Identification and Prioritization of Health IT Patient Safety Measures

DRAFT REPORT

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Executive Summary

Adoption and implementation of health information technology (HIT) is widely viewed as essential to the transformation of health care, and a key to satisfying the diverse needs of stakeholders burdened by rising costs, inefficiency, preventable errors, and poor quality of care. With proper design, implementation, and use, HIT promises the ability to reduce medical errors and improve quality of care. Yet while the use of HIT presents many new opportunities to improve patient care and safety, it can also create new hazards and opportunities for error. HIT will fulfill its potential only if the risks associated with its use are identified and a coordinated effort is developed to mitigate those risks. Accordingly, there is a need for measures to help identify the nature, scope, and prevalence of HIT-related safety issues and to assess how well providers, vendors, and others are preventing and/or mitigating HIT-related safety concerns.

In order to address the rapidly-evolving area of HIT and its intersection with quality and outcomes, NQF initiated a project to develop a set of recommendations around the measurement of HIT-related safety issues. A multi-stakeholder Committee was convened to provide input and direction on the development of a conceptual framework for analyzing measures of safety in health IT and to identify priority measurement areas with the greatest potential for both improving the safety of HIT and using HIT to improve patient safety.

The Committee adopted a three-level framework for categorizing and conceptualize potential measurement concepts and gaps in the area of HIT safety, and to provide a framework for recommendations around future HIT safety measure development. The goals of the framework are to ensure (1) that clinicians and patients have a foundation of safe HIT; (2) that HIT is properly integrated and used within healthcare organizations to deliver safe care; and (3) that HIT is part of continuous improvement processes to make care safer and more effective.

In addition, the Committee identified nine key measurement areas for HIT safety, each of which include several measure concepts that could potentially reflect performance in that area, possible data sources or data collection strategies for each measurement topic, as well as the entities that could potentially be held accountable for performance in each area. The final list of key measurement areas is as follows:

1. **Clinical Decision Support**
2. **System Interoperability**
3. **Patient Identification**
4. **User-Centered Design and Use of Testing, Evaluation, and Simulation to Promote Safety across the HIT Lifecycle**
5. **System Downtime (Data Availability)**
6. **Feedback and Information-Sharing**
7. **Use of HIT to Facilitate Timely and High-Quality Documentation**
8. **Patient Engagement**
9. **HIT-Focused Risk-Management Infrastructure**

Additional details on each measurement area are available in the report.

This report is intended to serve as a basis for continuing efforts to develop measures that can be incorporated throughout the HIT lifecycle as part of an iterative development process; through this iterative process, a knowledge base may emerge to inform future quality and safety improvement efforts.

Advancing the safety and safe use of HIT will require stakeholders to share responsibility and accountability for patient safety; this may require a substantial cultural shift for the many groups involved in the development and use of HIT systems. The Committee recognizes that there are many hurdles to effective measurement of HIT safety, including these potential cultural barriers, as well as collection of data, associated costs, and other practical limitations along with a rapidly evolving sociotechnical environment. Because HIT innovation is moving at a fast pace, it will be vital to develop mechanisms to identify and measure new safety issues that arise from HIT. However, these challenges should not prevent the field from moving forward with meaningful efforts to measure and improve the safety of HIT; indeed, the changing landscape offers a significant opportunity to ensure that patient safety considerations are incorporated into all phases of the HIT lifecycle as we move into the future. This framework and the Committee's recommendations should be viewed as a living document that will itself continue to evolve as evidence, practices, and technologies mature.

Background

Adoption and implementation of health information technology (HIT) is widely viewed as essential to the transformation of health care, and a key to satisfying the diverse needs of stakeholders burdened by rising costs, inefficiency, preventable errors, and poor quality of care. With proper design, implementation, and use, HIT promises the ability to reduce medical errors and improve quality of care.[1,2] When fully integrated, the goal of HIT is to facilitate substantial improvements in quality and safety. Potential benefits of HIT include:

- Reduction of patient harm from medication errors and facilitation of evidence-based care through capabilities such as clinical decision support (CDS). Clinical decision support can help guide clinicians in diagnosis and decision-making by providing access to a wealth of information at the point of care, including evidence-based best practices, guidance for treatment or preventive care (*e.g.*, immunizations and routine screening tests), and information on potential allergies and medication interactions.
- With seamless interoperability, patient records can be stored centrally and easily accessed from multiple locations, making crucial health information available when and where it is needed as patients move within and between health care organizations. For example, when a patient presents to the emergency department to providers who have no prior knowledge of their care, providers can provide the most informed treatment through access to prior records through electronic health records (EHRs).
- HIT may be used to efficiently report, track, and aggregate patient data within and across organizations. This may allow providers to more readily track quality of care and manage systematic problems, such as hospital-acquired illnesses. In addition, disease outbreaks can be monitored, allowing for improved population health and identification of widespread threats to health, such as flu epidemics.
- Through the use of computerized provider order entry (CPOE), HIT can also to help to reduce prescription and other errors resulting from the illegible handwriting frequently found in paper-based record-keeping and orders.

Because of HIT's potential to yield substantial benefits in quality, safety, and efficiency of health care, the federal government has been engaged in a concerted effort to encourage and incentivize adoption of HIT. Since the creation of the Office of the National Coordinator for Health Information Technology (ONC) in 2004, over $24 billion has been spent in economic incentives for eligible health care providers to adopt and meaningfully use certified EHR technology.[3]

However, despite the considerable investment in HIT and its contribution to substantial improvements in care, the widespread, rapid adoption of HIT has led to the potential for unintended consequences. For instance, there is broad variation in how HIT has been implemented within and across healthcare settings, which has resulted in a lack of interoperability across many settings. In addition, user interfaces have sometimes proven to be unclear, confusing, cumbersome, or time-consuming for clinicians to use, leading to inadvertent mistakes in entry or retrieval of information, workarounds, and other opportunities for error. While the use of HIT presents many new opportunities to improve patient care and safety, it can also create new hazards. HIT will fulfill its potential only if the risks associated with its use are identified and a coordinated effort is developed to mitigate those risks, as envisioned by the ONC Patient Safety Action and Surveillance Plan.[4] Accordingly, there is a need for measures to help identify the nature, scope, and prevalence of HIT-related safety issues and to assess how well providers, vendors, and others are preventing and/or mitigating HIT-related safety concerns.

In order to address the rapidly-evolving area of HIT and its intersection with quality and outcomes, NQF initiated a project to develop a set of recommendations around the measurement of HIT-related safety issues. To accomplish this task, NQF:

1. Conducted an environmental scan of relevant HIT measures and measure concepts;
2. Convened a multi-stakeholder committee to guide and provide input on all phases of the project, as well as engage NQF members and public stakeholders at key points throughout the project;
3. Developed a conceptual framework for HIT safety as a way to categorize measure concepts and gaps in measurement;
4. Identified challenges to the measurement of HIT-related safety events and adoption of best practices to strengthen measurement efforts; and
5. Identified and prioritized key measurement areas and potential measure concepts related to HIT safety.

HIT Safety Committee

Through a public call for nominations, NQF convened a multi-stakeholder Committee with diverse representation; the Committee included experts in health information technology data systems, electronic health records (EHRs), and patient safety, providers across different settings, front-line clinicians, health plan representatives, and experts in patient safety issues related to the use of HIT. NQF also involved federal government partners in a consultative role. The full HIT Safety Committee roster can be found in Appendix A.

The Committee provided input on all phases of the work (*e.g.*, guidance on the environmental scan, framework development, and measure concept prioritization) through a series of in-person meetings and conference calls.

Environmental Scan

NQF first conducted an environmental scan to determine what is known from the existing literature about the effect of HIT on patient care and about measurement and prevention of HIT-related safety events. The following questions guided the search:

- What are the most effective ways to monitor for and identify HIT-related safety events?
- Why and under what circumstances do HIT-related safety events occur?
- What is the best/most useful way to categorize HIT-related safety events?
- What kinds of barriers or confounding factors limit our ability to accurately and comprehensively measure HIT-related safety events?
- What measures of HIT-related safety events currently exist?

The results of this scan were used as the foundation for a measure gap analysis, which provided a preliminary roadmap of the existing measurement landscape and areas where additional measure development may be needed. The HIT Safety Committee used this analysis during its in-person and web-based meetings to provide input and direction on the development of a conceptual framework for analyzing measures of safety in HIT and to identify priority measurement areas with the greatest potential for both improving the safety of HIT and using HIT to improve patient safety.

Methodology

The environmental scan was guided by key search terms and parameters informed by the Committee. NQF also consulted with the Committee and other stakeholders to identify additional key informants or sources from the public and private sectors to query about relevant performance measures and measure concepts. In addition, NQF engaged public audiences and its membership of over 400 organizations and individuals participating on related NQF projects (*e.g.*, MAP members, the Common Formats Expert Panel, the Patient Safety Standing Committee and other Standing Committees, the Health Information Technology Advisory Committee, and other relevant groups) to assist in this effort. (For additional details on the search strategy and results, please see **Appendix B**, and see **Appendix C** for a list of key definitions)

Impact of HIT on Safety – Review of the Evidence

As has been noted by the Institute of Medicine (IOM) Committee on Patient Safety and Health Information Technology and others examining the issue, the evidence regarding HIT's impact on safety is mixed.[5] The IOM Committee, commissioned by ONC to study and address issues related to HIT and patient safety, could not point to any systematic reviews or studies as representing the most definitive evidence of the impact of HIT on patient safety. However, among practicing clinicians, HIT safety is a major issue of great interest and importance and many individual studies in specific settings have shown both care improvements and patient safety problems associated with HIT. NQF's environmental scan resulted in similar findings. While many studies have suggested that elements of HIT can be helpful in improving patient safety—particularly medication safety—other studies have found no effect, or even deleterious effects in some instances. A summary of key findings from reviews of the evidence identified in our search can be found in **Appendix D**.

Limitations of the evidence

While there are several studies demonstrating specific patient harms from HIT, systematic harm/adverse effects often do not appear in the peer-reviewed literature, are poorly indexed in the medical databases, and can be difficult to identify, limiting the ability of researchers to comprehensively assess the effects of HIT on patient safety.[6] In addition, studies of HIT's impact on patient safety are often narrowly-focused—*i.e.*, addressing a particular aspect or function of HIT, such as ePrescribing or clinical decision support, or a particular process of care, such as identification of patients at high risk for adverse medication events[7].

The high degree of variability and uncertainty in the literature makes it hard to draw definitive conclusions about the impact of HIT on patient safety, particularly on HIT's link to clinical harm. In addition, there is increasing recognition that the complex relationships between HIT systems, system designers and developers, HIT implementers and users, relevant policies (both internal and external) and regulations, and various other factors mean that many HIT-related safety issues cannot be ascribed to a single causative factor, further limiting the insights that can be drawn from studies with a relatively narrow or specific focus.[8,9] Several of the reviews identified in our scan noted this challenge explicitly.[10,11,12] Therefore, given that harm and adverse effects, as well as the benefits of HIT, are often software-specific and context-specific, it is challenging to generalize about the safety of HIT as a whole, or of any specific function. As an analogy, it would be difficult to make general conclusions about automobile safety by assessing certain vehicles in certain driving conditions, except to say that certain automobiles are better and safer than others, and that they perform differently when faced with

different circumstances and different drivers. Because of the inherent variation in technology itself, its local use, and its users, there is a great need for tools and methods for assessing the effect of HIT on both care improvements and patient safety, including measures specifically related to the design, implementation, usability, and safe use of HIT.[13]

Defining, identifying, and classifying potential risks associated with HIT

Despite the limitations of the published literature, it is well-acknowledged among researchers and users of HIT that a variety of risks may be associated with the implementation and use of HIT, introducing new patient safety challenges into the health care system.[14,15] An HIT-related safety event—sometimes called "e-iatrogenesis"—has been defined as "patient harm caused at least in part by the application of health information technology."[16] Sittig and Singh have described HIT-related error as occurring "anytime the HIT system is unavailable for use, malfunctions during use, is used incorrectly, or when HIT interacts with another system component incorrectly, resulting in data being lost or incorrectly entered, displayed, or transmitted."[17] Factors across the spectrum of design, implementation, and use of HIT systems contribute to safety hazards and conditions that may induce or facilitate errors.[18,19,20]

HIT Design

Challenges related to the design of HIT include hardware and software reliability; interface usability; system interoperability; and data integrity, accessibility, and confidentiality. While user-centered design can facilitate improved patient care, flaws or inadequacies in design can cause safety hazards such as inaccurate recording or reporting of patient information (*e.g.*, allergies or medications); data loss or corruption; inefficient workflow leading to delays, frustration, and workarounds; confusing user interfaces leading to incorrect entry or interpretation of information; and inability to exchange or communicate important information between systems ("record fragmentation"). [21,22,23,24]

HIT Implementation

Approaches to planning and managing the implementation of HIT systems can have a significant impact on patient safety. Organizations procuring and implementing a new HIT system must pay heed to a multitude of considerations, including customization of hardware or software for organization-specific needs; integration of new HIT into existing clinical workflows or redesign of clinical workflows to accommodate new HIT; staff education and training; adaptation to cultural changes associated with HIT use; ensuring adequate backup and security systems; and preparing for planned or unplanned system downtime. The potential implications of flawed implementation strategies include staff resistance and resulting suboptimal use or circumvention of safety features; inadequate functionality for clinical processes; disruption of workflow and reduced efficiency; and poor fit between new HIT and existing physical and technical infrastructures.[25,26,27,28]

HIT Use

The complexity of the healthcare work environment, the high cognitive demands placed on clinicians, and inadequacies in design or implementation of HIT systems can all contribute to mistakes or misuse of HIT in practice settings. Potential safety issues related to use of HIT systems include alert fatigue (leading clinicians to ignore warnings and reminders); automation bias (*i.e.*, following system orders even when they contradict the

clinician's training and other available information); inappropriate use of copy-and-paste functionality (risking creation and perpetuation of outdated, inaccurate, or redundant information); introduction of workarounds for features or tasks that are perceived to be inconvenient or inefficient; and errors in entry or interpretation of information due to misunderstanding or misuse of software features.[29,30, 31]

There is a high degree of overlap and interaction between these areas, and a wide, complex network of factors influencing the behavior and performance of people, systems, and organizations involved in the HIT enterprise. Detecting and preventing HIT-related safety events is challenging because these are often multifaceted events, involving not only potentially unsafe technological features of electronic health records, for example, but also user behaviors, organizational characteristics, and rules and regulations that guide most technology-focused activities. As a result, the extent to which health IT may have caused or contributed to medical errors is often unclear.[32]

Approaches to Assessing the Benefits and Safety of HIT

To aid researchers, policymakers, and other stakeholders in comprehending the complex web of interactions involved in the design, implementation, and use of health information technology, a number of theories, conceptual frameworks and methodologies have been developed or applied to aid in understanding and addressing the interaction between people and HIT, many focusing specifically on the safety implications of this relationship (See **Appendix E**).

Role of Human Factors in HIT Safety

Human factors issues are increasingly viewed as the core of many of the benefits and problems with HIT. Human factors and ergonomics (HFE) is a discipline addressing the cognitive, physical and organizational elements involved in systems and system design.[33] HFE approaches have been of growing interest in the field of patient safety, as safety events are frequently influenced by cognitive (e.g, cognitive overload, decision fatigue), physical (*e.g.*, inadequate or poorly designed tools or work environments), and organizational (e.g, hierarchical culture, delays in access to patient information) factors.

HFE acknowledges the cognitive, physical, and organizational limitations that influence human behavior and performance, and can thereby account for those limitations in system design.[34]

The incorporation of HIT into healthcare delivery introduces both opportunities and threats from an HFE perspective. While automation, decision support, quicker access to information, and other potential benefits of HIT can help to avoid errors, the design, implementation, and use of HIT introduce yet more layers of complexity to an already-complex system as well as additional opportunities for error, including data accessibility or integrity issues and human-machine interface flaws.

Sociotechnical Approaches to HIT Safety

The concept of a sociotechnical system has proven especially useful for describing the various factors influencing the safety and safe use of HIT. Building on HFE principles and other systems theory, sociotechnical models recognize that work systems are embedded in broader organizational and social contexts, and focus on improving the interactions among the various factors involved in an enterprise (people, processes, technologies, organizational and social environments) to optimize performance and meet needs across the system.[35]

A number of researchers have used sociotechnical approaches to analyze the safety issues posed by HIT.[36] Notably, Sittig and Singh have described an 8-dimensional sociotechnical model that further dissects the traditional domain of technology to identify specific HIT-related challenges and considerations.[37]

Sittig & Singh's sociotechnical model comprises eight dimensions of HIT Safety (see **Appendix F** for a visual diagram of the model):[38,39]

1. **Hardware and software:** The computing infrastructure required to run HIT applications
2. **Clinical content:** Data, information, and knowledge that is entered, displayed, or transmitted via HIT
3. **Human-computer interface:** Aspects of the HIT system that users can see, touch, or hear
4. **People:** The humans involved in the design, development, implementation, and use of HIT
5. **Workflow and communication:** The steps needed to ensure that each patient receives the care they need at the time they need it
6. **Organizational policies and procedures:** Internal culture, structures, policies, and procedures that affect all aspects of HIT management and health care
7. **External rules, regulations, and pressures:** External forces that facilitate or place constraints on the design, development, implementation, use, and evaluation of HIT in the clinical setting
8. **System measurement and monitoring:** Evaluation of system availability, use, effectiveness, and unintended consequences of system use

Sittig and Singh stress that the complex interaction and inter-dependence of these domains mean that none can be analyzed or addressed in isolation; the core purpose of the model is to understand the interactions and interdependencies between the domains. They also summarize a number of real-world applications of the model, indicating that their research and experiences suggest that the 8-dimensional sociotechnical model can be useful for analyzing safety issues in all phases of HIT design, implementation, use, and evaluation.

Sittig and Singh have also presented a three-phase framework for the development of EHR-specific patient safety goals (Sittig and Singh 2012), which forms the basis for ONC's SAFER Guide for EHRs.[40] This framework lays out three phases of EHR safety:[41,42,43]

- **Phase 1: Safe Health IT**
  - Addresses concerns unique to EHR technology, including data integrity, data confidentiality, data availability, and information transfer
- **Phase 2: Using HIT Safely**
  - Addresses concerns arising from failure to use EHRs appropriately (*e.g.*, alert fatigue and override) and from unsafe changes in workflow triggered by HIT (*e.g.*, 'workarounds')
- **Phase 3: Using HIT to Improve Safety**
  - Addresses efforts to optimize the use of EHRs to improve quality and safety and to proactively monitor and report on the safety and safe use of EHRs

The authors note that a focus on Phase 1 concerns may be more appropriate for new or recent adopters of HIT, who will need to ensure the safety and integrity of the technologies being adopted, while organizations that are more experienced with HIT are likely to be in better position to work toward improvement in all three phases. The authors also postulate that the three phases of EHR safety could be used as a framework for measurement and benchmarking of EHR-related safety performance.

Recognizing the value of the eight-dimensional sociotechnical model and the added utility of the three-phase framework for EHR safety, which helps to account for the changes in infrastructure and capabilities that occur as organizations transition from initial adoption of HIT to more sophisticated uses of the systems, Sittig and Singh, as well as Meeks and colleagues, have proposed a combination of these two models.[44,45] The authors suggest that the combined model facilitates analysis of HIT safety from a complex systems perspective—as organizations adopt and implement HIT systems, they evolve over time in terms of their 'sociotechnical' scale (*i.e.*, quantitative size), function, and structure (*e.g.*, interconnection of system elements). This evolution is mirrored in the three phases of EHR safety, and as organizations advance through those phases, the sociotechnical model can be used to identify, understand, and anticipate safety risks or opportunities unique to each stage of EHR use (See **Appendix G** for a visual diagram of the combined three-phase/sociotechnical model of HIT safety).

In another article, Sittig and colleagues lay out a framework for categorizing types of HIT-related safety concerns, including patient safety events that reached the patient, near-misses, and unsafe conditions.[46] The authors identify five main types of HIT-related safety concerns:

1. **HIT fails during use or is otherwise not working as designed.**
   - *The safety concern is directly attributable to the HIT.*
2. **HIT is working as designed, but the design does not meet user needs or expectations (*i.e.* bad design).**
   - *HIT is a contributing factor to the safety concern.*
3. **HIT is well designed and working correctly, but was not configured, implemented, or used in a way anticipated or planned for by system designers and developers.**
   - *These events are related to use of HIT rather than HIT itself, and may be referred to as configuration errors, 'workarounds' or incorrect usage.*
4. **HIT is working as designed, and was configured and used correctly, but interacts with external systems (*e.g.* via hardware or software interfaces) so that data are lost or incorrectly transmitted or displayed.**
   - *These events are inevitable due to the interactive complexity of tightly coupled systems. They are often referred to as HIT system interface safety concerns.*
5. **Specific HIT safety features or functions were not implemented or not available.**

The authors suggest these categories could form the basis for a nationwide HIT-related patient safety surveillance system, potentially being incorporated into the AHRQ Common Formats for Patient Safety Reporting.[47,48]

Conceptual Framework for Evaluating HIT Safety

After consideration of the various frameworks identified through the environmental scan, the HIT Safety Committee determined that a variation on the three-phase model proposed by Sittig and Singh[49] provided the best combination of simplicity and utility, and that it would be most helpful for framing the Committee's thinking about measurement and evaluation of the safety and safe use of HIT.

The central organizing principle of the three-level HIT quality and safety improvement model chosen by the Committee (see **Table 1**) is that the clinician, the patient, and others on the health care team are using HIT to optimize care for patients, and that systems should be designed, implemented, and continually assessed both

to ensure that HIT is being used as intended and to monitor safety. Continuous safety and quality improvement should be emphasized, with the goal of ensuring that the clinician has a foundation of safe HIT, that HIT is properly integrated and used within an organization to deliver safe care, and that HIT is part of continuous improvement processes to make care safer and more effective. The model was adapted using some of the concepts from Sittig and Singh's EHR-specific patient safety goals (ePSGs)[50] and Health IT Safety Framework,[51] and is aligned with the practices and principles discussed in the SAFER Guides for EHRs.[52] The purpose of the conceptual model is to serve as a way to categorize and conceptualize potential measurement concepts and gaps in the area of HIT safety, and to provide a framework for recommendations around future HIT safety measure development.

Table 1: Three-Level HIT Quality and Safety Improvement Model

Level 1 / Safe HIT: Addressing Safety Concerns Unique to Technology
A. **Data Availability** – HIT is accessible and usable upon demand by all care team members, including clinicians, patients, family members, and other authorized individuals.
B. **Data Integrity** – HIT data or information is complete, accurate and created appropriately and has not been altered or destroyed in an unauthorized manner
C. **Data Security** – HIT data or information is secure, protected, and available or disclosed only to authorized persons or processes
Level 2 / Using HIT Safely: Ensuring the Safe Use of Technology and Avoiding Unintended Consequences
A. **HIT System Usability** – HIT features and functionality are designed and implemented so that they can be used effectively, efficiently, and to the satisfaction of the intended users to minimize the potential for harm.
B. **Organizational Planning, Preparation, and Governance for HIT**
C. **Complete and Correct HIT Use** – HIT features and functionality are implemented and used as intended
D. **Surveillance and Monitoring** – As part of ongoing quality assurance and performance improvement, mechanisms are in place to monitor, detect, and report on the safety and safe use of HIT.
Level 3 / Improving Patient Safety: Using HIT to Make Care Safer
A. **Use of HIT to improve Patient Safety** – HIT is leveraged to reduce patient harm and improve safety
B. **HIT Facilitates Safe and Effective Patient Engagement**

Level 1 of the framework addresses safe HIT, meaning that HIT is designed and implemented in a manner that optimizes patient safety and actively addresses known and potential safety issues that are inherent to HIT software or hardware. This level includes the domains of data availability, data integrity, and data security.

Data availability refers to the ability of all care team members, including clinicians and patients or family members, to access information needed for patient care. Threats to data availability may include technical failure of a HIT system, causing system downtime, or failure of a system to properly communicate or receive information as designed and intended. Threats to data integrity may include data corruption, causing information to be lost, damaged, or altered; data integrity may also be compromised by unintended duplication of information, including patient records, creating opportunities for confusion and error. Threats to data security could include the release or disclosure of information to unauthorized parties due to loss, theft, or hacking of data.

Level 2 of the framework addresses the safe use of HIT, which includes issues related to the implementation, configuration, use, and governance of HIT systems. This level comprises the domains of HIT usability, organizational planning, preparation, and governance for HIT, complete and correct use of HIT, and surveillance and monitoring of HIT for safety concerns.

The domain of HIT usability includes the quality and characteristics of HIT user interfaces (*e.g.*, screen displays should be clear, accessible, and understandable), the HIT system's capabilities (*e.g.*, whether the system supports and enables critical tasks), and other issues. Usability may be affected by system design (a Level 1 concept), but also by the ways in which HIT hardware and software are implemented and configured by the healthcare organization, and how well clinical workflow is aligned with HIT design and capabilities. The organizational planning, preparation, and governance for HIT domain addresses the structures, processes, and procedures healthcare organizations have established to ensure the safety and safe use of HIT, which may include HIT procurement, preparation for HIT installation and implementation, disaster and/or emergency planning, user training, and other activities. Complete and correct use of HIT addresses whether the features and functionalities of HIT, including clinical decision support and alerts, computerized provider order entry, and other elements of HIT are being implemented, configured, and used in a way that ensures patient safety at both the facility and the clinician (*i.e.*, end-user) level. Threats to complete and correct use of HIT include improper configuration of clinical alerts (potentially leading to 'alert fatigue'), inappropriate response to alerts by clinicians, the presence of order sets for common tasks or conditions, use of free-text order entry when coded items are available, failure to use clinical decision support, and other issues. The surveillance and monitoring domain addresses the need for vendors and healthcare organizations to have effective mechanisms and processes in place to monitor for HIT-related safety issues, and to address and report any identified risks, hazards, or events.

Level 3 of the framework focuses on the ways in which HIT can be used to improve the safety of patient care and to facilitate meaningful and effective patient engagement.

HIT has the potential to advance patient safety in a variety of ways, including improvements in medication reconciliation, medication adherence, care coordination, and risk identification. HIT can be used to help facilitate evidence-based best practices through well-designed clinical decision support, and can enable safer and more patient-centered care by providing clinicians with access to important data so that each decision is made with full knowledge of prior care and the patient's wishes. HIT may also be used to predict and facilitate intervention for patients who are at risk for particular issues (*e.g.*, readmissions or postoperative complications). Beyond improving clinician performance, HIT can also enable patients to become more engaged in their care

through technologies such as patient portals, allowing patients to learn more about their care, facilitating shared decision-making, and providing a mechanism for patients to provide feedback and input on both their care and their medical records. As technology evolves, it is likely that new and unforeseen functions of HIT may emerge to help facilitate care, but also may introduce new patient safety issues that need to be addressed.

Because of the complex interactions between design, development, implementation, and use of HIT systems, multiple domains of this framework will likely apply to any given HIT safety issue. This is appropriate, as HIT safety concerns are frequently multidimensional, and thus require multidimensional approaches. For example, issues related to HIT system usability will likely require both Level 1 solutions (*i.e.*, improvements in hardware or software design) as well as Level 2 solutions (*i.e.*, improvements in system configuration and workflow design).

Input from the AHRQ Common Formats Expert Panel

Established by the Patient Safety and Quality Improvement Act of 2005, the Common Formats for Patient Safety Reporting is a program administered by the Agency for Healthcare Research and Quality (AHRQ) to enable reporting of patient safety events, hazards, and near-misses in standardized formats and with confidentiality protections.[53]

The Common Formats include the ability to report events that are related to HIT. To ensure that the HIT safety framework was consistent with the Common Formats and that all relevant considerations were being addressed, NQF facilitated review of a draft version of the framework by the Common Formats Expert Panel, which provides input to AHRQ on the Common Formats and makes recommendations for addressing public comments submitted on the Formats. The Expert Panel reviewed the chosen framework and provided feedback to the HIT Safety Committee for consideration.

Common Formats Expert Panel members noted that their activities are complementary to the HIT Safety Committee work, and that the three-level HIT quality and safety improvement model was well-aligned with the forms available for reporting HIT-related safety events.

The Expert Panel also noted that patient safety events rarely present themselves in neatly digested packages that fit precisely into a framework. In the case of HIT-related events, errors are often the result of a complex interaction between the human and the computer system, and many such events do not present as being HIT-related initially. Rather, such errors typically manifest as medication errors, wrong site surgeries, or delays in treatment as opposed to HIT-related errors, only being reclassified later as information emerges. Root cause investigation and analysis is often needed to fully understand an HIT-related event. However, many organizations often do not have the expertise needed (*e.g.*, informatics, human factors, ergonomics) to conduct these investigations properly.

Some Expert Panel members suggested that healthcare should move toward systems with capacity to synthesize data elements and be predictive (*e.g.*, analyzing patterns of data to alert system users of potential concern). It was noted that the ability of HIT systems to actually predict or identify problems before they occur and present to clinicians is an area that has not received enough emphasis. During discussion of the Common Formats Expert Panel's feedback, HIT Safety Committee members observed that automatic reporting of safety events from the EHR is probably a long way off, given the complexity of these events. However, use of EHRs as a way to detect

events as they are happening so that humans could recognize them and analyze them is likely to be more feasible in the short term. Some Committee members expected that, over the next ten years, we should expect to see the evolution of voluntary reporting systems that can heavily leverage data from the EHR, allowing people to validate information and then import the data into reporting systems. Committee members noted that much of the most effective and important learning in this area is taking place at a local level. The Committee noted that HIT safety measurement and reporting efforts will need to consider healthcare organizations' existing internal risk management and event reporting systems, given that these are often electronic systems that have been in place for a long time, and there may be reluctance to change internal taxonomies for the purposes of external reporting.

Common Formats Expert Panel members noted that patient identification errors (*e.g.*, ensuring that the correct patient record is before the clinician) are an important concern and should be addressed through HIT safety measurement efforts.

The Expert Panel also recommended consideration of HIT system uses that could facilitate patient engagement; *e.g.*, patient adherence to treatment plans to reduce returns to the emergency department, readmissions, and errors in taking medication. The Panel suggested that patient engagement should be an important focus of measurement.

The Expert Panel also noted that there is a cost associated with achieving higher levels of patient safety surveillance, measurement, and reporting, and that this will be an important consideration for implementation efforts.

AHRQ is currently considering updates and enhancements to the Common Formats, and suggested that the agency and the Expert Panel will reflect on how the HIT Safety conceptual framework can inform those efforts. HIT Safety Committee members noted that future iterations of the Common Formats, as well as HIT safety efforts, should examine information technology related to telemedicine, which is quickly emerging as a common use of technology in healthcare and will need to be considered from a patient safety standpoint.

Key Areas of Measurement for HIT Safety

Informed by the environmental scan and Common Formats Expert Panel input, The HIT Safety Committee engaged in a process of identifying and then prioritizing measure concepts over two in-person meetings in Washington, D.C., several conference calls, and through a final vote to identify the highest-priority measurement areas.

The initial in-person meeting was held on February 18-19, 2015 and included a presentation of the environmental scan and a general discussion of issues in HIT safety, and how to translate these concepts into potential measures. The group discussed which conceptual frameworks would be most appropriate to help categorize measures; this would ultimately serve as an overarching framework for presenting the measure concepts for consideration and prioritization. The group engaged in a brainstorming exercise where potential measure concepts were identified. This process yielded 114 measure concepts, which were then further processed by staff and combined where appropriate to yield a list of 108 measure concepts (included in

). These served as the basis for discussion and further prioritization at the second in-person meeting, which was held on September 16-17, 2015.

At the second meeting, Committee members were divided into four breakout groups, with each group assigned a subset of the HIT safety measure concept list. The overall goal for each group was to identify the five highest priority measure concepts from their assigned list. Each group first conducted a review of the assigned measures to determine if measure concepts could be eliminated or where concepts needed to be added. Each group then rated each of the remaining measure concepts on two domains: importance and feasibility. These criteria were chosen because of their relevance to prioritization of measure concepts for future development, and because these criteria could form the basis of an initial assessment without the need for detailed specifications. Importance was rated on a scale of High, Moderate, and Low. When assessing the importance of a measure concept, the Committee was instructed to consider the degree of impact on patient safety (*i.e.,* if a vendor, organization, or clinician had poor performance on this measure, what would be the effect on patient safety?), the evidence supporting the measure (*i.e.,* what is the strength of evidence that this measure concept reflects real and meaningful concerns related to the safety and safe use of HIT systems?), and "actionability" (*i.e.*, the likelihood that measuring this issue will drive changes in organizational or individual behavior). Similarly, feasibility was rated on a scale of High, Moderate, and Low. When rating the feasibility of a measure concept, the Committee was instructed to consider the availability and ease of capturing data (*i.e.* is this concept something that can be defined and specified in such a way that it could be measured consistently and accurately across measured entities?) and the potential readiness of organizations to tackle the problem (*i.e.*, would it be reasonable to expect organizations or individuals to have the resources and capabilities necessary to address the issue in question?). Each breakout group used these criteria to inform their selection of five measure concepts to present to the full Committee for further consideration and discussion.

The full Committee then worked collectively to consolidate, refine, and modify the resulting measure concepts through discussion and real-time editing of the concepts under consideration. Through this process, the Committee identified eleven key measurement areas, each of which included several measure concepts that could potentially reflect performance in that area. The Committee also worked to identify possible data sources or data collection strategies for each measurement topic, as well as the entities that could potentially be held accountable for performance in each area.

After the in-person meeting, the Committee conducted a final vote on prioritization of the key measurement areas using an online survey instrument, ranking each measurement area against the criteria of Importance (High/Moderate/Low) and Feasibility (High/Moderate/Low). In addition, each Committee member voted for their top five measure concepts and provided additional feedback about measurement issues and challenges for each area. NQF staff reviewed this information along with write-in comments from the Committee and, based on these recommendations and Committee input, consolidated several of the measurement areas, resulting in a final list of nine key measurement areas.

The final prioritized list of key measurement areas for HIT safety, in order from highest to lowest priority, is as follows:

1. **Clinical Decision Support**
2. **System Interoperability**
3. **Patient Identification**
4. **User-Centered Design and Use of Testing, Evaluation, and Simulation to Promote Safety across the HIT Lifecycle**
5. **System Downtime (Data Availability)**
6. **Feedback and Information-Sharing**
7. **Use of HIT to Facilitate Timely and High-Quality Documentation**
8. **Patient Engagement**
9. **HIT-Focused Risk-Management Infrastructure**

Details of the Committee's discussion of each area are included below.

1. Clinical Decision Support (CDS)

CDS is one of the most promising functionalities of HIT, providing clinicians with tools to analyze patient data and guidance in making critical decisions at the point of care. However, clinical decision support that is poorly-designed or configured improperly can be disruptive to care and has the potential to threaten patient safety. A well-documented safety concern related to CDS is "alert fatigue," where clinicians receive such a high volume of alerts that they begin to ignore them, even though those alerts may be flagging possible safety risks. Information overload was also an issue mentioned by Committee members. It is important that CDS is designed and implemented in a way that makes it relevant and helpful without overwhelming clinicians with unnecessary alerts or excessive information. At the same time, it is also important for clinicians to use clinical decision support as intended and to respond to alerts and other CDS-generated information appropriately, so that the full potential of HIT to improve the safety and effectiveness of patient care may be realized.

The Committee agreed that measuring the quality of CDS is important to ensuring HIT safety. The Committee agreed that measurement of CDS should address the appropriateness and timing of alerts, the appropriateness of clinicians' responses to those alerts, and monitoring of CDS content to ensure it remains useful, clinically relevant, up-to-date, and free of errors, particularly for high-risk situations. The Committee pointed to the ONC's SAFER Guides for EHRs, which include a set of recommended practices around the safe design, configuration, and use of CDS, as well as a number of CDS-related safety indicators that could be further developed for the purposes of performance measurement. It was noted that the Leapfrog EHR 'Flight Simulator' could also be used as part of measurement around CDS safety and effectiveness. The Committee also expressed a strong interest in leveraging CDS to aid in scoring or assessing risk, potentially helping to predict high-risk events such as falls or hospital readmissions and to determine when and how to intervene. Committee members noted that these were still somewhat aspirational goals to look toward as the tools and the evidence evolve.

Accountability for ensuring appropriate functionality, design, implementation, and use of CDS systems should be shared across stakeholders. Data sources could include the EHR or EHR metadata. Committee members noted that Stage 2 of Meaningful Use includes requirements related to the implementation and use of CDS systems, and that this could provide a framework within which measurement could be implemented. In addition,

Committee members also observed that alarm management is already an important priority for many organizations, increasing the feasibility of measurement in this area.

Measurement Related to Clinical Decision Support			
Potential Measure Concepts	• % of alerts that occur at the right time, for the right person, in the right context, and are useful • Instances of inappropriate alert overrides (# of patient allergic reactions/# of overrides that would be harmful – could have a simulation component) • % of alerts for situations that do not warrant alerting • Alert rate (as % of either total orders or of # of total patients) • SAFER guide metrics on CDS; Leapfrog simulator results • Monitoring of content for CDS based on new evidence or errors in CDS		
Accountable Entities	Vendor; Facility; Clinician		
Potential Data Sources	EHR; EHR metadata; SAFER Guide Assessments		
Primary Framework Domain	2C: Complete/Correct HIT Use		
Other Applicable Framework Levels	2A: HIT System Usability 2B: Organizational Planning, Preparation, & Governance for Health IT 3A: Use of HIT to improve Patient Safety		
Committee Ratings	*High*	*Moderate*	*Low*
Importance	**17**	5	0
Feasibility	**14**	6	2

2. System Interoperability

Interoperability of HIT – defined as the ability of IT systems and software to communicate with each other through data exchange and to allow the use of exchanged information – is important to patient safety and quality of care. Complete information about a patient's care enables more informed and cost-effective decisions about medical care, and reduces the likelihood of conflicting treatment plans.[54] Healthcare is frequently delivered and managed across multiple providers and locations, and it is critical for patient medical histories and treatment records to be available to the right people at the right time. Ensuring information is available and shared between systems may significantly reduce the likelihood of communication-related problems in treatment decisions. Currently, many EHRs are not interoperable within and across health systems, and problems often emerge from the interfaces between EHRs and other clinical systems, such as lab information systems. Recognizing the importance of interoperability to quality and safety, as well as the existence of significant gaps in interoperability, the Committee agreed that this would be a high-priority area for measure development.[55]

With regard to measurement of interoperability, the Committee focused on availability of information for clinical decision-making. Committee members noted that failures in communication (*e.g.*, failure of a provider to receive abnormal test results or allergy information) are among the leading causes of patient safety events, and that a lack of system interoperability can also lead to delays in treatment or wrong patient/wrong procedure problems. Measurement in this area could involve structural measures, possibly assessing whether systems have the ability to communicate and exchange specific types of data; interoperability could also be assessed using process measures, such as the number of times diagnostic test results are unavailable when needed. The Committee stated that if the availability of information were to be measured, there should be consideration of whether that information was expected to be available—if a system was not designed or configured to exchange certain data, it would be inappropriate to measure whether or not those data were available. The Committee also noted that both internal and external interoperability were important areas of measurement.

While Committee members agreed that interoperability is important to ensuring HIT safety and effectiveness, some also suggested that assessing interoperability may be a challenge, and that measurement in this area may yield information that has limited "actionability." Improving interoperability depends not only on actions and interventions by organizations and IT vendors across diverse internal systems—challenging tasks in their own right—but also on a wide range of external factors, including the cooperation and performance of other healthcare providers, the existence of regional databases facilitating information exchange, and the legal, policy, and regulatory environment. However, Committee members stressed that interfaces can be improved, and that their ability to exchange information can be measured. Potential ways of collecting information on effective interoperability include surveys of users to assess how often the lack of interoperability was a barrier to medical care, assessment of help desk reports, and information provided by vendors. In addition, other measures could be developed that would gather data from providers or the EHR itself at the point of care. Some Committee members argued that measures should be focused on known patient safety hazards (*e.g.*, the lack of availability of prior stress test results in patients with chest pain).

Measurement Related to System Interoperability			
Measure Concepts	• Number of times diagnostic test results not available, transmitted, or displayed for the clinician or patient group as expected as a result of a problem at the interface between two different clinical HIT systems • The extent to which meaningful external data is available to make diagnosis or management decisions (*e.g.*, % of completed transactions between any two systems)		
Accountable Entities	Vendor; Facility; Other (*e.g.*, Regional)		
Possible Data Sources	EHR; User surveys; Help desk reports		
Primary Framework Domain	1A: Data Availability		
Other Applicable Framework Domains	2B: Organizational Planning & Preparation		
Committee Ratings	***High***	***Moderate***	***Low***

Importance	15	7	0
Feasibility	6	**14**	1

3. Patient Identification

Among the patient safety concerns that have emerged with increasing use of EHRs is the issue of accurate and reliable patient identification. Potential safety issues related to patient identification include the creation of duplicate patient records within an organization's system, 'overlay' of a patient's information into the wrong patient's record, orders entered for the wrong patient, and care delivered to the wrong patient because of problems with identification. Wrong-patient errors have been identified as being among the most common human-computer interface issues.[56] Patient identification errors are of particular concern in the context of EHRs, as once wrong information is introduced into a system it may spread across other systems and affect other encounters, having cascading effects and creating additional opportunities for error. Committee members noted that identifying the right patient is one of the most important components to patient safety, and that errors in this area have the potential to cause catastrophic events.

Because of the safety risks in this area, the Committee agreed that patient identification was an important area for measurement. NQF is currently reviewing a measure related to patient identification (NQF #2723: Wrong Patient Retract and Reorder (WP-RAR)) through its endorsement process; this measure assesses the number of times an order was entered on the wrong patient, then retracted and reordered on another patient within a 10-minute period of time. These events can happen when physicians are entering orders and mistakenly order care for the wrong patient, and are generally considered to be HIT-related errors. In addition to this measure, the Committee discussed other potential measures around patient identification, including the proportion of duplicate patients within an EHR. Duplicate records can occur when several accounts are created for the same patient, which can confuse clinicians because important information may be missing from some of the accounts. Measurement in this area is supported by the American Health Information Management Association (AHIMA),[57] and could include both facility-level and enterprise-level (*i.e.*, across multiple healthcare organizations) rates of duplicate patient records.

The Committee suggested that accountability for patient identification could be shared across all stakeholders, including vendors, healthcare organizations, clinicians, and even patients. Each stakeholder can take an important role in ensuring that patients are accurately identified, duplicate records are merged, and systems are designed to detect and remediate patient identification problems. Committee members did caution that patient accountability would need to be framed and implemented carefully, with consideration that patients are often ill and vulnerable. The Committee generally agreed that measurement in this area is feasible, with some noting that tools related to patient selection and monitoring have improved dramatically. However, some Committee members questioned whether measurement of patient identification could be implemented consistently and accurately across institutions, and others suggested that even when identified, the causes of patient identification errors can be difficult to correct.

Measurement information could come from a variety of sources, including directly from EHR or from monitoring of administrative data. Some Committee members suggested that wrong-patient errors that affect the patient could be considered sentinel events.

Measurement Related to Patient Identification			
Potential Measure Concepts	- Percentage of potential duplicate patients in EHR - Retract-and-reorder tool - Use of barcode scanning in medication preparation and administration % of incorrect patient ID alerts in barcode medication administration) - Record overlay (>=2 different patients; info in the same record): # of chart corrections - AHIMA Measures[58]: - Facility-level rate of duplicate patient records (for static database) (Total # of individual duplicate pt. records * 100)/(Total # of pt. records in the MPI[59] database) - Facility-level rate of duplicate record creation (Total # of individual duplicate pt. records for a given time period * 100)/(Total # of registrations, preregistration, or scheduling events for the same time period) - Enterprise-level overlap (across-facility duplicate) rate (Total # of individual overlap[60] enterprise patient records * 100)/(Total no. of unique patient records across two or more MPI databases (*i.e.*, facilities))		
Accountable Entities	Vendor; Facility; Clinician; Patient		
Potential Data Sources	EHR; Administrative Records		
Primary Framework Domain	1B: Data Integrity		
Other Applicable Framework Levels	2B: Organizational Planning, Preparation, & Governance for HIT 2C: Complete/Correct HIT Use 2D: Surveillance and Monitoring of HIT		
Committee Ratings	*High*	*Moderate*	*Low*
Importance	**18**	3	1
Feasibility	**17**	5	0

4. User-Centered Design and Use of Testing, Evaluation, and Simulation to Promote Safety Across the HIT Lifecycle

The importance of user-centered design was a major focus of the Committee's discussion. Better-designed systems that are more user-friendly could potentially reduce error rates and make care safer, and Committee members agreed that user-centered design is essential for safe and effective HIT. Usability testing for both

evaluation and user-centered design is important to achieving these goals.[61] Another key means of promoting user-centered design is through simulation.[62] Using simulation, safety issues related to the overall design of the system and its local implementation may be detected not only during production and prior to implementation, but also during upgrades or periodic evaluations as part of an iterative development cycle.

The Committee discussed a range of potential measure concepts related to user-centered design. Committee members observed that there are existing standards for user-centered design that could be used to assess EHRs or the use of EHRs within healthcare organizations. In addition, there could be measures of whether and how end-users were involved in the lifecycle of HIT from design and development to implementation and use. There could also be surveys of usability that could be administered to users, which may include the concept of usability in the context of patient safety. Specifically, the degree to which the design of the system may make errors more or less likely to occur was an important concept.

Committee members acknowledged that usability issues – including burdensome data entry requirements – often lead to workarounds and incomplete or inaccurate data, and that they may be correlated with patient safety issues. The Committee expressed an interest in identifying potential measures that could assist in the identification of workarounds, their causes, and their risk to patient safety. Several examples were discussed by the Committee, including the length of time that passes between patient encounters and chart documentation, and the extent to which scribes and/or dictation systems are being used; the Committee thought these could be indicators of usability issues requiring workarounds.

ONC released a set of certification and meaningful use requirements for EHRs for stage 2 of Meaningful Use. These require that EHR vendors include evidence of user-centered design and user test results in their certification submission. To be able to obtain the ONC certification (and Meaningful Use funding) EHR vendors must follow a formal User Centered Design process and perform summative usability testing on specific areas of the product. Given this existing framework, quality measurement could be incorporated as part of this process.

The Committee agreed that both user-centered simulation and organization/system-centered simulation could be important areas for measurement. Simulation creates needed awareness of potential safety risks or vulnerabilities in processes, workflows, and HIT systems, and creates opportunities to address those issues proactively. User-centered simulation—the use of simulation to test end users' ability to use HIT safely and effectively—could be measured as the proportion of users who are tested on a simulator, such as the Leapfrog flight simulator. User competency scores on simulation testing could also be reported as a measure of quality. Organization- or system-centered simulation would focus on an organization or vendor's use of simulation to inform design and implementation of HIT. This could be approached by assessing whether testing/simulation of systems is performed to identify potential HIT-related safety risks or problems, and whether it is performed across the HIT 'lifecycle,' from design and development through implementation, use, and evaluation. In addition, the results of simulations themselves could be used to measure and evaluate the impact of systems on user workload or the degree to which workarounds were employed during a simulation.

Because simulation should be used in various ways across the HIT lifecycle, accountability could be applied to all parties involved in that lifecycle. Clinicians could be measured on their participation or performance during a simulation; healthcare organizations could be measured on whether and how they conduct simulations, or the performance of clinicians; vendors could be held accountable for the use of simulation during the development

of HIT systems. Data around the use of simulation could be derived from attestations or directly from simulators (*e.g.*, whether simulation was used, and what the results of the simulation were).

Accountability for usability and user-centered design should be shared between vendors, who are responsible for designing usable systems and ensuring involvement of end-users in that process, and facilities, who are responsible for ensuring that systems are implemented and configured in a manner that makes them usable in a local context. Committee members noted that a standardized approach to usability is necessary for meaningful and comparable measurement, and recently-released NIST guidelines should help in this area.[63] Data on usability and user-centered design could be gathered from surveying users, surveying designers, from administrative documents, or through analysis of simulation data. The Committee thought that measures of usability and user-centered design would need to be coordinated with ONC and NIST.

The Committee noted that measurement around simulation could include specific elements such as training, competency evaluation, usability evaluation, workflow analysis, and sociotechnical analysis at both the user and organizational levels. Some Committee members suggested that measures related to simulation should focus on specific high-risk scenarios; others cautioned that promoting the use of simulation might be better handled through accreditation or regulation rather than performance measurement. From a feasibility perspective, some noted that development of simulation and training programs is likely to require substantial financial and human resources, and may be more difficult for providers to implement than some of the other measure concepts under consideration. In addition, it may be challenging to measure the effectiveness and adequacy of simulations; some Committee members noted that human factors experts should be involved in order to derive the greatest benefit from these activities, but suggested that such expertise may be in limited supply.

Measurement Related to User-Centered Design and Use of Testing/Simulation to Promote HIT Safety	

Potential Measure Concepts	• Use of existing standards for user-centered design
	 • End user involvement in lifecycle (design, development, implementation, use, evaluation) of HIT
	 • Testing conducted to assess usability
	 • Usability evaluation that promotes patient safety
	 • Assessments for the use of increasing EHR usability during all phases of the lifecycle for the purpose of increasing patient safety
	 • Use (or inappropriate use) of scribes and dictation systems
	 • User-centered simulation
	     ○ % of users that are tested in a simulator (*e.g.*, Leapfrog flight simulator)
	     ○ User competency scores on simulation testing (overall scores and by test category) (user-slide)
	 • Organization/system-centered simulation
	     ○ Testing/simulation of systems are being used to identify potential HIT risks or problems is conducted across the lifecycle (design, development, implementation, use, evaluation)
	     ○ Workloads and workarounds in simulation

Accountable Entities	Vendor; Facility; Clinician		
Potential Data Sources	Surveys; Administrative data; Attestations; Simulation data		
Primary Framework Domain	2A: HIT System Usability		
Other Applicable Framework Levels	2B: Organizational Planning, Preparation, & Governance for HIT 2C: Complete/Correct HIT Use 2D: Surveillance and Monitoring of HIT		
Committee Ratings	*High*	*Moderate*	*Low*
Importance	**15**	7	0
Feasibility	8	**9**	4

5. System Downtime

When EHR systems are implemented, clinical care processes become highly dependent on their effective functioning. If and when systems are unavailable for periods of time, this is referred to as "downtime."[64] Downtime can occur in a scheduled manner, where it is planned in advance and required to improve the functioning of the system (*i.e.* system patches or new software), but it can also occur unexpectedly due to data corruption, system failure, or other events, requiring rapid changes to clinical processes in real time and threatening patient safety.[65] During episodes of downtime, providers may implement alternative systems (*e.g.*, use of paper charts) for record keeping, patient billing, and clinical order entry, which can be highly disruptive to clinical care. Committee members stressed that functioning EHRs are "mission-critical," underscoring the importance of downtime prevention and mitigation.

Committee members noted that downtime cannot be totally avoided, so it is important for organizations to have backup or redundant systems in place. Having multilevel, overlapping systems that work both together and in isolation to protect EHR data in instances of downtime can ensure that clinicians have access to needed information. In addition, healthcare organizations must be able rapidly coordinate and support ongoing patient care processes in the event of unexpected downtime. Comprehensive and effective disaster or emergency planning can help reduce the disruptive impact of downtime.

With regard to measurement of system downtime, the Committee contemplated measures around the frequency and length of unexpected downtime as well as organizational preparedness for inevitable downtime events. Committee members discussed the degree of specificity that should be applied to downtime measures (*e.g.*, should downtime be measured only if it exceeds a certain amount of time?) The severity of a downtime event may be exacerbated by its scope (*i.e.*, whether it is widespread or localized to a specific system), its duration, and its setting. For example, in the emergency department or operating room, downtime even for a short period can be very disruptive, while in other settings unexpected downtime could occur for longer periods

with less disruption of clinical care. Accordingly, timeframes applied to downtime measures could be context-specific. Committee members agreed that regardless of its length of time, the occurrence of any downtime affecting clinical care should be captured in measurement.

 The Committee also discussed measuring the number of times that downtime procedures are activated. If downtime occurs only for a short period of time and does not require downtime procedures (such as temporary transition to paper documentation), this was seen by the Committee as less disruptive. Structural measures around downtime and organizational preparedness could include the presence of a disaster preparedness plan supporting patient care processes and billing during downtime, and the frequency of downtime drills or downtime risk assessments. Measures developed in this area should be consistent with applicable accreditation requirements. Committee members suggested that measurement around downtime preparation should include preparedness drills and potentially audits or inspections, such as those conducted by The Joint Commission, rather than simple attestation that appropriate polices are in place.

In general, the Committee agreed that measurement of system downtime is highly feasible and salient to HIT safety and quality; downtime events are usually detectable, although capture of information may be delayed in some instances. Data sources for downtime measurement could include the EHR itself, surveys, administrative records such as system logs, and audits or inspections. The Committee agreed that there should be shared accountability for downtime between the vendor and the facility, and that this could be an appropriate basis on which to compare the performance of institutions and vendors. Some Committee members observed that it can be expensive to maintain a high level of data protection and availability; with competition for available funds at healthcare organizations, this could be a potential barrier to performance.

Measurement Related to System Downtime	
Potential Measure Concepts	- Unexpected downtime affecting clinical care (timeframe may be context-specific) - Frequency and length of time - Response time greater than mean of 15 seconds (as proxy for functional downtime) % system uptime or availability (ideally >99.9%) - Number of times that downtime procedures are activated - Availability of disaster preparedness plan supporting patient care processes and billing during downtime - Frequency of downtime drills (consistent with regulatory and accreditation requirements) - Frequency of downtime risk assessment (consistent with regulatory and accreditation requirements)
Accountable Entities	Vendor; Facility
Potential Data Sources	EHR; surveys; administrative records; audits and/or inspections (*e.g.*, by accreditation bodies)
Primary Framework	1A: Data Availability

Domain			
Other Applicable Framework Domains	1c: Data Security 2B: Organizational Planning, Preparation, & Governance for HIT		
Committee Ratings	*High*	*Moderate*	*Low*
Importance	14	6	2
Feasibility	17	4	1

6. Feedback and Information-Sharing

EHRs can sometimes experience patient safety problems that are identified by an institution or by a vendor. Because EHRs are a rapidly evolving technology, it is vital to publicly share "lessons learned" and solutions about patient safety problems across the user community. Meaningful feedback and information-sharing among vendors, users, and healthcare organizations supports and enhances the safety and safe use of HIT. This information sharing should occur in a timely manner to permit institutions and clinicians to understand EHR patient safety problems that have occurred in other settings in order to prevent and mitigate similar errors. Committee members raised concern that some vendor contracts contain broad non-disclosure and confidentiality provisions as well as other intellectual property protections which prevent certain EHR software information, including screenshots and comparative user experiences, to be publicly shared. The Committee believed that such contract terms should not be broader than reasonably necessary to protect the vendor's legitimate intellectual property interests when balanced against patient safety concerns. The Committee further believed that such provisions are in direct conflict with the goal of sharing patient safety knowledge for quality improvement purposes across settings.

The Committee considered a number of approaches to measurement in this area. For example, measures could assess whether and when vendors send notifications to all relevant institutions following identification of software, hardware, or other issues that materially affect patient safety. Measures could also evaluate the effectiveness of vendor user groups in identifying and sharing patient safety concerns, or assess the extent to which user experiences and other information relevant to HIT design and implementation are being shared freely and transparently across both vendors and user communities.

While vendor accountability is important in this area, Committee members agreed that accountability should still be shared between both vendors and healthcare organizations. It was noted that software license and hardware purchase agreements should support and facilitate information-sharing, and that both vendors and healthcare organizations bear some responsibility in this area; measures could potentially be developed to hold both vendors and healthcare organizations accountable for ensuring that such agreements are crafted in a manner to reflect that the party who has the most control over the factors giving rise to a particular HIT patient safety risk is in the best position to prevent and mitigate that risk, and thus is the one charged with responsibility for preventing or mitigating such risk in the agreement.

Data supporting measurement of feedback and information-sharing could come from vendor contracts, surveys of users, analysis of help-desk reports, or data from accreditation and certification bodies (ACBs). Some Committee members thought that measurement in this area could be challenging, requiring a high level of commitment and cooperation, and an infrastructure that may be lacking at the moment. Confidentiality issues may also pose a barrier. Others suggested that feasibility is high in principle, and that vendors in particular should be engaging in these activities to ensure customer satisfaction, but noted that a shift in culture may be needed. A number of Committee members felt that in comparison to some other areas, this may be a lower priority for measurement.

Measurement Related to Feedback and Information-Sharing			
Potential Measure Concepts	- Timely vendor notifications are sent to all organizational users following identification of software, hardware, or other issues that materially affect patient safety - Vendor provides solutions to identified patient safety risks and errors ASAP following event - Vendors share comparative user experiences across organizational users - Vendor user groups effectively identify and share patient safety concerns (could incorporate user feedback/survey information) - Free and transparent bilateral exchange of information about real-time comparative user experiences and issues with HIT design and implementation - Software license and hardware purchase agreements permit shared learning of comparative user experiences , timely vendor response to provider requests for information, and use of vendor product information in research studies for peer reviewed journals (*e.g.* screen shots) and promote shared accountability for HIT safety		
Accountable Entities	Vendor; Facility; Clinician		
Potential Data Sources	Vendor contracts; surveys; data from ACBs (accreditation and certification bodies); help-desk reports		
Primary Framework Domain	2D: Surveillance and Monitoring of HIT		
Other Applicable Framework Levels	2B: Organizational Planning, Preparation, & Governance for HIT		
Committee Ratings	*High*	*Moderate*	*Low*
Importance	**10**	**10**	1
Feasibility	6	**9**	5

7. Use of HIT to Facilitate Timely and High-Quality Documentation

Timely documentation and communication of information during care transitions is vital to ensuring patient safety. This is true even in the absence of HIT, but the rapid implementation of EHRs has created both new opportunities and new challenges. Committee members noted that ONC has identified care transition as one of the primary areas in which the EHRs can improve the quality of care. Good clinical documentation can facilitate transitions in care and ensure that diagnoses, medication lists, allergies, and other critical information is captured and communicated appropriately as patients move across care settings. Timeliness is similarly important, particularly for transitions in care that are immediate (*e.g.*, an emergency department patient being admitted to the hospital). Committee members agreed that HIT systems and associated workflows should facilitate the timely capture and transmission of high-quality clinical information, and that this would be an important focus for measurement efforts.

The Committee noted that there are a number of topics that could feasibly be addressed in the short-term, including the timeliness of documentation and transmission of clinical data, the timeliness of follow-up on diagnostic results, the quality of discharge information, and the use of structured or designated fields vs. the use of free text for documentation of active problems (*e.g.*, allergies, medications). This is an important issue for HIT safety because entry of information in free text fields rather than structured data fields may limit the extent to which that information can be exchanged and interpreted across systems.

The Committee also suggested that in the longer-term, measurement could help drive the use of HIT to facilitate medication reconciliation and adherence, for example through improved patient verification and use of patient portals or other technologies. Committee members noted that the HIT landscape is evolving rapidly, and that new opportunities for quality improvement and measurement in this area will likely emerge in the future.

Measures in this area could use information from EHRs, administrative claims, and pharmacy data. Some Committee members cautioned that measurement around care transitions and timeliness of documentation can be more difficult than expected, noting that the time-stamping of events can be problematic. In addition, ensuring that technology optimally supports clinical processes and workflows at patient handoffs and transitions remains a challenge for many organizations. It was noted that Stage 2 of Meaningful Use includes a number of measures around electronic transmission of summary care records for transitions of care and referrals, and could potentially serve as a vehicle for implementation of measures in this area.

Measurement Related to Documentation Quality and Timeliness	
Potential Measure Concepts	- Areas for immediate focus: - Timely clinical documentation and timely transmission of available clinical information at the transition of care (post-visit or time of referral) - Information available, sent, received, viewed % of patients in the hospital who have at least one progress note per day written within an established time period - Timely follow-up on diagnostic tests (*i.e.*, labs, imaging) as determined by manual or electronic audit - Follow-up may include: communication to patient, ordering necessary tests or documentation, or referral to

	other care providers
	• Time from result availability to outcome, (*e.g.*, communication to patient or clinician follow-up, clinician response) could be measured
	o Discharge and transition note quality (ie. Reason for referral) and completeness
	o Percent of [number] charts with allergies in free text vs. in structured or designated fields
	• Areas for future consideration:
	o Medication reconciliation performed, including patient verification either during the encounter or through technology (*e.g.*, patient portals or HIE if available)
Accountable Entities	Facility; Clinician
Potential Data Sources	EHR; Claims; Pharmacy
Primary Framework Domain	2C: Complete/Correct HIT Use
Other Applicable Framework Levels	2A: HIT System Usability 3A: Use of HIT to improve Patient Safety

Committee Ratings	*High*	*Moderate*	*Low*
Importance	**16**	6	0
Feasibility	8	**10**	3

8. Patient engagement

The Committee discussed patients' increasing ability to engage in their own care through technology, and agreed that this was emerging as an important area for HIT safety. Committee members agreed that patient engagement is an important component of health care, noting studies have shown that consumers who are engaged and vested in their health care plans tend to have more favorable health outcomes (especially when measured against the consumers' health goals). Particularly with the promulgation of patient portals, the usability, usefulness, and use of these portals should be a focus of quality measurement.

The Committee's discussion focused on the effectiveness of patient portals in facilitating patient engagement, and touched on a number of concepts that could serve as indicators in this area, including the rates of patients who use their portals to acknowledge test results, suggest corrections to their records, or to view, edit, or annotate their records. Other measure concepts focused on the structural characteristics of patient portals, such as patients' ability to view progress notes in their records, and the presence of mechanisms for patients to identify errors, omissions, or other potential safety concerns in their records. The Committee also suggested getting direct patient feedback on the usability and usefulness of portals through surveys; some raised the

prospect of incorporating additional HIT-related questions into Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys.

Committee members cautioned that patient portals are still in a somewhat nascent phase; many patients are not yet used to interacting with healthcare in this way and will need to be educated and empowered by those within the healthcare system to ensure that measurement of their engagement is interpreted accurately. In order for performance results to bring about meaningful change, it will be critical to drill down and examine those results in detail to see why patients are or are not engaging in their care. In addition, there are disparities in both access to and ability to interact with technology that will need to be considered for measurement in this area to be meaningful. Committee members also noted that with the evolution of technology and its use, the means by which patients engage with their healthcare providers will also evolve (*e.g.*, use of text messages vs. emails), and this will create challenges in establishing trend data over time.

Committee members agreed that multiple stakeholders should share accountability for the effective design, implementation, and use of patient portals.

Measurement Related to Patient Engagement	

Potential Measure Concepts	• Survey based measure of the patient and providers' experience with patient safety and technology
	• % of patient acknowledgement of diagnostic test results via patient-facing technology
	• % of patients who suggest corrections to the EHR information
	• % Patients viewing and annotating and editing the medical record
	    o Can patients view the information
	    o Do they view the information
	    o Do they annotate (*i.e.,* suggest corrections)
	• Ability to access and annotate the EHR
	• % of patient portals that include viewable patient progress notes – Open Notes Initiative
	• Respond to patient electronic communication (*e.g.*, telemedicine, portals) within 48 hours
	• Do patient portals have mechanisms to identify errors, omissions and other safety risks or problems and have corrections reflected in other clinical information systems? Includes HIT issues and other safety concerns
	    o Structural measure: Is feature present?
	    o Process measure: How often is feature used?

Accountable Entities	Facility; Clinician
Potential Data Sources	EHR; Claims; Pharmacy
Primary Framework Domain	3B: HIT Facilitates Safe and Effective Patient Engagement
Other Applicable Framework Levels	2A: HIT System Usability 3A: Use of HIT to improve Patient Safety

Committee Ratings	High	Moderate	Low
Importance	11	8	3
Feasibility	8	7	7

9. HIT-focused risk-management infrastructure

In order to ensure the safety and safe use of HIT, it is important that both healthcare organizations and vendors have a focused risk-management infrastructure in place that can rapidly address and remediate patient safety problems in real time. Health care organizations and small ambulatory practices in particular need tools to help them identify and assess patient safety risks attributable to HIT.

The Committee discussed a number of potential concepts for measuring the adequacy of organizational structures, policies, procedures, governance practices, and other activities related to HIT safety risk management. These include whether organizations use multiple sources to assess HIT risks to patient safety; whether organizations engage in formal processes to evaluate and respond to risks identified by other organizations; and the proportion of risk managers who received specific training from the Joint Commission on HIT safety. Committee members suggested that organizations should also be evaluated on whether key HIT safety metrics are shared with their governing boards; the sharing of such metrics illustrates the organization's culture and commitment to monitoring and responding to HIT-related safety risks, and demonstrates that HIT safety is an organizational priority.

The Committee agreed that accountability for having a HIT safety infrastructure would primarily rest with healthcare organizations; however, it is important for vendors to have similar mechanisms to rapidly respond to and remediate software or hardware issues that cause safety risks and problems. The data sources for these measures could come from SAFER guide assessments, security risk assessments, trigger tools, patient complaints, or even lawsuits.

Measurement Related to the HIT-focused risk-management infrastructure	
Potential Measure Concepts	- Organizations assess HIT risks to patient safety using multiple sources, such as IT help desk tickets, risk management information systems, trigger tools, patient complaints/corrections - Organizations engage in formal processes for evaluating and responding to risks identified by other organizations, such as PSOs, vendor user groups, and the published literature - EHR safety metrics shared with the governing board - Examples of such governing board metrics include: - EHR system uptime rates - Alert override and adjustment rates - Diagnostic test results either incorrectly reported or delayed in reporting - Results of network penetration testing to assess the confidentiality, integrity and availability of ePHI

	- Adherence to clinical decision support protocols - All EHR-related serious safety events - Open patient orders (*i.e.*, not acted upon by clinicians) after a set period - Changes in mortality rate following EHR system implementation - Serious EHR error fix rate % of risk managers who have received continuing education units (CEU) from The Joint Commission's safe HIT module (free)
Accountable Entities	Facility
Potential Data Sources	SAFER Guide Assessments; Security risk assessment; trigger tools; complaints; lawsuits
Primary Framework Domain	2B: Organizational Planning, Preparation, & Governance for HIT
Other Applicable Framework Levels	1C: Data Security 2D: Surveillance and Monitoring of HIT

Committee Ratings	*High*	*Moderate*	*Low*
Importance	**11**	8	2
Feasibility	**8**	7	6

Overarching issues

During the course of the Committee's deliberations, a number of overarching issues were identified:

1. HIT quality and safety should be a shared responsibility of clinicians, healthcare organizations, vendors, and in some instances, patients. Because of the complexity of HIT and the interconnected relationship among hardware, software, the local environment, and providers, it is vital for the quality and safety of HIT to be a shared responsibility across stakeholders. Much like any medical device, HIT is an instrument by which patient care is delivered and improved, but simultaneously can cause harm. Therefore, the responsibility for quality and safety problems should not fall disproportionately on one stakeholder, but rather should be shared among stakeholders that are in the best position to prevent and mitigate a particular patient safety risk and thereby control the intended and unintended consequences of HIT. The Committee reviewed a set of HIT safety-related measure concepts developed specifically for consideration in a shared risk environment, and incorporated aspects of these concepts into their recommendations; the full set of concepts can be found in **Appendix I**.

2. Many if not most HIT safety issues require attention and solutions across the full HIT lifecycle. The safety and safe use of HIT systems should be addressed continuously across the cycle of design, implementation, use, evaluation, and feedback. Problems are rarely isolated to any single stage of this cycle, regardless of where and

when they are identified; improving HIT safety must be part of an iterative development process that involves all stakeholders.

3. Many important measures of HIT quality and safety may be limited by feasibility considerations. Many of the measure concepts identified in this process were considered by the Committee to be of high importance but not immediately feasible given limitations in technology, data availability, and resources. As a result, measurement of some of these concepts may be a challenge for both measure developers and implementers. Measure developers and others may need to develop innovative strategies to gather data on concepts important to HIT safety measurement.

4. The increased data entry burden for clinicians and other staff needs to be considered as one of the most important, broad unintended consequences of HIT. The implementation of new HIT systems has often been accompanied by a significant increase in the amount of data that clinicians and other staff are required to enter into the EHR. This amount of data entry through user interfaces that may not be user-friendly can pull clinicians away from the bedside, and can require that providers spend many hours documenting charts during and after their shifts have ended. Increased data entry burden can lead to inappropriate workarounds, which can threaten or undermine patient safety.

5. Constantly evolving technology may be both a challenge and an opportunity for HIT measure development. Because HIT is an area of constant evolution and innovation, quality issues may be remediated or solved through new technology. Therefore, it will be important for measure developers to stay ahead of the curve by identifying not only current issues, but also anticipating future issues as new hardware and software are developed.

6. There are a variety of mechanisms through which HIT safety can be promoted. The Committee agreed that certain aspects of HIT safety could be addressed through performance measurement and reporting, while others may be better addressed by regulation of HIT or accreditation and certification mechanisms. In addition, there may be measure concepts that straddle multiple mechanisms. Developers should carefully consider the evolving regulatory, accreditation, and certification landscape as they generate new ideas and concepts for quality measures.

7. Addressing HIT safety problems can be costly, but it is important that healthcare organizations invest the resources required to address them. Because of the complex nature of HIT safety problems, it can be costly from both a time and capital investment perspective for healthcare organizations to address them. However, because HIT safety is such an important area for 21st century healthcare organizations, it is vital that this investment be made and sustained to ensure safety across the HIT lifecycle. This underscores the importance of creating useful measures of HIT safety which can be used to ensure organizations, vendors, and clinicians invest resources to address these issues in a timely and ongoing manner.

8. Many HIT safety issues are being addressed in other programs or initiatives and should be considered as measure developers work to develop new metrics in this area. For example, Stage 2 of Meaningful Use includes a number of requirements aligned with measurement goals identified by the Committee.[66] The Office of the National Coordinator for HIT (ONC)'s SAFER Guides are also closely aligned with measurement areas prioritized by the Committee, and offer tools to address issues as well as potential metrics for further development.[67] In addition, the National Institute for Standards and Technology recently released guidelines

around evaluating EHR system usability and promoting patient safety through standardization of EHR design elements.[68]

9. Current NQF criteria for endorsement may not be directly applicable to many HIT quality measure concepts. Currently, there are very specific criteria that must be met for importance, scientific acceptability, usability and feasibility in order for Committees to recommend NQF endorsement of quality measures. These criteria and related guidance have been primarily developed to assess structure, process and outcomes measures for clinical care. Because of the design and nature of HIT, many important measures of patient safety may not fit into these algorithms, particularly with respect to evidence (*e.g.*, the link between HIT-related structures or processes and relevant outcomes) and standards for measure testing. For these reasons, the Committee thought that NQF should contemplate adapting the current criteria to include specific considerations for measurement of HIT safety issues.

The Path Forward

The implementation and use of HIT holds great promise for the overall improvement of healthcare quality in the United States. However, in order for this promise to be fully realized, patient safety must be a primary focus for every stakeholder involved in the design, development, implementation, and use of HIT systems as those systems become increasingly integrated into all aspects of patient care. The work of this Committee is intended to help advance this goal through the creation of a conceptual framework for measuring and addressing HIT safety, and through the identification of key measurement areas and measure concepts that may help to ensure the safety and safe use of HIT systems.

Given the current lack of existing measures for HIT safety, there will be a need for additional research relating the best ways to assess the safety and safe use of HIT, and coordinated measure development efforts focused on the areas that are most important and impactful for patient safety. This report can serve as a basis for continuing efforts to develop measures that can be incorporated throughout the HIT lifecycle as part of an iterative development process; through this iterative process, a knowledge base may emerge to inform future quality and safety improvement efforts.

Advancing the safety and safe use of HIT will require stakeholders to share responsibility and accountability for patient safety; this may require a substantial cultural shift for the many groups involved in the development and use of HIT systems. The Committee recognizes that there are many hurdles to effective measurement of HIT safety, including these potential cultural barriers, as well as collection of data, associated costs, and other practical limitations along with a rapidly evolving sociotechnical environment. Because HIT innovation is moving at a fast pace, it will be vital to develop mechanisms to identify and measure new safety issues that arise from HIT. However, these challenges should not prevent the field from moving forward with meaningful efforts to measure and improve the safety of HIT; indeed, the changing landscape offers a significant opportunity to ensure that patient safety considerations are incorporated into all phases of the HIT lifecycle as we move into the future. This framework and the Committee's recommendations should be viewed as a living document that will itself continue to evolve as evidence, practices, and technologies mature.

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[59] MPI = master patient index

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Appendix A: HIT Safety Committee Roster

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Appendix B: Search Strategy

Search Strategy

PubMed Search 1:

("health information technology" OR HIT OR "electronic health record" OR "electronic medical record" OR "decision support" OR CPOE OR "technology-induced") AND (safety OR "medical error" OR "adverse event" OR "adverse drug event" OR "reporting system" OR "risk management" OR iatrogenesis OR "e-iatrogenesis" OR "hospital-acquired" OR "hospital-associated" OR "healthcare-associated" OR complication OR failure)

Limits: Systematic Reviews, Meta-Analysis; Published in last 5 years; Published in English

Results: 178

Included in initial scan for relevancy: 79

Selected for detailed review: 65

PubMed Search 2:

("health information technology" OR HIT OR "electronic health record" OR "electronic medical record" OR "decision support" OR CPOE OR "Electronic Medication Administration Record" OR EMAR OR "Picture Archiving and Communication System" OR PACS) AND ("medical error" OR "adverse event" OR "adverse drug event" OR iatrogenesis OR "e-iatrogenesis" OR "hospital-acquired" OR "hospital-associated" OR "healthcare-associated" OR "technology-induced" OR complication OR failure) AND ("reporting system" OR "risk management" OR surveillance OR monitor* OR standard* OR classif* OR detect* OR categor* OR "safety measure" OR "quality measure" OR "performance measure" OR "safety metric" OR "quality metric" OR "performance metric" OR "quality indicator" OR "safety indicator" OR "performance indicator" OR "measure concept")

Limits: Published in last 5 years; Published in English; Species: Humans

Results: 621

Included in initial scan for relevancy: 92

Selected for detailed review: 23

Additional Parameters:
- Specifically address issues of HIT-related safety (*i.e.*, not only HIT systems issues or patient safety issues, but the impact of HIT on patient safety)
- For the purposes of this review, Health Information Technology (HIT) includes:
    - Electronic Health Records (EHRs)
    - Computerized Prescriber Order Entry (CPOE) Systems
    - Clinical Decision Support (CDS) Systems

o   Picture Archiving and Communications Systems (PACS)
o   Electronic Medication Administration Records (EMAR)

Additional sources:
- Review of bibliographies from articles identified through search
- Review of NQF's portfolio of endorsed measures;
- Review of AHRQ's National Quality Measures Clearinghouse and National Guidelines Clearinghouse;
- Review of the Health Indicators Warehouse;
- Review of the CMS Measures Inventory, including measures under development;
- Review of previous environmental scans conducted by NQF
- Review of references provided by Committee members, colleagues, and federal partners

Total results: 142 articles

Appendix C: Key Definitions

Health Information Technology
Health information technology (HIT) is the broad definition of linked software and hardware systems used to collect, store, display, and communicate patient information between providers and health care organizations (Sittig & Singh, 2011 - Defining health information technology related errors: New developments since *To Err Is Human*)

Electronic Medical Record (EMR)
An EMR is a record of health related information within a single provider or care delivery organization. EMRs do not incorporate interoperability standards and health related information cannot be shared outside of the care delivery organization.

Electronic Health Record (EHR)
An EHR is a record of health related information that is structured for interoperability across providers and care delivery organizations, through the use of nationally recognized standards for information exchange.

Personal Health Record (PHR)
A PHR is a record of health related information controlled by an individual who determines what information is shared with providers and among care delivery organizations. PHRs also incorporate nationally recognized standards for information exchange.

Health Information Exchange (HIE)
The electronic exchange of health related information between care delivery organizations based on nationally recognized standards. (From The National alliance for health information systems report to the office of the national coordinator for Health information Technology. "Defining key health information technology terms."
https://www.nachc.com/client/Key%20HIT%20Terms%20Definitions%20Final_April_2008.pdf)

Clinical Data Repository (CDR)
A centralized database of continuously updated health related records that document all care provided to individuals within a care organizations, including radiology and laboratory results, care notes, and pharmacy records. http://www.nasbhc.org/atf/cf/%7bB241D183-DA6F-443F-9588-3230D027D8DB%7d/GlossaryOfHITterms.pdf

Picture Archiving and Communications System (PACS)
A system that digitizes and stores radiological images, eliminating the need for storage of X-ray film and the possibility that films can be lost or misfiled and images can easily be shared between care organizations. (Strickland, N PACS (picture archiving and communication systems): filmless radiology Arch Dis Child 2000;83:82-86 doi:10.1136/adc.83.1.82)

Computerized Clinical Decision Support Systems (CCDSS/CDS)
A software-based system incorporating a knowledge base of information on diagnoses, drug interactions and care guidelines, and health related information for an individual, used to guide clinical decision-making. CDS systems support clinical care through alerts and reminders, recommended order sets for

diagnosis and care plans. (AHRQ "CDS State of the Art" retrieved from
http://healthit.ahrq.gov/sites/default/files/docs/page/09-0069-EF_1.pdf)

e-Prescribing
The electronic transmission of prescription or prescription information directly to a pharmacy or dispenser from a health care provider. (http://www.hrpub.org/download/20131215/UJCM1-16900871.pdf).

Appendix D: Key findings from selected evidence reviews related to the Impact of HIT on safety

Article	Objectives/Methods	Key Findings
Wong, et al 2010[69]	Systematic review of the literature on Drug Interaction Detection Software (DIS) in preventing adverse drug events	Did not identify any quality studies addressing the specific benefits and harms or cost-effectiveness of drug interaction software on medication safety or clinical outcomes
Shojania, et al 2010[70]	Systematic review to quantify the effects of computer reminders delivered to clinicians during their routine activities	Results showed that computer reminders improved adherence to processes of care by around 4-6% A trend toward larger improvements was seen for reminders that required users to enter a response Computer reminders produced much smaller improvements than those generally expected, and could not reliably predict clinically-worthwhile improvements in care
Collins, et al 2011[71]	Before-and-after cohort study to determine the effect of CPOE on oral chemotherapy order, review and administration processes, as well as its effect on chemotherapy-related prescribing errors	CPOE implementation significantly reduced prescribing error risk and eliminated certain types of errors that can lead to significant patient harm, including wrong dosing schedule/duration errors, prescriptions without an indication, and omission (or unclear communication) of drug name or route of administration
Georgiou, et al 2011[72]	Systematic review aimed at assessing the impact of CPOE on medical-imaging services and patient outcomes	Findings revealed the potential for CPOE to contribute to increased efficiency and effectiveness in imaging services, with most benefits coming in the form of greater adherence to test ordering guidelines The authors noted that additional work will be required to develop sophisticated evaluation models capable of taking account of the multiple ways in which technology impacts health care delivery
Maslove et al 2011[73]	Literature review of CPOE in the critical care environment	Findings suggested that CPOE shows promise as tool for improving the safety of health care, particularly in complex environments such as the ICU However, the evidence remains equivocal, and must be balanced against the potential for unintended consequences

Article	Objectives/Methods	Key Findings
		The authors argue that novel research methods borrowed from the social sciences should continue to be used to generate hypotheses and to explore the complex human engineering factors that affect use of CPOE
Souza, et al 2011[74]	Review of randomized controlled trials (RCTs) assessing the effects of CDS for primary preventive care (PPC) on process of care, patient outcomes, harms, and costs	Findings showed that CDS's effects on patient outcomes, safety, costs of care, and provider satisfaction remain poorly supported However, the authors suggested that definite conclusions about CDS's effectiveness are premature, especially with respect to patient outcomes, because of heterogeneity in systems, settings, and outcomes assessed.
Clyne 2012[75]	Overview of the current evidence in relation to the use of technologies such as ePrescribing and CDSS to reduce inappropriate medication use in older people, focusing on the prescribing stage	The evidence suggests that various types of e-prescribing and CDSS interventions have the potential to reduce inappropriate prescribing and polypharmacy in older people, but there was significant heterogeneity in study designs, interventions, care settings, and outcomes measured, limiting the conclusions that can be drawn from the results The authors noted a persistent problem with clinicians overriding or ignoring alerts
Cresswell, et al 2012[76]	Interpretative review of the empirical evidence on computerized decision support systems, their contexts of use, and evidence related to the effectiveness of these tools	Results suggested that CDS resulted in improved provider adherence to guidelines and promotion of preventive medicine under certain conditions However, evidence regarding the impact of these systems on patient outcomes was inconclusive, with reviews finding little to no consistent benefit in this regard
Carling et al 2013[77]	Systematic review to evaluate assertions that electronic applications for medication management in ambulatory care can themselves result in errors that might harm patients or increase risks to patient safety	Only a minority of studies that investigated the interventions of interest included threats to patients' safety as outcomes or monitored for adverse events, meaning there was little evidence to substantiate claims of patient harm or increased risks However, the authors noted that more research is needed to focus on the draw-

Article	Objectives/Methods	Key Findings
		backs and negative outcomes technology may introduce
Georgiou, et al 2013[78]	Systematic review of the quantitative literature related to the effect of computerized provider order entry systems in the emergency department (ED).	The review found tangible benefits of CPOE and decision support in ED environments, including decreased medication errors, improved laboratory turnaround time, and improved guideline compliance. However, the authors acknowledged the limitations imposed by the heterogeneity of study design and outcomes assessed, as well as the difficulty of evaluating the impact of interactions among various aspects of the ED system
Lainer, et al 2013[79]	Systematic review of the effects of IT interventions on medication safety in primary care	Only 5 of 10 RCTs revealed a reduction of medication errors in response to IT interventions The authors suggest that CPOE with CDS was effective if targeted at a limited number of potentially inappropriate medications and/or pre-specified medication problems in high-risk groups, such as patients with renal insufficiency When decision support systems included extensive and exhaustive information about, for example, potential drug–drug interactions, physicians seemed to be overwhelmed by the complexity of information The authors identified alert fatigue and override as a safety issue related to IT use
Van der Linden et al 2013[80]	Systematic review to identify systems (electronic and non-electronic) that can prevent the re-prescription of drugs withdrawn because of an adverse drug event and the effects of these systems	Several systems to prevent the re-prescription of drugs that elicited an adverse drug event have been developed, but the evidence of these systems' effectiveness is limited
Nuckols, et al 2014[81]	Systematic review and meta-analysis of studies assessing the effectiveness of CPOE at reducing preventable adverse drug events (pADEs) in hospital-related settings, and examination of the	CPOE implementation was associated with a 50% decline in pADEs in inpatient settings, though the authors note that these studies were poorly designed. The authors suggest that there is not

Article	Objectives/Methods	Key Findings
	reasons for heterogeneous effects on medication errors	sufficient reporting on many context and implementation variables to evaluate their association with CPOE effectiveness
Ranji, et al 2014[82]	Narrative review of specialized literature to identify reviews of the effect of CPOE combined with CDSS on Adverse Drug Event (ADE) rates in inpatient and outpatient settings	CPOE in combination with CDSS is effective at reducing prescribing errors, these benefits to not appear to extend to medication administration errors or clinical ADEs

The authors acknowledged the impact of other system factors and the difficulty of assessing particular HIT tools in isolation |

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[70] Shojania KG, Jennings A, Mayhew A, Ramsay C, Eccles M, Grimshaw J. Effect of point-of-care computer reminders on physician behaviour: a systematic review. *CMAJ*. 2010 Mar 23;182(5):E216-25.

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[80] Van der Linden CMJ, Jansen PAF, Grouls RJE, et al. Systems that prevent unwanted represcription of drugs withdrawn because of adverse drug events: a systematic review. *Therapeutic Advances in Drug Safety* 2013;4(2):73-90.

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[82] Ranji SR, Rennke S, Wachter RM. Computerised provider order entry combined with clinical decision support systems to improve medication safety: a narrative review BMJ Qual Saf 2013-Published Online First: 12 April 2014.

Appendix E: Conceptual Frameworks for Assessment of HIT

Author, Date	Article Title	Focus of Framework	Framework Elements
Sittig and Singh 2010[1]	A New Socio-technical Model for Studying Health Information Technology in Complex Adaptive Healthcare Systems	Understanding the interactions and interdependencies between the various sociotechnical factors involved in HIT, and the effects of those relationships	1. Hardware and software 2. Clinical Content 3. Human-computer interface 4. People 5. Workflow and communication 6. Organizational policies and procedures 7. External rules, regulations, and pressures 8. System measurement and monitoring
Borycki and Kushniruk 2010[2]	Towards an Integrative Cognitive-Socio-Technical Approach in Health Informatics: Analyzing Technology-Induced Error Involving Health Information Systems to Improve Patient Safety	To integrate cognitive and socio-technical approaches to assess the impact of health information systems across various modes of user-system interaction	1. Individual interacting with the system (*cognitive level*) 2. User interacting with the system and environment to do basic work task (*basic workflow level*) 3. Multiple users interacting with each other and the system to carry out multiple tasks as part of the organization (*organizational level*)
Borycki and Keay 2010[3]	Methods to Assess the Safety of Health Information Systems (HIS)	To classify the methods used in predicting, preventing, and evaluating the potential for a HIS to cause technology-induced error	1. Before HIS implementation (*i.e., design, development, procurement, and pre-implementation processes*) 2. After HIS implementation 3. After an error has occurred

[1] Sittig DF, Singh H. A New Socio-technical Model for Studying Health Information Technology in Complex Adaptive Healthcare Systems. *Quality & safety in health care* 2010;19(Suppl 3):i68-i74.

[2] Borycki E., Kushniruk A. Towards an Integrative Cognitive-Socio-Technical Approach in Health Informatics: Analyzing Technology-Induced Error Involving Health Information Systems to Improve Patient Safety. The Open Medical Informatics Journal 2010;4:181-187.

[3] Borycki E, Keay E. Methods to Assess the Safety of Health Information Systems. *Healthcare Quarterly* 2010: Vol.13, Special Issue; 47-52.

Author, Date	Article Title	Focus of Framework	Framework Elements

Magrabi, et al 2011[4]	Using FDA reports to inform a classification for health information technology safety problems	Advancing a systematic classification of HIT safety problems	1. Information Input Problems
			  a. Human
			  b. Machine
			2. Machine Information Transfer Problems
			  a. Machine
			3. Information Output/ Data Retrieval Problems
			  a. Human
			  b. Machine
			4. General Technical Problems
			  a. Machine
			5. Contributing Factors
			  a. Human

Sittig and Singh 2012[5]	Electronic Health Records and National Patient Safety Goals	To advance a three-phase framework for the development of EHR-specific patient-safety goals, accounting for the variation and stages of complexity across practice settings	1. Safe HIT 2. Safe Use of HIT 3. Using HIT to Improve Safety

Paez, et al 2013[6]	Health Information Technology and Hospital Patient Safety: A Conceptual Model to Guide Research	To advance a conceptual model that describes how specific health IT functions could affect different types of inpatient safety errors and that accounts for contextual factors influencing successful health IT implementation	1. Health IT Functions
			  a. Health Information and Data
			  b. Results Management
			  c. Computerized Provider Order Entry
			  d. Decision Support
			  e. Administrative Process and Reporting
			  f. Reporting and Population Health Management
			2. Contextual Factors
			  a. End Users
			  b. IT System
			  c. System Deployment and Maintenance
			3. Categories of Patient Safety Errors
			  a. Communication

[4] Magrabi F, Ong MS, Runciman W, Coiera, E. Using FDA reports to inform a classification for health information technology safety problems. *J Am Med Inform Assoc* 2012;19:45-53

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[6] Paez K, Roper RA, Andrews RM. Health information technology and hospital patient safety: a conceptual model to guide research. *Jt Comm J Qual Patient Saf*. 2013: 39(9):415-25.

| Author, Date	Article Title	Focus of Framework	Framework Elements

			b. Patient Management
			c. Clinical Performance
			    i. Diagnosis
			    ii. Intervention

Meeks, et al 2014[7]	Exploring the sociotechnical intersection of patient safety and electronic health record implementation	To examine the applicability of two previously developed conceptual models comprehensively to understand safety implications of EHR implementation
		
		[Combination of Sittig & Singh 2010 and Sittig & Singh 2012]
			4. Safe HIT
			    a. Hardware and software
			    b. Human-computer interface
			    c. People
			    d. Workflow and communication
			    e. Organizational policies and procedures
			    f. External rules, regulations, and pressures
			    g. System measurement and monitoring
			5. Safe Use of HIT
			    a. Hardware and software
			    b. Human-computer interface
			    c. People
			    d. Workflow and communication
			    e. Organizational policies and procedures
			    f. External rules, regulations, and pressures
			    g. System measurement and monitoring
			6. Using HIT to Improve Safety
			    a. Hardware and software
			    b. Human-computer interface
			    c. People
			    d. Workflow and communication
			    e. Organizational policies and procedures
			    f. External rules, regulations, and pressures
			    g. System measurement and monitoring

[7] Meeks DW, Takian A, Sittig D, Singh H, Barber N. Exploring the sociotechnical intersection of patient safety and electronic health record implementation. *J Am Med Inform Assoc* 2014: 21; e28–e34.

Appendix F: Eight-Dimensional Sociotechnical Model of Safe and Effective EHR Use

Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care. 2010: Oct;19 Suppl 3:i68-74.

Appendix G: SAFER/Sociotechnical Model
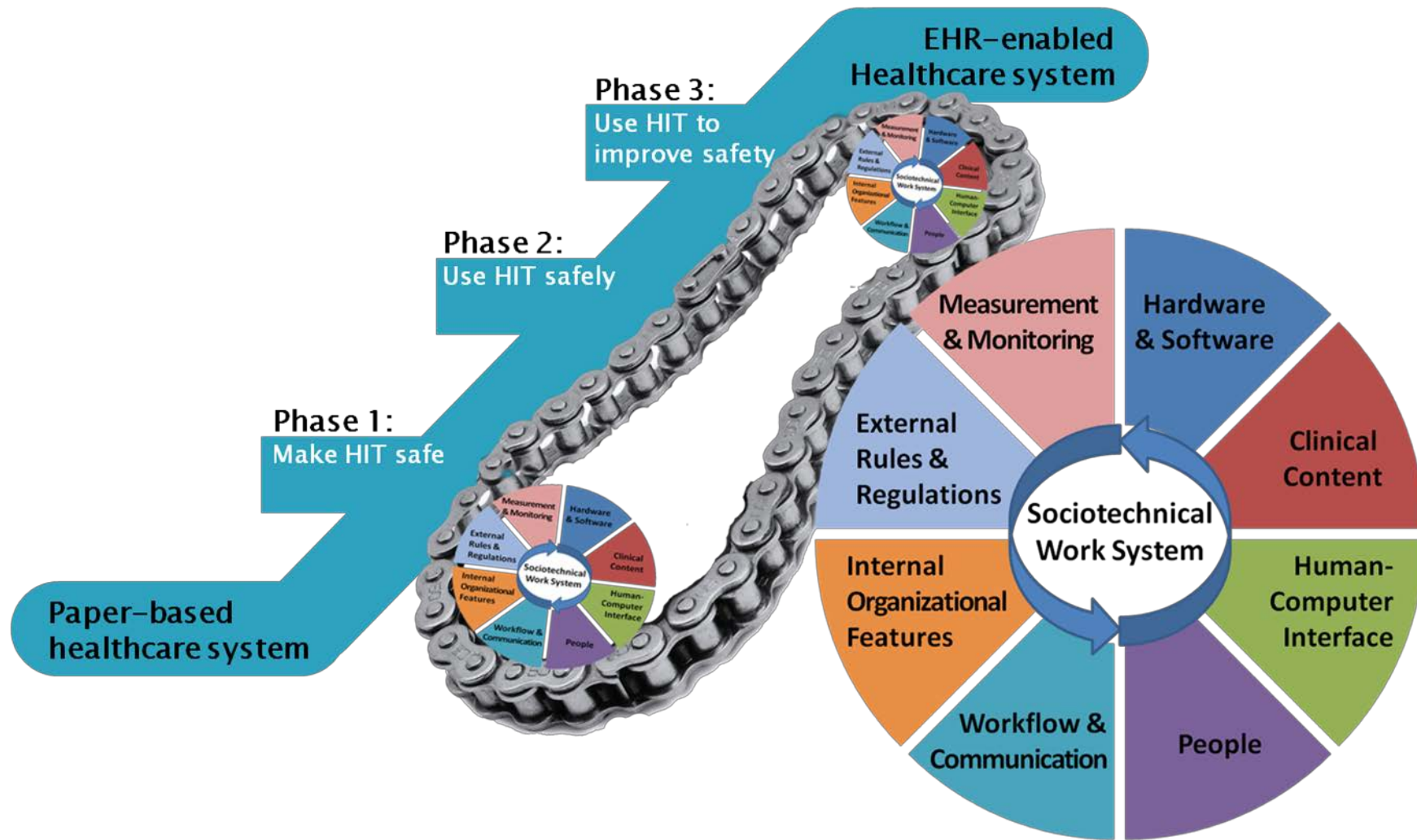
Meeks DW, Takian A, Sittig D, Singh H, Barber N. Exploring the sociotechnical intersection of patient safety and electronic health record implementation. J Am Med Inform Assoc 2014: 21; e28–e34.

Appendix H: List of Measure Concepts Considered for Prioritization

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
1	# of times key test results not available for diagnosis	HIT systems and associated workflows should be designed, configured, and implemented to allow for efficient access to necessary information; Clinicians should search for necessary information (*e.g.* old test results; clinic notes; care plans) and use this information for the current encounter	Vendor, Facility	1A - Data Availability
2	% of lab results that do not cross interface between EHR and LIS	HIT systems should be designed, configured, and implemented to allow for complete and accurate transmission of data across internal and external systems	Vendor, Facility	1A - Data Availability
3	Ability to document individualized patient goals and preferences	HIT system design, development, and implementation should ensure systems can document individualized patient goals and preferences; All team members should be able to add to this individualized list of goals, including the patient	Vendor, Facility	1A - Data Availability
4	Inability to retrieve necessary information	HIT systems and associated workflows should be designed, configured, and implemented to allow for efficient access to necessary information	Vendor, Facility	1A - Data Availability
5	Is system interoperable with other healthcare systems? Regionally? Nationally?	HIT systems should be designed, configured, and implemented to allow for interoperability with other healthcare systems	Vendor, Facility	1A - Data Availability
6	System design to facilitate information transfer at transitions in care	HIT systems and associated workflows should be designed, configured, and implemented to allow for efficient, timely, and complete transmission of appropriate information	Vendor, Facility	1A - Data Availability
7	System supports HIE between systems (*e.g.*, EHR, LIS), mobile health applications?	HIT systems should be designed, configured, and implemented to enable transmission of HIE data as appropriate	Vendor, Facility	1A - Data Availability

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
8	System supports HIE between vendors	HIT systems should be designed, configured, and implemented to enable transmission of HIE data as appropriate	Vendor, Facility	1A - Data Availability
9	External data via HIE is added to patient record	HIT systems should be designed, configured, and implemented to enable the pushing of data to HIE	Vendor, Facility	1A - Data Availability
10	Unexpected downtime affecting >100 patients and lasting >8hours	HIT system design, development, and implementation should ensure systems are reliable and available when needed; Facilities should have appropriate plans and processes in place to prevent unexpected downtime and to minimize its length and impact if it does occur.	Vendor, Facility	1A - Data Availability
11	% duplicate patients in EHR	HIT systems and associated workflows should be designed, configured, implemented, and used in in a way that prevents duplication of patient records	Vendor, Facility, Clinician	1B - Data Integrity
12	Quality of external prescription data	HIT systems should be designed, configured, and implemented to allow for complete and accurate transmission of data across internal and external systems	Vendor, Facility	1B - Data Integrity
13	Ability to chart necessary information	HIT systems and associated workflows should be designed, configured, and implemented to allow for efficient and timely entry of/access to appropriate information	Vendor, Facility	2A - Health IT System Usability
14	Diagnostics or testing with patients conducted to assess usability	Design, development, and implementation of HIT systems should involve diagnostics and testing with patients to ensure adequate system usability	Vendor, Facility	2A - Health IT System Usability
15	End user involvement in design and development process	Vendors should involve end users in the design and development of HIT systems	Vendor, Facility	2A - Health IT System Usability
16	Readability of alerts and other messages	HIT systems should be designed, configured, and implemented to ensure alerts and other messages are readable by users	Vendor, Facility	2A - Health IT System Usability

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
17	Speed of system/EHR response time	HIT systems and associated workflows should be designed, configured, and implemented to ensure adequate system usability and to promote safe and efficient HIT use	Vendor, Facility	2A - Health IT System Usability
18	Ability of HIT system to pick up problem prescriptions across different systems	HIT systems and associated workflows should be designed, configured, and implemented to pick up problem prescriptions across different systems	Vendor, Facility	2D - Surveillance and Monitoring
19	Best practices for implementation, CDS, and knowledge management shared across organizations and vendors	Vendors and facilities should identify and disseminate best practices across organizations and vendors	Vendor, Facility	2D - Surveillance and Monitoring
20	System limitations determined and communicated with end users	System limitations should be determined and should be fully and clearly communicated to end users	Vendor, Facility	2D - Surveillance and Monitoring
21	Vendor notifications sent to all users following identification of software, hardware, or other issues that materially affect patient safety	Upon identification of software, hardware, or other issues that materially affect patient safety, vendors should notify all users of the affected product	Vendor	2D - Surveillance and Monitoring
22	Vendor provides solutions to identified errors to all users ASAP following event	Vendors should identify and disseminate solutions for safety events caused by HIT software or hardware as soon as possible	Vendor	2D - Surveillance and Monitoring
23	Vendors share lessons across each other	Vendors should identify lessons from implementation experience and share them within the vendor community	Vendor	2D - Surveillance and Monitoring
24	Vendors share lessons across institutions	Vendors should identify lessons from implementation experience and share them across user institutions	Vendor	2D - Surveillance and Monitoring

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
25	Effective vendor user groups	Vendors should establish effective user groups to help in identification of problems and lessons	Vendor	2D - Surveillance and Monitoring
26	Free and transparent exchange of information about HIT user experiences and issues	The Health IT vendors with whom the organization contracts for hardware or software licenses and related services support the free exchange of information about Health IT user experiences and issues and do not prohibit sharing of such information, including details (*e.g.*, screenshots) relating to patient safety, and make comparative user experiences publicly available	Vendor, Facility	2D - Surveillance and Monitoring
27	Software and hardware agreements permit shared learning and research, and promote shared accountability	Health IT software license and maintenance agreements and hardware purchase agreements contain contractual provisions which promote patient safety by permitting shared learning and research on Health IT and patient safety, including research on usability and interoperability. Such agreements should fairly allocate responsibility for acts and omissions to parties who are primarily responsible for the conduct that led to the acts or omissions	Vendor, Facility	2D - Surveillance and Monitoring
28	Lack of adequate data security/ data security not continuously improved to address new threats	HIT systems and associated workflows should be designed, configured, implemented, used, maintained, and governed in a way that ensures appropriate data security	Vendor, Facility, Clinician	1C - Data Security
29	Test results released via portal to wrong patients	HIT systems and associated workflows should be designed, configured, implemented, and used in a way that ensures patient information is released only to appropriate and authorized parties	Vendor, Facility, Clinician	1C - Data Security
30	Organization has addressed security risks in compliance with applicable standards and requirements	The organization has implemented measures of security risk compliance consistent with the HIPAA Security Rule, HITECH Meaningful Use Requirements, guidance of the National Institute of Standards and Technology, applicable accreditation standards and patient	Vendor, Facility	1C - Data Security

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
		safety-related best practices to ensure that: (i) EHR system data or information is accessible and useable upon demand by an authorized person; (ii) EHR system data or information have not been altered or destroyed in an unauthorized manner; and (iii) the EHR system employs currently available patient matching technology and capabilities to accurately match data to a particular patient consistent with commercially reasonable standards		
31	"Through-time" or number of clicks needed to perform common tasks (compared across types and levels of users)	HIT systems and associated workflows should be designed, configured, and implemented to ensure adequate system usability and to promote safe and efficient HIT use	Vendor, Facility	2A - Health IT System Usability
32	# of hours per provider FTE spent charting after shift	The interface for clinical documentation should be designed in a way that facilitates ease of and minimizes time burdens for documenting histories / physicals / re-evaluations and clinical care actions; One process measure may be the number of hours that clinicians spend documenting charts during or after their shift.	Facility, Clinician	2A - Health IT System Usability
33	# of records not completed (or % complete) during patient visit/ clinical scheduled shift	Care must be documented contemporaneously in the medical record; one way to measure this would be to count the number or proportion of medical records not completed during or after a scheduled clinical shift.	Facility, Clinician	2A - Health IT System Usability
34	Documentation interface	The interface for clinical documentation should be designed in a way that facilitates ease of and minimizes time burdens for documenting histories / physicals / re-evaluations and clinical care actions	Vendor, Facility	2A - Health IT System Usability
35	End users requirements determined prior to implementation	Facilities should determine end user requirements before implementing new or redesigned HIT systems	Vendor	2A - Health IT System Usability
36	Extent of HIT system integration (*e.g.*, fully integrated vs. separate applications for different	HIT systems and associated workflows should be designed, configured, and implemented in a way that ensures appropriate integration	Vendor, Facility	2A - Health IT System Usability

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
	functions, requiring frequent switches between applications)	within and across systems and/or applications		
37	Increased cost of system workarounds (overtime, scribes, decrease in patient throughput/seen, *etc.*) shared by vendor (usability)	HIT systems and associated workflows should be designed, configured, implemented, and employed in a way that reduces the need for/use of workarounds; When poor system usability leads to workarounds, vendors should share in any increased costs generated by these workarounds	Vendor, Facility	2A - Health IT System Usability
38	Robust usability evaluation for system redesign	Prior to implementing system redesigns, facilities should ensure that new systems have undergone robust usability evaluations	Vendor, Facility	2A - Health IT System Usability
39	Survey-based measure derived from a psychometric scale or multi-item survey instrument allowing users to rate system usability	HIT systems and associated workflows should be designed, configured, and implemented to account for user needs and ensure adequate system usability	Vendor, Facility	2A - Health IT System Usability
40	Appropriate software license and maintenance agreement	The organization has a written hardware purchase or software license and maintenance agreement with Health IT vendors specifying how the vendors will work with their customers on safety and quality involving the implementation, customization and use of Health IT products and services. The agreement contains language consistent with evolving standards on quality and risk management of clinical health information technology systems and networks	Vendor, Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
41	Presence of advanced decision support (*e.g.*, geriatric dosing, renal dosing)	HIT systems and associated workflows should be designed, configured, and implemented to enable advanced decision support	Vendor, Facility	2C - Complete/Correct Health IT Use
42	Presence of order sets for the most common admission diagnoses	HIT systems and associated workflows should be designed, configured, and implemented to enable appropriate decision support	Vendor, Facility	2C - Complete/Correct Health IT Use

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
43	Whether the EHR implementation supports tiered alerting	HIT systems and associated workflows should be configured and implemented to support tiered alerting	Vendor, Facility	2C - Complete/Correct Health IT Use
44	Risk-based analysis of help desk reports	Facilities should analyze help desk reports to identify potential HIT-related safety risks	Facility	2D - Surveillance and Monitoring
45	# or % of patients that access and use their patient portal	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; The frequency with which patients access portals should be measured to inform assessments of patient portal usability	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
46	% of the complete record (including progress notes) available to patient in PHR	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patient portals should include the ability of patients to view all appropriate information	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
47	Ability/transparency of patient to contribute to the record and be able to see their contributions in EHR	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patient portals should include the ability for patients to contribute to their health record	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
48	Completeness of patient portal data	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
49	Patient portal incorporates clinical view	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
50	Patient portal is difficult/ confusing to navigate	HIT systems, features, and functionality, including patient portal applications, should be	Vendor, Facility	3B - Health IT Facilitates Safe

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
		designed, implemented, and used in a way that facilitates safe and effective patient engagement		and Effective Patient Engagement
51	Patient portals are not linked to all providers	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
52	Patient satisfaction with patient portal and clinician interaction with patient	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patient satisfaction with the design, implementation, and clinician use of portals should be assessed through surveys or other methods of feedback	Vendor, Facility, Clinician	3B - Health IT Facilitates Safe and Effective Patient Engagement
53	Patient's discharge summary offered in print and digitally available via patient portal or email (patient's choice)	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Discharge information should be available through patient portals in addition to printed materials	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
54	Proficiency of patients to use portals o Are there education modules? o Can they use the systems?	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patients should receive education and assistance to ensure they are using portals safely and effectively	Vendor, Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
55	Existence of shared data warehouse within regions	Could be applied at a community or regional level?	?	1A - Data Availability
56	Post-downtime testing or assessment to ensure all systems are back up and running.	Facilities should have appropriate plans and processes in place to minimize the length and impact of downtime and other system failures	Facility	1A - Data Availability
57	Appropriateness of HIT	HIT systems should be implemented in a way	Vendor, Facility	2A - Health IT

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
	installment (*e.g.*, no printer in office, back to patient when on device)	that ensures usability and accounts for the needs of patients and clinicians		System Usability
58	Use of Leapfrog EMR flight simulator to measure risk	Design, configuration, and implementation of HIT systems should involve use of 'flight simulation' to ensure system safety and usability	Vendor, Facility	2A - Health IT System Usability
59	% of clinicians participating in a downtime drill in last 12 months	Facilities should have appropriate plans and processes in place to minimize the length and impact of downtime and other system failures	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
60	% time dedicated to training & implementation	When implementing new or redesigned HIT systems, facilities should ensure that adequate time is allotted for training and implementation needs	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
61	Communication/training o System build o System update	Facilities should ensure that users receive appropriate communication and training on HIT system changes (builds or updates)	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
62	Presence, documentation, and maintenance of an IT-focused disaster recovery plan consistent with HIPAA requirements	As part of its overall emergency preparedness plan, the organization has an IT focused Disaster Recovery Plan consistent with the requirements of the HIPAA Security Rule to establish (and implement as needed) procedures to: (i) create and maintain retrievable exact copies of ePHI; (ii) restore any loss of data; (iii) enable continuation of critical business processes for protection of the security of ePHI while operating in emergency mode; and (iv) procedures for obtaining necessary ePHI during an emergency. Such a plan is documented and routinely updated	Vendor, Facility	2B - Organizational Planning, Preparation, and Governance for Health IT

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
63	Disaster recovery plan addresses disruptions in access and ensures EHR availability	If the organization utilizes a cloud-based EHR, the disaster recovery plan addresses disruptions in access to an ISP or cloud-based EHR vendor to ensure the availability of the EHR for both treatment and billing services	Vendor, Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
64	Security risk analysis and correction of identified security deficiencies	The organization conducts a security risk analysis of the potential threats and vulnerabilities to the confidentiality, integrity and availability of electronic protected health information (ePHI) that may affect its disaster preparedness efforts consistent with the requirements of the HIPAA Security Rule and HITECH Meaningful Use Requirements, and corrects identified security deficiencies	Vendor, Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
65	Evidence of backup plans for inevitable failures	Facilities should have appropriate plans and processes in place to minimize the length and impact of downtime and other system failures	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
66	Lack of an emergency preparedness plan or failure to update EP plan	Facilities should create plans, processes, and security precautions to ensure emergency preparedness and update those plans as appropriate	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
67	Proficiency testing of users	Facilities should conduct proficiency testing of users as needed to ensure that HIT systems will be used safely and correctly	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
68	Provider arranges for needed training	Facilities should ensure that users have access to any training needed for HIT system use	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
69	Repetitive proficiency testing of users (annual?) to accommodate updates and changes	Facilities should conduct proficiency testing of users as needed to ensure that HIT systems will be used safely and correctly	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
70	Users know what to expect after implementation (workflow changes)	Facilities should ensure that users are trained and prepared for any changes in workflow due to HIT system implementation	Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
71	% of clinicians with >100 in-basket alerts per day	HIT systems should be configured and implemented to ensure appropriate calibration of alerts	Facility	2C - Complete/Correct Health IT Use
72	Alert rate (as % of total orders of % of total patients)	HIT systems should be configured and implemented to ensure appropriate calibration of alerts	Facility	2C - Complete/Correct Health IT Use
73	Average & max alerts per day per provider inbox	HIT systems should be configured and implemented to ensure appropriate calibration of alerts	Facility	2C - Complete/Correct Health IT Use
74	False positive alert rate (% of alerts for which action was taken?)	HIT systems should be configured and implemented to ensure appropriate calibration of alerts	Facility	2C - Complete/Correct Health IT Use
75	Survey of end users on workarounds • Results should be analyzed from a human-computer, workflow process, and hardware/software perspective	Facilities should use surveys or other methods of feedback to assess whether clinicians are using HIT systems completely and correctly	Facility	2C - Complete/Correct Health IT Use
76	Survey of users - "do you use xyz function?" or "do you know if this function exists?"	Facilities should use surveys or other methods of feedback to evaluate user knowledge and to assess whether clinicians are using HIT systems completely and correctly	Facility	2C - Complete/Correct Health IT Use

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
77	Whether CDS is set to default	HIT systems and associated workflows should be configured and implemented to enable appropriate decision support	Facility	2C - Complete/Correct Health IT Use
78	Workflow is matched with expected use cases	Design, configuration, and implementation of HIT systems and associated workflows should involve matching of workflow with expected use cases	Facility	2C - Complete/Correct Health IT Use
79	Workflow with cognitive mapping completed before implementation	Design, configuration, and implementation of HIT systems and associated workflows should involve cognitive mapping to ensure adequate system usability	Facility	2C - Complete/Correct Health IT Use
80	Organization has conducted a self-assessment with SAFER guides	Facilities should conduct self-assessments using the SAFER guides to ensure that HIT systems are being implemented and used in a way that protects patient safety	Facility	2D - Surveillance and Monitoring
81	Patient validation of abnormal test results	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patients should have the ability to validate information through portals, and clinical workflow should incorporate routine patient verification of abnormal test results	Facility, Clinician	3A - Use of HIT to improve Patient Safety
82	Organizational culture – HIT Safety	The organization's culture of safety includes shared involvement and responsibility to address the potential risks associated with the use of Health IT. This requires periodic re-evaluation of the roles and responsibilities of all stakeholders, including the healthcare organization, clinicians, and vendors/developers	Vendor, Facility	2B - Organizational Planning, Preparation, and Governance for Health IT
83	# of times CDS (or alerts) module turned off	HIT systems should be configured and implemented to ensure appropriate calibration of alerts; Clinicians should use HIT features and functionality as intended, employing decision support as appropriate and being mindful of alerts	Facility, Clinician	2C - Complete/Correct Health IT Use
84	# of times cut/paste	Clinicians should minimize use of cut/paste to	Clinician	2C -

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
	used	avoid potential errors information entry		Complete/Correct Health IT Use
85	# of times data available from/ through HIE source is accessed/viewed/used	HIT systems and associated workflows should be designed, configured, and implemented to incorporate use of data available through HIE; Clinicians should identify and use available data (including HIE data) as appropriate	Facility, Clinician	2C - Complete/Correct Health IT Use
86	# of use and user errors	HIT systems and associated workflows should be designed, configured, and implemented to ensure adequate system usability and to promote safe and efficient HIT use; Clinicians should use HIT features and functionality as intended	Vendor, Facility, Clinician	2C - Complete/Correct Health IT Use
87	# of workarounds employed	HIT systems and associated workflows should be designed, configured, implemented, and employed in a way that reduces the need for/use of workarounds	Vendor, Facility, Clinician	2C - Complete/Correct Health IT Use
88	# or % of abnormal test results not followed up	HIT systems and associated workflows should be configured, implemented, and used in a way that ensures abnormal test results are identified and addressed	Facility, Clinician	2C - Complete/Correct Health IT Use
89	% of [#] randomly selected charts with active problems/ allergies in free text not in problem list/ allergy fields	Clinicians should use HIT features and functionality as intended, and avoid the use of free text when relevant fields or pre-populated lists are available	Clinician	2C - Complete/Correct Health IT Use
90	% of orders entered by the prescriber (or % verbal orders)	HIT systems and associated workflows should be designed, configured, and implemented to allow for efficient and timely entry of appropriate information; Prescribing clinicians should enter orders promptly, completely, and appropriately	Vendor, Facility, Clinician	2C - Complete/Correct Health IT Use
91	% physician adoption of CPOE o % of CPOE use	HIT systems and associated workflows should be designed, configured, and implemented to ensure adequate system usability and to promote safe and efficient HIT use; Clinicians should use HIT features and functionality as	Facility, Clinician	2C - Complete/Correct Health IT Use

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
		intended		
92	Content of transition of care information	Transition record must be complete; specifically with a focus on outstanding issues, clinical questions, or test results that need to be addressed	Facility, Clinician	2C - Complete/Correct Health IT Use
93	Delays in clinician documentation that result in missed alerts	Care must be documented contemporaneously in the medical record; delays in documentation may lead to missed alerts where clinical decision support that recommends an action is not triggered because documentation is not contemporaneous.	Facility, Clinician	2C - Complete/Correct Health IT Use
94	Free text charting when there is a coded item available	Clinicians should use HIT features and functionality as intended, and avoid the use of free text when a relevant coded item is available	Clinician	2C - Complete/Correct Health IT Use
95	Medication reconciliation performed through interoperable information exchange (if available)	HIT systems and associated workflows should be designed, configured, and implemented to support medication reconciliation through interoperable information exchange; Clinicians should identify and use information available through interoperable exchanges for medication reconciliation	Facility, Clinician	2C - Complete/Correct Health IT Use
96	Patient transition record reviewed by the treating provider	Clinicians should review available information during care transitions	Facility, Clinician	2C - Complete/Correct Health IT Use
97	Patient transition record transmitted electronically at the transition in care (*e.g.* post-visit or at time of referral)	Clinicians should ensure timely transmission of information to facilitate care transition	Facility, Clinician	2C - Complete/Correct Health IT Use
98	Presence of hybrid workflows - partially electronic, partially paper	HIT systems and associated workflows should be designed, configured, and implemented to enable fully-electronic workflows and eliminate or minimize the need for hybrid electronic/paper workflows; Clinicians should use HIT features and functionality as intended, and avoid the use of hybrid workflows	Vendor, Facility, Clinician	2C - Complete/Correct Health IT Use

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
99	Review of a care plan when a care plan is available	Care plans should be reviewed when available in the electronic health record to ensure that care during the current encounter is in line with the care plan	Facility, Clinician	2C - Complete/Correct Health IT Use
100	The use of scribes	HIT systems and associated workflows should be designed, configured, and implemented to allow for efficient and timely entry of appropriate information; Clinicians should enter orders promptly, completely, and appropriately	Vendor, Facility, Clinician	2C - Complete/Correct Health IT Use
101	Use of barcode scanning in medication preparation	HIT systems and associated workflows should be designed, configured, and implemented to enable and ensure the use of barcode scanning in medication preparation; Clinicians should use HIT features and functionality as intended, and use barcode scanning in medication preparation if available	Facility, Clinician	2C - Complete/Correct Health IT Use
102	Routine patient verification of medication list	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patients should have the ability to validate information through portals, and clinical workflow should incorporate routine patient verification of medication lists	Facility, Clinician	3A - Use of HIT to improve Patient Safety
103	Patient messages sent through patient portals receive responses within 24 hours	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Messages sent by patients through secure portals should receive prompt and appropriate responses	Clinician	3B - Health IT Facilitates Safe and Effective Patient Engagement
104	Patient preferences for access obtained and implemented	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patient preferences around use and access of portals should be obtained and implemented	Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement

#	Concept	Rationale	Accountable Entity	Primary Framework Domain
105	Recording of patient preferences regarding how information is transmitted and to whom (patient, caregiver, etc.)	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Patient preferences around use and access of portals should be obtained and implemented	Facility, Clinician	3B - Health IT Facilitates Safe and Effective Patient Engagement
106	Timely transmission of patient lab/test results to patient portal	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Lab/test results and other important information should be transmitted to patients through portals promptly and completely	Facility, Clinician	3B - Health IT Facilitates Safe and Effective Patient Engagement
107	# of patient portals that a patient has	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Structures and processes should be put in place to ensure that patients do not have multiple portals	Facility	3B - Health IT Facilitates Safe and Effective Patient Engagement
108	Use of open notes	HIT systems, features, and functionality, including patient portal applications, should be designed, implemented, and used in a way that facilitates safe and effective patient engagement; Clinicians should make use of open notes to ensure transparency of information for patients	Clinician	3B - Health IT Facilitates Safe and Effective Patient Engagement

Appendix I: Proposed Measure Concepts for a Shared Risk Environment

1. **Allocation of Responsibility for Health IT and Converging Technologies[8] Safety Among Participating Stakeholders**

    1.1   The organization's culture of safety includes shared involvement and responsibility to address the potential risks associated with the use of Health IT. This requires periodic re-evaluation of the roles and responsibilities of all stakeholders, including the healthcare organization, clinicians, and vendors/developers. The importance of Health IT and patient safety has been recognized by the recent efforts of regulatory agencies,[9] accrediting organizations,[10] certification bodies, recommendations of the Institute of Medicine to improve the safe design, implementation, and use of Health IT; [11] and patient safety-related best practices.[12] As part of the Health IT vendor selection criteria, healthcare organizations and clinicians should consider the willingness of a particular vendor to meet the measures described below.

    1.2   The organization has a written hardware purchase or software license and maintenance agreement with Health IT vendors specifying how the vendors will work with their customers on safety and quality involving the implementation, customization and use of Health IT products and services. The agreement contains language consistent with evolving standards on quality and risk management of clinical health information technology

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[8] The Joint Commission recognizes that technology may adversely affect the quality and safety of care if it is designed or implemented improperly or if user-technology interfaces are misinterpreted or subverted, and suggests approaches to the implementation of Health IT and "converging technologies" — the interrelationship between medical devices and Health IT— to minimize errors that may adversely affect patient care. *See* The Joint Commission Sentinel Event Alert No. 42: Safely implementing health information and converging technologies (December 11, 2008) *available online at* http://www.jointcommission.org/assets/1/18/SEA_42.pdf.   *See also* The Joint Commission Sentinel Event Alert No. 54: Safe Use of Health Information Technology (March 31, 2015) *available online at* http://www.jointcommission.org/assets/1/18/SEA_54.pdf.

[9] See 42 C.F.R. §482.12(a)(50 (The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients).   Healthcare governing boards have a fiduciary obligation to oversee the quality of care and patient safety rendered within their institutions This oversight obligation is based upon the application of the fiduciary duty of care board members owe the organization and, for non-profit organizations, the duty of obedience to charitable mission. In *re* Caremark International Inc. Derivative Litigation, 698 A. 2d 959 (Del. Ch. 1996). Additionally, standards set by The Joint Commission reinforce the principle that a healthcare organization's "governing body is ultimately accountable for the safety and quality of care, treatment, and services." *See* The Joint Commission Hospital Accreditation Standards, Leadership (LD) Standards, LD.01.03.01, p. 101 (2009).

[10]   The Joint Commission (www.jointcommission.org), Healthcare Facilities Accreditation Program (www.hfap.org) and Det Norske Veritas Health, Inc. (www.dnv.com/industry/healthcare) all have deeming authority from CMS. Section 1865(a)(1) of the Social Security Act (the Act) permits providers and suppliers "accredited" by an approved national accreditation organization (AO) to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions. Accreditation by an AO is voluntary and is not required for Medicare certification. Section 1865(a)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity by a national accreditation body demonstrates that all applicable conditions are met or exceeded, the Secretary deems those requirements to be met by the provider or supplier. Other accrediting bodies include COLA (clinical laboratory accreditation) (www.cola.org), CARF International (rehabilitation facilities) (www.carf.org), American College of Radiology (diagnostic imaging accreditation) (www.acr.org) and Intersocietal Accreditation Commission (specialty imaging accreditation) (www.intersocietal.org). *See also* The Joint Commission Sentinel Event Alert No. 54: Safe Use of Health Information Technology (March 31, 2015) *available online at* http://www.jointcommission.org/assets/1/18/SEA_54.pdf.

[11]   *See* the Institute of Medicine recommendation on coordination of efforts to increase our understanding of risks associated with Health IT and improve its safe design, implementation, and *See* IOM (Institute of Medicine). 2012. *Health IT and Patient Safety: Building Safer Systems for Better Care.* Washington, DC: The National Academies Press.

[12] *See, e.g.,* Safety Assurance Factors for EHR Resilience (SAFER) Guides, Organizational Responsibilities, *available online at* http://www.health it.gov/safer/safer-guides. *See also* guidance of the National Institute of Standards and Technology *available online at* http://www.nist.gov

systems and networks.[13]   The following contractual elements are included to minimize the associated risks and promote the safe use of Health IT:

- The agreement clearly defines and documents the roles of the participating organization, clinicians, Health IT vendors, and software and hardware developers with respect to the safe deployment, implementation and use of the supporting tools and technologies, and ongoing maintenance and upgrades.

- The agreement requires Health IT vendors to cooperate in the investigation of technology-related deaths, serious injuries or unsafe conditions associated with the use of such technology.

- The agreement requires Health IT vendors to be responsible to timely notify users if they identify or become aware of software deficiencies, hardware defects, implementation errors, poor design or usability, misinterpreted user-technology interfaces or other causes that materially affect patient safety.

- The agreement requires Health IT vendors to be responsible for collaborating with organizations and clinicians to provide solutions for identified patient safety issues to **all** users (*e.g.*, workflow guidance, features that should not be used, software updates).

- The agreement clearly allocates responsibility for ensuring adequate training and education of users, appropriate resourcing, customization, and use of Health IT in accordance with risk assessment, vendor recommendations, and organizational policy.

- The party who has the most control over the factors giving rise to a particular HIT patient safety risk is in the best position to prevent and mitigate a such risk and thus is the one charged with responsibility for preventing and mitigating such risk in the agreement.

1.3   The Health IT vendors with whom the organization contracts for hardware or software licenses and related services support the free exchange of information about Health IT user experiences and issues and do not prohibit sharing of such information, including details (*e.g.*, screenshots) relating to patient safety, and make comparative user experiences publicly available.[14]

1.4   Health IT software license and maintenance agreements and hardware purchase agreements contain contractual provisions which promote patient safety by permitting shared learning and research on Health IT and patient safety, including research on usability and interoperability. Additionally, such agreements should fairly allocate responsibility for acts and omissions to parties who are primarily responsible for the conduct that led to the acts or omissions.[15] In negotiating with Health IT vendors, healthcare organizations and vendors consider the following provisions:

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[13] *See* ISO IEC 80001-1:2010(en), Application of Risk Management for IT-networks incorporating medical devices–Part 1: Roles, Responsibilities and Activities *available online at* https://www.iso.org/obp/ui/#iso:std:iec:80001:-1:ed-1:v1:en which embraces the concept of a "Responsibility Agreement.".   Other related and relevant standards include ISO 31000 (Risk Management), IEC 14971 (Medical device risk management), ISO 62304 (Software Risk Management) and IEC 27005 (IT Security Risk Management). Standards-based guidance is being developed specifically to address risk management of clinical health IT software systems, including health management health IT, not regulated by the Food and Drug Administration.   See http://healthit.gov/facas/sites/faca/files/IUSWG_AAMI_Proposal_Package_2014-12-12.pdf.

[14] *See* IOM (Institute of Medicine). 2012. *Health IT and Patient Safety: Building Safer Systems for Better Care.* Recommendations # 2 and 3, Washington, DC: The National Academies Press.

[15] *See* discussion in EHR Contracts: Key Contract Terms for Users to Understand, prepared by Westat for the Office of the National Coordinator for Health Information Technology (June 25, 2013) *available online at* https://www.healthit.gov/sites/default/files/ehr_contracting_terms_final_508_compliant.pdf.

o   Customers should avoid "hold harmless" clauses in vendor contract that require them to indemnify vendors for the vendors' acts or omissions, including errors, injuries or malpractice claims arising from use of the product.

o   Customers should ensure that "limitations of liability" clauses in vendor contracts are sufficient to cover customers' reasonable damages caused by the vendor's breach and do not limit the vendor's liability for certain kinds of conduct including: (i) claims subject to indemnification; (ii) personal injury (including death) and damage to real or tangible personal property; (iii) privacy and security breaches; (iv) damages arising from the other party's negligence or willful misconduct; and (v) damages relating to the vendor's repudiation of or wrongful refusal to perform its obligations under the agreement.

o   Contract terms, including non-disclosure, confidentiality, and other intellectual property protections should not be broader than reasonably necessary to protect the vendor's legitimate intellectual property interests, when balanced against patient safety concerns. Vendor contracts should not prohibit complete and accurate adverse event reporting (including disclosure of screenshots as part of voluntary adverse event reports to Patient Safety Organizations or accrediting organizations). Moreover, such provisions should not prohibit public disclosure of comparative user experiences with respect to identified health IT products or independent, third-party safety-related research and reporting, including on the usability or interoperability of specific health IT vendor products and services.

o   Contracts should include performance warranties with respect to the Health IT vendor's standard system, customizations and third party software integral to the expected functionality of the system which specifically address Health IT safety during design, implementation, and ongoing maintenance in areas of known risk (*e.g.*, failure to conform with acceptance criteria; system availability and response time; equipment configuration necessary to meet performance warranties; quality and timeliness of service; keylocks or other devices which allow vendors to automatically disable the system in the event of a dispute; malicious programs or devices such as viruses, worms, malware or other forms of computer sabotage).

2.   Ensuring Confidentiality, Integrity and Availability of EHR Data

2.1   The organization conducts a security risk analysis of the potential threats and vulnerabilities to the confidentiality, integrity and availability of electronic protected health information (ePHI) that may affect its disaster preparedness efforts consistent with the requirements of the HIPAA Security Rule[16] and HITECH Meaningful Use Requirements,[17] and corrects identified security deficiencies.

2.2   As part of its overall emergency preparedness plan, the organization has an IT focused Disaster Recovery Plan consistent with the requirements of the HIPAA Security Rule to establish (and implement as needed) procedures to: (i) create and maintain retrievable exact copies of ePHI;[18] (ii) restore any loss of data;[19] (iii)

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[16] *See* 45 CFR § 164.308(a).

[17] The HITECH Meaningful Use requirements include a requirement for conducting a security risk analysis and implementing security updates as necessary and correcting identified security deficiencies EHR technology certification criteria includes the criteria found at 45 C.F.R. § 170.302(p)- Emergency Access. Certified EHR technology must "be capable of permitting authorized users to access electronic health information during an emergency." *See* the HITECH Act § 4101(a), amending SSA § 1848, codified at 42 U.S.C. § 1395w-4(o) (Feb. 17, 2009). Title XIII of Division A and Title IV of Division B of the ARRA are commonly referred to as the "Health Information Technology for Economic and Clinical Health Act."

[18] *See* 45 CFR § 164.308 (a)(7)(ii)(A).

[19] *See* 45 CFR § 164.308(a)(7)(ii)(B). *See also* The Joint Commission Standard IM.2.20 (IM.02.01.03*) requires the safeguarding of data and information against loss, destruction and tampering.

enable continuation of critical business processes for protection of the security of ePHI while operating in emergency mode;[20] and (iv) procedures for obtaining necessary ePHI during an emergency.[21] Such a plan is documented and routinely updated.

2.3   The organization has implemented measures of security risk compliance consistent with the HIPAA Security Rule, HITECH Meaningful Use Requirements, guidance of the National Institute of Standards and Technology, applicable accreditation standards and patient safety-related best practices[22] to ensure that: (i) EHR system data or information is accessible and useable upon demand by an authorized person; (ii) EHR system data or information have not been altered or destroyed in an unauthorized manner; and (iii) the EHR system employs currently available patient matching technology and capabilities to accurately match data to a particular patient consistent with commercially reasonable standards.

2.4   If the organization utilizes a cloud-based EHR, the disaster recovery plan addresses disruptions in access to an ISP or cloud-based EHR vendor to ensure the availability of the EHR for both treatment and billing services.

- o The cloud-based EHR vendor provides a copy of its disaster recovery plan to the organization and agrees to perform disaster recovery testing involving one or more of the organization's facilities, shares the results of such testing and promptly advises the organization of any changes in its disaster recovery plan.

- o The cloud-based EHR vendor agreement includes specific contract provisions that address disaster recovery.

- o The organization has negotiated the extent to which contractual language will excuse the cloud-based EHR vendor if a *force majeure* event occurs (*e.g.*, language should be conditioned on the existence of execution of the vendor's disaster recovery plan as required by other provisions of the contract).

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[20] *See* 45 CFR § 164.308(a)(7)(ii)(C).

[21] *See* 45 CFR § 164.312(a)(2)(ii). *See also* The Joint Commission Standard IM.2.30 (IM.01.01.03*) requires a disaster recovery plan for information systems and the periodic testing of the plan to ensure its effectiveness.

[22] *See, e.g.*, Safety Assurance Factors for EHR Resilience (SAFER) Guides, Patient Identification, *available online at* http://www.health it.gov/safer/safer-guides.