GW, et al. Antithrombotic and thrombolytic therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008 Jun;133(6 Suppl):110S-112S.

Huber, 2008: Huber CS, Levett JM, Atkinson JM. A tool to assess compliance in anticoagulation management. IN: Advances in Patient Safety: New Directions and Alternative Approaches. Volumes 1-4, AHRQ Publication Nos. 08-0034 (1-4).Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2008 Jul: Vol.3, Performance and Tools: Tools and Practices. Available at http://www.ahrq.gov/downloads/pub/advances2/vol3/Advances-Huber_96.pdf. Last accessed October 28, 2009.

Hull, 1986: Hull RD, Raskob GE, Hirsh J, et al. Continuous intravenous heparin compared with intermittent subcutaneous heparin in the initial treatment of proximal-vein thrombosis. N Engl J Med 1986 Oct 30;315(18):1109-14.

IHI, 2009: [No authors listed.] High-Alert Medication Safety. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement; 2009. Available at http://www.ihi.org/imap/tool/#Process=b8541097-7456-4aab-a885-38c31950e6bf. Last accessed October 28, 2009.

ISMP, 2007: Institute for Safe Medication Practices. Example of a health care failure mode and effects analysis for anticoagulants. 2007. Available at http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf. Last accessed September 23, 2009.

ISMP, 2008: Institute for Safe Medication Practices. Improving Medication Safety with Anticoagulant Therapy. 2008. Available at http://www.ismp.org/Tools/anticoagulantTherapy.asp. Last accessed September 23, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. National Patient Safety Goal NPSG.03.05.01. Oak Brook (IL): Joint Commission Resources; 2010.

Jennings, 2008: Jennings HR, Miller EC, Williams TS, et al. Reducing anticoagulant medication adverse events and avoidable patient harm. Jt Comm J Qual Patient Saf 2008 Apr;34(4):196-200.

Koo, 2004: Koo S, Kucher N, Nguyen PL, et al. The effect of excessive anticoagulation on mortality and morbidity in hospitalized patients with anticoagulant-related major hemorrhage. Arch Intern Med 2004 Jul 26;164(14):1557-60.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 23, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 23, 2009.

Mazza, 2009: Mazza JJ, Yale SH. New oral anticoagulants: a brief review. WMJ 2009 Feb;108(1):35-9.

MEDMARX, 2005: USP MEDMARX Database, 2005. Available at http://www.usp.org/products/medMarx/. Last accessed September 23, 2009.

Merli, 2009: Merli GJ, Tzanis G. Warfarin: what are the clinical implications of an out-of-range-therapeutic international normalized ratio? J Thromb Thrombolysis 2009 Apr;27(3):293-9. Epub 2008 Apr 5.

NPSA, 2007: National Health Service (NHS) [UK]. Actions that can make anticoagulant therapy safer. National Patient Safety Agency (NPSA). 2007 Mar 28. Available at http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/anticoagulant/. Last accessed September 23, 2009.

NQF, 2009: National Quality Forum. National Voluntary Consensus Standards for Medication Management. Washington, DC: National Quality Forum; 2009. Available at http://www.qualityforum.org/Projects/i-m/Medication_Management/Med_Management_Voting_Report.aspx. Last accessed January 14, 2010.

Pengo, 2009: Pengo V, Cucchini U, Denas G, et al. Standardized low-molecular-weight heparin bridging regimen in outpatients on oral anticoagulants undergoing invasive procedure or surgery: an inception cohort management study. Circulation 2009 Jun 9;119(22):2920-7. Epub 2009 May 26. Available at http://circ.ahajournals.org/cgi/reprint/119/22/2920. Last accessed November 2, 2009.

Poller, 2009: Poller L, Roberts C, Ibrahim S, et al. Screening computer-assisted dosage programs for anticoagulation with warfarin and other vitamin K-antagonists: minimum safety requirements for individual programs. J Thromb Haemost 2009 Jul 17. [Epub ahead of print]

Robert-Ebadi, 2009: Robert-Ebadi H, Le Gal G, Righini M. Use of anticoagulants in elderly patients: practical recommendations. Clin Interv Aging 2009;4:165-177. Epub 2009 May 14. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2685237&blobtype=pdf. Last accessed November 2, 2009.

Roberts, 2010: Roberts LN, Arya R. New anticoagulants for prevention and treatment of venous thromboembolism. Curr Vasc Pharmacol 2010 Jan 1. [Epub ahead of print]

Schumock, 2004: Schumock GT, Blackburn JC, Nutescu EA, et al. Impact of prescribing guidelines for inpatient anticoagulation. Ann Pharmacother 2004 Oct;38(10):1570-5. Epub 2004 Aug 10.

TJC, 2008: The Joint Commission. Preventing errors relating to commonly used anticoagulants. Sentinel Event Alert #41. September 24, 2008. Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_41.htm. Last accessed September 23, 2009.

TMIT, 2008: TMIT. Preventing VTE and Improving the Safety of Anticoagulant Therapy. TMIT High Performer Webinar presented 2008 Mar 5. Available at http://www.safetyleaders.org/pages/idPage.jsp?ID=4875. Last accessed October 28, 2009.

Warkentin, 2008: Warkentin TE, Greinacher A, Koster A, et al. Treatment and Prevention of Heparin-Induced Thrombocytopenia: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008 Jun;133(6 Suppl):340S-380S.

Winterstein, 2002 : Winterstein, Hatton RC, Gonzalez-Rothi R, et al. Identifying clinically significant preventable adverse drug events through a hospital's database of adverse drug reaction reports. Am J Health Syst Pharm 2002 Sep 15;59(18):1742-9.

Zhan, 2008: Zhan C, Smith SR, Keyes MA, et al. How useful are voluntary medication error reports? The case of warfarin-related medication errors. Jt Comm J Qual Patient Saf 2008 Jan;34(1):36-45.

SAFE PRACTICE 30: CONTRAST MEDIA-INDUCED RENAL FAILURE PREVENTION

The Objective

Reduce adverse events resulting from the administration of intravenous contrast dye in patients with diminished renal function.

The Problem

Contrast-induced nephropathy (CIN) is a common cause of hospital-acquired acute renal failure in the United States. Contrast-induced nephropathy is defined as an increase in serum creatinine of 0.5 mg/dL, or a 25 percent increase from the baseline value, 48 hours after intravascular injection of contrast media. [Barrett, 2006; Palevsky, 2009] Many radiologic procedures (e.g., angiography, intravenous pyelograms, and computerized tomography scans) utilize iodine-containing contrast media. Adverse events resulting from the intravenous administration of contrast dye include allergic reactions, anaphylaxis, and kidney damage. Nephrogenic systemic fibrosis (NSF), a scleroderma-like disease, is a systemic fibrosing disease that involves skin, as well as potentially involving subcutaneous tissue and internal organs, in patients with underlying abnormal renal function. [Weigle, 2008] There is an association between gadolinium-based contrast agents (GBCA) administered during some magnetic resonance imaging studies and the development of NSF. [Grobner, 2006; Marckmann, 2006]

It is estimated that 75 million doses of contrast are administered annually in the United States; [Christiansen, 2005] however, the frequency of complications associated with intravenous contrast media in patients with pre-existing renal disease is under-reported. For those without pre-existing renal impairment, figures range from 3.3 percent to 8 percent [Barrett, 2006] and increase to 12 percent to 26 percent for those with renal disease or diabetes. [Goldenberg, 2005] Studies of large cohorts of patients admitted to the hospital show that approximately 11 percent of cases of hospital-acquired renal insufficiency can be attributed to CIN. [Nash, 2002] Since its recognition in 1997, more than 215 cases have been recorded at the national NSF Registry. [NSF, 2008] NSF's physical manifestations often arise abruptly, over several days to weeks, and include skin discoloration and thickening, joint contracture, muscle weakness, and generalized pain. [Cowper, 2003] NSF is a rare but serious condition, and, as a result of the link between NSF and GBCA renal disease, it is now considered a contraindication to receiving GBCA.

Patients who develop acute renal failure secondary to CIN may require dialysis or have complications that lead to death. Despite the low incidence, the severity of the occurrences is alarming. [Levinson, 2008] The hospital mortality rate is as high as 30 percent, and the two-year mortality rate is 80 percent. [Wong, 2007] In a large retrospective analysis of more than 16,000 inpatients receiving intravenous contrast media, less than 2 percent developed CIN. Despite the low incidence, the risk of death for the group that developed CIN was 34 percent, compared with 7 percent in the group that did not develop CIN. This was a 5.5-fold increased risk of death. [Levy, 1996] Studies have also shown an increased mortality rate one and two years after the development of CIN. [McCullough, 2006] Patients who develop CIN have worse clinical outcomes, higher complication rates, longer hospital stays, and a higher mortality rate than patients who received contrast medium but did not

develop CIN. Moreover, CIN in patients statistically leads to a greater number of future adverse events. [Solomon, 2009b] Identifying patients at risk for CIN and taking precautions to reduce that risk is essential in the prevention of harm from contrast media. [McCullough, 2006]

The preventability of CIN and NSF is dependent on the appropriate screening and monitoring of patients with renal disorders. [Solomon, 2009a] Screening protocols have been developed to identify patients who need baseline kidney function assessment (e.g., serum creatinine, glomerular filtration rate) and risk-reduction precautions, such as the use of low osmolar contrast media. [Kanal, 2007; Sadowski, 2007; Cronin, 2009; Sinert, 2009; Vasheghani-Farahani, 2009] The use of intravenous contrast media in diagnostic procedures is a potential risk for the development of acute renal failure. [Herts, 2009] To reduce the occurrence of CIN, monitoring and assessment and minimization of risk factors are imperative. If a patient is at high risk, concomitant nephrotoxic medications should be discontinued, alternative imaging techniques should be explored, and the amount of intravenous contrast media should be minimized. In addition, adequate intravenous hydration is recommended in all patients. [Anderson, 2006] High-risk patients should be closely monitored post procedure.

The true cost impact and economic burden of CIN and NSF have not been substantiated in the literature. CIN has been associated with increased lengths of stay, delays in treatment, and increased mortality rates. One study showed that the length of stay increased from 10 to 17 days in patients with diabetes who developed CIN and that the mean hospital charge was three times higher than the length of stay of patients who did not develop CIN. [Weisbord, 2002] CIN is a preventable disorder if appropriate assessment and monitoring are conducted. The cost impact is substantial, as is the impact to the patient's quality of life.

Safe Practice Statement

Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and gadolinium-associated nephrogenic systemic fibrosis, and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient's risk evaluations. [Ellis, 2009]

Additional Specifications

- Use evidence-based protocols, developed by a multidisciplinary team that includes a pharmacist and that are approved by the medical staff, for the prevention of contrast media-induced nephropathy (ensure frequent updates based on the rapid evolution of contrast agents). [Reddan, 2009; ACR, 2008; ASHP, N.D.]
- Monitor and document the use of evidence-based protocols (include variance and rationale for departing from protocol).
- Document provider education that encompasses all aspects of contrast media-induced nephropathy prevention and care.
- Specify the qualifications for staff who are authorized to initiate protocols for imaging that include contrast media, and screen patients at risk for contrast media-induced nephropathy.
- Perform risk assessments on all patients that are based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified).

- Ensure that there is documentation by a licensed clinician placed in the patient's health record that risk assessment/ stratification was completed.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory surgical center, inpatient service/hospital, and outpatient hospital.

Example Implementation Approaches

- Ensure that the patient undergoing intravenous contrast procedures is hydrated sufficiently according to standard protocol.
- Use low osmolar contrast media to prevent contrast media-induced renal failure in patients with impaired renal function.
- Check the GFR level prior to scheduling a contrast study in a patient who has uncertain kidney function.
- If gadolinium must be administered in patients at known increased risk, consideration should be given to utilizing reduced dosing of GBCA without impairing the diagnostic utility of the MR exam. Strong consideration should also be given to selecting a GBCA that may have a safer profile based on validated comprehensive clinical data and scientific evidence.
- If a new diagnosis of NSF is made, it is recommended that the Food and Drug Administration (FDA) be notified through MedWatch program [MedWatch, 2008] and that the international NSF registry at Yale University be notified as well [Int. NSF, 2008] to ensure that each database is kept as current as possible. [Kanal, 2007]

Strategies of Progressive Organizations

- Organizational models are in place to ensure that those administering contrast media and managing and monitoring these patients have received sufficient training, experience, and continued education or certification.

Opportunities for Patient and Family Involvement

- Educate patients about contrast media-induced nephropathy prevention and NSF.
- Discuss the patient's risk for contrast media-induced nephropathy with the patient and family, as appropriate.
- Encourage the patient and family to ask questions about contrast media use.
- Consider including patients or families of patients who have experienced contrast-related adverse events to serve on appropriate patient safety or performance improvement committees.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include trending adverse drug events related to contrast media administration in relation to other medication classes. All cases of contrast media-induced renal failure should be evaluated through root cause analysis to identify and mitigate future potential risks and hazards.

- NQF-endorsed® process measures:
  1. #0513: Use of Contrast: Thorax CT [Ambulatory Care (office/clinic)]: Thorax CT – Use of combined studies (with and without contrast). Estimate the ratio of combined (with and without) studies to total studies performed. A high value would indicate a high use of combination studies (71270). Results to be segmented based upon data availability by rendering provider, rendering provider group, and facility. This measure calculates the percentage of thorax studies that are performed with and without contrast out of all thorax studies performed (those with contrast, those without contrast, and those with both). Current literature clearly defines indications for the use of combined studies; that is, examinations performed without contrast followed by contrast enhancement. The intent of this measure is to assess questionable utilization of contrast agents that carry an element of risk and significantly increase examination cost. While there may be a direct financial benefit to the service provider for the use of contrast agents due to increased reimbursements for "combined" studies, this proposed measure is directed at the identification of those providers who typically employ interdepartmental/facility protocols that call for its use in nearly all cases. The mistaken concept is that more information is always better than not enough. The focus of this measure is one of the specific body parts where the indications for contrast material are more specifically defined.

- **Process Measures** include assessment of compliance with policies and procedures, including assessment of patients at risk and subsequent actions based on risk scores.
- **Structure Measures** include identification, stratification, and trending of specific risk factors of patients who have developed contrast media-induced renal failure to determine the success of mitigation strategies.
- **Patient-Centered Measures** include surveys of patients on satisfaction related to contrast media administration, management, and communication by caregivers about what they should anticipate.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings where contrast media are administered.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings where contrast media are administered.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings where contrast media are administered.

New Horizons and Areas for Research

Research continues on the effects of contrast media and strategies aimed at reducing the risk of adverse events. Technological capabilities to communicate patient historical responses to contrast media to other providers prior to administration have relevance in assessing individual patient overall risk factors.

With the introduction of new contrast agents, it is important to monitor FDA and American College of Radiology recommendations about safe and effective use.

Other Relevant Safe Practices

This safe practice has direct relevance to tracking and monitoring of outcomes as part of Safe Practice 2: Culture Measurement, Feedback, and Intervention and Safe Practice 4: Identification and Mitigation of Risks and Hazards.

Notes

ACR, 2008: [No authors listed.] Manual on Contrast Media. Version 6. Reston (VA): American College of Radiology (ACR); 2008 May. Available at http://acr.org/SecondaryMainMenu Categories/quality_safety/contrast_manual.aspx. Last accessed October 28, 2009.

Anderson, 2006: Anderson AL, Smith KM. Prevention of contrast-induced nephropathy: a pharmacological overview. Orthopedics 2006 Oct;29(10):893-5.

ASHP, N.D.: [No authors listed.] Resource Center: Contrast Media and Medication Management. Bethesda (MD): American Society of Health-system Pharmacists (ASHP); No Date. Available at http://www.ashp.org/Import/PRACTICEAND POLICY/PracticeResourceCenters/ContrastMedia.aspx. Last accessed October 28, 2009.

Barrett, 2006: Barrett BJ, Parfrey PS. Clinical practice. Preventing nephropathy induced by contrast medium. N Engl J Med 2006 Jan 26; 354(4): 379–86.

Christiansen, 2005: Christiansen C. X-ray contrast media – an overview. Toxicology 2005 Apr 15;209(2):185-7.

Cowper, 2003: Cowper SE. Nephrogenic fibrosing dermopathy: the first 6 years. Curr Opin Rheumatol 2003 Nov;15(6):785-90.

Cronin, 2009: Cronin RE. Contrast-induced nephropathy: pathogenesis and prevention. Pediatr Nephrol 2009 May 15. [Epub ahead of print]

Ellis, 2009: Ellis JH, Cohan RH. Reducing the risk of contrast-induced nephropathy: a perspective on the controversies. AJR Am J Roentgenol 2009 Jun;192(6):1544-9.

Goldenberg, 2005: Goldenberg I, Matetzky S. Nephropathy induced by contrast media: pathogenesis, risk factors and preventive strategies. CMAJ 2005 May 24;172(11):1461-71.

Grobner, 2006: Grobner T. Gadolinium – a specific trigger for the development of nephrogenic fibrosing dermopathy and nephrogenic systemic fibrosis? Nephrol Dial Transplant 2006 Oct 11. [Epub ahead of print] Available at http://ndt.oxfordjournals.org/cgi/reprint/21/12/3604-b. Last accessed September 23, 2009.

Herts, 2009: Herts BR, Schneider E, Obuchowski N, et al. Probability of reduced renal function after contrast-enhanced CT: a model based on serum creatinine level, patient age, and estimated glomerular filtration rate. AJR Am J Roentgenol 2009 Aug;193(2):494-500.

Int. NSF, 2008: The International Center for Nephrogenic Systemic Fibrosis Research (ICNSFR). Available at http://www.icnsfr.org/. Last accessed November 4, 2009.

Kanal, 2007: Kanal E, Barkovich AJ, Bell C, et al. ACR [American College of Radiology] Guidance Document for Safe MR Practices: 2007. AJR 2007 Jun;188(6):1447-74. Available at http://www.ajronline.org/cgi/reprint/188/6/1447?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=Kanal&fulltext=Guidance+document&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT. Last accessed September 23, 2009.

Levinson, 2008: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 23, 2009.

Levy, 1996: Levy EM, Viscoli CM, Horwitz RI. The effect of acute renal failure on mortality. A cohort analysis. JAMA 1996 May 15;275(19):1489–94.

Marckmann, 2006: Marckmann P, Skov L, Rossen K, et al. Nephrogenic systemic fibrosis: suspected causative role of gadodiamide used for contrast-enhanced magnetic resonance imaging. J Am Soc Nephrol 2006 Sep;17(9):2359-62. Epub 2006 Aug 2. Available at http://jasn.asnjournals.org/cgi/content/full/17/9/2359. Last accessed September 23, 2009.

McCullough, 2006: McCullough PA, Adam A, Becker CR, et al.; CIN Consensus Working Panel. Epidemiology and prognostic implications of contrast-induced nephropathy. Am J Cardiol 2006 Sep 18;98(6A):5K-13K.

MedWatch, 2008: U.S. Food and Drug Administration. MedWatch. The FDA Safety Information and Adverse Event Reporting Program. Available at http://www.fda.gov/medwatch/. Last accessed September 23, 2009.

Nash, 2002: Nash K, Hafeez A, Hou S. Hospital-acquired renal insufficiency. Am J Kidney Dis 2002 May;39(5):930–6.

NSF, 2008: Nephrogenic Systemic Fibrosis (NSF) Registry. Available at http://www.nephrogenic-systemic-fibrosis.org/nsf-registry. Last accessed November 4, 2009.

Palevsky, 2009: Palevsky PM. Defining contrast-induced nephropathy. Clin J Am Soc Nephrol 2009 Jul;4(7):1151-3. Epub 2009 Jun 18.

Reddan, 2009: Reddan D, Laville M, Garovic VD. Contrast-induced nephropathy and its prevention: What do we really know from evidence-based findings? J Nephrol 2009 May-Jun;22(3): 333-51.

Sadowski, 2007: Sadowski EA, Bennett LK, Chan MR, et al. Nephrogenic systemic fibrosis: risk factors and incidence estimation. Radiology 2007 Apr; 243(1):148–57. Epub 2007 Jan 31. Available at http://radiology.rsnajnls.org/cgi/content/full/243/1/148. Last accessed September 23, 2009.

Sinert, 2009: Sinert R, Doty CI. Update: Prevention of contrast-induced nephropathy in the emergency department. Ann Emerg Med 2009 Jul;54(1):e1-5. Epub 2008 Oct 16.

Solomon, 2009a: Solomon R. Preventing contrast-induced nephropathy: problems, challenges and future directions. BMC Med 2009 May 13;7:24. Available at http://www.biomedcentral.com/content/pdf/1741-7015-7-24.pdf. Last accessed September 23, 2009.

Solomon, 2009b: Solomon RJ, Mehran R, Natarajan MK, et al. Contrast-induced nephropathy and long-term adverse events: cause and effect? Clin J Am Soc Nephrol 2009 Jul;4(7): 1162-9. Epub 2009 Jun 25.

Vasheghani-Farahani, 2009 : Vasheghani-Farahani A, Sadigh G, Kassaian SE, et al. Sodium bicarbonate plus isotonic saline versus saline for prevention of contrast-induced nephropathy in patients undergoing coronary angiography:a randomized controlled trial. Am J Kidney Dis 2009 Jul 18. [Epub ahead of print]

Weigle, 2008: Weigle JP, Broome DR. Nephrogenic systemic fibrosis: chronic imaging findings and review of the medical literature. Skeletal Radiol 2008 May;37(5):457-64. Epub 2008 Mar 7.

Weisbord, 2002: Weisbord SD, Bruns F, Saul MI, et al. The high costs of acute renal failure following the administration of intravenous contrast media in hospitalized patients [Abstract]. J Am Soc Nephrol 2002; 13: 447A.

Wong, 2007: Wong GT, Irwin MG. Contrast-induced nephropathy. Br J Anaesth 2007 Oct;99(4):474-83. Epub 2007 Aug 6.

SAFE PRACTICE 31: ORGAN DONATION

The Objective

Ensure that the opportunity to be an organ, tissue, or eye donor is made available to every eligible donor and that no transplant candidate dies because of the lack of an available organ.

The Problem

Organ transplantation has become one of the treatments of choice for patients suffering end-stage organ failure of the heart, lung, liver, kidney, pancreas, and intestine. The single most significant limiting factor to providing a transplant for each eligible patient is the lack of a donor organ. Approximately 100,000 people in the United States are currently waiting for an organ transplant, and 18 patients die each day because of the lack of a donated organ. [OPTN, 2009] Thousands more need tissue and cornea transplants. [OPTN, 2009]

The frequency of deaths resulting from the lack of appropriate organs is substantial; in 2007, more than 6,600 patients died while waiting. Nearly 4,500 of these patients were waiting for kidney transplants. Despite significant strides in the last five years to close the gap between the number of organs and tissues needed and the number available, nearly 30 percent of organ donation opportunities do not occur. Meanwhile, national surveys indicate that 97 percent of Americans would donate a family member's organs if the family member's wishes were known. [DHHS, 2005; Gallup, 2005; Shafer, 2008]

In individual patients, the true severity of the lack of suitable organs is unknown. However, more potential donors are realizing how many lives are being lost because of the lack of organs for eligible transplantation candidates. This realization is leading, albeit slowly, to increased donation rates.

The preventability of morbidity and mortality in eligible organ recipients, and increased donation rates, can occur if hospital senior leaders create expectations for improved performance and collaborate within and among acute care hospitals. Ninety percent (90 percent) of the nation's eligible organ donors are in 840 hospitals. More than 400 hospitals are already demonstrating that collaboration among critical care physicians, nurses, social worker, chaplains, other end-of-life professionals, and organ donation specialists can lead to organ donation occurring in 75 percent or more of eligible cases. The practices used by hospitals and organ procurement organizations (OPOs) to generate high performance are increasingly known and can be replicated. Pioneering new organ procurement procedures, such as uncontrolled donation after cardiac death (UDCD), could potentially eliminate the organ donation waiting list. [DuBois, 2009; Wall, 2009] Simply put, there is a gap between what we know generates these high rates and the performance of the current organ donation system.

Transplantation extends lives and decreases healthcare costs. The 2006 cost of a kidney transplant procedure per patient year was $24,951, as opposed to $71,889 for hemodialysis. [DHHS, 2005] Long-term mortality for patients with kidney transplants is 48 percent to 82 percent lower when compared to dialysis patients on the waiting list. [Wolfe, 1999]

Safe Practice Statement

Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specifying the roles and desired outcomes for every stage of the donation process. [DHHS, 2005]

Additional Specifications

Key organ donation effective practice strategies are:

- Hospitals and organ procurement organizations (OPOs) maintain a focus on joint accountability and intent for implementing highly effective organ donation programs on behalf of donors, donor families, and patients with end-stage organ failure who are in need of transplantation. [Antommaria, 2009; TJC, 2009]
- Key hospital and OPO donation staff are linked rapidly and early to support and assist potential donor families and to implement donor evaluation, organ optimization, organ placement, and organ procurement procedures. [Rudow, 2009]
- Hospitals and OPOs establish and manage an integrated donation process that clearly defines roles and responsibilities; focuses on the needs of donors, donor families, and transplant candidates; and provides feedback about results. [AHRQ, 2001; JCR, 2010]
- Hospitals and OPOs build and sustain a network of quick response and collaborative relationships among the donor family, the hospital staff, the OPO staff, medical examiners/coroners, transplant physicians and surgeons, and the transplant program staff. [Guadagnoli, 2003]
- Every organ donation opportunity is highly valued and is routinely evaluated through death record reviews, quick deployment, re-approaches, and organ optimization to ensure that every suitable organ can be transplanted and that the end-of-life intentions of the donor and donor family have been honored. [Iltis, 2009; JCR, 2010]
- Hospital-specific organ donation performance outcomes are published by the Scientific Registry of Transplant Recipients. [SRTR, N.D.]
- The hospital addresses the wishes of the patient, or surrogate decisionmaker, regarding donation by incorporating processes and staff education that focus on the following: [JCR, 2010]
  - Donor identification and referral are implemented using processes jointly developed by hospital and OPO experts. [Shafer, 2006]
  - Donation consent discussions are informed by previously registered donation intentions and conducted by experienced healthcare team members that are jointly identified by hospital and OPO representatives. [DHHS, 2005]
  - Organ function optimization protocols are developed and jointly implemented by hospital and OPO experts and are evidence based. [Wood, 2004; DHHS, 2005]
  - The donation process is documented by the hospital, beginning with donor identification and concluding with the operative procedure to retrieve donated organs.
  - Continual quality improvement methods are utilized to evaluate the effectiveness of donation protocols. Outcomes are benchmarked against national goals and those of other similar organizations. [IOM, 2006]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include inpatient service/hospital.

Example Implementation Approaches

- In-house organ procurement coordinator: For institutions with a large annual number of eligible donors, an OPO employee may be "housed" within the hospital and should be readily accessible to staff and to families of eligible donors to discuss donation options and facilitate organ procurement, and, in collaboration with hospital partners, develop, implement, and evaluate hospital organ donation policies and procedures. Alternatively, a hospital employee may be designated as the in-house organ procurement representative who works in cooperation with the OPO. [Shafer, 2003; JCR, 2010]
- Hospital policies, consistent with applicable law and regulation, should be in place and should address patient and family preferences for donation, as well as specifying roles and desired outcomes for every stage of the donation process. [JCR, 2010]
- Linking organ procurement goals and targets to the hospital's overall quality improvement plan: Organ donation performance goals should be established jointly by OPO and hospital leaders, and progress toward results should be monitored routinely by quality improvement representatives from both organizations. Opportunities for improvement should be identified and implemented on an ongoing basis. [TJC, 2008]

Strategies of Progressive Organizations

- The hospital considers representatives of the OPO as members of the end-of-life care delivery team and as integral to the process of discerning donation intentions and implementing organ optimization strategies. The hospital includes organ donation outcomes on its internal quality dashboard and identifies a senior leader responsible for improving and sustaining results. [DHHS, 2005]
- Some hospitals are currently exploring electronic notification of OPOs of the presence of eligible donor candidates in critical care units. Notification is based on a mutually agreed set of clinical indicators (such as a Glasgow Coma Scale score) that, when placed in the electronic medical record, triggers a notification to, and timely response from, the OPO.
- Teams of critical care physicians from the same donation service areas (but different hospitals) are convening with transplant physicians/surgeons and organ procurement professionals to develop organ optimization goals (a bundle of clinical indicators such as blood pressure, urine output, pH, CVP, or PA pressures) and strategies to achieve these goals in every case. Progress toward meeting these goals, and the number of organs transplanted from each donor in cases in which the goals are met, is reviewed by the critical care team to identify opportunities for improvement in organ optimization procedures.

Opportunities for Patient and Family Involvement

- Educate patient and family members on the importance of organ donation.
- Include patient and family members on internal committees about organ donation.
- Encourage patient and family members to ask questions about organ donation.
- Include patient and family members of organ donation recipients in staff meetings and grand rounds to share their stories.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include evidence that actions taken mirror the patient's (or the surrogate decisionmaker's) wishes; evidence that outcomes are reflective of national benchmarking goals; and evidence of compliance with standards of accrediting organizations. Specific outcome measures include the number of organ donors (donation after brain death and donation after cardiac death); number of viable organs transplanted from each donor; and number of tissue and eye donors. The effectiveness of performance outcomes can be described by the conversion rate, which indicates the rate at which donation-eligible deaths result in donation.
- **Process Measures** include adherence to organizational policy that reflects effective donation practices utilized by progressive organizations. Effectiveness can be measured by assessing performance at various points along the continuum of care: rate of hospital referral of eligible deaths to the OPO (referral rate); rate of donation conversations in eligible cases (request rate); rate of authorization for donation procedures in eligible cases (consent or authorization rate); the number of organs procured and transplanted from each donor (organs transplanted per donor); and the frequency with which organ optimization targets are met (percentage of donor management goals, or DMGs, met).
- **Structure Measures** include the presence of an organizational policy. Effective organ donation programs require multifaceted organizational policies addressing issues such as declaration of death, donor identification, referral, consent, (donation authorization), organ optimization, withdrawal of mechanical support, and donation after cardiac death. Policy impact is evaluated by hospital committees (quality improvement committees, organ donation committees, medical advisory committees, critical care committees) in partnership with representatives of OPOs. Effective policies should produce results that are consistent with the national performance goals of a 75 percent conversion rate, 3.75 organs transplanted per donor, and 10 percent donations after cardiac death.
- **Patient-Centered Measures** include evidence that patients' values and preferences are respected.

Settings of Care Considerations

This practice is applicable in all acute care and critical access hospital settings.

- **Acute Care Healthcare Settings:** Ensuring effective donation systems in large acute care healthcare settings requires performance accountability to a senior healthcare setting executive and an active quality improvement team that includes critical care specialists, performance improvement experts, information systems experts, academic training program partners (physician, nurse, chaplain, social worker), OPO representatives, and other appropriate partners to achieve the desired performance outcomes.
- **Rural Healthcare Settings:** Any healthcare setting with an operating room and the capability to support patients on ventilators can participate in organ donation procedures regardless of geographic proximity to a transplant center. All hospitals can participate in tissue and eye donation procedures. Healthcare settings capable of identifying eligible donor candidates but unable to fulfill other donation requirements could consider partnering with the designated OPO and a larger healthcare setting to transfer eligible candidates after donation procedures, and the transfer, are authorized using previously stated donation intentions and/or by the next of kin.
- **Children's Healthcare Settings:** Due to the extraordinarily limited number of eligible pediatric donors as compared to the number of children on the transplant waiting list, it is particularly important that pediatric hospitals develop and implement effective organ donation programs. Developing policies and procedures to pronounce death according to neurologic criteria is of particular concern in pediatric settings. [Bratton, 2006] Several pediatric hospitals have successfully developed and implemented procedures for donation after cardiac death. [Mazor, 2007; Antommaria, 2009]
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings with critical care settings.

New Horizons and Areas for Research

One of the main aspects of CMS' new transplant regulations is the requirement that every transplant center maintain a "Quality Assessment and Program Improvement" (QAPI) system to monitor and improve performance. This system will make use of an internal feedback and analysis system, among other data, so that an organization's management can act on important information. [Hamilton, 2008] The organ transplant community has developed one of the better, risk-adjusted outcome measurement systems that spans the national medical community, and regulation by CMS is an important part of the quality assurance program of any transplant hospital. [Hamilton, 2009]

There is very little published research describing next-of-kin opinions on donation practices and the roles and responsibilities of hospital and organ procurement professionals in implementing the donation process. [Lewin, 2009] Research of this kind may better inform professionals about the necessity of and/or the manner in which organizational affiliation is disclosed during donation consent conversations and the information most needed by families to make informed donation decisions in the absence of previously registered donation intentions. Effective organ optimization practices draw upon current critical care strategies,

such as UDCD, [DuBois, 2009] but more research to identify appropriate hemodynamic goals, or to link goals to outcomes, such as the number of organs transplanted or immediate graft function, would help strengthen existing organ optimization protocols.

Other Relevant Safe Practices

This safe practice has direct relevance to tracking and monitoring of outcomes as part of Safe Practice 2: Identification and Mitigation of Risks and Hazards.

Notes

AHRQ, 2001: [No authors listed.] Organ donations increase when families have good information about the donation process. Press Release. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2001 Jul 3. Available at http://www.ahrq.gov/news/press/pr2001/organpr.htm. Last accessed October 28, 2009.

Antommaria, 2009: Antommaria AH, Trotochaud K, Kinlaw K, et al. Policies on donation after cardiac death at children's hospitals: a mixed-methods analysis of variation. JAMA 2009 May 13;301(18):1902-8. Available at http://jama.ama-assn.org/cgi/reprint/301/18/1902. Last accessed October 14, 2009.

Bratton, 2006: Bratton S, Kolovos N, Roach E, et al. Pediatric organ transplantation needs: organ donation best practices. Arch Pediatr Adolesc Med 2006 May;160(5):468-72.

DHHS, 2005: Department of Health and Human Services Health Resources and Services Administration. Organ Transplantation Breakthrough Collaborative: Best Practices Final Report. September 2005. Contract Number HHSP 23320045017. Chapter 4.

DuBois, 2009: DuBois JM. Increasing rates of organ donation: exploring the Institute of Medicine's boldest recommendation. J Clin Ethics 2009 Spring;20(1):13-22.

Gallup, 2005: 2005 National Survey of Organ and Tissue Donation Attitudes and Behaviors. Site maintained by Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB), Division of Transplantation, an agency of the U.S. Department of Health and Human Services. Washington, DC: The Gallup Organization; 2005. Available at http://www.organdonor.gov/survey2005/introduction.shtm. Last accessed October 28, 2009.

Guadagnoli, 2003: Guadagnoli E, Christiansen CL, Beasley CL. Potential organ-donor supply and efficiency of organ procurement organizations. Health Care Financ Rev 2003 Summer;24(4):101-10. Available at http://www.cms.hhs.gov/HealthCareFinancingReview/Downloads/03summerpg101.pdf. Last accessed October 28, 2009.

Iltis, 2009: Iltis AS, Rie MA, Wall A. Organ donation, patients' rights, and medical responsibilities at the end of life. Crit Care Med 2009 Jan;37(1):310-5.

IOM, 2006: Institute of Medicine. Organ Donation: Opportunities for Action. Washington, DC: The National Academies Press; 2006. 93-126. Available at http://books.nap.edu/openbook.php?record_id=11643&page=93. Last accessed October 14, 2009.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMH for Hospitals: The Official Handbook. Standards RI.01.05.01; TS.01.01.01; and TS.02.01.01. Oak Brook (IL): Joint Commission Resources; 2010.

Lewin, 2009: Lewin JK. Barriers to organ donation. Improve staff infrastructure. BMJ 2009 May 20;338:b2013.

Mazor, 2007: Mazor R, Baden HP. Trends in pediatric organ donation after cardiac death. Pediatrics 2007 Oct;120(4):e960-6.

OPTN, 2009: Organ Procurement and Transplantation Network. Available at http://www.optn.org/. Last accessed October 28, 2009.

Rudow, 2009: Rudow DL. The living donor advocate: a team approach to educate, evaluate, and manage donors across the continuum. Prog Transplant 2009 Mar;19(1):64-70.

Shafer, 2003: Shafer TJ, Davis KD, Holtzman SM, et al. Location of in-house organ procurement organization staff in level I trauma centers increases conversion of potential donors to actual donors. Transplantation 2003 Apr 27;75(8):1330-5.

Shafer, 2006: Shafer TJ, Wagner D, Chessare J, et al. Organ donation breakthrough collaborative: increasing organ donation through system redesign. Crit Care Nurse 2006 Apr; 26(2):33-42, 44-8; quiz 49.

Shafer, 2008: Shafer TJ, Wagner D, Chessare J, et al. US organ donation breakthrough collaborative increases organ donation. Crit Care Nurs Q 2008 Jul-Sep;31(3):190-210.

SRTR, N.D.: Scientific Registry of Transplant Recipients. Available at http://www.ustransplant.org. Last accessed October 28, 2009.

TJC, 2008: The Joint Commission [formerly The Joint Commission on Accreditation of Healthcare Organizations]. Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients. Oakbrook Terrace (IL): The Joint Commission; 2004. Available at http://www.jointcommission.org/NR/rdonlyres/E4E7DD3F-3FDF-4ACC-B69E-AEF3A1743AB0/0/organ_donation_white_paper.pdf. Last accessed October 28, 2009.

TJC, 2009: [No authors listed.] Public Policy: Organ Donation and Transplantation. Oakbrook Terrace (IL): The Joint Commission; 2009 Apr 28. Available at http://www.jointcommission.org/PublicPolicy/organ_donation.htm. Last accessed October 28, 2009.

Wall, 2009: Wall SP, Dubler NN, Goldfrank LR, et al. Translating the IOM's "boldest recommendation" into accepted practice. J Clin Ethics 2009 Spring;20(1):23-6; author reply 41-3.

Wolfe, 1999: Wolfe RA, Ashby VB, Milford EL, et al. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. N Engl J Med 1999 Dec 2;341(23):1725-30. Available at http://content.nejm.org/cgi/reprint/341/23/1725.pdf. Last accessed September 23, 2009.

Wood, 2004: Wood KE, Becker BN, McCartney JG, et al. Care of the potential organ donor. N Engl J Med 2004 Dec 23;351(26):2730-9. Available at http://content.nejm.org/cgi/reprint/351/26/2730.pdf. Last accessed September 23, 2009.

Hamilton, 2008: Hamilton TE. Improving organ transplantation in the United States – a regulatory perspective. Am J Transplant 2008 Dec;8(12):2503-5. Epub 2008 Oct 6.

Hamilton, 2009: Hamilton TE. Accountability in health care – transplant community offers leadership. Am J Transplant 2009 Jun;9(6):1287-93. Epub 2009 May 20.

SAFE PRACTICE 32: GLYCEMIC CONTROL

The Objective

Prevent patient harm as a result of hyperglycemia and hypoglycemia.

The Problem

Diabetes is a group of diseases marked by hyperglycemia resulting from defects in insulin production, insulin action, or both. Diabetes can lead to serious complications and premature death. Hyperglycemia is commonly seen in hospitalized patients and may suggest undiagnosed diabetes or prediabetes. It may also be attributable to stress hyperglycemia resulting from trauma or infection, or it may be medication induced. Uncontrolled diabetes can lead to life-threatening conditions such as diabetic ketoacidosis and nonketotic hyperosmolar coma, which are both attributed to chronic hyperglycemia. Hypoglycemia occurs when blood glucose levels drop too low. This condition can lead to coma and death.

The frequency of diabetes has reached epidemic proportions in the United States, affecting nearly 24 million individuals (an increase of more than 3 million in 2 years). It is estimated that another 57 million individuals are thought to have prediabetes, which puts them at an increased risk for developing the disorder. [CDC, 2008] Diabetes was the 7th leading cause of death in the United States listed on death certificates in 2006. Hyperglycemia is common in hospitalized patients. From 1980 through 2003, the number of hospital discharges associated with diabetes doubled from 2.2 million to 5.1 million. [CDC, 2006] The evidence continues to support the fact that poor glycemic control in hospitals is associated with increased morbidity and mortality, as well as increased costs.

The severity of harm related to poor glycemic control is remarkably high. [Levinson, 2008a] Hyperglycemia has been associated with poor outcomes in multiple patient populations, including critically ill patients, patients undergoing surgery, and patients with myocardial infarction and acute ischemic stroke. [Pomposelli, 1998; Capes, 2000; Williams, 2002; Estrada, 2003; Krinsley, 2003; Cheung, 2005; McAlister, 2005; Baker, 2006; Kao, 2009] Hyperglycemia is an independent marker of in-hospital mortality in patients with undiagnosed diabetes. [Umpierrez, 2002] Insulin is the primary modality for controlling glucose in the inpatient setting. The pharmacology of the drug, complexity of dosing, and variety of products all contribute to the potential for error and associated harm. Insulin has been identified by the Institute of Safe Medication Practices as a high alert medication, bearing an increased risk for harm when used in error. Hypoglycemia is the most common complication of any insulin therapy and is an extremely frequent adverse event in hospitals worldwide. [Runciman, 2003; AHRQ, 2009b] Adverse events associated with insulin and hypoglycemics increased substantially from 2004 to 2006. [AHRQ, 2009a] Despite literature that supports tight glycemic control in an inpatient setting, hypoglycemia is the customary reason given for not achieving glycemic control.

The preventability of complications associated with poor glycemic control is possible with appropriate treatment and monitoring. Recent literature has reported that manifestations of poor glycemic control can be preventable with intensive insulin therapy. In a study of critically ill and mixed medical and surgical intensive care unit (ICU) patients, the use of intensive

insulin therapy to achieve arterial whole blood glucose levels of 80–110 mg/dl reduced mortality by 34 percent, sepsis by 46 percent, renal failure necessitating dialysis by 41 percent, the need for blood transfusion by 50 percent, and critical illness-related polyneuropathy by 44 percent. [van den Berghe, 2001] Also, a meta-analysis of 35 clinical trials evaluating the effect of insulin therapy on mortality in hospitalized patients with critical illness found that insulin therapy decreased short-term mortality by 15 percent in a variety of clinical settings. [Pittas, 2004] The debate continues about "tight" glycemic control in critically ill adults. Recent studies have demonstrated that tight glycemic control can lead to poorer outcomes. NICE-SUGAR showed harm from tight glycemic control in a mixed ICU setting; however, the control group had a median glucose of 141 mg/dL, and 69 percent of patients were on an insulin drip. [NICE-SUGAR, 2009] Wiener and colleagues analyzed 29 randomized controlled trials, totaling 8,432 patients, to evaluate the benefit and risk of tight glycemic control versus usual care in critically ill adult patients. The authors concluded that there was no difference in hospital mortality between groups, but that tight glycemic control was associated with significantly reduced risk of septicemia. Also reported was an associated increased risk of hypoglycemia with tight glycemic control. [Wiener, 2008] The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial terminated the intensive-therapy arm in February 2008 after findings of higher mortality in this arm of the study. [ACCORD, 2008] Some patient populations may be more prone to hypoglycemia than others (medical ICU, septic > surgical) and may require less rigid glucose control targets. The particular infusion protocol does make a difference in glycemic control. The Leuven protocol has much higher rates of hyperglycemia than that of other protocols, such as Glucommander and Yale. [Van den Berghe, 2001; Goldberg, 2004a; Goldberg, 2004b; Davidson, 2005; Van den Berghe, 2006; Brunkhorst, 2008; NICE-SUGAR, 2009] Recent evidence demonstrates that the target level of glycemic control may be less important than the controlling the extent of variability in glucose levels in some patient populations in the ICU setting. Recent guidelines recommend the target range for critically ill patients is 140-180 mg/dL; for non-critically ill patients, pre-meal glucose target is <140 mg/dL. [ADA, 2009] The use of evidence-based standardized protocols and order sets has been shown to improve glycemic control and safety. [Maynard, 2009; Schnipper, 2009] Insulin infusions in the ICU setting have been shown to be both a safe and effective way to treat hyperglycemia. [Moghissi, 2009] In the non-ICU setting, basal-bolus subcutaneous insulin has been shown to be more safe and effective than sliding scale insulin. [Umpierrez, 2007]

The cost impact of diabetes is devastating. In 2007, diabetes was estimated to cost $174 billion in direct and indirect costs. The American Diabetes Association estimates that $58.3 billion was spent on inpatient hospital care directly attributed to diabetes. [ADA, 2007] The cost of inpatient diabetes care for 2002 was estimated at $40 billion, the single largest component of direct medical costs for the disease. [ACE/ADA, 2006]

Appropriate treatment and monitoring can help minimize the costs associated with the disease. Van den Berge and colleagues showed that the intensive insulin management protocol that was implemented resulted in improved medical outcomes, with a reduction of ICU stay resulting in an estimated yearly cost savings of $40,000 per ICU bed. [van den Berghe, 2001]

The Centers for Medicare & Medicaid Services (CMS) selected manifestations of poor glycemic control (hypoglycemic coma, diabetic ketoacidosis, nonketotic hyperosmolar coma, and secondary diabetes with ketoacidosis or hyperosmolarity) as hospital-acquired conditions that will no longer receive a higher reimbursement when not present on admission, beginning October 1, 2008. [CMS/HAC, 2009] The National Quality Forum (NQF) also has deemed patient death or serious disability associated with hypoglycemia as a serious reportable event when acquired after admission to a healthcare facility. [NQF, 2006; Levinson, 2008b]

There is intense research of glycemic control, and it will take time to understand the absolute magnitude of preventability and value of risk-assessment methods; however, there is full consensus that actions need to be taken now to reduce glycemic control with what is currently known.

Safe Practice Statement

Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.

Additional Specifications

Essential elements of improving glycemic control: [ADA, 2008; IHI, 2009; TJC, N.D.]

- A multidisciplinary team is established that is empowered to develop and guide processes for improving glycemic control for patients. This team should be charged with assessing and monitoring the quality of glycemic management within the organization. Members of this team should include all key stakeholders.
- Organizations systematically track glucose data and medication error or near miss reports to assess the quality of care delivered and share this data with senior leadership and frontline clinicians. [IHI, N.D.]
- Evidence-based protocols and order sets are developed to guide the management of hyperglycemia and hypoglycemia throughout the organization. Specifically, written protocols are developed for the management of patients on intravenous insulin infusions.
- Patient medications are reconciled appropriately, including, upon discharge, restarting prehospital antiglycemic agents when appropriate.
- Patients with newly diagnosed diabetes or educational deficits have at least the following educational components reflected in their plan of care: [Kerr, 2008]
  - Medication management, including how to administer insulin (when appropriate) and potential medication interactions.
  - Nutritional management, including the role of carbohydrate intake in blood glucose management.
  - Exercise.
  - Signs, symptoms, and treatment of hyperglycemia and hypoglycemia.
  - Importance of blood glucose monitoring and how to obtain a blood glucose meter.
  - Instruction on the use of a blood glucose meter if available.
  - Sick-day guidelines.
  - Information on whom to contact in case of emergency or for more information.
  - A plan for postdischarge education or self-management support. [ADA, 2008; TJC, N.D.]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare and Medicaid Services (CMS) care settings, to include inpatient service/hospital.

Example Implementation Approaches

- Participants in a multidisciplinary team may include medical staff, nursing and case management, pharmacy, nutrition services, dietary, laboratory, quality improvement and information systems personnel, and administration. [AHRQ, 2008]
- Ensure that documentation of patients with diabetes occurs in the medical record, at admission and at discharge. Documentation of diabetes in the medical record reflects the individual's type of diabetes; preadmission medications for the control of diabetes including dosages as stated by the patient; weight; nutritional screening results; nutrition management plan; degree of control prior to admission; severity of hyperglycemia on admission; current and anticipated nutritional status (e.g., NPO); risk factors for hypoglycemia (e.g., unpredictable PO intake, long-standing diabetes, type 1 diabetes, pancreatic dysfunction, history of hypoglycemia); and level of comprehension and competence related to diabetes self-management activities.
- An A1c is drawn at the time of admission, unless the results of the patient's A1c (drawn within the last 60 days) are known, or the patient has a medical condition or has received therapy that would confound the results.
- Plans for the treatment of hypoglycemia and hyperglycemia are established for each patient with diabetes. A plan for coordinating administration of insulin and delivery of meals should be implemented. A plan for monitoring patients who have an abrupt discontinuation of PO intake or enteral feeding should be implemented. [Varghese, 2007] Episodes of hypoglycemia are identified, and contributing reasons for these are captured and evaluated for systemic trends (e.g., difficulty having food trays delivered, improper ordering or timing of insulin or antidiabetic medications, drug interactions).
- Standardized order sets promoting the use of scheduled insulin therapy for both subcutaneous and infusion insulin regimens.
  - Protocols should suggest starting dose and adjustment strategies based on target glucose ranges.
  - If a protocol does not seem to be effective in a specific patient, then urgent input is needed from a clinician with expertise in diabetes management.
  - Standardization across an institution should be considered for practical and logistical reasons.
  - The important transition to subcutaneous administration of insulin must be an integral part of any insulin infusion protocol. The importance of transition of care during hospitalization should be addressed on protocols, such as from the operating room to post-op, or from the ICU to a medical unit.
  - Personnel implementing the protocol should be asked to help troubleshoot when specific concerns arise.
  - Preprinted algorithms or computerized systems and adequate technical support should be available. [SHM, 2008]
  - Protocols should be periodically reviewed to ensure that they continue to meet the needs of the hospital and its patients.

- Nutritional/dietary routine processes in place for addressing special needs of inpatients with diabetes.
- A glycemic control program is incorporated as part of the organization's medication safety program for high alert medications; pharmacist critical review of all insulin orders is included.
- The organization has a plan for communication with outpatient clinicians for transition issues.
- Transition-in-care issues are addressed adequately, including a medical regimen that is tailored to the patient that is affordable and understood; a glucose meter machine/strips covered by insurance; and defined follow-up for the patient.

Strategies of Progressive Organizations

- Progressive organizations may consider the following:
  - Comprehensive patient education to teach the principles of diabetes self-management. [Clement, 2004]
  - A mechanism to screen for undiagnosed diabetes and to follow up on patients without a diabetes diagnosis who have random high blood glucose/stress-induced hyperglycemia.
  - A reliable method in place for educating non-English-speaking patients.
  - Use of dose-error reduction infusion pumps for insulin infusions.
  - A specific glycemic management clinical team to offer subspecialty assistance for those patients who do not achieve adequate glycemic control with the use of protocols alone.

Opportunities for Patient and Family Involvement

- Educate patients and families about the proper nutritional and dietary routines to assist in controlling glucose levels.
- Use "teach-back" method about medication administration, that is, insulin injections and glucose meter machine readings.
- Teach patients and families to recognize signs and symptoms of hyperglycemia and hypoglycemia.
- Encourage patient and family members to ask questions about their medication regimens and request consultations by a pharmacist.
- Include patients and families in performance improvement and patient safety committees to focus on optimal and safe treatment of patients with diabetes.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures** include trending the percentage of eligible patient days with one or more value: <40mg/dL extreme hypoglycemia, <70mg/dL hypoglycemia, >300mg/dL extreme hyperglycemia, and percentage of eligible patient days with mean <140 or <180 mg/d, and/or with all values <180. Evaluate patient glycemic control data and create a performance improvement strategy to close the gaps. [Schnipper, 2008]

- **Process Measures** include adherence to organizational policy that reflects effective glycemic control practices utilized by progressive organizations. For example:
  - Glucose measured within 8 hours of hospital admission.
  - A1c measurement obtained or available within 30 days of admission.
  - Percentage of non-ICU patients with inpatient hyperglycemia on basal insulin.
  - Percentage of ICU patients with hyperglycemia (e.g. >150 mg/dL) on an insulin infusion protocol; time to glucose control on that protocol; protocol violations.
  - Percentage of patients with diabetes or inpatient hyperglycemia who are receiving point-of-care glucose testing at least 4 times a day.
  - NQF-endorsed® process measures:
    1. #0300: Cardiac patients with controlled 6 A.M. postoperative serum glucose [Hospital].
    2. #0057: Hemoglobin A1c testing: Percentage of adult patients with diabetes aged 18-75 years receiving one or more A1c test(s) per year.
    3. #0059: Hemoglobin A1c management: Percentage of adult patients with diabetes aged 18-75 years with most recent A1c level greater than 9.0 percent (poor control).
    4. #0060: Hemoglobin A1c test for pediatric patients: Percentage of pediatric patients with diabetes with a HbA1c test in a 12-month measurement period.
    5. #0451: Call for a Measure of Glycemic Control with Intravenous Insulin Implementation [Hospital, Other]: Intravenous insulin glycemic control protocol implemented for cardiac surgery patients with diabetes or hyperglycemia admitted into an intensive care unit.
- **Structure Measures** include the presence of and adherence to an organizational policy.
- **Patient-Centered Measures** include evidence that patients' values and preferences are respected. No specific measures of this type have been identified.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings with critical care facilities.
- **Children's Healthcare Settings:** Based on risk assessment for your organization, insulin safe practices are important for pediatric patients.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings with critical care facilities.

New Horizons and Areas for Research

Research is needed to further explain the central mechanisms underlying the development and exacerbation of hyperglycemia in the hospitalized patient and by what mechanisms hyperglycemia produces harm. This would help provide insight into mechanisms that may help develop additional targets for therapy. Research also is needed in best practices to improve the practical aspects of achieving

inpatient glycemic control and in infusion protocols to determine which are safest and most effective. Further randomized controlled trials are needed to document the benefits of glycemic control, especially in non-ICU patients; trials also could determine which critical care patients would benefit from tighter glucose targets. Strategies that support the maintenance of glycemic control (after discharge) need to be explored for discharge planning. The evolution of new devices, such as implantable insulin devices, and the implications of more accurate and continuous glucose monitoring, may affect the future direction of this safe practice.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 17: Medication Reconciliation and Safe Practice 18: Pharmacist Leadership Structures and Systems are vitally important to a successful glycemic control program.

Notes

ACCORD, 2008: Action to Control Cardiovascular Risk in Diabetes Study Group; Gerstein HC, Miller ME, Byington RP, et al. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 2008;358(24):2545-2559. Epub 2008 Jun 6.

ACE/ADA, 2006: ACE/ADA Task Force on Inpatient Diabetes. American College of Endocrinology and American Diabetes Association Consensus statement on inpatient diabetes and glycemic control. Diabetes Care 2006 Aug;29(8):1955-62. Available at http://care.diabetesjournals.org/cgi/content/extract/29/8/1955. Last accessed September 25, 2009.

ADA, 2007: American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2007. Diabetes Care 2008 Mar;31(3):596-615.

ADA, 2008: American Diabetes Association Clinical Practice. Executive Summary: Standards of Medical Care in Diabetes – 2008. Diabetes Care 2008;31:S5-S11. Available at http://care.diabetesjournals.org/content/vol31/Supplement_1/. Last accessed October 28, 2009.

ADA, 2009: American Diabetes Association. Standards of medical care in diabetes – 2009. Diabetes Care 2009 Jan;32 Suppl 1:S13-61.

AHRQ, 2008: [No authors listed.] Health Information Technology: A computer-based intravenous protocol can improve glycemic control in surgical ICU patients. Research Activities Newsletter. No. 329. AHRQ Publication No. 08-0015. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2008 Jan. Available at http://www.ahrq.gov/research/jan08/0108RA12.htm. Last accessed October 28, 2009.

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Baker, 2006: Baker EH, Janaway CH, Philips BJ, et al. Hyperglycaemia is associated with poor outcomes in patients admitted to hospital with acute exacerbations of chronic obstructive pulmonary disease. Thorax 2006 Apr;61(4):284-9. Epub 2006 Jan 31. Available at http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=2104606&blobtype=pdf. Last accessed September 9, 2009.

Brunkhorst, 2008: Brunkhorst FM, Engel C, Bloos F, et al. Intensive insulin therapy and pentastarch resuscitation in severe sepsis. N Engl J Med 2008 Jan 10;358(2):125-39. Available at http://content.nejm.org/cgi/reprint/358/2/125.pdf. Last accessed September 9, 2009.

Capes, 2000: Capes SE, Hunt D, Malmberg K, et al. Stress hyperglycemia and increased risk of death after myocardial infarction in patients with and without diabetes: a systematic overview. Lancet 2000 Mar 4;355(9206):773-8.

CDC, 2006: Centers for Disease Control and Prevention. Number (in Thousands) of Hospital Discharges with Diabetes as Any-Listed Diagnosis, United States, 1980-2003. U.S. Dept. Health & Human Services; Centers for Disease Control & Prevention, 2006. Available at http://www.cdc.gov/diabetes/statistics/dmany/fig1.htm. Last accessed September 25, 2009.

CDC, 2008: Centers for Disease Control and Prevention. Press Release: Number of People with Diabetes Increases to 24 Million. U.S. Dept. Health & Human Services, Centers for Disease Control & Prevention; 2008. Available at http://www.cdc.gov/media/pressrel/2008/r080624.htm. Last accessed September 25, 2009.

Cheung, 2005: Cheung NW, Napier B, Zaccaria C, et al. Hyperglycemia is associated with adverse outcomes in patients receiving total parenteral nutrition. Diabetes Care 2005 Oct;28(10):2367-71. Available at http://care.diabetesjournals.org/content/28/10/2367.full.pdf+html. Last accessed September 9, 2009.

Clement, 2004: Clement S, Braithwaite SS, Magee MF, et al. American Diabetes Association Diabetes in Hospitals Writing Committee. Management of diabetes and hyperglycemia in hospitals. Diabetes Care 2004 Feb;27(2):553-91.

CMS/HAC, 2009: CMS. Hospital-Acquired Conditions (Present on Admission Indicator) Overview. Baltimore (MD): Centers for Medicare & Medicaid Services; 2009. Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed October 30, 2008.

Davidson, 2005: Davidson PC, Steed RD, Bode BW. Glucommander: a computer-directed intravenous insulin system shown to be safe, simple, and effective in 120,618 h of operation. Diabetes Care 2005 Oct;28(10):2418-23. Available at http://care.diabetesjournals.org/content/28/10/2418.full.pdf+html. Last accessed September 9, 2009.

Estrada, 2003: Estrada CA, Young JA, Nifong LW, et al. Outcomes and perioperative hyperglycemia in patients with or without diabetes mellitus undergoing coronary artery bypass grafting. Ann Thorac Surg 2003 May;75(5):1392-9.

Goldberg, 2004a: Goldberg PA, Sakharova OV, Barrett PW, et al. Improving glycemic control in the cardiothoracic intensive care unit: clinical experience in two hospital settings. J Cardiothorac Vasc Anesth 2004 Dec;18(6):690-7.

Goldberg, 2004b: Goldberg PA, Siegel MD, Sherwin RS, et al. Implementation of a safe and effective insulin infusion protocol in a medical intensive care unit. Diabetes Care 2004 Feb;27(2):461-7. Available at http://care.diabetesjournals.org/content/27/2/461.full.pdf. Last accessed September 9, 2009.

IHI, 2009: [No authors listed.] Glycemic Control in Critical Care. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=844d43dd-7c9b-4d4d-ba52-e725650246c9. Last accessed October 28, 2009.

IHI, N.D.: [No authors listed.] Glycemic control goal. Cambridge (MA): Institute for Healthcare Improvement (IHI); No date. Available at http://www.ihi.org/IHI/Topics/CriticalCare/Sepsis/Measures/GlycemicControlGoal.htm. Last accessedOctober 28, 2009.

Kao, 2009: Kao LS, Meeks D, Moyer VA, et al. Peri-operative glycaemic control regimens for preventing surgical site infections in adults. Cochrane Database Syst Rev 2009 Jul 8;(3):CD006806.

Kerr, 2008: Kerr EA. Results: Assessing Glycemic Control and Other Key Discussion Items. IN: Assessing Quality of Care for Diabetes. Conference Final Report. AHRQ Publication No. 08-0037-EF. Rockville (MD): Agency for Healthcare Research and Quality; 2008 Jan. Available at http://www.ahrq.gov/qual/diabetescare/diabcare2.htm. Last accessed October 28, 2009.

Krinsley, 2003: Krinsley JS. Association between hyperglycemia and increased hospital mortality in a heterogeneous population of critically ill patients. Mayo Clin Proc 2003 Dec;78(12):1471-8.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 25, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 25, 2009

McAlister, 2005: McAlister FA, Majumdar SR, Blitz S, et al. The relation between hyperglycemia and outcomes in 2,471 patients admitted to the hospital with community-acquired pneumonia. Diabetes Care 2005 Apr;28(4):810-5. Available at http://care.diabetesjournals.org/content/28/4/810.full.pdf+html. Last accessed September 9, 2009.

Moghissi, 2009: Moghissi ES, Korytkowski MT, DiNardo M, et al. American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. Endocr Pract 2009 Jul-Aug;15(4):353-69.

NICE-SUGAR, 2009: NICE-SUGAR Study Investigators, Finfer S, Chittock DR, et al. Intensive versus conventional glucose control in critically ill patients. N Engl J Med 2009 Mar 26;360(13):1283-97. Epub 2009 Mar 24. Available at http://content.nejm.org/cgi/reprint/360/13/1283.pdf. Last accessed October 14, 2009.

NQF, 2006: National Quality Forum. Serious Reportable Events in Healthcare: 2005-2006 Update. Available at http://www.qualityforum.org/projects/completed/sre/. Last accessed September 9, 2008.

Pittas, 2004: Pittas AG, Siegel RD, Lau J. Insulin therapy for critically ill hospitalized patients: a meta-analysis of randomized controlled trials. Arch Intern Med 2004 Oct 11;164(18):2005-11.

Pomposelli, 1998: Pomposelli JJ, Baxter JK 3rd, Babineau TJ, et al. Early postoperative glucose control predicts nosocomial infection rate in diabetic patients. JPEN J Parenter Entaeral Nutr 1998 Mar-Apr;22(2):77-81.

Runciman, 2003: Runciman WB, Roughead EE, Semple SJ, et al. Adverse drug events and medication errors in Australia. Int J Qual Health Care 2003 Dec;15 Suppl 1:i49-59.

Schnipper, 2008: Schnipper JL, Magee M, Larsen K, et al. Society of Hospital Medicine Glycemic Control Task Force summary: practical recommendations for assessing the impact of glycemic control efforts. J Hosp Med 2008 Sep;3(5 Suppl):66-75.

Schnipper, 2009: Schnipper JL, Ndumele CD, Liang CL, Pendergrass ML. Effects of a subcutaneous insulin protocol, clinical education, and computerized order set on the quality of inpatient management of hyperglycemia: Results of a clinical trial. J Hosp Med. 2009;4:16-27.

SHM, 2008: Glycemic Control Resource Room Project Team. Glycemic Control Resource Room. Philadelphia (PA): Society of Hospital Medicine; 2008. Available at http://www.hospitalmedicine.org/ResourceRoomRedesign/html/01HowtoUse/01_HowtoUse.cfm. Last accessed October 28, 2009.

TJC, N.D.: The Joint Commission. Inpatient Diabetes Certification. Oakbrook Terrace (IL): The Joint Commission; No Date. Available at http://www.jointcommission.org/CertificationPrograms/Inpatient+Diabetes/. Last accessed October 28, 2009.

Umpierrez, 2002: Umpierrez GE, Isaacs SD, Bazargan N, et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. J Clin Endocrinol Metab 2002 Mar;87(3):978-82. Available at http://jcem.endojournals.org/cgi/reprint/87/3/978. Last accessed September 9, 2009.

Umpierrez, 2007: Umpierrez GE, Smiley D, Zisman A, et al. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes (rabbit 2 trial). Diabetes Care 2007;30:2181-6.

Van den Berghe, 2001: Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. N Engl J Med 2001 Nov 8;345(19):1359-67. Available at http://content.nejm.org/cgi/reprint/345/19/1359.pdf. Last accessed November 4, 2009.

Van den Berghe, 2006: Van den Berghe G, Wilmer A, Hermans G, et al. Intensive insulin therapy in the medical ICU. N Engl J Med 2006 Feb 2;354(5):449-61. Available at http://content.nejm.org/cgi/reprint/354/5/449.pdf. Last accessed November 4, 2009.

Varghese, 2007: Varghese P, Gleason V, Sorokin R, et al. Hypoglycemia in hospitalized patients treated with antihyperglycemic agents. J Hosp Med 2007 Jul;2(4):234-40.

Wiener, 2008: Wiener RS, Wiener DC, Larson RJ. Benefits and risks of tight glucose control in critically ill adults: a meta-analysis. JAMA 2008 Aug 27;300(8):933-44.

Williams, 2002: Williams LS, Rotich J, Qi R, et al. Effects of admission hyperglycemia on mortality and costs in acute ischemic stroke. Neurology 2002 Jul 9;59(1):67-71.

SAFE PRACTICE 33: FALLS PREVENTION

The Objective

Reduce the risk of patient harm resulting from falls.

The Problem

A fall is defined as a sudden, unintentional, downward movement of the body to the ground or other surface. [USDVA, 2004] When a patient falls, he or she is at risk of serious injury, disability, and, in some cases, death.

Falls occur frequently among hospitalized patients and long-term care residents, [Rubenstein, 1994; Wilson, 1998; HCM, 2000; Healey, 2004; Johal, 2009] and are the leading cause of injury-related death for individuals 65 and older. [CDC, 2006] Patients in nursing homes and hospitals fall three times more often than community-dwelling persons age 65 and older. [JAGS, 2001; Gillespie, 2003; McClure, 2005] All ages of patients who are admitted to oncology, critical care, and infectious disease units are also at increased risk for falls. [Wilson, 1998] Up to 84 percent of all adverse inpatient incidents are fall related, [Wilson, 1998] and patient falls are the sixth most commonly reported sentinel event in The Joint Commission's Sentinel Event Database. [TJC, 2009]

The severity of harm from falls is far-reaching. [Levinson, 2008a] Most falls are not witnessed by staff, [Healey, 2007] and approximately 30 percent result in injury; 4 percent to 6 percent of these falls result in serious injuries that include bone fractures and soft tissue and head injuries. [Hitcho, 2004; McClure, 2005] In the United States, falls result in approximately 250,000 hip fractures, which is the most serious fall-related injury in older people. [Greenspan, 1994] Death occurs in 15 percent of the elderly who fall in the hospital, and 33 percent of elderly patients who fall do not survive beyond one year after a fall. [McClure, 2005] Fear of falling and postfall anxiety syndrome are psychological problems that persist after a fall. [Oliver, 2000; JAGS, 2001]

More evidence is required to positively demonstrate the absolute preventability of any given intervention on the rate or seriousness of injury resulting from falls. However, it is apparent that risk assessment, combined with interventions that target the reduction of multiple risk factors, is more effective than interventions that seek to eliminate a single risk factor. [Feder, 2000; NCCNSC, 2004] A recent study indicated that some reductions in rates of falls were seen with a multi-intervention strategy; however, the number of fractures in hospitalized patients did not decrease in this study. [Oliver, 2007] Most research on hospital-related falls has focused on prevention of falls. More research is needed to determine the severity of injuries resulting from falls, as well as how to prevent injury. [Spice, 2009; Vind, 2009]

In 2000, the total direct cost of all fall injuries for people 65 and older exceeded $19 billion: $0.2 billion for fatal falls, and $19 billion for nonfatal falls. [Stevens, 2006] By 2020, the annual direct and indirect cost of fall injuries is expected to reach $54.9 billion (in 2007 dollars). [Englander, 1996] In a study of people age 72 and older, the average healthcare cost of a fall injury totaled $19,440. This cost included hospital, nursing home, emergency room, and home health care, but excluded physician services. [Rizzo, 1998; Oliver, 2008]

The Centers for Medicare & Medicaid Services (CMS) has selected fall-related injuries (fracture, dislocation, intracranial injury, and crushing injury) as hospital-acquired conditions that will no longer receive a higher reimbursement when not present on admission, beginning October 1, 2008. [CMS, 2007; CMS/HAC, 2009; Inouye, 2009; Spice, 2009] The National Quality Forum (NQF) also has deemed falls and related trauma as serious reportable events when acquired after admission to a healthcare facility. [Levinson, 2008b]

There is intense research ongoing about falls, and it will take time to understand the absolute magnitude of preventability and the value of risk-assessment methods; however, there is full consensus that actions need to be taken now to reduce falls with what is currently known. [Batchelor, 2009; Dykes, 2009]

Safe Practice Statement

Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices.

Additional Specifications

- The hospital or healthcare organization must establish a fall reduction program. [IHI, 2009; JCR, 2010]
- The fall reduction program includes an evaluation appropriate to the patient population, settings, and services provided. [JCR, 2010]
- An organization may consider individual patient assessments for what the organization deems to be the high-risk groups in its patient population. [Agostini, 2001; JCR, 2010]
- The fall reduction program includes interventions to reduce the patient's fall risk factors. [HCANJ, 2007; JCR, 2010]
- Staff receive education and training about the fall reduction program. Education occurs upon hire and annually thereafter. [Dempsey, 2009; JCR, 2010]
- The patient, and family as needed, is educated about the fall reduction program and any individualized fall reduction strategies.
- The organization evaluates the fall reduction program to determine its effectiveness. [NICE, 2004; JCR, 2010]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.

Example Implementation Approaches

- Identify patients at risk for falls using a standardized individual risk-assessment tool, such as the Morse Fall Risk Assessment or the Hendrich Fall Risk Assessment. [Hendrich, 1995; Morse, 1996; USDVA, 2004; Heinze, 2009]
- Reassess patients for their fall risk at various points during their stay, because a patient's status changes over the course of the stay in an organization setting. Consider patient fall assessment upon admission to the facility; following transfer from one unit to another within the facility; following any change in physical or mental status; following a fall;

or otherwise at regular intervals such as biweekly. [USDVA, 2004]

- Regularly review and modify patient medications that may predispose patients to falls, especially psychotropic medications, diuretics, and others. [USDVA, 2004] Not all fall risk-assessment tools include the provision for medication review; including a pharmacist in the organizational fall reduction program is essential.
- Perform multidisciplinary (healthcare provider, technician, administration, housekeeping) environmental risk assessments, and eliminate or minimize hazards (e.g., clean dry floors, personal articles within reach). [NCCNSC, 2004; USDVA, 2004]
- Consider alternative patient management strategies (e.g., low beds, safe transfer and exercise training, alarm devices). [Hendrich, 1995; NCCNSC, 2004; USDVA, 2004; Healey, 2008]
- Consider walking aids to assist mobility.
- Visual impairment increases with age and is often unnoticed by those who have it. Encourage regular eye examinations among elderly patients as a preventive measure against falls. [AHRQ, 2009a]
- Provide physical assistance to high-risk patients while they are ambulating or attempting difficult maneuvers (toileting, transfers, etc.), and promote mobility to strengthen postural control through physiotherapy, for example. [Hendrich, 1995; NCCNSC, 2004; USDVA, 2004]
- Introduce programs to offer regular opportunities for assisted toileting. [USDVA, 2004; Hendrich, 1995]

Strategies of Progressive Organizations

- Host fall problem-solving sessions with patients, their families, and staff, and provide ongoing education. [USDVA, 2004]
- Encourage staff to report all falls and "near misses" through an accessible and user-friendly reporting system. [AHRQ, 2009b]

Opportunities for Patient and Family Involvement

- Patients at risk of falls, and their families, should receive and participate in education programs on strategies and interventions to reduce the risk of falls in the home and other environments. [NICE, 2004; Sherrington, 2008; Hill, 2009a; Ryu, 2009]
- Patients at risk of falls, and their families, are an important source of information about a history of previous falls and other risk factors.
- Patients at risk of falls, and their families, should be included in alternative strategies to reduce the likelihood of falls and to be vigilant for fall hazards.
- Patients at risk of falls, and their families, should be included in the postfall debriefing to discuss the incident and strategies for prevention of future falls. [Nyman, 2009]
- Consider including patients or families of patients who have experienced a fall-related injury to serve on appropriate patient safety or performance improvement committees. [Hill, 2009b]

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs. [Dacenko-Grawe, 2008]

- **Outcome Measures** include percentage of patient falls and percentage of fall-related injuries.
  - NQF-endorsed® outcome measures:
    1. #0141: Patient Fall Rate [Hospital]: All documented falls, with or without injury, experienced by patients on an eligible unit in a calendar quarter.
    2. #0202: Falls with injury [Hospital]: All documented patient falls with an injury level of minor (2) or greater.
- **Process Measures** include adherence to organizational policy that reflects effective falls prevention practices utilized by progressive organizations: percentage of patients screened for falls and percentage of patients educated about fall prevention strategies and risks.
  - NQF-endorsed process measures:
    1. #0035: Fall risk management in older adults [Ambulatory]: a. Discussing fall risk: Percentage of patients aged 75 and older who reported that their doctor or other health provider talked with them about falling or problems with balance or walking. b. Managing fall risk: Percentage of patients aged 75 and older who reported that their doctor or other health provider had done anything to help prevent falls or treat problems with balance or walking.
    2. #0101: Falls: Screening for Fall Risk [Ambulatory Care (office/clinic)]: Percentage of patients aged 65 years and older who were screened for fall risk (2 or more falls in the past year or any fall with injury in the past year) at least once within 12 months.
    3. #0537: Multifactor Fall Risk Assessment Conducted in Patients 65 and Older [Home Health]: Percent of home health episodes in which the patient was 65 or older and was assessed for risk of falls (using a standardized and validated multifactor Fall Risk Assessment) at start or resumption of home health care.
- **Structure Measures** include the presence of an organizational falls prevention policy and measurable structures in place to ensure accountability for performance.
- **Patient-Centered Measures** include evidence that patients' values and preferences are respected.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural healthcare settings with critical care facilities.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to pediatric or acute care healthcare settings with pediatric critical care settings.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty healthcare settings with critical care settings.

New Horizons and Areas for Research

The impact of architectural and interior design improvements (e.g., soft flooring) and injury prevention devices, such as hip protectors, should be explored.

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards.

Notes

Agostini, 2001: Agostini JV, Baker DI, Bogardus ST. Prevention of falls in hospitalized and institutionalized older people. IN: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ): 2001 Jul: Ch. 26. Available at http://www.ahrq.gov/clinic/ptsafety/chap26a.htm. Last accessed October 28, 2009.

AHRQ, 2009a: [No authors listed.] National Healthcare Disparities Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhdr08/nhdr08.pdf. Last accessed October 30, 2009.

AHRQ, 2009b: [No authors listed.] National Healthcare Quality Report 2008. Agency for Healthcare Research and Quality (AHRQ). 2009 Mar. Available at http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf. Last accessed October 30, 2009.

Batchelor, 2009: Batchelor FA, Hill KD, Mackintosh SF, et al. The FLASSH study: protocol for a randomised controlled trial evaluating falls prevention after stroke and two sub-studies. BMC Neurol 2009 Mar 31;9:14. Available at http://www.biomedcentral.com/content/pdf/1471-2377-9-14.pdf. Last accessed September 23, 2009.

CDC, 2006: Centers for Disease Control and Prevention. National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS). Available at http://www.cdc.gov/ncipc/wisqars/. Last accessed September 25, 2009.

CMS, 2007: [No authors listed.] CMS Manual System: Pub. 100-07 State Operations: Provider Certification: Transmittal 27. Revisions to Appendix PP: Guidance to Surveyors for Long Term Care Facilities. Baltimore (MD): Centers for Medicare & Medicaid Services; 2007 Aug 17. Available at http://www.cms.hhs.gov/transmittals/downloads/R27SOMA.pdf. Last accessed October 28, 2009.

CMS/HAC, 2009: CMS. Hospital-Acquired Conditions (Present on Admission Indicator) Overview. Baltimore (MD): Centers for Medicare & Medicaid Services; 2009. Available at http://www.cms.hhs.gov/hospitalacqcond/. Last accessed October 30, 2009.

Dacenko-Grawe, 2008: Dacenko-Grawe L, Holm K. Evidence-based practice: a falls prevention program that continues to work. Medsurg Nurs 2008 Aug;17(4):223-7, 235; quiz 228.

Dempsey, 2009: Dempsey J. Nurses values, attitudes and behaviour related to falls prevention. J Clin Nurs 2009 Mar;18(6):838-48.

Dykes, 2009: Dykes PC, Carroll DL, Hurley AC, et al. Why do patients in acute care hospitals fall? Can falls be prevented? J Nurs Adm 2009 Jun;39(6):299-304.

Englander, 1996: Englander F, Hodson TJ, Terregrossa RA. Economic dimensions of slip and fall injuries. J Forensic Sci 1996 Sep;41(5):733-46.

Feder, 2000: Feder G, Cryer C, Donovan S, et al. Guidelines for the prevention of falls in people over 65. The Guidelines' Development Group. BMJ 2000 Oct 21;321(7267):1007-11.

Gillespie, 2003: Gillespie LD, Gillespie WJ, Robertson MC, et al. Interventions for preventing falls in elderly people. Cochrane Database Syst Rev 2003;(4):CD000340.

Greenspan, 1994: Greenspan SL, Myers ER, Maitland MA, et al. Fall severity and bone mineral density as risk factors for hip fracture in ambulatory elderly. JAMA 1994 Jan 12;271(2):128-33.

HCANJ, 2007: Health Care Association of New Jersey (HCANJ). Fall management guideline. Hamilton (NJ): Health Care Association of New Jersey (HCANJ); 2007 Mar. Available at http://www.guideline.gov/summary/summary.aspx?view_id=1&doc_id=13484. Last accessed October 28, 2009.

HCM, 2000: [No authors listed.] Prevention program cut patient falls by 10%. Hosp Case Manag 2000 Mar;8(3):38, 43-4.

Healey, 2004: Healey F, Monro A, Cockram A, et al. Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial. Age Ageing 2004 Jul;33(4):390-5. Epub 2004 May 19.

Healey, 2007: Healey F, Scobie S. National Health Service. National Patient Safety Agency. The third report from the Patient Safety Observatory: Slips, trips and falls in hospital. 2007. Available at http://www.npsa.nhs.uk/nrls/alerts-and-directives/directives-guidance/slips-trips-falls/. Last accessed September 25, 2009.

Healey, 2008: Healey F, Oliver D, Milne A, et al. The effect of bedrails on falls and injury: a systematic review of clinical studies. Age Ageing 2008 Jul;37(4):368-78. Epub 2008 May 20. Available at http://ageing.oxfordjournals.org.ezp-prod1.hul.harvard.edu/cgi/reprint/37/4/368. Last accessed September 4, 2009.

Heinze, 2009: Heinze C, Dassen T, Halfens R, et al. Screening the risk of falls: a general or a specific instrument? J Clin Nurs 2009 Feb;18(3):350-6. Epub 2008 Aug 13.

Hendrich, 1995: Hendrich A, Nyhuis A, Kippenbrock T, et al. Hospital falls: development of a predictive model for clinical practice. Appl Nurs Res 1995 Aug;8(3):129-39.

Hill, 2009a: Hill AM, Hill K, Brauer S, et al. Evaluation of the effect of patient education on rates of falls in older hospital patients: description of a randomised controlled trial. BMC Geriatr 2009 Apr 24;9:14. Available at http://www.biomedcentral.com.ezp-prod1.hul.harvard.edu/content/pdf/1471-2318-9-14.pdf. Last accessed September 4, 2009.

Hill, 2009b: Hill AM, McPhail S, Hoffmann T, et al. A randomized trial comparing digital video disc with written delivery of falls prevention education for older patients in hospital. J Am Geriatr Soc 2009 Aug;57(8):1458-63. Epub 2009 Jun 8.

Hitcho, 2004: Hitcho E, Krauss MJ, Birge S, et al. Characteristics and circumstances of falls in a hospital setting: a prospective analysis. J Gen Intern Med 2004 Jul;19(7):732-9.

IHI, 2009: [No authors listed.] Falls Prevention. IHI Improvement Map. Cambridge (MA): Institute for Healthcare Improvement (IHI); 2009. Available at http://www.ihi.org/imap/tool/#Process=3c061d92-9c22-42bb-af04-26ae02ed191c. Last accessed October 28, 2009.

Inouye, 2009: Inouye SK, Brown CJ, Tinetti ME. Medicare nonpayment, hospital falls, and unintended consequences. N Engl J Med 2009 Jun 4;360(23):2390-3.

JAGS, 2001: [No authors listed.] Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. J Am Geriatr Soc 2001 May;49(5):664-72.

JCR, 2010: Joint Commission Resources (JCR). 2010 Comprehensive Accreditation Manual: CAMLTC for Long Term Care. National Patient Safety Goal NPSG.09.02.01. Oak Brook (IL): Joint Commission Resources; 2010.

Johal, 2009: Johal KS, Boulton C, Moran CG. Hip fractures after falls in hospital: a retrospective observational cohort study. Injury 2009 Feb;40(2):201-4. Epub 2008 Dec 18.

Levinson, 2008a: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf. Last accessed September 23, 2009.

Levinson, 2008b: Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: state reporting systems. 2008 Dec. OEI-06-07-00471. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Last accessed September 25, 2009

McClure, 2005: McClure R, Turner C, Peel N, et al. Population-based interventions for the prevention of fall-related injuries in older people. Cochrane Database Syst Rev. 2005 Jan 25;(1):CD004441.

Morse, 1996: Morse JM. Preventing Patient Falls. Thousand Oaks (CA): Sage Publications, Inc.; 1996.

NCCNSC, 2004: National Collaborating Centre for Nursing and Supportive Care. Clinical practice guideline for the assessment and prevention of falls in older people. London (UK): National Institute for Clinical Excellence (NICE); 2004. Available at http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=6118&nbr=3968. Last accessed October 28, 2009.

NICE, 2004: [No authors listed.] Falls: The assessment and prevention of falls in older people. London (UK): National Institute for Health and Clinical Excellence (NICE)/National Health Service (NHS); 2004 Nov. Available at http://www.nice.org.uk/CG21. Last accessed October 28, 2009.

NQF, 2007: National Quality Forum. Serious Reportable Events in Healthcare: 2006 Update. Washington, DC: National Quality Forum (NQF); 2007. Available at http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx. Last accessed October 28, 2009.

Nyman, 2009: Nyman SR, Yardley L. Usability and acceptability of a website that provides tailored advice on falls prevention activities for older people. Health Informatics J 2009 Mar;15(1):27-39.

Oliver, 2000: Oliver D, Hopper A, Seed P. Do hospital fall prevention programs work? A systematic review. J Am Geriatr Soc 2000 Dec;48(12):1679-89.

Oliver, 2007: Oliver D, Connelly JB, Victor CR, et al. Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. BMJ 2007 Jan 13;334(7584):82. Epub 2006 Dec 8.

Oliver, 2008: Oliver D, Killick S, Even T, et al. Do falls and falls-injuries in hospital indicate negligent care – and how big is the risk? A retrospective analysis of the NHS Litigation Authority Database of clinical negligence claims, resulting from falls in hospitals in England 1995 to 2006. Qual Saf Health Care 2008 Dec;17(6):431-6.

Rizzo, 1998: Rizzo JA, Friedkin R, Williams CS, et al. Health care utilization and costs in a Medicare population by fall status. Med Care 1998 Aug;36(8):1174-88.

Rubenstein, 1994: Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. Ann Intern Med 1994 Sep 15;121(6):442-51.

Ryu, 2009: Ryu YM, Roche JP, Brunton M. Patient and family education for fall prevention: involving patients and families in a fall prevention program on a neuroscience unit. J Nurs Care Qual 2009 Jul-Sep;24(3):243-9.

Sherrington, 2008: Sherrington C, Whitney JC, Lord SR, et al. Effective exercise for the prevention of falls: a systematic review and meta-analysis. J Am Geriatr Soc 2008 Dec;56(12):2234-43. Review.

Spice, 2009: Spice CL, Morotti W, George S, et al. The Winchester falls project: a randomised controlled trial of secondary prevention of falls in older people. Age Ageing 2009 Jan;38(1):33-40. Epub 2008 Oct 1. Available at http://ageing.oxfordjournals.org/cgi/reprint/38/1/33. Last accessed September 23, 2009.

Stevens, 2006: Stevens JA, Corso PS, Finkelstein EA, et al. The costs of fatal and non-fatal falls among older adults. Inj Prev 2006 Oct;12(5):290-5. Available at http://injuryprevention.bmj.com/cgi/content/full/12/5/290. Last accessed September 25, 2009.

TJC, 2009: The Joint Commission. Sentinel Event Statistics – Updated through September 30, 2009. Available at http://www.jointcommission.org/SentinelEvents/Statistics/. Last accessed October 28, 2009.

USDVA, 2004: [No authors listed.] U.S. Department of Veterans Affairs. National Center for Patient Safety. National Center for Patient Safety 2004 Falls Toolkit. Ann Arbor (MI): Department of Veterans Affairs, National Center for Patient Safety; 2004 Available at http://www.va.gov/ncps/SafetyTopics/fallstoolkit/index.html. Last accessed October 28, 2009.

Vind, 2009: Vind AB, Andersen HE, Pedersen KD, et al. An outpatient multifactorial falls prevention intervention does not reduce falls in high-risk elderly Danes. J Am Geriatr Soc 2009 Jun;57(6):971-7.

Wilson, 1998: Wilson EB. Preventing patient falls. AACN Clin Issues 1998 Feb;9(1):100-8.

SAFE PRACTICE 34: PEDIATRIC IMAGING

The Objective

Ensure that an appropriate radiation dose is delivered to pediatric patients during computed tomography (CT) studies.

The Problem

The frequency of pediatric CT has rapidly increased. In March 2009, the National Council on Radiation Protection and Measurements (NCRP) reported that there is a 6-fold increase in the amount of medical radiation exposure to the U.S. population since the early 1980s. This medical radiation now accounts for 48 percent of the total radiation exposure and 25 percent of the total yearly exposure; and 50 percent of the exposure from medical imaging is from CT. [NCRP, N.D.] There are more than 60 million CT scans performed annually in the United States; 11 percent (7 million) of those are on children. [Brody, 2007] The use of CT in the past 10 years has increased nearly 700 percent. [NCI, 2008] Furthermore, growth in the use of CT scans on children is estimated to be 10 percent per year. [Frush, 2004a] The amount of ionizing radiation generated to patients imaged by CT depends on protocols and equipment settings used for individual examinations. Current settings often default to adult parameters. A change in CT exam parameters for children could reduce the dose delivered to them from 5 percent to 90 percent, while retaining diagnostic accuracy. [Brody, 2007] Several consensus statements suggest that the low-level radiation used in diagnostic imaging may pose a risk, albeit small, of causing cancer. [Brody, 2007]

The severity of adverse events that can be sustained by patients exposed to ionizing radiation is greater for children than it is for adults. Children are particularly susceptible (2-5x) to the harmful effects of ionizing radiation for three reasons: 1) growing tissues and organs are more sensitive to radiation effects; 2) children have a longer lifetime during which radiation-related cancers may manifest; and 3) children receive a higher dose than necessary when adult CT settings are used. [Brody, 2007] The dose from each CT scan is cumulative over a lifetime; multiple scans may result in greater lifetime risk of fatal cancer for an individual. Children may receive a higher dose than necessary when adult CT settings are used for children. [Brody, 2007; NCI, 2008] The radiation from a single abdominal CT can be 100 to 250 times that of a plain chest radiograph (average effective estimated dose for abdomen CT is 5 mSv). [Brody, 2007] The effective dose from a single pediatric CT scan may range from 5 mSv to 60 mSv. [NCI, 2008]. The natural background radiation effective dose is approximately 3 mSv/year. Furthermore, the evidence suggests that there is a lack of provider awareness about dose exposure and associated risks, [Frush, 2004a] with 75 percent of physicians surveyed underestimating the equivalent number of chest radiographs for a CT examination. [Lee, 2004; Frush, 2008; Huda, 2009; Linet, 2009]

The preventability of adverse events to children is directly related to the technique and procedural protocols used during the generation of the CT image. CT is a valuable diagnostic tool that may be the only study that can provide specific answers to a patient's medical problem. CT studies should only be used when it is the best study for the clinical situation, as determined by the referring physician and radiologist. [Brody, 2007] Application of the concept of ALARA (as low

as reasonably achievable) can reduce radiation exposure. [ALARA, 2002] Dose-reduction techniques, such as automated exposure controls, have been shown to reduce radiation dose by 20 percent to 40 percent. [Frush, 2004b] A wide range of techniques with variable radiation exposure can be used in CT scans to produce very similar image quality. [Karmazyn, 2009] Recent survey data indicate that CTsettings (tube current–mA–and peak kilovoltage– kVp) used by pediatric radiologists are significantly lower than was indicated by data obtained in 2001, implying that guidelines and education have had a substantial impact. [Arch, 2008] Without appropriate guidelines, errors in CT scanning in children (including unnecessary radiation exposure) can be frequent. [Frush, 2002b; Goske, 2008]

There are no additional costs incurred to implement practices of "child-sizing" a pediatric CT scan (using a lower kVp and mA): The cost of the exam is the same. Child-size CT protocols can be easily implemented at little to no additional cost by radiologists, technologists, and medical physicists through routine maintenance of equipment. In addition, with adherence to the principle of avoiding unnecessary CT exams, decreased utilization would positively affect rising healthcare costs. [Cohen, 2009]

Safe Practice Statement

When CT imaging studies are undertaken on children, "child-size" techniques should be used to reduce unnecessary exposure to ionizing radiation.

Additional Specifications

Organizations should establish a systematic approach to regularly updating protocols for computed tomography (CT) imaging of children. Four simple steps should be undertaken by imaging team members to improve patient care in the everyday practice of radiology: [Goske, 2008]

- Scan only when necessary. This provides an opportunity to discuss the benefits of the CT exam as well as the potential risks with the child's pediatrician or other healthcare provider, who has unique medical knowledge critical to the care of the patient. Commit to making a change in daily practice by working as a team with technologists, medical physicists, referring doctors, and parents to decrease the radiation dose.
- Reduce or "child-size" the amount of radiation used. This can be accomplished by contacting a medical physicist to determine the baseline radiation dose for an adult for CT equipment and comparing that dose with the maximum recommended by the American College of Radiology's (ACR's) CT Accreditation Program. If the doses are higher than those suggested, reduce the technique for adult patients. Use evidence-based protocols for children. Refer to the Image Gently™ website (www.imagegently.org), and view the protocols provided for children. [Strauss, 2009] These protocols are independent of equipment manufacturer, age of machine, or number of detectors. Although an institution or site may wish to lower scan technique even more, these protocols provide a starting point for making this important change. Work with radiologic technologists to implement the protocols. These professionals control the critical "last step" before a scan is obtained. [Singh, 2009]
- Scan only the indicated area required to obtain the necessary information. Protocols in children should be individualized. Be involved with patients. Ask the questions

required to ensure that the scan is "child-sized." Decisions about shielding those radiosensitive areas (such as reproductive organs) outside of the scan range or those within the scan field (in-plane shielding) should be based on discussion with a qualified physicist and should incorporate local and national standards of practice.

- Scan once; single-phase scans are usually adequate in children. Pre- and postcontrast and delayed CT scans rarely add additional information in children, yet can double or triple the radiation dose to the child. Consider removing multiphase protocols from routine practice.

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, inpatient service/hospital, and outpatient hospital.

Example Implementation Approaches

- Considerable work has been published in the literature on protocols to reduce the dose to children undergoing CT examinations. Many of these protocols are scanner specific and are not transferable to other CT units. The Image Gently™ website provides a simple, step-by-step procedure to assist imaging facilities and providers in either developing CT protocols for children or verifying that their current protocols are appropriate.
- An interpreting radiologist, in consultation with a medical physicist, must evaluate any changes to a practice's techniques that reduce radiation dose so that the adequate diagnostic information is available. [Cohen, 2009] The radiologist should verify that CT technical factors do not deliver estimated radiation doses larger than those recommended by the American College of Radiologist's (ACR's) CT Accreditation Program. No universal CT technique can be used with all vendors CT equipment for the adult patient. Differences in CT scanner design make it impossible to estimate patient radiation dose based on technique factors alone. Thus, a qualified medical physicist (i.e., one who is board certified in diagnostic radiological physics) should measure the radiation output from CT scanners in order to estimate the dose and help establish appropriate techniques. Any qualified medical physicist who has assisted facilities in obtaining ACR accreditation of their CT scanners should be familiar with this test protocol.
- The supervising radiologist should work with CT technologists to familiarize them with techniques used for both adults and children.

Strategies of Progressive Organizations

- National public and private quality and research organizations are encouraging all stakeholders to recognize that pediatric CT dose-reduction strategies should be considered, efforts should work towards optimal utilization, and existing devices not specifically designed with children in mind should meet pediatric-specific safety considerations. Radiology professional associations are advocating that the CT dose-reduction strategies embodied in this practice be considered as a template for performance improvement programs for both adult and pediatric radiology. [Denham, 2005; Kuettner, 2009]

Opportunities for Patient and Family Involvement

- Consider including families of patients with children who have received a pediatric imaging event to serve on appropriate patient safety or performance improvement committees.
- Educate family members about pediatric imaging risks and benefits. [Bulas, 2009]
- Empower family members to request the results of imaging studies within an appropriate time frame.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts and may not necessarily address all external reporting needs.

- **Outcome Measures:** The carcinogenic effects of ionizing radiation manifest many years after exposure; however, outcome measures might include increased rates of cancer and other radiation-related conditions in children who frequently undergo imaging evaluation (e.g., children with cystic fibrosis, oncology, central nervous system abnormalities such as shunt malfunction, primary or acquired immune disorders). Ample sources indicate the potential risk of carcinogenesis and low-level (such as CT) radiation, including the BEIR VII report and the UNSCEAR report. [Linet, 2009] Through available healthcare practice assessment organizations (e.g., Arlington Medical Resources), the number of pediatric CT scans performed annually can be tracked to assess for change in practice patterns. [UNSCEAR, 2000]
- **Process Measures:** Compliance with use of child-sized CT protocols and frequency of updates might be used as process measures. This can be assessed through a CT accreditation process and periodic surveys of CT practices.
- **Structure Measures:** The existence of formal structures ensures that pediatric CT protocols are updated on a regular basis as evidenced by documentation. The ACR has an established program for CT accreditation, and the Image Gently Campaign website can be used for documentation through data gathering, such as annual surveys for adherence to pediatric CT protocols and data tracking of the campaign website "hits" when updates in CT protocols are made available.
- **Patient-Centered Measures:** Patient families might be polled about their comfort related to the efforts a healthcare organization takes to ensure that the CT scanning process is as safe for their children as possible. Moreover, as progress is made in proposals for tracking CT, or any radiation dose in patients, [Birnbaum, 2008] this type of record may promote informed discussions with families and may facilitate such surveys.

Settings of Care Considerations

- **Rural Healthcare Settings:** This practice applies in rural settings.
- **Children's Healthcare Settings:** This practice applies to children's healthcare settings.
- **Specialty Healthcare Settings:** Specialty healthcare settings are expected to implement this safe practice.

New Horizons and Areas for Research

New horizons include cooperative efforts in technology assessment and development directed at dose reduction and the preservation of image quality, including automatic exposure control, and newer investigations such as iterative reconstruction, improving image quality for a given dose (under development), and making improvements in current technology, consisting of improved estimates for pediatric CT dose (CTDI) and dose displays. [Strauss, 2009] This is also ongoing and requires efforts through the scientific community, manufacturers, and regulatory agencies. In addition, simulation CT is a potentially powerful new tool for assessing radiation dose reduction and image quality without unethical investigational exposure of children to additional radiation. [Frush, 2002b; Frush, 2002a; Li, 2008] Results for this research have direct clinical applications. [Paulson, 2008] Evidence-based pediatric CT should be cultivated, and periodic surveys of utilization and techniques will be helpful in assessing the impact of safe practices. [Broder, 2007; Arch, 2008] Tracking CT dose of the cumulative imaging radiation exposure as part of the evolving electronic healthcare record should also be pursued.

Other Relevant Safe Practices

Refer to Safe Practice 4: Identification and Mitigation of Risks and Hazards and Safe Practice 30: Contrast Media-Induced Renal Failure Prevention.

Notes

ALARA, 2002: [No authors listed] The ALARA (as low as reasonably achievable) concept in pediatric CT intelligent dose reduction. Multidisciplinary conference organized by the Society of Pediatric Radiology. August 18-19, 2001. Pediatr Radiol 2002 Apr;32(4):217-313. Epub 2002 Mar 6.

Arch, 2008: Arch ME, Frush DP. Pediatric body MDCT: a 5-year follow-up survey of scanning parameters used by pediatric radiologists. AJR Am J Roentgenol 2008 Aug;191(2):611-7.

Birnbaum, 2008: Birnbaum S. Radiation safety in the era of helical CT: a patient-based protection program currently in place in two community hospitals in New Hampshire. J Am Coll Radiol 2008 Jun;5(6): 714-718.e5.

Broder, 2007: Broder J, Fordham LA, Warshauer DM. Increasing utilization of computed tomography in the pediatric emergency department, 2000-2006. Emerg Radiol 2007 Sep;14(4): 227-32. Epub 2007 May 16.

Brody, 2007: Brody AS, Frush DP, Huda W, et al. Radiation risk to children from computed tomography. Pediatrics 2007 Sep; 120(3):677-82.

Bulas, 2009: Bulas DI, Goske MJ, Applegate KE, et al. Image Gently: why we should talk to parents about CT in children. AJR Am J Roentgenol 2009 May;192(5):1176-8.

Cohen, 2009: Cohen MD. Pediatric CT radiation dose: how low can you go? AJR Am J Roentgenol 2009 May;192(5):1292-303.

Denham, 2005: Denham CR. Radiology: can it be a performance impact center? J Patient Saf 2005 Jun;1(2):114-7.

Frush, 2002a: Frush DP, Slack CC, Hollingsworth CL, et al. Computer-simulated radiation dose reduction for abdominal multidetector CT of pediatric patients. AJR Am J Roentgenol 2002 Nov;179(5):1107-13. Available at http://www.ajronline.org/cgi/content/full/179/5/1107. Last accessed September 25, 2009.

Frush, 2002b: Frush DP, Soden B, Frush KS, et al. Improved pediatric multidetector body CT using a size-based color-coded format. AJR Am J Roentgenol 2002 Mar;178(3):721-6. Available at http://www.ajronline.org/cgi/content/full/178/3/721. Last accessed September 25, 2009.

Frush, 2004a: Frush DP, Applegate K. Computed tomography and radiation: understanding the issues. J Am Coll Radiol 2004 Feb;1(2):113–9.

Frush, 2004b: Frush DP. Review of radiation issues for computed tomography. Semin Ultrasound CT MR 2004 Feb;25(1):17-24.

Frush, 2008: Frush DP. Pediatric dose reduction in computed tomography. Health Phys 2008 Nov;95(5):518-27.

Goske, 2008: Goske MJ, Applegate KE, Boylan J, et al. Image Gently(SM): a national education and communication campaign in radiology using the science of social marketing. J Am Coll Radiol 2008 Dec;5(12):1200-5.

Huda, 2009: Huda W. What ER radiologists need to know about radiation risks. Emerg Radiol 2009 Sep;16(5):335-41. Epub 2009 Feb 27.

Karmazyn, 2009: Karmazyn B, Frush DP, Applegate KE, et al. CT with a computer-simulated dose reduction technique for detection of pediatric nephroureterolithiasis: comparison of standard and reduced radiation doses. AJR Am J Roentgenol 2009 Jan;192(1):143-9.

Kuettner, 2009: Kuettner A, Gehann B, Spolnik J, et al. Strategies for dose-optimized imaging in pediatric cardiac dual source CT. RöFo 2009 Apr;181(4):339-48. Epub 2009 Mar 16.

Lee, 2004: Lee CI, Haims AH, Monico EP, et al. Diagnostic CT scans: assessment of patient, physician, and radiologist awareness of radiation dose and possible risks. Radiology 2004 May;231(2):393-8. Epub 2004 Mar 18.

Li, 2008: Li X, Samei E, Delong DM, et al.Three-dimensional simulation of lung nodules for paediatric multidetector array CT. Br J Radiol 2009 May;82(977):401-11. Epub 2009 Jan 19.

Linet, 2009: Linet MS, Kim KP, Rajaraman P. Children's exposure to diagnostic medical radiation and cancer risk: epidemiologic and dosimetric considerations. Pediatr Radiol 2009 Feb;39 Suppl 1:S4-26. Epub 2008 Dec 16.

NCI, 2008: National Cancer Institute. Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers. Bethesda, MD: National Cancer Institute, 2002. Available at http://www.cancer.gov/cancertopics/causes/radiation-risks-pediatric-CT. Last accessed September 23, 2009.

NCRP, N.D.: [No authors listed.] NCRP. Informing the public about radiation exposure and protection. Bethesda (MD): National Council on Radiation Protection & Measurements (NCRP); No Date. Available at http://www.ncrponline.org/. Last accessed October 28, 2009.

Paulson, 2008: Paulson EK, Weaver C, Ho LM, et al. Conventional and reduced radiation dose of 16-MDCT for detection of nephrolithiasis and ureterolithiasis. Am J Roentgenol 2008 Jan;190(1):151-7.

Singh, 2009: Singh S, Kalra MK, Moore MA, et al. Dose reduction and compliance with pediatric CT protocols adapted to patient size, clinical indication, and number of prior studies. Radiology 2009 Jul;252(1):200-8. Epub 2009 May 12.

Strauss, 2009: Strauss KJ, Goske MJ, Frush DP, et al. Image Gently Vendor Summit: working together for better estimates of pediatric radiation dose from CT. AJR Am J Roentgenol 2009 May;192(5):1169-75.

UNSCEAR, 2000: United Nations Scientific Committee on the Effects of Atomic Radiation UNSCEAR 2000 Report to the General Assembly, with scientific annexes. Sources and Effects of Ionizing Radiation. Report to the General Assembly. Volume II: Effects. Available at http://www.unscear.org/unscear/en/publications/2000_2.html. Last accessed September 23, 2009.

Chapter 9: Opportunities for Patient and Family Involvement

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Introduction

OUR HEALTHCARE SYSTEM IS NOT A SYSTEM. It is a mosaic of cottage businesses that has organically developed through great procedural innovation and a microtransaction financial reward model leading to production-centered care. This has led to islands of greatness in a sea of complexity. Fragmented and unreliable integration along a patient's trajectory is only too common. Production-centered care unfortunately does not take the individuality of the patient into consideration at all and is truly unsafe–there is indeed a "quality chasm." The Institute of Medicine (IOM) has articulated, in its landmark report, *Crossing the Quality Chasm: A New Health System for the 21st Century,* the following principle critical to closing this gap: The healthcare system must be redesigned to be evidence based, patient centered, and systems-performance focused. [IOM, 2001] The purpose of this chapter is to address the practical implementation of patient-centered care in the National Quality Forum (NQF) safe practices.

From Production-Centered Care to Patient-Centered Care and Beyond

IOM defined the essential dimensions of patient-centered care to include, but not be limited to, customized information, communication, and education; coordination and integration of care across conditions and settings, and over time; shared decisionmaking of clinicians with patients and families; self-efficacy and self-management skills for patients; patient's experience of care; effective provider-patient partnership; and enhanced cultural competence of healthcare providers. [Hurtado, 2000; AHRQ, 2005] The first stage of any healthcare organization should be to improve the reliability of its care to achieve the IOM goals, which are to make care safe, effective, efficient, patient centered, timely, and equitable. Patient advocate experts and great leaders believe that, once this is achieved, the whole person can be addressed through integrative care by adding selected complementary care methods that are evidence based. [Schultz, 2009] There is strong evidence that integrative care can heal and improve basic conventional care by addressing the mind, body, and spirit connection. [Denham, 2006] Patient advocates do not believe that there are shortcuts to improved quality without making care safe first.

The research is beginning to show that there is a direct correlation of quality and patient satisfaction, leading to the belief that characteristics of hospitals that are more reliable in delivering clinical quality are intrinsically more likely to deliver a better patient experience. This should be no surprise, because customer satisfaction is almost always coupled to higher quality of service provided in other industries, such as airlines and consumer goods. [Jha, 2008]

Safe Practices for Better Healthcare 2010 Update: Involvement of Patients and Families

The gravitational pull of transparency, energized by pay for performance, is pulling back the sea of complexity to reveal substantial patient safety gaps, especially in hospitals. Not the

least of these is the lack of inclusion of patients and families as fully vested members of care teams. National stakeholders, convened as the National Priorities Partnership by NQF, have identified key areas such as 1) patient and family engagement to ensure that patients and their families have access to tools and support in order to be fully informed about and play a key role in making healthcare decisions; 2) improved population health; 3) increased patient safety by eradicating preventable medical errors; 4) well-coordinated patient-centered care; 5) increased access to hospice and palliative care services for patients who are diagnosed with severe illnesses and those facing the end of their lives; and 6) elimination of overuse of unnecessary or risky care, and bringing greater focus to efficient, appropriate, preventive care. Clearly, patients and families have a critical role to play in these areas. [NPP, N.D.; Denham, 2009]

Each safe practice in this updated NQF consensus report includes a section titled "Opportunities for Patient and Family Involvement." [Johnson, 2008; DFCI, 2009; Jack, 2009; TJC, 2009a; TJC, 2009b] This section provides specific information about how to involve patients and families in the implementation of each safe practice. A consensus process was undertaken with input from many patient advocates who have become published patient safety experts, and from numerous technical subject matter experts who contributed to the development of the clinical and administrative aspects of the practices. Finally, the members of the NQF Safe Practices Consensus Committee also contributed to the 2009 and 2010 updates to the practices.

Safe Practices Chapters and Patient Advocate Contributions

The following sections are organized according to the functional chapters of the NQF safe practices report. Selected contributions from patient advocate experts have been provided as examples of the themes that are believed to be important for all of the practices. Specific recommendations are embodied formally in each practice.

Improving Patient Safety by Creating and Sustaining a Culture of Safety Chapter (Safe Practices 1-4)

Safe Practice 1: Leadership Structures and Systems

Everyone, including patient advocates and patient safety experts, is realizing that leadership is the critical ingredient to safe healthcare. In the words of Dr. David Hunt, a former leader at the Centers for Medicare & Medicaid Services, and now a Chief Medical Officer with the U.S. Department of Health and Human Services, "most important to safety practice adoption are leadership, resources, and systems." Engaged leadership applies financial and talent resources through systematic processes and accountability. Put simply, and quoting Dr. Don Berwick, leader of the Institute for Healthcare Improvement, "Some is not a number, soon is not a time." This is the kind of accountability we need. [Denham, 2005] The most important aspect of such systems is communication.

Safe, high-quality healthcare is neither accidental nor static. Rather, it is the result of deliberate actions by dedicated people—continuous actions, including active listening, planning, implementation, and evaluation by organizational leaders and providers of care within their healthcare enterprise. Active listening by leaders and providers, to each other and to patients and families, is a dynamic communication process that is key to the accurate assessment, diagnosis, and treatment of patients and that is key to a culture of safety that fosters the prevention of medical errors. Listening and responding to the acute and emerging concerns and complaints of patients and families, 24/7, from admission to discharge, throughout the continuum of care, as well as following a harmful error, are indispensable components—the sixth vital sign—of safe, responsible, and ethical healthcare practice. [Patti O'Regan. Written communication. December 13, 2008] Such an approach must be fostered by leadership structures and systems. We must recognize that there is much potential that can be realized by Patient and Family Advisory Committees; however, these partnerships should not be limited by considering them as merely content review groups. They can be much more. Further, their success revolves around them having a clear mission and vision with expectations for and of members so that they may be sustained. [Farris Timimi, MD, Cardiovascular Diseases, Mayo Clinic Rochester. Written Communication. November 23, 2009]

This practice applies to all leaders across administrative, medical, and frontline personnel; however, it must be owned by the governance team that is the conscience of the organization and the CEO who serves it.

Safe Practice 2: Culture Measurement, Feedback, and Intervention

Culture is the collective behaviors of an organization, or what some have described as "what people do when no one is looking." It reflects the operational values of the organization, which may not necessarily be those espoused in brochures or on the walls of the lobby. The patient experience has been a long-ignored issue in some organizations and of lower priority in others, and, at least until recently, it has been coupled to payment. Patient expert advocates state that it is important that caregivers ask for the patient's and family's feedback on care and level of satisfaction concerning their sense of being listened to, included on the team, and communicated with, in a full, open, and honest way. It is also important for leadership to answer the questions: "What does an effective listening environment look like, and where are we measuring up to that vision?" [Mary Foley and Julie Thao. Written communication. December 13, 2008]

One patient safety expert, advocate, and patient, who has suffered from metastatic cancer and who has been a "frequent flyer" in many hospitals, states that what patients want is very simple: "Know me, love me, and make it simple." [Moose Millard, Oral Communication, August 1, 2006] "Know me" means that every effort needs to be made to have the information available about a patient when he or she touches our care. Fear and threat loom when we seem to fail to have what we need. "Love me" means showing simple compassion at the

frontline, which goes a long way to cover our shortfalls in performance. "Make it simple": In our current designs, we make the experience difficult for patients when we design everything around our production silos. This practice is about measuring the behaviors that reflect our values. We must involve patients and families in the design of the measures and the interventions we use to improve our culture.

Safe Practice 3: Teamwork Training and Skill Building

Often, we lose sight of the whole purpose of a team training program. It is important to have input on team training from patients in order to put the patient and family in the center of team improvement. In order to create and sustain a culture of safety, a facility must first recognize the value of teamwork in each patient's unique situation. In this culture, the goal must always focus on the patient, and keeping the patient safe from medical harm must be just as important as treating the illness or disease. Listening to patients, families, and advocates must not only be tolerated but welcomed and endorsed by all levels of management. [Jennifer Dingman. Written communication. December 13, 2008] Teamwork training, human factors, and interventions need to be refreshed constantly, with input from patients who have received care at the organization. It makes the training real and applicable to the participants. Clearly, governance team members must learn these lessons as well. They hold the direction of the organization in their grasp.

Safe Practice 4: Identification and Mitigation of Risks and Hazards

The integration of the silos of risk management and performance improvement may be one of the most difficult tasks an organization must undertake in order to be in compliance with the 2009 NQF safe practices. Patient safety experts and advocates recommend that patients and family members be 1) involved in planning for and establishing guidelines for mitigating patient safety risks and hazards; 2) forewarned about safety risks and hazards when entering the hospital; and 3) listened to when they observe risks and hazards while in the hospital. This should all be done in a practical and helpful manner. [Dan Ford. Written Communication. November 7, 2008] Great organizations, such as the Dana Farber Cancer Institute, have built patient and family input and accountability into almost every area of functionality. They have addressed this area with great impact and no increase in malpractice risk. [James Conway. Oral Communication. December 10, 2007] It is critical that leaders also look outside their own organizations and learn, not only from tragic events but also from near misses, how to develop rapid response teams to reduce the risks to children and adults in their care. Putting the systems in place to learn from other organizations is the responsibility of leaders. Not allowing patients to be harmed from clearly publicized risks is the direct responsibility of healthcare leaders. [Dennis Quaid. Written Communication. November 22, 2009]

Improving Patient Safety Through Informed Consent, Life-Sustaining Treatment, Disclosure, and Care of the Caregiver Chapter (Safe Practices 5-8)

Safe Practice 5: Informed Consent

Patients must be given by providers full details of all treatment, procedures, and medication side effects in easy-to-understand terms. Risks and benefits must always be discussed, with provider recommendations offered as suggestions, not demands. Patient and family wishes must always be respected, and everything humanly possible must be done by providers to honor the wishes of the patient and family. When errors do occur, honesty and efforts to find the root cause of the issue must be addressed and followed up in order for this culture to sustain. [Jennifer Dingman. Written communication. December 13, 2008] Some patients do not seek care because of fear. Healthcare providers can improve their patients' acceptance of their diseases through listening to their concerns and educating them about their choices. What may seem routine to caregivers can be overwhelming to patients. Listening, reassurance, and education are keys to a healthy patient. [Arlene Salamendra. Written Communication. October 1, 2009] The use of multimedia tools and techniques must be considered to optimize the recognition of health literacy gaps and to ensure consistent and reliable message delivery and assimilation.

Safe Practice 6: Life-Sustaining Treatment

Fully honest, complete, transparent, and early disclosure to the patient and the family that imparts the *clear* and *realistic* risks, benefits, expectations, and potential for improvement offered by all possible life-sustaining treatments is important, followed by a full assessment for complete understanding. [Mary Foley and Julie Thao. Written communication. December 13, 2008] As organizations treat an aging population, communication regarding life-sustaining treatments must be constantly improved. This is not possible without patient and family input.

Safe Practice 7: Disclosure

Nondisclosure of medical errors has been described in an article by Sue Sheridan and other patient safety advocate experts:

> It is so hard to articulate the profound sense of betrayal and abandonment that my family felt. I can only describe it as a hit-and-run health care accident. My family was abandoned at the side of the road, injured and traumatized by a well meaning motorist who fled because of legal and personal fears. We were left to seek out help on our own with our own resources. No one looked back. They pretended as if nothing had happened, including those eyewitnesses on the side of the road. A hit-and-run, in our world, is considered criminal. Why is it OK in medicine? The nondisclosure of medical error is the most destructive phenomenon in health care. Trust and confidence disappears in a heartbeat. [Sheridan, 2008]

This practice provides a rich opportunity for organizations to include patients and families, because so many organizations are still in the early stages of their journey to full disclosure.

Progressive organizations, such as the University of Illinois and the University of Michigan, provide role models that organizations can follow.

Safe Practice 8: Care of the Caregiver

An organized approach to caring for caregivers who are involved in an unintentional, catastrophic event provides a rich opportunity to move from harm to healing for all concerned. The focus must change from "Who is at fault? Whom should we blame?" to that of the patient and family, and what they deserve. Overwhelmingly, patients experiencing an event want the entire organization to learn from the event and to work together with them to ensure that the same thing will never happen again. [Julie Thao. Written Communication. November 10, 2008] Forgiveness is a healing medication for the disorders that afflict those involved in harming patients. Such healing can occur when we involve patients and families in the development of systems to address both patients and caregivers after catastrophic events. [Worthington, 2005; Denham, 2007; Denham, 2008]

Matching Healthcare Needs with Service Delivery Capability Chapter (Safe Practices 9-11)

Safe Practice 9: Nursing Workforce

Involving patients and families in improving nursing care is vital to performance improvement. For example, input from patients should be sought to help caregivers put systems in place to provide both the patient and family with an understanding of how nursing care is delivered in a particular unit, including what to expect from nursing care, each hour, each shift, and every day; who is in charge; and how to get help. Information on whom the patient or family should go to with a problem, concern, or complaint should also be provided. Caregivers must listen to patient and family feedback about the effects that short-staffed nursing shifts had on their care and incorporate that feedback into strategies for improvement and action plans. [Mary Foley and Julie Thao. Written communication. December 13, 2008]

Safe Practice 10: Direct Caregivers

Nurses are not the only caregivers who are vital to patient safety and the patient experience. Staff members, such as respiratory technologists, radiology personnel, and clinical pharmacy personnel, are subject to the same issues that nursing faces. Staffing matters must be addressed by management in order to sustain a culture of patient safety. Caregiver staffing levels must always be reasonable, allowing the caregivers to spend adequate time providing patient care, completing paperwork, and performing other duties. Cuts must never be made in this area, because of the critical need for safe inpatient care. Input from patients and families to committees that are examining risks pertaining to workforce issues is vital, as is input on patient education. [Jennifer Dingman. Written communication. December 13, 2008]

Safe Practice 11: Intensive Care Unit Care

Leadership in critical care is critical. Direct input from patients and families to leadership is vital to ensure high performance. It is important to have a clearly defined person in charge of intensive care. The patient and family should experience no confusion about who is managing care. The patient and family should know to whom they need to talk first about their plan of care. [Mary Foley and Julie Thao. Written communication. December 13, 2008] Patient and family input to the operation of intensive care units is vital to ensure patient safety.

Improving Patient Safety by Facilitating Information Transfer and Clear Communication Chapter (Safe Practices 12-16)

This chapter deals with specific internal hospital systems. It includes Safe Practice 12: Patient Care Information; Safe Practice 13: Order Read-Back and Abbreviations; Safe Practice 14: Labeling of Diagnostic Studies; Safe Practice 15: Discharge Systems; and Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry.

The two safe practices in this chapter that can be most enhanced by input from patients and families are Safe Practice 12: Patient Care Information and Safe Practice 15: Discharge Systems. They both address areas in which information circuits between caregivers, and between caregivers and patients, must be closed. Delayed diagnosis and treatment as well as communication breakdowns that can harm patients can be much improved by reengineering discharge programs to include procedures that include these practices. [Jack, 2009] Until all information regarding care is in digital form and patients and families are no longer required to be part of the information transfer process, we must work on our transmission of information to and through patients and families. One very real opportunity for improvement exists at the interface between acute care hospitals and nursing homes. Discharges to nursing homes, first-time admissions to hospital from nursing homes, and especially readmissions to hospital from nursing homes provide ample opportunity for coordination of information transfer that can greatly reduce suffering, harm, stress to families, and cost.

It is critical for caregivers to listen to patients and their families. They must anticipate breakdowns in information transfer. The patient's symptoms and expressed concerns should be acknowledged, documented, and directed appropriately as the patient navigates the complexities of the healthcare system. That information, along with the patient's diagnosis, needs to follow the patient through his or her follow-up care as well. Critical laboratory values and test results must be effectively communicated in a timely manner. Failing to do so puts us all at risk—the facility, the staff, and especially the patient. It is important to tighten the links in the chain. [Becky Martins. Written communication. December 13, 2008]

Improving Patient Safety Through Medication Management Chapter (Safe Practices 17-18)

This chapter includes Safe Practice 17: Medication Reconciliation and Safe Practice 18: Pharmacist Leadership Structures and Systems.

The medication delivery system and subset processes are much better understood than other areas of healthcare. We understand the source of adverse events and their impact on clinical, operational, and financial performance. The two safe practices in this chapter address the vital issues of communication and leadership.

In the case of medication reconciliation, the role of the patient is crucial. Patients often have a good understanding and knowledge of their own bodies and medications. If they do not, caregivers need to know about it. Regular and consistent patient and family input to processes of medication reconciliation is vital to full systems improvement. [Dan Ford. Written communication. December 13, 2008]

Good leadership of pharmacy services requires input from all stakeholders. Patients and families are crucial to reducing medication errors, not only through learning to properly use medications, but in providing suggestions to pharmacists and other caregivers regarding their role in the system. They have a vested interest in the process and can be attuned to detect even the slightest details that may be out of place or that do not seem right. Systems need to be put into place to ensure that providers are reminded to be sensitive and responsive to questions asked by patients and family members. Listening is crucial. [Dan Ford. Written Communication. November 7, 2008]

Improving Patient Safety Through Prevention of Healthcare-Associated Infections Chapter (Safe Practices 19-25)

This chapter includes Safe Practice 19: Hand Hygiene; Safe Practice 20: Influenza Prevention; Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention; Safe Practice 22: Surgical-Site Infection Prevention; Safe Practice 23: Care of the Ventilated Patient; Safe Practice 24: Multidrug-Resistant Organism Prevention; and Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention. These practices all involve healthcare-associated infections for which patient advocates have two main recommendations.

The first is that because the role of patients and visitors is critical to the prevention of healthcare-associated infections, the awareness of patients and visitors must be raised to ensure that they understand the seriousness of the processes that can affect healthcare-associated infections. For instance, high-contact surfaces that patients and families touch frequently, such as TV remote controls and pulse oximeters in hospitals, pose real risks and great new opportunities for low-cost interventions to reduce exposure to pathogens. [Dr. Robert Cima, MD, Colon and Rectal Surgery, Mayo

Clinic. Written communication. November 18, 2009] The caregiver organization should encourage partnership with patients and families to improve the reliability of those processes. [Becky Martins. Written communication, December 13, 2007] [Johnson, 2008]

The second is that education should be provided to the patient and the family to address their concerns. Hospital leadership should promote cleanliness, not only among staff, but also among visiting family, by actively engaging patients and family in education regarding infection control. This is accomplished by emphasizing the spirit of teamwork between the staff and family. Partnership among caregivers, patient, and family could be emphasized. Patients and families should be provided a place to go with their concerns about lack of hand hygiene or other infection-related issues. [Mary Foley and Julie Thao. Written communication. December 13, 2008]

Improving Patient Safety Through Condition- and Site-Specific Practices Chapter (Safe Practices 26-34)

This chapter includes of Safe Practice 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention; Safe Practice 27: Pressure Ulcer Prevention; Safe Practice 28: Venous Thromboembolism Prevention; Safe Practice 29: Anticoagulation Therapy; Safe Practice 30: Contrast Media-Induced Renal Failure Prevention; Safe Practice 31: Organ Donation; Safe Practice 32: Glycemic Control; Safe Practice 33: Falls Prevention; and Safe Practice 34: Pediatric Imaging.

The inclusion of patients and families on patient safety and performance improvement committees that address the areas targeted by these practices should be strongly recommended or required. The closer patients and families are to the planning for preventing adverse events, the more patients and family members will feel vested in this process. Patients and family members are not necessarily clinical experts, but they do have ideas to share, along with eyes and ears for observing. [Dan Ford. Written Communication. November 7, 2008]

In the case of organ donation, more education is needed regarding the importance of giving the gift of life to another human being. Patients and families sharing stories publicly will increase donor willingness. [Jennifer Dingman. Written Communication. November 12, 2008]

Anticoagulation issues and the prevention of deep vein thrombosis and pulmonary embolism are critical. The involvement of patients in the goals and processes of care is vital, because of the ongoing need for monitoring medications and risk factors. Patient and family input to systems design and implementation are critical. The same information is important for processes addressing glycemic control.

In the cases of imaging risks related to contrast agents and the exposure of children to ionizing radiation, patients and families need to understand critical issues. The risk of gadolinium is becoming better understood as time goes on, and patients need to be aware of this evolving information.

Conclusion: Leadership, Resources, and Systems

Leaders drive values, values drive behaviors, and behaviors drive performance. Patients and families believe that it is time for governance, administrative, and medical leaders to step up and make the change from playing defense of the status quo to playing offense against the faceless enemy of systems failures. The best leaders will engage patients and families as fully vested teammates.

Resources, especially dark green dollars of cash, are in short supply, yet the resources of patient and family help and time are almost limitless, are ready to be tapped, and can have a huge impact on improving the reliability and overall success of an organization.

"Every system is perfectly designed to deliver the results it gets," is an applicable, often-used quote by Dr. Don Berwick, which he attributes to Paul Bataldon. [Carr, 1997] Patient and family involvement starts with educating patients and families and ends with listening to them and taking them seriously. [Denham, 2008] If patient and family input is emphatically built into our systems of performance improvement, and if patients and families are taken seriously, as real experts, and are respected for their valuable perspectives regarding how we can improve care, we can improve at improving. We can begin to know patients and families better, love them better, and make it easier for them to transition through our healthcare organizations. [Moose Millard. Oral Communication. August 1, 2006]

Engaged *leaders* need to provide the *resources* necessary to ensure that the *systems* are in place to ensure that vital patient and family input are built into the practices we adopt. Leadership, resources, and systems–these three elements are critical to success.

Notes

AHRQ, 2005: Agency for Healthcare Research and Quality. Notice Number: NOT-HS-05-005. Special Emphasis Notice: Research Priorities for the Agency for Healthcare Research and Quality. November 30, 2004. Available at http://grants.nih.gov/grants/guide/notice-files/NOT-HS-05-005.html. Last accessed December 23, 2009.

Carr, 1997: Carr S. A Quotation With a Life of Its Own. Patient Safety & Quality Healthcare. Editor's Notebook. July/August 2008. Available at http://www.psqh.com/julaug08/editor.html. Last accessed December 23, 2009.

Denham, 2005: Denham CR, Bagian J, Daley J, et al. No excuses: the reality that demands action. J Patient Saf 2005 Sep;1(3):154-69.

Denham, 2006: Denham CR. From Harmony to Healing: join the Quality Choir. J Patient Saf 2006 Dec;2(4):225-32.

Denham, 2007: Denham CR. TRUST: the Five Rights of the Second Victim. J Patient Saf 2007 Jun;3(2):107-19.

Denham, 2008: Denham, CR, Dingman J, Foley ME, et al. A. Are you listening... are you really listening? J Patient Saf 2008 Sep;4(3):148-61.

Denham, 2009: Denham CR. The No Outcome No Income Tsunami is here. Are you a Surfer, Swimmer or Sinker? J Patient Saf 2009 Mar; 5(1):42-52.

Hurtado, 2000: Hurtado MP, Swift EK, Corrigan JM, eds. Committee on the National Quality Report on Health Care Delivery, Board on Health Care Services. Envisioning the National Health Care Quality Report. Institute of Medicine (IOM). Washington, DC: The National Academies Press; 2000.

IOM, 2001: Institute of Medicine (IOM). Committee on Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: The National Academies Press; 2001.

Jack, 2009: Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009 Feb 3;150(3):178-87.

Jha, 2008: Jha AK, Orav EJ, Zheng J, et al. Patients' perception of hospital care in the United States. NEJM 2008 Oct;339(18): 1921-31.

Johnson, 2008: Johnson B, Abraham M, Conway J, et al. Partnering with Patients and Families to Design a Patient- and Family-Centered Health Care System. Bethesda, MD: Institute for Family-Centered Care; 2008. Available at http://www.familycenteredcare.org/pdf/PartneringwithPatientsandFamilies.pdf. Last accessed December 23, 2009.

NPP, N.D.: National Priorities Partnership. Priorities: A Vision for World-Class, Affordable Healthcare. Available at http://www.nationalprioritiespartnership.org/Priorities.aspx. Last accessed January 12, 2010.

Schultz, 2009. Schultz AM, Chao SM, McGinnis M. Integrative Medicine and the Health of the Public: A Summary of the February 2009 Summit. Institute of Medicine of the National Academies. Washington, DC: The National Academies Press; 2009. Available at http://books.nap.edu/openbook.php?record_id=12668&page=R1. Last accessed December 23, 2009.

Sheridan, 2008: Sheridan S, King C, Conrad N, et al. Disclosure through our eyes. J Patient Saf 2008 Mar;4(1):1 8-26.

Worthington, 2005: Worthington EL Jr, van oyen Witvliet C, Lerner AJ, et al. Forgiveness in health research and medical practice. Explore (NY) 2005 May;1 (3):169-76.

Appendix A
Crosswalk of 2009 Updated Safe Practices with Harmonization Partner Initiatives

SAFE PRACTICES	AHRQ	CMS	IHI	LFG	NQF	TJC
Leadership Structures and Systems [SP 1]	●	●	●	●	●	●
Culture Measurement, Feedback, and Intervention [SP 2]	●	N/A	●	●	●	●
Teamwork Training and Skill Building [SP 3]	●	N/A	●	●	●	●
Identification and Mitigation of Risks and Hazards [SP 4]	●	●	●	●	●	●
Informed Consent [SP 5]	●	●	●	●	●	●
Life-Sustaining Treatment [SP 6]	●	●	●	●	●	●
Disclosure [SP 7]	●	N/A	●	N/A	●	●
Care of the Caregiver [SP 8]	N/A	N/A	N/A	N/A	N/A	N/A
Nursing Workforce [SP 9]	●	N/A	●	●	●	●
Direct Caregivers [SP 10]	N/A	N/A	●	N/A	●	N/A
Intensive Care Unit Care [SP 11]	●	N/A	●	N/A	●	●
Patient Care Information [SP 12]	●	N/A	●	●	●	●
Order Read-Back and Abbreviations [SP 13]	●	●	●	N/A	●	●
Labeling of Diagnostic Studies [SP 14]	●	N/A	●	●	●	●

more

AHRQ - Agency for Healthcare Research and Quality
CMS - Centers for Medicare & Medicaid Services
IHI - Institute for Healthcare Improvement
LFG - The Leapfrog Group
NQF - National Quality Forum
TJC - The Joint Commission

SAFE PRACTICES	AHRQ	CMS	IHI	LFG	NQF	TJC
Discharge Systems [SP 15]	●	●	●	●	●	●
Safe Adoption of Computerized Prescriber Order Entry [SP 16]	●	●	●	●	●	●
Medication Reconciliation [SP 17]	●	●	●	●	●	●
Pharmacist Leadership Structures and Systems [SP 18]	●	●	●	N/A	●	●
Hand Hygiene [SP 19]	●	●	●	●	●	●
Influenza Prevention [SP 20]	●	●	●	N/A	●	●
Central Line-Associated Bloodstream Infection Prevention [SP 21]	●	●	●	●	●	●
Surgical-Site Infection Prevention [SP 22]	●	●	●	N/A	●	●
Care of the Ventilated Patient [SP 23]	●	●	●	●	●	●
Multidrug-Resistant Organism Prevention [SP 24]	●	●	●	N/A	●	●
Catheter-Associated Urinary Tract Infection Prevention [SP 25]	●	●	●	●	●	●
Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention [SP 26]	●	●	●	N/A	●	●
Pressure Ulcer Prevention [SP 27]	●	●	●	N/A	●	●
Venous Thromboembolism Prevention [SP 28]	●	●	●	●	●	●
Anticoagulation Therapy [SP 29]	●	●	●	●	●	●
Contrast Media-Induced Renal Failure Prevention [SP 30]	●	N/A	N/A	N/A	●	N/A
Organ Donation [SP 31]	●	●	●	N/A	N/A	●
Glycemic Control [SP 32]	●	●	●	N/A	N/A	N/A
Falls Prevention [SP 33]	●	●	●	N/A	N/A	●
Pediatric Imaging [SP 34]	N/A	●	●	N/A	N/A	N/A

AHRQ - Agency for Healthcare Research and Quality
CMS - Centers for Medicare & Medicaid Services
IHI - Institute for Healthcare Improvement
LFG - The Leapfrog Group
NQF - National Quality Forum
TJC - The Joint Commission

Appendix B
Crosswalk of Safe Practices with Serious Reportable Events and CMS Hospital-Acquired Conditions

NQF 2009 Safe Practices: CMS Hospital-Acquired Conditions and NQF Serious Reportable Events Relevant to Safe Practices

NQF 2009 SAFE PRACTICES	HOSPITAL-ACQUIRED CONDITIONS (HACs)	SERIOUS REPORTABLE EVENTS (SREs)
SP 1: Leadership Structures and Systems	Leadership is foundational to all HACs	Leadership is foundational to all SREs
SP 2: Culture Measurement, Feedback, and Intervention	N/A	N/A
SP 3: Teamwork Training and Skill Building	N/A	N/A
SP 4: Identification and Mitigation of Risks and Hazards	Foreign object retained after surgery, air embolism, blood incompatibility All HACs will require a formalized process for identification and mitigation of each organization's risks and hazards	All SREs will require a formalized process for identification and mitigation of each organization's risks and hazards
SP 5: Informed Consent	N/A	N/A
SP 6: Life-Sustaining Treatment	N/A	N/A
SP 7: Disclosure	N/A	N/A
SP 8: Care of the Caregiver	N/A	N/A
SP 9: Nursing Workforce	N/A	N/A
SP 10: Direct Caregivers	N/A	N/A
SP 11: Intensive Care Unit Care	N/A	N/A
SP 12: Patient Care Information	N/A	N/A

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NQF 2009 Safe Practices: CMS Hospital-Acquired Conditions and NQF Serious Reportable Events Relevant to Safe Practices

NQF 2009 SAFE PRACTICES	HOSPITAL-ACQUIRED CONDITIONS (HACs)	SERIOUS REPORTABLE EVENTS (SREs)
SP 13: Order Read-Back and Abbreviations	N/A	N/A
SP 14: Labeling of Diagnostic Studies	N/A	N/A
SP 15: Discharge Systems	N/A	N/A
SP 16: Safe Adoption of Computerized Prescriber Order Entry	N/A	N/A
SP 17: Medication Reconciliation	N/A	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparations, or wrong route of administration).
SP 18: Pharmacist Leadership Structures and Systems	N/A	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).
SP 19: Hand Hygiene	N/A	N/A
SP 20: Influenza Prevention	N/A	N/A
SP 21: Central Line-Associated Bloodstream Infection Prevention	Vascular catheter-associated infection.	N/A
SP 22: Surgical-Site Infection Prevention	Surgical-site infection following: mediastinitis after coronary artery bypass graft (CABG); certain orthopedic procedures (spine, neck, shoulder, elbow); bariatric surgery for obesity (laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery).	N/A
SP 23: Care of the Ventilated Patient	N/A	N/A
SP 24: Multidrug-Resistant Organism Prevention	N/A	N/A

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NQF 2009 Safe Practices: CMS Hospital-Acquired Conditions and NQF Serious Reportable Events Relevant to Safe Practices

NQF 2009 SAFE PRACTICES	HOSPITAL-ACQUIRED CONDITIONS (HACs)	SERIOUS REPORTABLE EVENTS (SREs)
SP 25: Catheter-Associated Urinary Tract Infection Prevention	Catheter-associated urinary tract infection.	N/A
SP 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention	N/A	Surgery performed on the wrong body part, surgery performed on the wrong patient, wrong surgical procedure performed on a patient.
SP 27: Pressure Ulcer Prevention	Stage III and IV pressure ulcers.	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
SP 28: Venous Thromboembolism Prevention	Deep vein thrombosis/ pulmonary embolism following total knee and hip replacement.	N/A
SP 29: Anticoagulation Therapy	N/A	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).
SP 30: Contrast Media-Induced Renal Failure Prevention	N/A	N/A
SP 31: Organ Donation	N/A	N/A
SP 32: Glycemic Control	Manifestations of poor glycemic control (hypoglycemic coma, diabetic ketoacidosis, nonkeotic hyperosmolar coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity).	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
SP 33: Falls Prevention	Falls and trauma (fractures, dislocations, intracranial injuries, crushing injuries, burns, electric shock).	Patient death or serious disability associated with a fall while being cared for in a healthcare facility.
SP 34: Pediatric Imaging	N/A	N/A

NQF Serious Reportable Events Relevant to NQF 2009 Safe Practices and CMS Hospital-Acquired Conditions

SERIOUS REPORTABLE EVENTS (SREs)	NQF 2009 SAFE PRACTICES*	CMS HOSPITAL-ACQUIRED CONDITIONS (HACs)
1. Surgery performed on the wrong body part	SP 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention	N/A
2. Surgery performed on the wrong patient	SP 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention	N/A
3. Wrong surgical procedure performed on a patient	SP 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention	N/A
4. Unintended retention of a foreign object in a patient after surgery or other procedure	SP 4: Identification and Mitigation of Risks and Hazards	Foreign object retained after surgery
5. Intraoperative or immediately post-operative death in an ASA Class 1 patient	N/A	N/A
6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	N/A	N/A
7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	N/A	N/A
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	SP 4: Identification and Mitigation of Risks and Hazards	Air embolism
9. Infant discharged to wrong person	N/A	N/A
10. Patient death or serious disability associated with patient elopement (disappearance)	N/A	N/A
11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	N/A	N/A
12. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	SP 17: Medication Reconciliation SP 18: Pharmacist Leadership Structures and Systems SP 29: Anticoagulation Therapy	N/A

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*Leadership is foundational to all SREs. All SREs will require a formalized process for identification and mitigation of each organization's risks and hazards.

NQF Serious Reportable Events Relevant to NQF 2009 Safe Practices and CMS Hospital-Acquired Conditions

SERIOUS REPORTABLE EVENTS (SREs)	NQF 2009 SAFE PRACTICES*	CMS HOSPITAL-ACQUIRED CONDITIONS (HACs)
13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products	SP 4: Identification and Mitigation of Risks and Hazards	Blood incompatibility
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the healthcare facility	N/A	N/A
15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	SP 32: Glycemic Control	Manifestations of poor glycemic control (hypoglycemic coma, diabetic ketoacidosis, nonkeototic hyperosmolar coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity)
16. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia neonates	N/A	N/A
17. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	SP 27: Pressure Ulcer Prevention	Stages III and IV pressure ulcers
18. Patient death or serious disability due to spinal manipulative therapy	N/A	N/A
19. Patient death or serious disability associated with electric shock or elective cardioversion while being cared for in a healthcare facility	N/A	N/A
20. Any incident in which a line designed for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	N/A	N/A
21. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	N/A	N/A
22. Patient death associated with a fall while being cared for in a healthcare facility	SP 33: Falls Prevention	Falls and trauma (fractures, dislocations, intracranial injuries, crushing injuries, burns, electric shock)
23. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	N/A	N/A

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NQF Serious Reportable Events Relevant to NQF 2009 Safe Practices and CMS Hospital-Acquired Conditions

SERIOUS REPORTABLE EVENTS (SREs)	NQF 2009 SAFE PRACTICES*	CMS HOSPITAL-ACQUIRED CONDITIONS (HACs)
24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	N/A	N/A
25. Abduction of a patient of any age	N/A	N/A
26. Sexual assault on a patient within or on the grounds of a healthcare facility	N/A	N/A
27. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility	N/A	N/A
28. Artificial insemination with the wrong donor sperm or egg	N/A	N/A

CMS Hospital-Acquired Conditions Relevant to NQF 2009 Safe Practices and Serious Reportable Events

CMS HOSPITAL-ACQUIRED CONDITIONS (HACs)	NQF 2009 SAFE PRACTICES	NQF SERIOUS REPORTABLE EVENTS (SREs)
Foreign object retained after surgery	SP 4: Identification and Mitigation of Risks and Hazards	Unintended retention of a foreign object in a patient after surgery or other procedure
Air embolism	SP 4: Identification and Mitigation of Risks and Hazards	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
Blood incompatibility	SP 4: Identification and Mitigation of Risks and Hazards	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
Stages III and IV pressure ulcers	SP 27: Pressure Ulcer Prevention	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
Falls and trauma (fractures, dislocations, intracranial injuries, crushing injuries, burns, electric shock)	SP 33: Falls Prevention	Patient death or serious disability associated with a fall while being cared for in a healthcare facility
Manifestations of poor glycemic control (hypoglycemic coma, diabetic ketoacidosis, nonkeotic hyperosmolar coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity)	SP 32: Glycemic Control	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
Catheter-associated urinary tract infection	SP 25: Catheter-Associated Urinary Tract Infection Prevention	N/A
Vascular catheter-associated infection	SP 21: Central Line-Associated Bloodstream Infection Prevention	N/A
Surgical-site infection following: mediastinitis after coronary artery bypass graft (CABG); certain orthopedic procedures (spine, neck, shoulder, elbow); bariatric surgery for obesity (laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery)	SP 22: Surgical-Site Infection Prevention	N/A
Deep vein thrombosis or pulmonary embolism following knee and hip replacements	SP 28: Venous Thromboembolism Prevention	N/A

Appendix C
Centers for Medicaid & Medicare Services Care Setting Definitions

- **Care Setting, Ambulatory Care:** All types of health services that do not require an overnight hospital stay.
- **Care Setting, Ambulatory Surgical Center:** A place other than a hospital that does outpatient surgery. At an ambulatory (in and out) surgery center, the patient may stay for only a few hours or for one night.
- **Care Setting, Dialysis Facility:** A unit, hospital-based or freestanding, that is approved to furnish dialysis services directly to end-stage renal disease patients.
- **Care Setting, Emergency Room:** A portion of the hospital where emergency diagnosis and treatment of illness or injury are provided.
- **Care Setting, Home Health Care:** Limited part-time or intermittent skilled nursing care and home health aide services, physical therapy, occupational therapy, speech-language therapy, medical social services, durable medical equipment (such as wheelchairs, hospital beds, oxygen, and walkers), medical supplies, and other services.
- **Care Setting, Home Health Services/Agency:** An organization that gives home care services, such as skilled nursing care, physical therapy, occupational therapy, speech therapy, and personal care by home health aides.
- **Care Setting, Hospice:** Hospice is a special way of caring for people who are terminally ill, and for their families. This care includes physical care and counseling. Hospice care is covered under Medicare Part A (Hospital Insurance).
- **Care Setting, Inpatient Service/Hospital:** A facility, other than psychiatric, that primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by or under the supervision of physicians, to patients admitted for a variety of medical conditions.
- **Care Setting, Outpatient Services/Hospital:** A portion of a hospital that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
- **Care Setting, Skilled Nursing Facility:** A facility (meeting specific regulatory certification requirements) that primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services, but that does not provide the level of care or treatment available in a hospital.

CMS Glossary. Available at: http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English.

Appendix D
Glossary

- **Abbreviations:** A shortened form of a written word or phrase used in place of the whole. [Medline Online Dictionary. Available at http://www.merriam-webster.com/dictionary/abbreviation]
- **Additional Specifications:** Clarifying elements or indicators provided by the National Quality Forum for each Safe Practice. [The Leapfrog Group. Safe Practices Leap Glossary of Terms and Operational Definitions. April 30, 2005. Available at https://leapfrog.medstat.com/pdf/Glossary.pdf]
- **Adverse Drug Event (ADE):** An adverse reaction to a drug or medication. [FDA. Reporting Adverse Drug and Medical Device Events. Available at http://www.ama-assn.org/ama/upload/mm/369/ceja_report_051.pdf]
- **Adverse Event:** Any harm (injury or illness) caused by medical care. Identifying adverse events indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease, but does not imply an error, negligence, or poor quality care. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Alternative/Complementary Medications:** Any of various systems of healing or treating disease (as chiropractic, homeopathy, or faith healing) not included in the traditional medical curricula taught in the United States and Britain. [Medline Online Dictionary. Available at http://www.nlm.nih.gov/medlineplus/mplusdictionary.html]
- **Benchmark:** In healthcare settings, refers to an attribute or achievement that serves as a standard for providers or institutions to emulate. Benchmarks differ from other "standard of care" goals, in that they derive from empiric data—specifically, performance or outcomes data. [AHRQ. Available at http://www.psnet.ahrq.gov/glossary.aspx#B]
- **Care Setting, Ambulatory Care:** All types of health services that do not require an overnight hospital stay. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Ambulatory Surgical Center:** A place other than a hospital that does outpatient surgery. At an ambulatory (in and out) surgery center, the patient may stay for only a few hours or for one night. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]

- **Care Setting, Dialysis Facility:** A unit, hospital-based or freestanding, that is approved to furnish dialysis services directly to end-stage renal disease patients. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Emergency Room:** A portion of the hospital where emergency diagnosis and treatment of illness or injury are provided. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Home Health Care:** Limited part-time or intermittent skilled nursing care and home health aide services, physical therapy, occupational therapy, speech-language therapy, medical social services, durable medical equipment (such as wheelchairs, hospital beds, oxygen, and walkers), medical supplies, and other services. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Home Health Services/Agency:** An organization that gives home care services, such as skilled nursing care, physical therapy, occupational therapy, speech therapy, and personal care by home health aides. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Hospice:** Hospice is a special way of caring for people who are terminally ill, and for their families. This care includes physical care and counseling. Hospice care is covered under Medicare Part A (Hospital Insurance). [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Inpatient Service/Hospital:** A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by or under the supervision of physicians, to patients admitted for a variety of medical conditions. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Outpatient Services:** Outpatient hospital—a portion of a hospital that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Care Setting, Skilled Nursing Facility:** A facility (meeting specific regulatory certification requirements) that primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services, but does not provide the level of care or treatment available in a hospital. [CMS. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=ALL&Language=English]
- **Clinical Pharmacist:** Clinical pharmacists care for patients in all healthcare settings. They possess in-depth knowledge of medications that is integrated with a foundational understanding of the biomedical, pharmaceutical, socio-behavioral, and clinical sciences. [ACCP. Available at http://www.accp.com/docs/govt/advocacy/ga_overview.pdf]

- **Clinical Pharmacy:** A health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care; it blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes. As a discipline, clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life. [ACCP. Available at http://www.accp.com/docs/govt/advocacy/ga_overview.pdf]
- **Computerized Physician Order Entry or Computerized Provider Order Entry (CPOE):**
  A. Refers to a computer-based system of ordering medications and, often, other tests. Physicians (or other providers) enter orders directly into a computer system that can have varying levels of sophistication. Basic CPOE ensures standardized, legible, complete orders, and thus primarily reduces errors due to poor handwriting and ambiguous abbreviations. [AHRQ. Available at http://www.psnet.ahrq.gov/glossary.aspx#C]
  B. Clinical systems that utilize data from pharmacy, laboratory, radiology, and patient monitoring systems to relay the physician's or nurse practitioner's diagnostic and therapeutic plans, and to alert the provider to any allergy or contraindication that the patient may have, so that the order may be immediately revised at the point of entry prior to being forwarded electronically for the targeted medical action. [SP-SQS. Available at http://www.who.int/patientsafety/highlights/COE_patient_and_medication_safety_gl.pdf]
- **Corrective Action Plan:** Policy and procedural actions that hospitals prepare to respond to an adverse event and to prevent recurrence. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Critical Information:** Decisive state or turning-point, revealing a crisis or essential nature of some process. The most important elements of a process; point at which some action, property, or condition passes over into another, constituting an extreme or limiting case. [Oxford English Dictionary. 2nd Edition on CD-ROM, VERSION 3.0, 2002]
- **Culture of Safety:** Safety culture and culture of safety are frequently encountered terms referring to a commitment to safety that permeates all levels of an organization, from frontline personnel to executive management. More specifically, "safety culture" calls up a number of features identified in studies of high-reliability organizations, organizations outside of healthcare with exemplary performance with respect to safety. These features include: 1. acknowledgment of the high-risk, error-prone nature of an organization's activities; 2. a blame-free environment where individuals are able to report errors or close calls without fear of reprimand or punishment; 3. an expectation of collaboration across ranks to seek solutions to vulnerabilities; and 4. willingness on the part of the organization to direct resources for addressing safety concerns. [AHRQ. Available at http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1.section.61719]

- **Discharge System:** Discharge is the release of a patient from a course of care. The doctor may then dictate a discharge summary. The system is composed of factors that could be modified during the hospital discharge process to reduce post-hospital adverse events and rehospitalizations. [Medicine.net. Available at http://www.medterms.com/script/main/art.asp?articlekey=3010] For example, protocols could be established to guide prescribing medications, during hospitalizations and upon discharge, to avoid medication error upon discharge. [ISMP. Available at http://www.ismp.org/Newsletters/acutecare/articles/20010613.asp]
- **Electronic Health Record (EHR):** The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, medical history, immunizations, laboratory data, and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter—as well as supporting other care-related activities directly or indirectly via interface—including evidence-based decision support, quality management, and outcomes reporting. [HIMSS. Available at http://www.himss.org/ASP/topics_ehr.asp]
- **Electronic Medication Administration Record (eMAR):** An electronic system that provides detailed information to improve safety and efficiency, such as start and stop dates of medication, trade and generic names, dosage, route, and frequency, and/or when medication was last given and is next scheduled. The user can access related information from nursing assessments and labs and access detailed information about the use of the medication. [AHRQ. Available at http://www.ahrq.gov/about/annualmtg07/0926slides/mcquay/Mcquay-16.html]
- **Evidence-Based:** In connection with an assertion about some aspect of medical care–a recommended treatment, the cause of some condition, or the best way to diagnose it–reflects the preponderance of results from relevant studies of good methodological quality. [AHRQ. Available at http://www.psnet.ahrq.gov/glossary.aspx#S]
- **Evidence-Based Clinical Practice Guidelines:** Practices found to increase patient safety and improve care, generated by systematic and evidentiary research. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Failure Mode and Effect Analysis (FMEA):**
  A. A prospective risk-assessment tool originally developed in the manufacturing industry, adapted to processes in healthcare. A Health Care Failure Mode Effects Analysis (HFMEA) system includes tools to prospectively identify process risks in an organization, analyze the ways in which the process can fail, prioritize those failure modes, and take corrective action before failures have occurred. [AHRQ. Available at http://psnet.ahrq.gov/resource.aspx?resourceID=1531]
  B. A systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change. [IHI. Available at http://www.ihi.org/ihi/workspace/tools/fmea/]

- **Five Rights of Medication Management:** Administering the right medication, in the right dose, at the right time, by the right route, to the right patient. [AHRQ. The "five rights." ISMP Medication Safety Alert! Acute Care Edition. April 7, 1999. Additional definition available at http://www.psnet.ahrq.gov/glossary.aspx#S]
- **Healthcare-Associated Infection:** A localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that 1) occurs in a patient in a healthcare setting (e.g., a hospital or outpatient clinic), 2) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting, and 3) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC. [Horan TC, Gaynes R. Surveillance of nosocomial infections. In: Mayhall CG, editor. Hospital epidemiology and infection control. Philadelphia: Lippincott Williams & Wilkins; 2004. p: 1659-702]
- **High Alert Medications:** Medications that have a high risk of causing serious injury or death to a patient if they are misused. Errors with these products are not necessarily more common, but their results can be more devastating. Examples of high-alert medications include warfarin and IV antithrombotics, insulin, chemotherapy, concentrated electrolytes, IV digoxin, opiate narcotics, neuromuscular blocking agents, and adrenergic agonists. [ISMP. Available at http://www.ismp.org/Tools/highalertmedications.pdf]
- **Hospital-Acquired Condition:** Medical condition not present prior to admission to a hospital. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Implementation Bundle:** A bundle is a group of interventions related to a disease process that, when executed together, result in better outcomes than when implemented individually. Successful implementation of bundles is based on the "all or nothing" strategy; that is, teams must comply with all components of the bundle to be successful, unless medically contraindicated. [IHI. Available at http://www.ihi.org/IHI/Topics/PerinatalCare/PerinatalCareGeneral/EmergingContent/ElectiveInductionandAugmentationBundles.htm]
- **Implementation Expectations for the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™:** A guideline that provides detailed implementation requirements, exceptions, and adaptations for special surgery adaptations. [The Joint Commission. Available at http://www.jointcommission.org/NR/rdonlyres/4CF3955D-CD1F-4230-86C5-D04485CAFBEA/0/IG_final.pdf]
- **Informed Consent:** Informed consent involves a discussion between a person who would receive the treatment and a professional person who explains the treatment, provides information about possible benefits and risks, and answers questions. Informed consent involves the process of discussion about a treatment. Signing the informed consent form provides a record of the discussion but does not take the place of the discussion. [AHRQ. Available at http://effectivehealthcare.ahrq.gov/tools.cfm?tooltype=glossary&TermID=35]

- **Just Culture:**
  A. Healthcare organization culture that recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, "routine rule violations"), but has zero tolerance for reckless behavior. [AHRQ. Available at http://www.psnet.ahrq.gov/glossary.aspx#S]
  B. Just culture is a key element of a safe culture. It reconciles professional accountability and the need to create a safe environment to report medication errors; seeks to balance the need to learn from mistakes and the need to take disciplinary action. [SP-SQS. Available at http://www.who.int/patientsafety/highlights/COE_patient_and_medication_safety_gl.pdf].
  C. An environment in which personnel feel comfortable disclosing errors (including their own) while maintaining professional accountability; holds that individuals should not be held responsible for systems breakdowns. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Labeling Studies: Clinical Trials Designed to Support Labeling Claims of Pharmaceuticals.** Pharmaceutical labeling should provide a concise, accurate summary of the evidence supporting effectiveness of a drug or biologic for its approved indication. [FDA. Available at http://www.fda.gov/cder/guidance/1890dft.htm#P111_3234]
- **Life-Sustaining Treatment:** Any treatment that serves to prolong life without reversing the underlying medical condition. Life-sustaining treatment may include, but is not limited to, mechanical ventilation, renal dialysis, chemotherapy, antibiotics, and artificial nutrition and hydration. [HospiceDirectory.org. Available at http://www.hospicedirectory.org/cm/about/choosing/glossary/life_treatment]
- **Magnet Hospital Status:** Designation by the Magnet Hospital Recognition Program administered by the American Nurses Credentialing Center. The program has its genesis in a 1983 study conducted by the American Academy of Nursing that sought to identify hospitals that retained nurses for longer-than-average periods of time. The study identified institutional characteristics correlated with high retention rates, an important finding in light of a major nursing shortage at the time. These findings provided the basis for the concept of "magnet hospital" and led 10 years later to the formal Magnet Program. [AHRQ. Magnet hospitals. Attraction and retention of professional nurses. Task Force on Nursing Practice in Hospitals. American Academy of Nursing. ANA Publ. 1983;(G-160):i-xiv, 1-135]
- **Measure, Financial:** An outcome measurement of the effect of an activity on the financial health and activity of the organization. Financial measures might be "cost per day," "average daily pharmacy costs for patients with the intervention," or "nursing hours per patient day," which is a key building block to "cost per day." [IHI. Available at http://www.ihi.org/IHI/Topics/LeadingSystemImprovement/Leadership/Tools/GlossaryofFrequentlyUsedFinancialTerms.htm]

- **Measure, Operational:** Operational measures are measures of process. Operational and utilization measures track the activities (inputs, resource uses) that drive different outcomes. To manage a program, an organization needs to measure what it does and show that it causes or is correlated with a different result (outcome). Operational measures might be such items as "number of patients who received the intervention," or "percentage of time that nursing staff spend with direct patient care." These indicate the scope, scale, and impact of the program, and are building blocks for quality and financial measures. [IHI. Available at http://www.ihi.org/IHI/Topics/Flow/EmergencyDepartment/EmergingContent/MeasuresforEDOperationalandClinicalImprovement.htm]
- **Measure, Performance:** A gauge used to assess the performance of a process or function of any organization. Quantitative or qualitative measures of the care and services delivered to enrollees (process) or the end result of that care and services (outcomes). Performance measures can be used to assess other aspects of an individual or organization's performance, such as access and availability of care, utilization of care, health plan stability, beneficiary characteristics, and other structural and operational aspect of healthcare services. [Data Resource Center for Child and Adolescent Health. Available at http://childhealthdata.org/Content/Glossary.aspx#P]
- **Medication:** Any prescription medications; sample medications; herbal remedies; vitamins; nutriceuticals; over the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug Administration as a drug. This definition of medication does not include enteral nutrition solutions, oxygen, and other medical gases. [TJC. Available at http://www.jointcommission.org/NR/rdonlyres/BDEA5518-D791-46D4-92A5-867920906C6C/0/06_obs_mm.pdf]
- **Medical Error:** The failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Medication Error:** Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. [NCC MERP. Available at http://www.nccmerp.org/aboutMedErrors.html]
- **Medication Management:** The following standards address the components of medication management: selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration, and monitoring effect. [TJC. Available at http://www.jointcommission.org/NR/rdonlyres/5B27D3A9-5FE3-44EE-880E-AD6396109592/0/BHC2008MMChapter.pdf]

- **Medication Reconciliation:**
  A. Process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. [TJC. Using medication reconciliation to prevent errors Sentinel Alert. January 25, 2006. Available at http://www.jointcommission.org/sentinelevents/sentineleventalert/sea_35.htm]
  B. Medication reconciliation refers to the process of avoiding inadvertent inconsistencies across transitions in care by reviewing the patient's complete medication regimen at the time of admission/transfer/discharge and comparing it with the regimen being considered for the new setting of care. [AHRQ. Tam VC, Knowles SR, Cornish PL, Fine N, Marchesano R, Etchells EE. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. [CMAJ 2005;173:510-515]
- **Near Miss:**
  A. An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient (e.g., a patient with penicillin allergy receives penicillin, but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart). This definition is identical to that for close call. [AHRQ. Available at http://psnet.ahrq.gov/glossaryPrintView.aspx].
  B. An event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Never Event:** An event or a situation that should never occur in a healthcare setting. The National Quality Forum initially used the term "never events" to describe its list of serious events, but began in 2005 to refer to the list as "serious reportable events." [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Nosocomial Infection:** Healthcare-associated infections. [CDC. Available at http://www.cdc.gov/ncidod/dhqp/nnis.html]
- **Order Read-Back or Read-Back:** When information is conveyed verbally, miscommunication may occur in a variety of ways, especially when transmission may not occur clearly (e.g., by telephone or radio, or if communication occurs under stress). For names and numbers, the problem often is confusing the sound of one letter or number with another. To address this possibility, the military, civil aviation, and many high-risk industries use protocols for mandatory "read-backs," in which the listener repeats the key information, so that the transmitter can confirm its correctness. [AHRQ. http://www.psnet.ahrq.gov/glossary.aspx#R]
- **Outcome:** In healthcare, an outcome may be measured in a variety of ways, but it tends to reflect the health and well-being of the patient and the associated costs of care. [Medline Online Dictionary. Available at http://www.nlm.nih.gov/medlineplus/mplusdictionary.html]

- **Outcome Measures:** Measures that tell an organization whether changes are actually leading to improvement–that is, helping to achieve the overall aim of reducing negative impact to patients. Examples include adverse drug events per 1,000 population, intensive care unit mortality, and number of days to appointment. [IHI. Available at http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Measures/]
- **Over-the-Counter (OTC):** Therapeutic agent available to the patient at a store without a healthcare practitioner's prescription. [Medline Online Dictionary. Available at http://www.nlm.nih.gov/medlineplus/mplusdictionary.html]
- **Patient-Centered Care:** Patient-centered care is quality healthcare achieved through a partnership between informed and respected patients and their families and a coordinated healthcare team. Patient-centered care will reflect patients' values and will engage them as partners in their care. Patients and their families must be involved in decision-making. They need education, information, and coaching to facilitate their informed and full participation. Responsibility and accountability for health should be shared among members of the provider team: payers, patients, families, communities, businesses and governments—essentially all elements of society. [The National Health Council's Putting Patients First® initiative. Part of the Patient-Centered Care 2015: Scenarios, Vision, Goals & Next Steps. Available at http://www.altfutures.com/pubs/Picker%20Final%20Report%20May%2014%202004.pdf]
- **Patient Safety:**
  A. Patient safety is defined as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes. [WHO. The Conceptual Framework for the International Classification for Patient Safety v.1.0 for Use in Field Testing in 2007-2008, ICPS. Available at http://www.who.int/patientsafety/taxonomy/icps_form/en/]
  B. Freedom from accidental or preventable injuries produced by medical care. [AHRQ. Available at http://www.psnet.ahrq.gov/glossary.aspx#P].
  C. Freedom from accidental or preventable injuries caused by medical care. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Patient Safety Officer:** Personnel whose sole duty is to understand, manage, and optimize all activities relating to quality of patient and provider care within the hospital; reports to a C-level executive within the organization; and is part of briefing board members and trustees. Safe Practices Leap Glossary of Terms. Available at https://leapfrog.medstat.com/pdf/ Glossary.pdf]
- **Performance Improvement Projects:** Projects that examine and seek to achieve improvement in major areas of clinical and nonclinical services. These projects are usually based on information such as enrollee characteristics, standardized measures, utilization, diagnosis and outcome information, data from surveys, grievance and appeals processes, etc. They measure performance at two periods of time to ascertain if improvement has occurred. These projects are required by the state and can be of the MCO/PHP's [Managed Care Organization/Prepaid Health Plan] choosing, or prescribed by the state. [CDC. Available at http://www.cms.hhs.gov/apps/glossary/default.asp?Letter=P]

- **Potentially Compensable Event:** Potential adverse event. [Princeton Insurance Risk Review. Available at http://www.pinsco.com/downloads/Risk_Review_Downloads/11.2006/11.2006_Risk.Review.pdf]
- **Probabilistic Risk Assessment (PRA):** PRA has been used to assess the designs of high-hazard, low-risk systems, such as commercial nuclear power plants and chemical manufacturing plants, and is now being studied for its potential in the improvement of patient safety. PRA examines events that contribute to adverse outcomes through the use of event-tree analysis, and determines the likelihood of event occurrence through fault-tree analysis. [Nemeth C, Wreathall J. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. Qual Saf Health Care 2004:13:206-212. Available at http://www.ctlab.org/documents/QSHCPRA-Assessing%20Risk.pdf]
- **Process:** A series of related actions to achieve a defined outcome, such as prescribing medication or administering medication. [SP-SQS. Available at http://www.who.int/patientsafety/highlights/COE_patient_and_medication_safety_gl.pdf]
- **Process Measures:** To affect the outcome measure of reducing harm, changes are made to improve many core processes in the medication system, including the processes for ordering, dispensing, administering, and reconciling medications, as well as changes to improve the culture as it relates to safety and reporting errors. Measuring the results of these process changes will tell if the changes are leading to an improved, safer system. Examples include Percentage of Staff Reporting a Positive Safety Climate, and Pharmacy Interventions per 100 Admissions. [IHI. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Measures/]
- **Regular:** Recurring at fixed, uniform, or normal intervals. In the context of the Safe Practices, the term "regular" is intended to promote the occurrence of certain actions or functions on a planned or periodic basis, as opposed to an *ad hoc* basis
- **Remediation:** The act or process of remedying. (Example: remediation of learning disabilities.) [Medlineplus. Available at http://www.nlm.nih.gov/medlineplus/mplusdictionary.html]
- **Risk Management:** Identifying, assessing, analyzing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits, and costs. [SP-SQS. Available at http://www.who.int/patientsafety/highlights/COE_patient_and_medication_safety_gl.pdf]
- **Risk Management:** Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors, and the risk of loss to the organization itself. [SP-SQS. Available at http://www.who.int/patientsafety/highlights/COE_patient_and_medication_safety_gl.pdf]
- **Risk-Reduction Strategies:** Interventions, actions, and strategies designed to reduce the risk of recurrence of an event. Typically part of a corrective action plan. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Root Cause Analysis:** A focused review of systems and processes to identify the basic or contributing factors that cause adverse events. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]

- **Safety Climate:** Employees' perceptions of particular aspects of the organization's culture of safety. [Blegen MA, Pepper GA, Rosse J. Safety Climate on Hospital Units: A New Measure. Advances in Patient Safety: Vol. 4. Available at http://www.ahrq.gov/downloads/pub/advances/vol4/Blegen.pdf]
- **Sentinel Event:** An adverse event in which death or serious harm to a patient has occurred; usually used to refer to events that are not at all expected or acceptable, such as an operation on the wrong patient or body part. The choice of the word "sentinel" reflects the egregiousness of the injury (e.g., amputation of the wrong leg) and the likelihood that investigation of such events will reveal serious problems in current policies or procedures. [AHRQ. Available at http://www.psnet.ahrq.gov/glossary.aspx#S]
- **Serious Reportable Event:** An unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. In 2002, the National Quality Forum (NQF) published a report, *Serious Reportable Events in Healthcare,* that identified 27 adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers. That list has been updated to the *Serious Reportable Events in Healthcare: 2006 Update.* [NQF. Available at http://www.qualityforum.org/projects/completed/sre/]
- **Structure, Process, Outcome Triad:** Quality has been defined as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition, like most others, emphasizes favorable patient outcomes as the gold standard for assessing quality. In practice, however, one would like to detect quality problems without waiting for poor outcomes to develop in such sufficient numbers that deviations from expected rates of morbidity and mortality can be detected. Avedis Donabedian first proposed that quality could be measured using aspects of care with proven relationships to desirable patient outcomes. For instance, if proven diagnostic and therapeutic strategies are monitored, quality problems can be detected long before demonstrable poor outcomes occur. Aspects of care with proven connections to patient outcomes fall into two general categories: process and structure. [Institute of Medicine (IOM). Margarita P. Hurtado, Elaine K. Swift, and Janet M. Corrigan (eds.). Committee on the National Quality Report on Health Care Delivery, Board on Health Care Services. Envisioning the National Health Care Quality Report. National Academy Press: Institute of Medicine. 2000. Appendix D. Available at http://www.nap.edu/html/envisioning/appd.htm]
- **Systems Approach:** Theory that most errors reflect predictable human failings in the context of poorly designed systems. [Levinson D. Department of Health and Human Services. Office of Inspector General. Adverse events in hospitals: overview of key issues. 2008 Dec. OEI-06-07-00470. Available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf]
- **Transparency:** A transparent healthcare system is one that is accountable to the public, works openly, makes results known, and builds trust through disclosure. [HealthInsight. Available at http://www.healthinsight.org/archives/assets/quality_insight/QualityInsight%20Fall%202005_web.pdf]
- **Universal Protocol:** The organization fulfills the expectations set forth in the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ and associated implementation guidelines. [TJC. Available at http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf]

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