NQF-Endorsed Measures for Patient Safety

TECHNICAL REPORT

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Executive Summary

Medical errors and unsafe care kill hundreds of thousands of people each year. Patient safety-related events can occur in a variety of healthcare settings, and can include healthcare-associated infections (HAIs), medication errors, falls, and other potentially avoidable occurrences. The societal costs of patient safety events are passed on in a number of ways—hospital and other health care services, premiums, taxes, lost work time and wages, and reduced quality of life, to name a few. Proactively addressing medical errors and reducing unsafe care that can lead to patient safety events will protect patients from harm and lead to more affordable, effective, and equitable care.

Currently, NQF's portfolio of safety measures spans a variety of topic areas. These include medication safety, healthcare-associated infections, falls, pressure ulcers, surgical complications, workforce issues, and other subjects. Several of the measures in the portfolio currently are used in public and/or private accountability and quality improvement programs. However, significant gaps remain in the measurement of patient safety and how providers approach minimizing the risk of patient safety events. There is also a recognized need to expand available patient safety measures beyond the hospital setting and harmonize safety measures across sites and settings of care.

In order to evaluate quality measures, NQF has recently changed its approach and moved to a "Standing Committee" instead of committees that are convened for each project. The Patient Safety Committee is among the first NQF panels to transition to this Standing Committee arrangement. The 25-member Patient Safety Standing Committee has been charged with overseeing the NQF Patient Safety measure portfolio, evaluating both newly-submitted and previously-endorsed measures against NQF's measure evaluation criteria, identifying gaps in the measurement portfolio, providing feedback on how the portfolio should evolve, and contributing to any *ad hoc* or expedited projects in its designated topic areas. All other elements of the standard endorsement process have remained unchanged.

On April 17-18, 2014, the Patient Safety Standing Committee evaluated 4 new measures and 12 measures undergoing maintenance review against NQF's standard evaluation criteria. Eight of the measures were recommended for endorsement by the Committee, and eight were not recommended. The 8 measures that were recommended by the Standing Committee include:

- 0138 National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
- 0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
- 0555 INR Monitoring for Individuals on Warfarin
- 0556 INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications
- 0541 Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category

- 0684 Percent of Residents with a Urinary Tract Infection (Long-Stay)
- 2337 Antipsychotic Use in Children Under 5 Years Old
- 2371 Annual Monitoring for Patients on Persistent Medications

In addition, the Patient Safety Standing Committee was asked to conduct an *ad hoc* review of measure 0500, Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital). During this measure's endorsement maintenance review in 2013 by NQF's Infectious Disease Steering Committee, concerns were raised about the level of evidence supporting element 'F' of the composite, which relates to the use of invasive monitoring of central venous pressure and oxygenation levels in patients with severe sepsis or septic shock. In 2012, measure #0500 was recommended for endorsement by the Infectious Disease Committee; however, at that time there was a spirited discussion about the requirement for the use of invasive monitoring in all patients with severe sepsis and septic shock. The CSAC and Board ultimately recommended continued endorsement of the measure based on current peer review literature, on the condition that an *ad hoc* review would be initiated immediately upon the emergence of new evidence related to item 'F' – the invasive monitoring component of the composite.

On March 18, 2014, the Protocolized Care for Early Septic Shock (ProCESS) trial published its findings in the *New England Journal of Medicine*. The trial found that outcomes for protocolized early goal- directed therapy (EGDT) in severe sepsis and septic shock with invasive monitoring were no different than either protocolized care without invasive monitoring, or usual care. In response to the results of this study, NQF initiated an ad hoc review of the evidence supporting item 'F' in measure 0500. As a standing committee with expertise in critical care and treatment of sepsis, the Patient Safety Standing Committee was assigned the duty of conducting the *ad hoc* review. Upon initial review, the Committee recommended removal of item 'F' from measure 0500; however, a compromise solution was subsequently reached between the measure developer and other key stakeholders, and the Committee approved this compromise approach. Additional details on this review are included in the full report.

Introduction

The Institute of Medicine (IOM) defines patient safety as "freedom from accidental injury due to medical care or medical errors." Medical errors and unsafe care kill hundreds of thousands of people each year; a recent analysis estimated that up to 440,000 Americans die annually from medical errors, and a 2010 study by the HHS Office of Inspector General (OIG), Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries, estimated that over a quarter of hospitalized Medicare beneficiaries experience an adverse event during their hospital stay. Adverse events can take many forms, including healthcare-associated infections, medication errors, falls, and other avoidable occurrences.

According to the Centers for Disease Control and Prevention (CDC), on any given day, about 1 out of every 20 hospitalized patients has a hospital-acquired infection (HAI), costing up to \$33 billion annually. The Institute of Medicine report *Preventing Medication Errors* identified error rates across a variety of settings and types, estimating that about 400,000 preventable adverse drug events (ADEs) occur each year in U.S. hospitals, another 800,000 in long-term care, and more than 500,000 among Medicare patients in outpatient settings. The report also noted that costs associated with preventable medication errors have not been well researched but conservatively estimated that the annual cost to hospitals of the 400,000 ADEs, in 2006 dollars, was \$3.5 billion.

HAIs and preventable medication errors, while occurring in relatively high numbers, are only two of the many types of patient safety-related events that occur in healthcare settings. The costs are passed on in a number of ways—premiums, taxes, lost work time and wages, and health threats, to name a few. Proactively addressing medical errors and unsafe care will protect patients from harm and lead to more affordable, effective, and equitable care.

NQF has a ten-year history of focusing on patient safety. Through various projects, NQF has previously endorsed over 100 consensus standards related to patient safety. In addition, NQF endorsed 34 safe practices in the 2010 update of the Safe Practices for Better Healthcare and 29 Serious Reportable Events (SRE). The Safe Practices, SREs, and NQF-endorsed patient safety measures are important tools for tracking and improving patient safety performance in American healthcare. However, significant gaps remain in the measurement of patient safety. There is also a recognized need to expand available patient safety measures beyond the hospital setting and harmonize safety measures across sites and settings of care.

National Quality Strategy

The National Quality Strategy (NQS) serves as the overarching framework for guiding and aligning public and private efforts across all levels (local, State, and national) to improve the quality of health care in the U.S. The NQS establishes the "triple aim" of better care, affordable care, and healthy people/communities, focusing on six priorities to achieve those aims: Safety, Person and Family Centered Care, Communication and Care Coordination, Effective Prevention and Treatment of Illness, Best Practices for Healthy Living, and Affordable Care.

As one of the six priorities of the NQS, safety is clearly a significant and important area of focus for the nation's healthcare system. In pursuit of the NQS goal of improving patient safety, the Department of

Health and Human Services (HHS) launched the Partnership for Patients initiative in 2011. The Partnership for Patients is focused on a number of specific areas that are closely aligned with topics addressed in NQF's patient safety measure portfolio, including adverse drug events, catheter-associated urinary tract infections (CAUTI), central line-associated bloodstream infections (CLABSI), falls, pressure ulcers, venous thromboembolism (VTE), and other subjects. The HHS Action Plan to Prevent Healthcare-Associated Infections is also a major nationwide safety initiative associated with the NQS goals.

Trends and Performance

While medical error rates remain high, a number of safety initiatives have achieved success in reducing adverse events through programs that involve measurement activity. For example, On the CUSP, an AHRQ-funded national CLABSI prevention initiative, has reduced the incidence of CLABSIs by 40 percent in participating institutions. A similar approach is being implemented to reduce CAUTI rates. Measurement through the Center for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN) has shown a 7 percent decrease in CAUTI rates between 2009 and 2010, as well as a 10 percent decrease in surgical site infections (SSI). Other efforts have also shown promising results—another AHRQ-funded initiative, the Reduce MRSA project, has achieved significant reductions in bloodstream infections, including MRSA, for participating hospitals.

Patient Safety Measure Evaluation: Refining the Evaluation Process

Recently, the NQF has made a change to the Consensus Development Process (CDP)—transitioning to a Standing Steering Committee—which has been incorporated into the ongoing maintenance activities for the Patient Safety portfolio. The change is described below.

Standing Steering Committee

In an effort to remain responsive to its stakeholders' needs, NQF is constantly working to improve the CDP. Volunteer, multi-stakeholder steering committees are the central component to the endorsement process, and the success of the CDP projects is due in large part to the participation of its Steering Committee members. In the past, NQF initiated the Steering Committee nominations process and seated new project-specific committees only when funding for a particular project had been secured. Seating new committees with each project not only lengthened the project timeline, but also resulted in a loss of continuity in process and consistency because committee membership changed—often quite substantially—over time.

To address these issues in the CDP, NQF is beginning to transition to the use of Standing Steering Committees for specific topic areas. These Standing Committees will oversee the various measure portfolios; this oversight function will include evaluating both newly-submitted and previously-endorsed measures against NQF's measure evaluation criteria, identifying gaps in the measurement portfolio, providing feedback on how the portfolio should evolve, and serving on any ad hoc or expedited projects that arise in their designated topic areas.

The Patient Safety Standing Committee currently includes 25 members (see <u>Appendix D</u>). Each member has been randomly appointed to serve an initial two- or three- year term, after which he/she may serve a subsequent 3-year term if desired.

NQF Portfolio of performance measures for Patient Safety

Due to the cross-cutting nature of patient safety, NQF's portfolio of safety measures spans a variety of topic areas. These include medication safety, healthcare-associated infections, falls, pressure ulcers, surgical complications, workforce issues, and other subjects. For the purposes of maintenance, the patient safety portfolio contains 64 measures: 24 process measures, 36 outcome measures, and 4 structure measures (see table below). 12 of these measures, as well as four newly-submitted measures, were evaluated by the Patient Safety Standing Committee under this project.

NQF Patient Safety Portfolio of Measures

Topic Area	Process	Outcome	Structure	Total
Medication Safety	9	0	0	9
Healthcare Associated Infections	3	5	0	8
Falls	3	4	0	7
Venous Thromboembolism (Vte)	6	1	0	7
Pressure Ulcers	1	5	0	6
Surgical Safety	0	7	0	7
Mortality	0	0	0	4
Radiation Safety	2	1	1	4
Workforce	0	0	3	3
Other	0	9	0	9
Total	24	36	4	64

Because patient safety impacts many clinical areas, a number of measures that could be considered safety-related have been assigned, for various reasons, to other NQF measure portfolios that focus on specific topics. These include Health and Well-Being, Care Coordination, Behavioral Health, Surgery, and Cardiovascular care, among others.

Endorsement of measures by NQF is valued not only because the evaluation process itself is both rigorous and transparent, but also because evaluations are conducted by multi-stakeholder committees comprised of clinicians and other experts from hospitals and other healthcare providers, employers, health plans, public agencies, community coalitions, and patients—many of whom use measures on a daily basis to ensure better care. Moreover, NQF-endorsed measures undergo routine "maintenance" (i.e., re-evaluation) to ensure that they are still the best-available measures and reflect the current science. Importantly, legislative mandate requires that preference be given to NQF-endorsed measures for use in federal public reporting and performance-based payment programs. NQF measures also are used by a variety of stakeholders in the private sector, including hospitals, health plans, and communities.

Over time, and for various reasons, some previously-endorsed safety-related measures have been dropped from the full NQF portfolio. In some cases, measure stewards elect to withdraw their measures from consideration; other measures have lost endorsement upon maintenance review. Loss of endorsement can occur for many different reasons including—but not limited to—a change in evidence without an associated change in specifications, universally high performance on a measure signifying no further opportunity for improvement, and endorsement of a superior measure.

The Patient Safety portfolio of measures is currently organized by topic area. However, the Standing Committee and other stakeholders are encouraged to consider other measurement domains, such as measure type (e.g. process, outcome, patient-reported, etc.), care setting, clinical area, or other relevant factors, for the purposes of identifying or highlighting gaps in safety measurement.

Use of measures in the portfolio

Many of the measures in the Patient Safety portfolio are among NQF's most long-standing measures, several of which have been endorsed since 2004. Many are in use in at least one federal program (see Appendix C). In addition, several of the measures have been included in the Safety Family of Measures by the NQF-convened Measure Applications Partnership (MAP).

Measures in the "pipeline"

NQF recently launched a *Measure Inventory Pipeline*—a virtual space for developers to share information on measure development activities. Developers can use the Pipeline to display data on current and planned measure development and to share successes and challenges. Information shared via the Pipeline is available in real time and can be revised at any time. NQF expects that developers will use the Pipeline as a tool to connect to, and collaborate with, their peers on measurement development ideas. Currently, no measures related to the patient safety topic area have been submitted to the Pipeline.

Patient Safety Measure Evaluation

On April 17-18, 2014 the Patient Safety Steering Committee evaluated 4 new measures and 12 measures undergoing maintenance review against NQF's standard evaluation criteria. To facilitate the evaluation, the committee and candidate standards were divided into 3 workgroups for preliminary review of the measures, prior to consideration by the entire Standing Committee. The Committee's discussion and ratings of the criteria are summarized in the evaluation tables beginning on page 25.

Patient Safety Summary

	Maintenance	New	Total
Measures under consideration	12	4	16
Measures withdrawn from consideration	2	0	2
Measures recommended	6	2	8
Measures not recommended	6	2	8

	Maintenance	New	Total
Reasons for not recommending	Importance – 3	Importance – 2	
	Scientific Acceptability – 1		
	Overall – 2		
	Competing Measure – 0		

Comments Received prior to Committee evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF has begun soliciting comments prior to the evaluation of measures via an online tool located on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from February 21-March 6 for the measures under review. All submitted comments were provided to the Committee prior to their initial deliberations held during the workgroups calls. A total of 24 pre-evaluation comments were received on 8 of the measures that were submitted for maintenance review (see Appendix F).

Comments Received After Committee Evaluation

The 30-day post-evaluation comment was open from May 28, 2014 through June 26, 2014. During this commenting period, NQF received 66 comments from 17 member organizations. These included measure-specific comments as well as comments about the draft report in general and about the measure evaluation process. The Committee discussed these comments and took action on measure-specific comments as needed during the Committee's post-comment conference call, which was held on July 14, 2014. In addition, because measure 0531 (Patient Safety for Selected Indicators) was modified by the developer in response to Committee member requests, NQF held a supplemental comment period from July 25, 2014 through August 7, 2014 to ensure transparency and gather feedback on the modified measure. During this comment period, NQF received an additional 30 comments, the majority of which expressed support for the measure and questioned the Committee's decision to not recommend it for endorsement. On the whole, comments on the general draft report were supportive of the Committee's recommendations.

Overarching Issues

During the Standing Committee's discussion of the measures, several overarching issues emerged that were factored into the Committee's ratings and recommendations for multiple measures and are not repeated in detail with each individual measure:

Types of measures

The Committee stressed the need for continued development of safety outcome measures. While NQF's safety portfolio contains a higher proportion of outcome measures than many other topic areas, gaps in certain areas, such as medication safety, remain. In particular, the Patient Safety Standing Committee noted gaps in radiation safety measures, many of which were reviewed by the Committee but ultimately

were not recommended for endorsement for a variety of reasons, because many were measures of structure and process, rather than outcome measures.

Data sources

The Committee noted the benefits of measures based on administrative and pharmacy claims, including ease of use and data collection, but also emphasized the need to move toward measures based on electronic health record data, which contain richer clinical information and may allow for more accurate measurement of important safety outcomes.

Use of measures for accountability purposes

The Committee noted that a number of the measures under consideration in this project are in use or planned for use in accountability programs, such as value-based purchasing and public reporting initiatives. Specifically, there was concern over the use in value-based purchasing programs because in some measures, there were questions about validity. This may make some of these more useful for case finding (i.e., identifying potential patient safety events) but may be unfair to use to modify payments to organizations based on their relatively low sensitivity and specificity for identifying actual safety events. Some Committee members suggested that for this reason, the current or proposed use of measures could have implications for endorsement decisions; staff noted that NQF is exploring the possibility of different 'levels' of endorsement, or endorsement 'fit for purpose'. However, staff reiterated that issues related to the proper use of measures are not strictly within the scope of endorsement committees, and are more appropriately addressed by the Measure Applications Partnership (MAP).

Summary of Measure Evaluation

The following brief summaries of the measures and the evaluation highlight the major issues that were considered by the Committee. Details of the Committee's discussion and ratings of the criteria are included in <u>Appendix A</u>.

Twelve previously NQF-endorsed measures and four newly submitted measures addressing patient safety were reviewed. Eight of the sixteen measures were recommended for endorsement. In addition, one measure was deferred to a subsequent cycle of safety work for a final endorsement decision.

0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (CDC): Recommended

Description: Standardized Infection Ratio (SIR) and Adjusted Ranking Metric (ARM) of healthcare-associated, catheter-associated urinary tract infections (UTI) will be calculated among patients in bedded inpatient care locations, except level II or level III neonatal intensive care units (NICU). **Measure Type**: Outcome; **Level of Analysis**: Facility, Population: National, Population: Regional, Population: State; **Setting of Care**: Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post-Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post-Acute/Long Term Care Facility: Long Term Acute Care Hospital, Other; **Data Source**: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Laboratory, Other, Paper Medical Records

This measure has been NQF-endorsed since 2009 and is used in several public reporting, accreditation, and payment programs, including the Hospital Inpatient Quality Reporting Program, The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, IRF Quality

Reporting Program, LTCH Quality Reporting Program, Public Health/Disease Surveillance, and National Healthcare Safety Network. Since its last endorsement maintenance review, this measure has been updated in two ways: the addition of the ARM for reporting purposes and the extension of the measure to hospital settings outside the ICU. The Committee was very supportive of the underlying concept of reporting outcomes for CAUTIs, which are a major issue in hospitals with real health and economic implications, and where there is still much room to improve. The Committee raised several concerns with the reliability and validity of this measure, specifically issues in measurement (e.g., measuring CAUTI at the day level would miss partial days, facilities sending many urine cultures would have more positive cultures, and difficulties in defining a UTI). The Committee agreed that extending the measure to non-ICU settings was appropriate, but was concerned that formal testing had not been performed in those settings. There was also concern that similar data are gathered through NDNQI by the American Nurses Association; the developer agreed to explore alignment with this program. There was extensive discussion on the differences between the SIR and the ARM, with some Committee members noting that the ARM would include smaller hospitals but could result in some reporting issues that may confuse consumers, such as small hospitals with zero infections being ranked lower than larger hospitals with more catheter days and some evidence of infections. There was also concern over the validity of these data, namely that only validity testing had been performed by the states and rates demonstrated wide ranges in sensitivities from as low as 63% to as high as 97%. Reported specificities ranged from 79% to as high as 99%. Because of this, there was concern with potential uses of the measures due to issues with validity. However, despite these concerns, the Committee recommended this measure for approval given importance of this measure and opportunities for improvement.

0139: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (CDC): Recommended

Description: Standardized Infection Ratio (SIR) and Adjusted Ranking Metric (ARM) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in bedded inpatient care locations. **Measure Type**: Outcome; **Level of Analysis**: Facility, Population: National, Population: Regional, Population: State; **Setting of Care**: Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Other; **Data Source**: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Laboratory, Other, Paper Medical Records

This measure has been NQF-endorsed since 2009 and is used in several public reporting, accreditation, and payment programs, including the Hospital Inpatient Quality Reporting Program, The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, IRF Quality Reporting Program, LTCH Quality Reporting Program, Public Health/Disease Surveillance, and National Healthcare Safety Network. As with measure 0138, this measure was modified since its last endorsement maintenance to include the ARM for reporting purposes and extension of the measure to hospital settings outside the ICU. The Committee was very supportive of the underlying concept of reporting outcomes for CLABSIs, noting both the cost and health impacts of these infections. However, the Committee raised some concerns about the measure's validity. Specifically, there was concern about the relatively low positive predictive value for this measure and modest results of inter-rater reliability testing. Given these issues with validity, there was concern with potential uses of the measure. There was also concern that similar data are gathered through NDNQI by the American Nurses Association; the developer agreed to explore alignment with this program. However, despite these concerns, the

Committee ultimately decided that the reliability and validity data that was submitted by the Developer was sufficient to merit recommending the measure for approval.

0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI)-Central Venous Catheter (CVC): Not Recommended

Description: Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed; **Measure Type:** Process; **Level of Analysis:** Clinician: Group/Practice, Clinician: Individual, Clinician: Team, Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source:** Administrative claims, clinical database/registry

This measure was previously endorsed in 2008, and is currently used for public reporting in the Physician Quality Reporting System (PQRS) as well as internal quality improvement efforts in many facilities. The Committee discussed the appropriate uses of this measure and its effectiveness in decreasing CRBSI rates in hospitals. Committee members raised concerns about the measure's lack of systematic testing for reliability and validity. The Committee also agreed that an outcome measure of CLABSI infection rate would be better, as was recommended in measure in 0139. Yet the Committee acknowledged that the measure addresses an important topic given that hospital-acquired infections and central line associated infections are high-impact conditions and that there is evidence that following the recommended steps in this measure can potentially reduce CLABSI rates. Although this measure was generally considered to be feasible, there was some discussion about the burden of data collection as this was gathered from registry data and was not available in claims. Ultimately, due to the lack of reliability testing, the measure did not pass the Scientific Acceptability criterion. During the public comment period, the developer (ASA) submitted comments requesting that the Committee reconsider its decision, stressing the measure's importance to improving the quality of anesthesiology practice. The developers cited observational data showing that a successful compliance rate of 90% among practices reporting on the bundle, and noted that 84% of these practices had CLABSI rates under the 2012 CLABSI Standardized Infection Ratio (SIR) reported by CDC's National Healthcare Safety Network (NHSN). The Committee discussed ASA's reconsideration request on its post-comment conference call and reaffirmed its initial decision.

0510 Exposure time reported for procedures using fluoroscopy: (American College of Radiology): Not Recommended

Description: Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time; **Measure Type:** Process; **Level of Analysis:** Clinician: Group/Practice, Clinician: Individual; **Setting of Care:** Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility; **Data Source:** Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Paper Medical Records

This measure was previously endorsed in 2008, and is currently used for public reporting in the Physician Quality Reporting System (PQRS), internal quality improvement, and is part of the American Board of Radiology's Approved Maintenance of Certification Part IV Practice Quality Improvement Project. The Committee acknowledged the importance of data collection as a foundation for developing programs around safety and radiation exposure, quality improvement, and reducing patient injury from radiation. Although the Committee recognized that greater fluoroscopic use and length of time does result in higher patient harm, there was not enough evidence linking documentation of exposure time to

improved outcomes. Consequently, the measure did not pass the Evidence criterion and the Committee voted not to recommend this measure for NQF endorsement.

0531 Patient Safety for Selected Indicators (PSI 90): Not Recommended

Description: Patient Safety for Selected Indicators (PSI 90) is a weighted average of the observed-to-expected ratios for the following component indicators: PSI 03 Pressure Ulcer Rate, PSI 06 latrogenic Pneumothorax Rate, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, PSI 08 Postoperative Hip Fracture Rate, PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate, PSI 13 Postoperative Sepsis Rate, PSI 14 Postoperative Wound Dehiscence Rate, and PSI 15 Accidental Puncture or Laceration Rate; **Measure Type:** Composite; **Level of Analysis:** Facility; **Setting of Care:** Hospital/Acute Care Facility; **Data Source:** Administrative Claims

This measure was originally endorsed in 2009 and is currently in use in the Hospital Inpatient Quality Reporting (IQR) program as well as the Hospital Value-Based Purchasing program. The measure is a composite of eight individual outcome measures, rolling up the results of those component measures into a single score. This composite score is based on a methodology that weights each component (i.e., safety event) based the prevalence of the event and the extent to which it can be reliably measured. The Committee raised concerns about the weighting scheme, suggesting that it seems to place too much emphasis on certain outcomes in the composite such as "PSI 15 Accidental Puncture or Laceration" which in the current specifications was weighted at almost 50% of the outcome. This in particular was a concern because this Accidental Puncture or Laceration may be considerably less preventable than other safety events, such as "PSI 03 Pressure Ulcer Rate", which were weighted at 2.2% and 0.1% of the outcome respectively. The Committee suggested that the developer also include three additional components – "PSI #9 Perioperative Hemorrhage or Hematoma Rate", "PSI #10 Postoperative Physiologic and Metabolic Derangement Rate", and "PSI #11 Postoperative Respiratory Failure Rate" that were not part of the AHRQ PSI composite in the measure, noting doing so could potentially improve the balance of the weighting scheme. The Committee commended the developer for the rigor and extent of evidence that was presented in support of the measures. The developer agreed to address the Committee's concerns, and confirmed that the measure would be revised and submitted for reconsideration by the committee after the public comment period. These revisions are described in a comment from the developer (AHRQ) that is posted on the project web page. In order to ensure full transparency and to provide an opportunity for public input on the revised measure, NQF held a supplemental comment period on measure 0531, with the Committee slated to hold a re-vote at the close of this supplemental period. However, upon further review of the updated measure, the Committee determined that an immediate revote would be premature, agreeing that additional review and discussion of the measure was warranted. Consequently, a final decision on measure 0531 will be deferred to the next cycle of measure evaluation by the Patient Safety Standing Committee, which is expected to occur in early 2015. This will also enable the developer to provide additional analyses for the Committee's review. To ensure that comments from the supplemental period are given proper and timely consideration, these comments will be provided to the Committee in advance of and during their full evaluation of the measure in the next cycle. Additional opportunities for public comment will also be available throughout the course of that project.

0532 Pediatric Safety for Selected Indicators (PDI 19): Not Recommended

Description: Pediatric Patient Safety for Selected Indicators (PDI 19) is a weighted average of the observed-to-expected ratios for the following component indicators: PDI 01 Accidental Puncture or Laceration Rate, PDI 02

Pressure Ulcer Rate, PDI 05 latrogenic Pneumothorax Rate, PDI 10 Postoperative Sepsis Rate, PDI 11 Postoperative Wound Dehiscence Rate, and PDI 12 Central Venous Catheter-Related Blood Stream Infection Rate; **Measure Type:** Composite; **Level of Analysis:** Facility; **Setting of Care:** Hospital/Acute Care Facility; **Data Source:** Administrative Claims

This measure was originally endorsed in 2009; it is currently in use through the Agency for Healthcare Research and Quality (AHRQ)'s Healthcare Cost and Utilization Project (HCUP) and is publicly reported through CPM Healthgrades. The measure is a composite of six individual outcome measures, rolling up the results of those component measures into a single score. This composite score is based on a methodology that weights each component (i.e., safety event) based the prevalence of the event and the extent to which it can be reliably measured. As with the adult safety composite measure (0531), the Committee raised concerns about the measure's weighting scheme, questioning whether the measure as constructed accurately distinguishes between high- and low-performing hospitals. The measure failed on the composite subcriterion due to expressed concerns about the weighting methodology. The Committee members were open to reconsidering the measure if AHRQ revisited the weighting of components within the composite.

0541 Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category: Recommended

Description: The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year. A performance rate is calculated seperately for the following medication categories: Renin Angiotensin System (RAS) Antagonists, Diabetes Medications, Statin; **Measure Type:** Process; **Level of Analysis:** Clinician: Group/Practice, Health Plan; **Setting of Care:** Ambulatory Care: Clinician Office/Clinic, Pharmacy; **Data Source**: Administrative claims

This medication adherence measure was originally endorsed in 2009 and is used by the Centers for Medicare and Medicaid Services in their Part D drug benefit program to evaluate Medicare prescription drug plans. The measure as originally endorsed included five rates by therapeutic category; however, two of these rates were removed from the measure prior to its submission for maintenance review. The measure as currently specified includes three rates for three drugs to treat high blood pressure, high blood sugar and high blood lipids. Although the Committee raised concerns over potential threats to validity, the measure was ultimately recommended for endorsement. The Committee agreed that these measures of adherence address a high impact area, since these three classes of chronic medications address the high-priority areas of diabetes, high blood pressure and high cholesterol.

0555: INR Monitoring for Individuals on Warfarin (Centers for Medicare & Medicaid): Recommended

Description: Percentage of individuals 18 years of age and older with at least 56 days of warfarin therapy who receive an International Normalized Ratio (INR) test during each 56-day interval with warfarin; **Measure Type:** Process; **Level of Analysis:** Clinician: Group/Practice, Health Plan, Integrated Delivery System, Population: State; **Setting of Care:** Ambulatory Care: Clinician Office/Clinic; **Data Source:** Administrative claims, Electronic Clinical Data: Pharmacy

This measure has been NQF-endorsed since 2009 and is used at the group, health plan, state and ACO levels for public reporting and quality improvement purposes, including the Quality and Resource Use Report (QRUR) Program. In addition to the QRUR program, the measure has been submitted to the Measures under Consideration list for the Medicare Shared Savings Program. The Committee questioned the modification of the required INR monitoring interval from an original interval of 40 days to a 56-day interval. The developer provided a rationale for this change, citing a study in the VA that clearly described a relationship between the 56-day interval and time in therapeutic range (TTR). The

guidelines presented by the developer differed on this issue, with recommendations for monitoring intervals ranging between 4 and 12 weeks; the developer chose the 56-day interval as a midway point, given recent data. Overall, the Committee agreed there was sufficient evidence to support the 56-day interval for monitoring and agreed that monitoring is linked to the desired outcome of increased time in therapeutic range, which leads to fewer bleeding and thromboembolic events.

0556 INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications: (Centers for Medicare & Medicaid): Recommended

Description: Percentage of episodes with an International Normalized Ratio (INR) test performed three to seven days after a newly started interacting anti-infective medication for individuals receiving warfarin; **Measure Type:** Process; **Level of Analysis:** Health Plan, Integrated Delivery System, Population: State; **Setting of Care:** Ambulatory Care: Clinician Office/Clinic; **Data Source:** Administrative claims, Electronic Clinical Data: Pharmacy

This measure has been NQF-endorsed since 2009. Although not currently in use, the measure was previously reported in the Quality and Resource Use Report (QRUR) program, but was found to be unreliable at the physician level due to sample size limitations. The measure has been submitted to the Measures under Consideration list for the Medicare Shared Savings Program. The developers envision the measure as a shared accountability measure, and have specified it for application at the health plan or integrated delivery system level. Overall, the Committee agreed that the measure was suitable for reendorsement, indicating that the testing results at the ACO level were acceptable and finding that there was sufficient evidence presented, including guideline recommendations on anticoagulation with warfarin from the British Committee for Standards in Hematology, systematic reviews about the interaction between warfarin and anti-infectives, and a summary of several studies demonstrating an association between such interactions and higher rates of hemorrhage.

0684 Percent of Residents with a Urinary Tract Infection (Long-Stay): Recommended

Description: This Minimum Data Set (MDS) 3.0 based measure estimates the percentage of long-stay residents who have a urinary tract infection on the target MDS assessment (OBRA, PPS, or discharge). In order to address seasonal variation, the proposed measure uses a 6-month average for the facility. Long-stay nursing facility residents are those with more than 100 cumulative days in the facility; **Measure Type:** Outcome; **Level of Analysis:** Facility; **Setting of Care:** Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility; **Data Source:** Electronic Clinical Data

This measure has been NQF-endorsed since 2011, and is currently being publicly reported through the Nursing Home Compare program. The Committee noted that the measure addresses an important and high-impact area, but expressed concerns about the currency of evidence submitted by the developer, noting that many of the references included in the submission form were somewhat outdated. The Committee's vote on evidence was close, with the measure falling in the grey area, suggesting that consensus had not been reached on this criterion. In accordance with NQF policy, the Committee continued to evaluate the measure against the remaining criteria; the measure passed each of the remaining criteria as well as the overall recommendation for endorsement. NQF stakeholders and members of the public are encouraged to provide input to the Committee on the appropriateness of endorsement for this measure.

0739 Radiation Dose of Computed Tomography (CT): Not Recommended

Description: The measure requires hospitals and output facilities that conduct Computed Tomography (CT) studies to assess the radiation dose associated with the most frequently conducted examination types – CT's of the head,

chest, abdomen/pelvis obtained in children and adults. The measure provides a simple framework for how facilities can assess their dose, a framework that currently does not exist. By assessing their doses, facilities can monitor the doses they use over time and compare their doses to benchmarks. The creation of benchmarks is not part of this measure per se. However, if facilities use this measure, I believe professional societies, researchers, and oversight organizations can separately create their benchmarks. Several research groups, including my own, have published benchmarks and published manuscripts that have used the framework of this measure to assess changes in radiation dose over time (Keagan, JACR, 2014) and to assess the impact of an educational intervention on doses, using the specifications of the measure to assess the results of a randomized trial (Miglioretti, JACR, 2014). This measure was initially developed for diagnostic CT, but can equally be used for CT used in conjunction with radiation therapy for cancer. Professional organizations within various medical specialties can create appropriate benchmarks depending on the application; Measure Type: Outcome; Level of Analysis: Facility, Health Plan, Integrated Delivery System; Setting of Care: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Ambulatory Care: Outpatient Rehabilitation, Ambulatory Care: Urgent Care, Hospital/Acute Care Facility, Imaging Facility; Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry

This measure was originally endorsed in 2011 and is not currently being used in any federal reporting program. The purpose of this measure is to provide a way for facilities to summarize the doses they have used in their population and compare it to other populations. The clinical problem this measure addresses is that the CT radiation dosing in the U.S. highly variable and not standardized within or across institutions. In addition, studies have found that radiation doses are sometimes much higher than needed for diagnoses, and several epidemiological studies using dose estimates suggest there may be an increased risk of cancer from medical imaging but currently, no direct link has been established. The Committee noted that the U.S. is one of the highest users of CT exams and that along with the variable dose of radiation for each CT exam, the frequency of usage in the population also leads to serious patient outcomes. The Committee acknowledged the importance of radiation safety and monitoring dosage levels to prevent the potential onset of later cancers, but suggested that evidence supporting the link between the higher doses and poorer outcomes was not definitive.

0740 Participation in a Systematic National Dose Index Registry: (American College of Radiology): Not Recommended

Description: Participation in a multi-center, standardized data collection and feedback program that will establish national dose index benchmarks for designated examinations. The registry will eventually provide a comparison of practice or facility dose indices such as CTDIvol and DLP for specified examinations relative to national and regional benchmarks. Data is captured electronically from the images of CT examinations using Digital Imaging and Communications in Medicine (DICOM) standards and the Integrating the Healthcare Enterprise (IHE) Radiation Exposure Monitoring (REM) profile; **Measure Type:** Structure; **Level of Analysis:** Facility, Clinician: Group/Practice, Population: National, Population: Regional; **Setting of Care:** Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Other; **Data Source**: Electronic Clinical Data: Registry

This measure was previously endorsed in 2011, and is currently used as part of the American Board of Radiology's Approved Maintenance of Certification Part IV Practice Quality Improvement Project. The Committee noted that this is a structural measure requiring participating facilities to provide a simple "Yes" or "No" response on whether they participate in a systematic national dose index registry. In 2011, 104 facilities participated in the ACR registry, and by 2013, the number of participating facilities increased to 510. The purpose of this measure is to promote accountability in radiology by improving the documentation of radiation doses used on patients and the potential long-term effects of radiation exposure. The Committee felt that this was a good way for radiologist to be scored on the amount of radiation they were delivering to their patients for radiographic studies, and to compare their radiation

doses to peer institutions. The Committee also agreed that radiation safety was an important, high impact area given the great variability in radiation dosing in U.S. hospitals, even for similar tests, and that there were few measures in this area. However, the Committee felt that there was insufficient evidence that participating in a registry would directly improve outcomes. The Committee also agreed that the evidence linking radiation doses from CT scans to the onset of later cancers is not definitive. In addition, the evidence submitted by the developer consisted of general summaries and some manuscripts that had not yet been published. There was also no comparative analysis conducted between participating and nonparticipating facilities to determine the effectiveness of this registry. Overall, the Committee agreed that there was not enough evidence to support the measure and suggested that this measure was not yet ready for endorsement. The Committee encouraged ACR to resubmit the radiation dose measures under development when available.

2337 Antipsychotic Use in Children Under 5 Years Old: Recommended

Description: The percentage of children under age 5 who were dispensed antipsychotic medications during the measurement period; **Measure Type:** Process; **Level of Analysis:** Health Plan, Population: State; **Setting of Care:** Health Plan; **Data Source:** Administrative Claims

This measure was newly-submitted for NQF endorsement review. The measure focused on the use of antipsychotic medications in children under five years old. There are currently no FDA-approved indications for these medications in children under five, but such use has been increasing nonetheless, particularly in foster children covered under the Medicaid program. This has prompted a national initiative within Medicaid to reduce the use of antipsychotics in young children. The Committee acknowledged that there could be some limited circumstances in which the use of antipsychotics in children would be appropriate, but generally agreed with the intent of this measure and voted to recommend endorsement.

2371 Annual Monitoring for Patients on Persistent Medications: Recommended

Description: This measure assesses the percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year; **Measure Type:** Process; **Level of Analysis:** Health Plan, Integrated Delivery System; **Setting of Care:** Ambulatory Care: Clinician Office/Clinic; **Data source:** Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Laboratory, Electronic Clinical Data: Pharmacy

This measure is newly-submitted for NQF endorsement review. The measure is currently in use in a variety of applications, including NCQA's Accountable Care Organization accreditation program and Health Plan rankings, and is planned for use in the Medicaid Adult Core Measure Set for 2014. Committee members discussed the need for outcome measures in this area, such as adverse drug event rates. However, the developer noted that one of the limitations of administrative claims data is that they do not currently provide enough information to accurately identify outcomes of interest in this area. It was noted that electronic health records may enable collection of outcomes data in the future. The Committee found the measure to be reliable and valid, and while members observed that there is already high performance on the measure, they agreed that remaining variation and room for further improvement warranted its continued endorsement of the measure.

2426 Elder Maltreatment Screening and Follow-Up Plan

Description: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic, Behavioral Health/Psychiatric: Outpatient; **Data Source**: Administrative claims, Paper Medical Records

This measure is newly-submitted for NQF endorsement consideration, but has been in use in the Physician Quality Reporting System (PQRS) since 2009; the measure was recently updated to cover a broader range of providers. The Committee agreed that assisting eligible providers in identifying cases of suspected elder maltreatment is conceptually important. However, the USPSTF has found insufficient evidence to recommend universal screening for all adults over the age of 65. Committee members also stated that providers have a legal, ethical, and moral responsibility to look for and report signs of neglect, abuse, and exploitation, but noted that there is a lack of validated screening tools for this purpose. The Committee found that the evidence for the measure was insufficient, but granted an exception on the evidence sub-criterion because of the importance of identifying and preventing elder abuse. However, because there was not enough information provided to demonstrate variable or low performance, the measure did not pass the performance gap sub-criterion and therefore was not evaluated further. Nevertheless, the Committee stressed that this is an important issue and encouraged the developers to return with a stronger measure in the future.

2564 Documenting the Radiation Dose of Computed Tomography in the Patient Medical Record: (University of San Francisco): Not Recommended

Description: The measure is a process measure. The measure records the proportion of consecutive CT examinations conducted at an institution (facility, health plan, etc.) where one or more measures of CT radiation dose are included in the radiology report, other imaging report or electronic medical record; **Measure Type**: Process; **Level of Analysis**: Facility, Health Plan, Integrated Delivery System; **Setting of Care**: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care: Outpatient Rehabilitation, Ambulatory Care: Urgent Care; **Data Source**: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Registry

This measure was newly submitted to NQF, and while not currently in use, it is anticipated to be used for public reporting and quality improvement. When reviewing this measure, the Committee noted it would likely increase dose awareness and permit tracking of radiation dose over time. The Committee also acknowledged that radiation safety is a priority gap area and performance measures with sufficient supporting evidence are critical. The Committee stated that although documentation of dose information in the medical record may force institutions to pay attention to dosing for the various radiologic procedures, minimal evidence was presented linking dose awareness and documentation to the outcome of safer CT scans. Consequently, the measure did not pass the Evidence criterion and the Committee voted not to recommend this measure for NQF endorsement.

Ad-Hoc Review

0500 Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital): Committee recommends removal of ITEM F, "In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >=4 mmol/L (36 mg/dl) measure central venous pressure and central venous oxygen saturation."

Description: This measure focuses on patients aged 18 years and older who present with signs of severe sepsis or septic shock. These patients will be eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management bundle. **Measure Type:** Composite; **Level of Analysis:** Facility, Integrated Delivery System; **Data Source:** Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Registry, Paper Medical Records

Measure 0500 was initially endorsed in 2008 and last underwent endorsement maintenance through NQF's Infectious Disease project, which concluded in April 2012. During the course of that review, concerns were raised about the level of evidence supporting item 'F' of the sepsis bundle—invasive monitoring of central venous pressure and oxygen levels. While the Infectious Disease Committee acknowledged these concerns, the Committee determined that current evidence at the time was sufficient to warrant endorsement of the full bundle, and the measure was approved as specified. Subsequently, NQF received an appeal of this decision. Upon reconsideration by the Consensus Standards Approval Committee (CSAC), the measure's endorsement was upheld, on the condition that NQF commit to an immediate re-evaluation of the measure upon release of new evidence from several ongoing studies. One of those studies, the Protocolized Care for Early Septic Shock (ProCESS) trial, published its findings in the March 18 issue of the *New England Journal of Medicine*. ¹¹

In response to the results of the ProCESS trial, the Patient Safety Standing Committee was asked to conduct an ad hoc review of measure 0500 based on a request by the American College of Emergency Physicians. Based upon new data from the ProCESS trial, the Patient Safety Committee determined that it would be appropriate to focus its review only on the evidence supporting item 'F' in Measure 0500 ("In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >=4 mmol/L (36 mg/dl) measure central venous pressure and central venous oxygen saturation"). Given the complexity of the topic, NQF asked several experts to brief the committee on the ProCESS trial to provide guidance. These experts included Donald Yealy, MD, Alan Jones, MD, and a sepsis researcher, Todd Slesinger, MD, Sean Townsend, MD, and Emanuel Rivers, MD, MPH, FACEP. During the briefing of the Committee, Dr. Yealy, Dr. Jones, and Dr. Slesinger provided information to support removing the requirement of invasive monitoring, while Dr. Townsend and Dr. Rivers (the steward of measure 0500) supported retaining item 'F' in Measure 0500 pending completion of similar trials in Australia and UK (see below). There was positive agreement by experts and the Committee that usual care for severe sepsis and septic shock had changed dramatically in the past decade with dramatic improvements in sepsis-related morbidity and mortality with several elements of measure 0500 being key to this improvement in outcomes.

The initial basis for the evidence supporting all the components was the Rivers trial, published in 2001 in the *New England Journal of Medicine*, in which patients with severe sepsis and septic shock were randomized to receive early goal directed therapy, which included the measurement of central venous pressure and ScVO2; this study demonstrated dramatic risk differences in mortality associated with early goal-directed therapy. ¹² Since that time, many studies have been published on this subject. These

studies have demonstrated that after the implementation of early-goal directed therapy sepsis programs, which include protocolized care, early recognition, early antibiotic administration, source control, aggressive fluid resuscitation, and use of central venous catheters for central venous pressure and oxygenation measurement, there have been dramatic improvements in sepsis-related mortality mirroring the Rivers trial. However, a question that has remained has been whether the use of central venous catheters and the measurement of central venous oxygenation were necessary in all patients. One study addressing this, authored by Dr. Alan Jones and colleagues, was conducted at three emergency departments in the U.S., and compared two protocols that both included central venous pressure measurement; however, one used lactate clearance and the other used central venous oxygenation monitoring as a way to guide resuscitation. Dr. Jones' study found no differences in mortality suggesting that using central venous oxygenation to guide resuscitation may not be necessary.

The ProCESS trial, which was a large multi-center randomized trial and the trigger for this *ad hoc* review, addressed the question of whether better outcomes would be realized using an invasive approach with central line and central venous oxygenation monitoring as compared to usual care or protocolized care without invasive monitoring. In the two non-invasive arms of the trial, it was left up to the clinician to decide whether a central venous catheter was necessary. In all three arms of the study, the cornerstones of sepsis management, including early recognition, antibiotics, and resuscitation were maintained. The ProCESS trial ultimately showed no difference in mortality outcomes. A total of 1,351 patients were enrolled in ProCESS, which was powered to detect a 6-7 percent absolute difference in 60-day mortality for any reason as the primary outcome. The new results from the ProCESS trial suggested that a mandate to measure central venous oxygenation and central venous pressure with an invasive line may not be necessary in all patients with severe sepsis and septic shock. Moreover, Committee members noted that the placement and use of use of central lines can add elements of risk to patients, including pneumothoraces and infections, suggesting a need for particular caution when considering whether the use of such lines should be mandated or encouraged.

Experts who supported keeping item 'F' in Measure 0500 thought that it would be premature to remove the requirement for patients to have invasive monitoring. They noted two pending trials—ARISE and PROMISE—which are actively testing similar questions about whether invasive monitoring is necessary. These studies are not being performed in the U.S. and will be smaller than the ProCESS trial. The results of these trials should become available within one year. In addition, supporters of item 'F' argued that the protocolized care and requirement for central venous pressure and oxygenation monitoring was particularly helpful in community hospitals, which were not included in ProCESS. In addition, they argued, in the ProCESS trial there was high use of central lines even in the control arms, which also may not be generalizable to the community setting—unless there is a mandate to use the line—since community hospitals have fewer resources to care for these critically ill patients.

Several public comments were received, both in support of retaining item 'F' and in support of its removal. Ultimately, after an extensive Committee discussion with expert panelists on both sides of the issue available for questions, the Committee voted to recommend removal of item 'F' from Measure 0500. The final vote was 11-7 in favor of removing item 'F'. The Committee's recommendation was released for public comment as part of this report.

During the draft report public and member comment period, several comments were received about the Committee's decision to recommend that item 'F', the requirement for invasive monitoring in all patients with severe sepsis and septic shock, be removed from the measure. Commenters that supported the committee's decision to remove item 'F' cited the results of the ProCESS trial and other randomized trials, (e.g., the Jones et al. trial), emphasizing that there were no differences in outcomes for patients receiving early-goal directed therapy (EGDT) with SCVO2 monitoring compared to patients receiving aggressive resuscitation without invasive monitoring. Commenters also noted the patient risks of central line placement, including the risk of infection and pneumothorax. There were concerns that many hospitals do not have the capacity to safely insert central lines in all patients with severe sepsis and septic shock thus, requiring facilities to do this without the capacity could increase patient harm. Other commenters suggested that the ProCESS trial only involved a small fraction (3%) of the total body of evidence on early-goal directed therapy. Given that the trial was conducted in academic sites, the true experience of community hospitals is not adequately reflected. There were also strong concerns over what the evidence really suggests about the utility of invasive monitoring, specifically noting that the Jones et al. non-inferiority trial on lactate clearance did not focus on the septic shock patients where lactate is not elevated (up to 30%). In addition, there was concern that the study was underpowered, which resulted in a major journal scoring it at a level 2 recommendation, despite it being a randomized trial.

Alternatively, several commenters indicated that it was premature to eliminate item 'F'. One commenter presented a physiological rationale: that central lines offer the need for clinicians to continuously monitor SCVO2 rather than intermittent sampling, which allows clinicians to respond better to the rapidly changing pathophysiology of sepsis. Commenters highlighted that the ProCESS trial had a much lower mortality rate (20%) than previous historical mortality (46%) and that 56% of the non-EGDT patients ultimately received a central venous catheter. It was noted in the results that there was a very low complication rate for central line placement in the ProCESS trial, which suggests that this intervention may have a lower complication rate than peripheral lines. One commenter suggested that the committee did not appropriately consider all the evidence – namely the quantity, quality and consistency of the evidence on this topic, which included a meta-analysis of data demonstrating that EGDT with invasive monitoring is superior.

Finally, commenters mentioned two additional ongoing studies that are being conducted outside the U.S. actively – the ARISE trial and the ProMISE trial – that may shed additional light on this question when the results are released within the year.

After extensive discussion at the in-person meeting and follow-up calls with expert panelists on both sides of the issue available for questions, the Committee reaffirmed its decision to recommend removal of item 'F' from Measure 0500. However, on the July 14 post-comment call, representatives of both the measure developer and the primary investigator of the ProCESS trial indicated their willingness to discuss a compromise approach to item F of the bundle.

After further discussion and negotiations, a compromise was reached for an evidence-based replacement element for the septic shock measure between the measure developers, ProCESS trial investigators, and specialty societies (including SCCM and ACEP). To conclude the ad hoc review of

NQF#0500, the Patient Safety Standing Committee voted to approve a new item F that will include optional measurement of CVP and Scv02, along with reassessment by other means:

• **Revised Item F:** Re-assess volume status and tissue perfusion after initial resuscitation and document findings.

NQF staff will work with the measure developers to submit detailed specifications for this measure element that will be shared with the Committee during their next review cycle.

Measures withdrawn by the developer from further consideration of endorsement

The following measures were withdrawn during the measure evaluation period

Measure	Measure Steward	Reason for withdrawal
0542 Adherence to Chronic Medications	CMS	The specifications of this measure were harmonized with measure 0541 to the extent possible, and 0542 was withdrawn from consideration.
2410 Bleeding Outcomes Related to Oral Anticoagulants	CMS/FMQAI	Withdrawn at request of developer in response to testing results.

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Appendix A: Details of Measure Evaluation

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Endorsed Measures

Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; IE=Insufficient with Exception; NA=Not

Applicable; Y=Yes; N=No

0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

<u>Submission</u> | <u>Specifications</u>

Description: Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in bedded inpatient care locations.

This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavioral health hospitals.

Numerator Statement: Total number of observed healthcare-associated CLABSI among patients in bedded inpatient care locations.

Denominator Statement: Total number of central line days for each location under surveillance for CLABSI during the data period.

Exclusions: 1. Pacemaker wires and other non-lumened devices inserted into central blood vessels or the heart are excluded as CLs.

- 2. Extracoporeal membrane oxygenation lines, femoral arterial catheters, intraaortic balloon pump devices, and hemodialysis reliable outflow catheters (HeRO) are excluded as CLs.
- 3. Peripheral intravenous lines are excluded as CLs.

Adjustment/Stratification:

Level of Analysis: Facility, Population: National, Population: Regional, Population: State

Setting of Care: Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Other

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic

Clinical Data: Laboratory, Other, Paper Medical Records

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-21; N-0**; 1b. Performance Gap: **H-21; M-1**; **L-0**; **I-0**; 1c. Impact: **H-19**; **M-2**; **L-0**; **I-0** Rationale:

• The Developer noted that CLABSI is an outcome and an issue that can be minimized through proper management of the central line. Efforts to improve central line insertion and maintenance practices, with early discontinuance of lines are recommended.

- CLABSI infection rates vary from a low of 0.0% per 1000 device days to a high of 3.4% per 1000 device days between all types of reporting locations.
- There are an estimated 248,000 bloodstream infections in U.S. hospitals each year. In a recent study, over 13% of HAIs in 9 acute care hospitals in the southeast United States were bloodstream infections and most were CLABIs.
- Estimates for the attributable cost of are CLABSI (\$5,734 to \$22,939 in 2003 dollars).
- The Committee felt that based on this information, this is an important measure that is high impact, with evidence of variation and room to improve.
- There was a comment from the Committee that recommended that efforts to improved CLABSI
 rates include nursing education as well as physician education. The Developer commented that
 this measure is stratified by location, not by physicians v. other providers.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-0; M-15; L-6; I-2 2b. Validity: H-5; M-15; L-3; I-0

Rationale:

- There was concern by the Committee that CLABSI had questionable validity based on reported studies in the literature, noting poor inter-rater reliability among infection preventionists, and that concluded there was significant variation for how blood stream infections were reported across medical centers. The Developer noted that these were important studies but not directly related to NHSN, which is where the data for the CLABSI measure come from, and that since that time, they have made changes to the definition of healthcare-associated infections. The Developer recognized that there was subjectivity and inconsistency across some of the definitions. The Committee recommended that the Developer should consider repeating reliability testing in light of the new definitions.
- There was concern from the Committee that the subjectivity of these measures and questions about validity should be approached with caution when it comes to using these measures for pay-for-performance, particularly with positive predictive values in the 70% range and kappa values in the 0.4 range.
- The Committee was concerned that there was no validity testing performed for this measure, and that according to the Developer, this function was left up to the states.
- There was a formal request from the Committee for additional reliability and validity testing during the next round of maintenance for this measure.

3. Feasibility: H-12; M-8; L-1; I-1

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- CLABSI and central line device days are collected by trained hospital staff from information available in clinical data sources. The NHSN analysis tool automatically calculates SIRs. Some of the data used in the measure can be mined from electronic data sources.
- It was noted that NHSN is moving towards an electronically captured CLABSI measure for future use. However, development and testing is not complete at this time.
- There was not an extensive Committee discussion on Feasibility.

4. Use and Usability: H-10; M-11; L-2; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is currently used in many reporting, accreditation, and payment programs including: the Hospital Inpatient Quality Reporting Program, The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, IRF Quality Reporting Program, LTCH Quality Reporting Program, Public Health/Disease Surveillance, National Healthcare Safety Network.
- There was not an extensive Committee discussion on the Usability of this measure.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-22; N-1

6. Public and Member Comment

• There was an in-person public comment from Dr. David Birnbaum, manager of Washington State Healthcare Associated Infections Program. The concern was raised about the ability of the Standardized Infection Ratio (SIR) to adequately rank hospitals, which he demonstrated using simulated and real data. He commented that negative binomial or Poisson distributions may be more appropriate, which are used in other low-risk industries. He stated that he supported the CLABSI measure, but recommended that NQF develop a way to assure accountability in validation protocols for measures.

Post Draft Comments Received

This measure received supportive comments as well as recommendations for improvement.
 Commenters agreed that this measure is important and addresses a high-priority area, and shared the committee's concern about the reliability and addition of the Adjusted Ranking Measure (ARM) given its potential to cause confusion for consumers. Additional commenters suggested that this measure should be expanded to non-ICU settings, including outpatient and home health settings where PICC lines are frequently used.

Committee Response:

Thank you for your comments; the Committee agrees that there is a need for additional HAI
measures in outpatient and other settings, and hopes to see such measures submitted for
endorsement in future projects.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0

8. Board of Directors Vote: Yes (November, 2014)

0138 National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

Submission | Specifications

Description: Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (UTI) will be calculated among patients in bedded inpatient care locations, except level II or level III neonatal intensive care units (NICU.

This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavior health hospitals.

Numerator Statement: Total number of observed healthcare-associated CAUTI among patients in bedded inpatient care locations (excluding patients in Level II or III neonatal ICUs).

Denominator Statement: Total number of indwelling urinary catheter days for each location under surveillance for CLABSI during the data period.

Exclusions: The following are not considered indwelling catheters by NHSN definitions:

- 1. Suprapubic catheters
- 2.Condom catheters
- 3."In and out" catheterizations
- 4. Nephrostomy tubes

Note, that if a patient has either a nephrostomy tube or a suprapubic catheter and also has an indwelling urinary catheter, the indwelling urinary catheter will be included in the CAUTI surveillance.

Adjustment/Stratification:

Level of Analysis: Facility, Population: National, Population: Regional, Population: State

Setting of Care: Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic

Clinical Data: Laboratory, Other, Paper Medical Records

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-23; N-1**; 1b. Performance Gap: **H-19; M-6**; **L-0**; **I-0**; 1c. Impact: **H-22**; **M-3**; **L-0**; **I-0** Rationale:

In the developers submission they noted that CAUTIs can be minimized by prevention efforts
(i.e. reducing the number of unnecessary indwelling catheters inserted, removing indwelling
catheters at the earliest possible time, securing catheters to the patient's leg to avoid bladder
and urethral trauma, keeping the urine collection bag below the level of the bladder, and
utilizing aseptic technique for urinary catheter insertion).

- The developer referred to a CDC guideline from 2009 for specific actions recommended to reduce the incidence of CAUTI (http://www.cdc.gov/hicpac/cauti/002_cauti_toc.html). These specific actions were graded 1B evidence using the GRADE criteria.
- CAUTI rates range from 0.0 5.3 per 1000 catheter days across location, by bed-size, and by medical school affiliation.
- CAUTI is the most common or second most common HAI, accounting for 15-30% of HAIs. 13K deaths, 450K CAUTIs per year, \$758 cost per CAUTI, >\$340 million attributable to CAUTI.
- The Committee agreed that CAUTIs were importance to measure and report, that there were
 gaps in care, and that it was a high impact area because of the high prevalence of the disease
 and high cost, the ability to improve CAUTIs through specific interventions where there was
 good evidence, and that variation existed in the performance on this measure.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **The Committee did not rate this criterion** 2b. Validity: **H-2**; **M-15**; **L-3**; **I-5** Rationale:

- There was concern by the Committee that because this is reported at the catheter day level that
 there may be some partial days that are missed. There was also a concern that facilities that
 send a lot of cultures would have more positive cultures, and that there are some difficulties in
 defining a UTI.
- In the update of the measure, the new specifications include non-ICU settings; however, there was no formal testing of reliability in those settings, which was of concern to the Committee.
- There was concern raised by the Committee that similar data are gathered through the NDNQI,
 a quality improvement and data gathering function of the American Nurses Association, which
 has rigorous reliability and validity testing. The Developer agreed to look into this further.
- In the update of the measure, the Developer added the adjusted ranking metric (ARM), along with the Standardized Infection Ratio (SIR) which was in the previous version of this approved measure. The ARM is a summary measure using to rank facilities, and can be used to measure performance over time. There was Committee discussion clarifying how the ARM is measured and its limitations. The Developer mentioned that the ARM was better in that it was more inclusive of smaller facilities, which may not have the sample size to report the SIR. However, the Committee was concerned that because of the way that the ARM is calculated, this could rank small hospitals with zero infections as lower performers than big hospitals with a small number of infections but a high number of catheter days.
- There was concern over the validation by the Committee, specifically noting that the Developer had reported data with relatively low sensitivity (63% was the lowest number mentioned). The developer noted that the external validation of the NHSN CAUTI has been done in at least 6 states, using a variety of sampling methods. For FL: Sens 64%, spec 92%, PPV 70%, NPV 90% for 113 medical records. The Developer commented that they did not have the resources to perform additional validity testing, and that CDC did not have the authority to go into hospitals to confirm the validity. This is done at the state level. The Committee was concerned that because of the low sensitivity and positive predictive value reported that using this for pay-for-performance could unfairly penalize hospitals inappropriately.

3. Feasibility: H-14; M-11; L-3; I-5

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- CAUTI and catheter days must be collected by trained hospital staff from information available in clinical data sources. The standard population's CAUTI rates are available from the NHSN Report. The NHSN analysis tool will automatically calculate SIRs. Some of the data used in the measure can be mined from electronic data sources.
- CAUTI rates and SIR using the methodologies described above have been in use by hospitals
 participating in CDC surveillance systems since 1986, and the rate measure has been endorsed
 by NQF in 2 measure sets since 2004. The criteria for UTI were streamlined in 2009 and the
 asymptomatic bacteriuria specific site of UTI dropped as it was felt to represent colonization
 rather than infection.
- The Committee did not have extensive discussion on Feasibility.

4. Use and Usability: H-9; M-11; L-1; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is currently used in public reporting across multiple programs.
- In the future, the Developers state that this will continue to be used for quality improvement.
- The On the CUSP to Stop CAUTI program has identified a 16.1% reduction in CAUTI rates after 14 months of interventions and data collection.
- There was not extensive Committee discussion on Usability.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-19; N-5

6. Public and Member Comment

• Dr. Matt Davis, Chief of Spinal Cord Injury at TIRR Memorial Hermann Rehab Hospital, appeared in person to give public comment on this measure, specifically about the inclusion of spinal cord injured patients in this measure. The concern is that with this measure, the clinical response is to pull out the urinary catheter as a general rule to prevent infection. While this might be a good idea in many patients, the spinal cord injured patient is a high-risk group because there is no sensation to the bladder. The bladder can fill up with urine, and lead to hydronephrosis and renal failure, which is the leading cause of death in spinal cord injured patients. It can also cause other problems, such as autonomic dysflexia, which can lead to a sympathetic storm and high blood pressures, which can cause seizures and strokes. Dr. Davis has been in active discussions with the Developer to address this issue.

Post Draft Comments Received

Commenters requested that the Committee continue to work with the developers to extend
this measure to non-ICU settings, create a similar separate measure that is subject to validity
and reliability testing to capture outpatient populations, and explicitly indicate that the
measure recognizes the variations in urinary culture frequency. Commenters also noted that
the use of this measure cannot be applied to certain populations such as pediatric patients,
where it is not commonly used, and in spinal cord injury populations where it has the
potential to lead to complications.

Developer Response:

 The developers addressed the concerns of the commenters by explaining their approach to developing this measure, including the advantages of the use of the ARM, population concerns, risk adjustment strategies, and surveillance and monitoring.

Committee Response:

- The Committee agrees that a measure extending across multiple settings would be valuable, and that concerns about application of the measure to certain populations should be addressed.
- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0
- 8. Board of Directors Vote: Yes (November, 2014)

0555 INR Monitoring for Individuals on Warfarin

<u>Submission</u> | <u>Specifications</u>

Description: Percentage of individuals 18 years of age and older with at least 56 days of warfarin therapy who receive an International Normalized Ratio (INR) test during each 56-day interval with warfarin

Numerator Statement: The number of individuals in the denominator who have at least one INR monitoring test during each 56-day interval with active warfarin therapy.

Denominator Statement: Individuals at least 18 years of age as of the beginning of the measurement period with warfarin therapy for at least 56 days during the measurement period.

Exclusions: Individuals who are monitoring INR at home.

Optional Exclusion Criteria

Individuals who are in long-term care (LTC) during the measurement period.

Adjustment/Stratification:

Level of Analysis: Clinician: Group/Practice, Health Plan, Integrated Delivery System, Population: State

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data: Pharmacy

Measure Steward: Centers for Medicare & Medicaid

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-21**; **N-2** 1b. Performance Gap: **H-4**; **M-21**; **L-0**; **I-0**; 1c. Impact: **H-18**; **M-7**; **L-0**; **I-0** Rationale:

- Evidence presented by the developers included guidelines for INR monitoring frequency from the American College of Chest Physicians and the American College of Cardiology/American Heart Association. Several systematic reviews were also presented demonstrating the importance of being in the therapeutic range for INR; however Committee members noted that the measure itself, performance of an INR monitoring test, is an action more distant from the outcomes of interest (thromboembolism or bleeding complications).
- The Committee questioned the modification of the required INR monitoring interval from an original interval of 40 days to a 56-day interval. The developer provided rationale for this change, citing a study in the VA, that clearly described this relationship between the 56-day interval and the time in the therapeutic range. The ACC and ACCP guidelines vary with a range between 4 weeks and 12 weeks, and the developer chose the 56 day interval as a midway point, given recent data on evidence.
- Overall, the Committee agreed there was sufficient evidence to support the 56 day time interval
 for monitoring and that monitoring is linked to the desired outcome of increased time in the
 therapeutic range leading to fewer bleeding and thromboembolic events.
- Data from Medicare Parts A, B, and D was presented showing a mean performance score of 75% at the state, plan, physician, group, and ACO levels. The Committee agreed the sample demonstrated a gap in care.
- The Committee agreed the measure address a high impact area, as data was presented warfarin-related adverse events and is related to several national health priorities, including patient safety.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-12**; **M-12**; **L-1**; **I-0** 2b. Validity: **H-7**; **M-14**; **L-4**; **I-0**

Rationale:

- The Committee questioned why home health monitoring patients are excluded. The developer explained that the claims data is limiting and there is not a way to reliably assess the frequency for which patients are monitoring INR at home.
- The developer presented reliability testing that was done at the level of group, health plan, state and ACO level. A signal to noise analyses using a beta-binomial model resulted in a score of 0.7 or greater for all four levels. The Committee questioned the lack of physician reliability testing and the importance of that in considering reliability of the measure. The developer responded that due to sample size issues, only a small percentage of physician groups (11.21%) had an adequate number of patients for reliable measurement. However, the measure is reliable at the physician group level. The majority of the Committee rated reliability as moderate or high.
- Validity testing was conducted at the level of the performance measure score, and both empirical validity testing and systematic assessment of validity testing were conducted. In

addition, the developer's Technical Expert Panel (TEP) evaluated the face validity of the measure and measure score after field testing was completed. Overall, the majority of Committee rated validity as moderate or high.

3. Feasibility: H-16; M-5; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

 The Committee agreed that testing demonstrated the measure was feasible to specify and calculate using CMS administrative claims data; and that data sources needed to implement the measure are readily available, accessible, and timely.

4. Use and Usability: H-10; M-11; L-3; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

 Overall, the Committee had no major concerns about use and usability. The measure is currently being used by CMS and no unintended consequences have been reported.

5. Related and Competing Measures

- This measure is related to NQF# 0556: INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications. Both measures have the same measure focus, which is INR testing, and their specifications for INR testing are harmonized. However, the two measures have different target populations.
- This measure is also related to #NQF 0586: Warfarin PT/ INR Test. The measure under review addresses the same measure focus (i.e., INR monitoring) and the same target population (i.e., individuals on warfarin).

Standing Committee Recommendation for Endorsement: Y-21; N-2

6. Public and Member Comment

Post Draft Comments Received:

• Comments on this measure questioned whether 56 days was the most appropriate time interval for monitoring, with one commenter suggesting a 90-day interval would allow more flexibility for patients whose testing threshold extends further than two months.

Developer Response:

• Evidence suggests that exceeding a 56 day interval decreases Time in the Therapeutic Range (TTR) which is closely linked to a reduction in thromboembolic/bleeding events. Evidence supporting the 90-day interval was limited to a small RCT and there were concerns about the study design. The 56-day interval provided the best balance of ensuring patient safety and increased flexibility from the prior specification of a 40-day interval.

Committee Response:

• The Committee was satisfied with the developer's response.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0

8. Board of Directors Vote: Yes (November, 2014)

0556 INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications

<u>Submission</u> | <u>Specifications</u>

Description: Percentage of episodes with an International Normalized Ratio (INR) test performed three to seven days after a newly started interacting anti-infective medication for individuals receiving warfarin

Numerator Statement: Number of episodes in the denominator with an INR test performed three to seven days after the start date of an anti-infective medication

Denominator Statement: Number of episodes with a newly started interacting anti-infective medication with an overlapping days' supply of warfarin.

Exclusions: We excluded the following individuals from the denominator:

- Individuals with a diagnosis of cancer
- Individuals who are monitoring INR at home

Adjustment/Stratification:

Level of Analysis: Health Plan, Integrated Delivery System, Population: State

Setting of Care: Ambulatory Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data: Pharmacy

Measure Steward: Centers for Medicare & Medicaid

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: Y-17; N-7; 1b. Performance Gap: H-13; M-7; L-1; I-1; 1c. Impact: H-17; M-4; L-1; I-1 Rationale:

- Evidence presented by the developers included guideline recommendations on anticoagulation with warfarin from the British Committee for Standards in Hematology, systematic reviews about the interaction between warfarin and anti-invective's, and a summary of several studies that demonstrate the interaction and higher rates of hemorrhage.
- The Committee noted that both the quality of evidence and the strength of the guideline recommendation cited in support of this measure are somewhat weak, and that, similar to measure 0555, the measure's focus is relatively distant from the outcomes of interest the evidence. The developer commented that underlying recommendations to reduce drug-drug

- interactions tends to be weak in general, because conducting randomized trials to study such interactions would be unethical.
- The Committee agreed there was a performance gap demonstrated based on the overall state level, the plan level, and the ACO level data presented that indicated a performance rate of around 20%.
- As warfarin has been determined to be one of the top medications that can lead to poor adverse events, the Committee agreed the measure addresses a high-impact area.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-5; M-17; L-1; I-0 2b. Validity: H-8; M-15; L-1; I-0

Rationale:

- Although the measure is currently specified to exclude cancer patients, the developers
 recommended that cancer patients are included in the measure denominator. The Committee
 agreed with the recommendation, which was based on testing results that showed the exclusion
 isn't relevant in terms of the data or the evidence.
- The Committee questioned the reliability being tested at the plan and ACO level and not at the practice level. The developer responded testing was conducted at the physician group level through its use in a CMS program; however results showed that the measure wasn't sufficiently reliable due to the sample size issues. The developers envision the measure as a shared accountability measure, and have specified it for application at the health plan or integrated delivery system level. Overall, the Committee rated reliability as high or moderate at the health plan and ACO level.
- Validity testing was conducted at the level of the performance measure score, and both
 empirical validity testing and systematic assessment of validity testing were conducted. In
 addition, the developer's Technical Expert Panel (TEP) evaluated the face validity of the measure
 and measure score after field testing was completed. Overall, the majority of Committee rated
 validity as moderate or high.

3. Feasibility: H-7; M-14; L-3; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

 Testing demonstrated that the measure was feasible to specify and calculate using CMS administrative claims data. Data sources needed to implement the measure are readily available, accessible, and timely.

4. Use and Usability: H-1; M-11; L-10; I-2

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

• The Committee recommended to the developer that in the next review cycle that usability data be provided. The developer was also strongly encouraged to present outcome data (bleeding,

thromboembolism) next cycle. The lack of this desired information led to a lower rating on use and usability by the Committee.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-17; N-7

6. Public and Member Comment

Post Draft Comments Received:

 Comments on this measure included agreement on the importance of the measure focus and support for the Committee's decision, as well as a request for clarification on the target population and concerns about the measure 's potential to result in unnecessary testing and avoidable costs. The developer clarified that the target population for this measure includes patients 18 years of age and older. The Committee encourages continued monitoring for unintended consequences as this measure is implemented.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0

8. Board of Directors Vote: Yes (November, 2014)

0541 Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category

<u>Submission</u> | <u>Specifications</u>

Description: The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year. A performance rate is calculated seperately for the following medication categories: Renin Angiotensin System (RAS) Antagonists, Diabetes Medications, Statins.

A higher score indicates better quality.

Numerator Statement: The number of patients who met the PDC threshold during the measurement year for each therapeutic category separately. Follow the steps below for each patient to determine whether the patient meets the PDC threshold.

Step 1: Determine the patient's measurement period, defined as the index prescription date (date of the first fill of the target medication) to the end of the calendar year, disenrollment, or death.

Step 2: Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3: Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4: Count the number of patients who had a PDC 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of combination product to another combination product where a least one of the drugs from the target therapeutic class is common.

Denominator Statement: Patients age 18 years and older who were dispensed at least two prescriptions in a specific therapeutic category on two unique dates of service during the measurement year.

For the Diabetes rate only: Exclude any patient with one or more prescriptions for insulin in the measurement period.

Exclusions: Exclusion criteria for the PDC category of Diabetes medications:

Patients who have one or more prescriptions for insulin in the measurement period.

Adjustment/Stratification:

Level of Analysis: Clinician: Group/Practice, Health Plan

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Pharmacy

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Pharmacy Quality Alliance (PQA, Inc.)

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-18**; N-2; 1b. Performance Gap: **H-8**; **M-13**; **L-0**; **I-0**; 1c. Impact: **H-6**; **M-12**; **L-2**; **I-0** Rationale:

- This medication adherence measure was originally endorsed in 2009 and initially included five rates by therapeutic category. The developer clarified that the measure has been revised to include only three rates for three drugs to treat high blood pressure, high blood sugar and high blood lipids. The developer provided the rationale that based upon new guidelines, new drugs, and usage of the measures, the PQA Measures Update Panel made a recommendation to concentrate on the three for which there is broad public use and pay-for-performance and public reporting systems.
- Evidence was presented to support the conceptual relationship between adherence to the
 medications and the patient outcomes of fewer hospitalizations, fewer deaths and lower costs
 of care. Overall, the Committee found the evidence to be sufficient, despite there being few
 randomized control trials within the area. It was noted that the evidence presented is not
 medication-specific, but relates to adherence in general.
- The Committee noted that CMS reporting over the past years has shown that there's considerable variation in the rates among the Medicare drug plans. Improvement in the rates has been demonstrated over the past five years, but the Committee agreed there is still room for improvement, even amongst the highest scoring plans.
- The Committee agreed these measures of adherence address a high impact area, for these three classes of chronic medications are for the chronic diseases of diabetes, high blood pressure and

the condition of high cholesterol. All are leading causes of cardiovascular diseases, heart attack and stroke, which are the leading causes of mortality in this country.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-15; M-5; L-0; I-0 2b. Validity: H-0; M-11; L-7; I-2

Rationale:

- The Committee found the empiric reliability testing results to be acceptable and the data elements to be precise. Testing was performed using an administrative claims database, allowing for data from a large population.
- Many Committee members had some concern over potential threats to validity such as a patient's medical indication changing or inability to afford the prescription co-pay. The developer clarified that the measure is not just looking at the adherence to one medication, rather one medication within that class of drugs. The developer also noted that there are many different choices within each of the three categories, and that the adherence threshold is 80 percent during the measurement year (not 100 percent of the time). Although many Committee members found the face validity to be weak, the majority gave a moderate or high rating on the validity criterion.

3. Feasibility: H-16; M-3; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

 The Committee agreed that the measure is feasible, as the data source for these measures is administrative claims data for which all elements are in defined fields and electronic claims.
 Prescription claims data is required for payment to health plans, so there is no extra burden or cost in the collection of the data.

4. Use and Usability: H-8; M-8; L-4; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

 The measure is used by the Centers for Medicare and Medicaid Services in their Part D drug benefit program to evaluate Medicare prescription drug plans, both PDPs and MAPDs. As such, it is used by a pay-for-performance program, driving quality bonus payments, as well as public reporting. The majority of the Committee had no major concerns with the use and usability criterion.

5. Related and Competing Measures

Standing Committee Recommendation for Endorsement: Y-18; N-2

6. Public and Member Comment

Post Draft Comments Received:

 Commenters expressed concerns about the use of administrative prescription data for compliance due to variability in access and the limitations of information collected through claims. Commenters noted that physicians may use drug samples, generic prescriptions under the \$4 program, and other workarounds to accommodate patients' financial constraints.

Developers Response:

The developer noted that clinical studies have demonstrated a link between patient outcomes
and adherence to medications as measured by the PDC metric, and suggested that there is
also evidence showing that plans measured by the PDC metric can improve the adherence of
their members. The developers argued that samples and cash prescriptions have little impact
on the measure score, providing a number of justifications for this position.

Committee Response:

• The Committee was satisfied with the developer's response.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0

8. Board of Directors Vote: Yes (November, 2014)

0684 Percent of Residents with a Urinary Tract Infection (Long-Stay)

<u>Submission</u> | <u>Specifications</u>

Description: This Minimum Data Set (MDS) 3.0 based measure estimates the percentage of long-stay residents who have a urinary tract infection on the target MDS assessment (OBRA, PPS, or discharge). In order to address seasonal variation, the proposed measure uses a 6-month average for the facility. Long-stay nursing facility residents are those with more than 100 cumulative days in the facility.

Numerator Statement: The numerator is the number of long-stay nursing facility residents with a selected target assessment (OBRA, PPS or discharge) that indicates a urinary tract infection within the last 30 days (Item I2300= [1]).

Denominator Statement: All MDS target assessments (OBRA, PPS, and discharge) in a selected quarter are included, except those with exclusions.

Exclusions: There are two exclusions applied to the denominator: one, the target assessment is an admission assessment ((A0310A = [01] or a PPS 5-day or readmission/return assessment (A0310B = [01, 06]), and two, the urinary tract infection value is missing (I2300 = [-]). Assessments of residents with only an admission assessment are excluded because these residents may have developed urinary tract infection in the hospital, rather than the nursing facility. It would be unfair to hold the nursing facility accountable for care received in the hospital.

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data

Measure Steward: Centers for Medicare and Medicaid Services

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: Consensus was not reached on the Importance criterion

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: Y-8; N-11; 1b. Performance Gap: H-2; M-14; L-2; I-0; 1c. Impact: H-8; M-9; L-0; I-0 Rationale:

- Some Committee members expressed concerns about the currency of evidence provided by the developer.
- The Committee agreed that there is both variation in performance and an opportunity for improvement in this area.
- The Committee also agreed that the measure addresses a high-priority area, given the impact of UTIs on patients and the associated costs to the healthcare system.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criterion

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-5; M-10; L-3; I-0 2b. Validity: H-6; M-11; L-0; I-0

Rationale:

- Committee members noted that the Minimum Data Set (MDS) 3.0 tool, which is used to collect measure data, has been demonstrated to be a stable, reliable, and accurate instrument.
- The Committee was also satisfied with the results of reliability testing on the measure, which showed strong levels of inter-rater agreement at the data element level and stability of performance scores over time.
- To demonstrate validity, the developer provided empirical evidence related to the measure's
 ability to accurately identify UTIs and its correlation with other nursing home quality measures,
 as well as an analysis of the impact of missing data; the Committee was satisfied with this
 information.
- Some Committee members expressed an interest in seeing the measure segmented into catheter-associated and non-catheter-associated UTIs, suggesting that the developer consider incorporating this information into the next version of the measure. The Committee also recommended stratifying the measure by quadriplegia and paraplegia.

3. Feasibility: H-8; M-6; L-3; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)
Rationale:

• The Committee agreed that the data required by the measure are readily available, gathered routinely in nursing homes, and can be captured electronically.

4. Use and Usability: H-3; M-13; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

 The Committee noted that the measure can be used for both accountability and quality improvement purposes, and that it is currently in being publicly reported through the Nursing Home Compare program.

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-13; N-5

6. Public and Member Comment

Post Draft Comments Received:

• Commenters agreed that this measure is highly important given the volume of admissions to long term care facilities and suggested that there is sufficient evidence to support the measure.

Developer's Response:

The developers reiterated that the literature provided to support the importance of this
measure includes the most up-to-date evidence based on US guidelines available at the time
of measure submission.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0

8. Board of Directors Vote: Yes (November, 2014)

2371 Annual Monitoring for Patients on Persistent Medications

<u>Submission</u> | <u>Specifications</u>

Description: This measure assesses the percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year.

- Angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB): At least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year.
- Digoxin: At least one serum potassium, one serum creatinine and a serum digoxin therapeutic monitoring test in the measurement year.
- Diuretics: At least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year.
- Total rate (the sum of the three numerators divided by the sum of the three denominators)

Numerator Statement: This measure is reported as three rates and a total rate.

For annual monitoring for patients on ACE inhibitors or ARBs: the number of patients with at least one serum potassium and serum creatinine therapeutic monitoring test in the measurement year.

For annual monitoring for patients on digoxin: the number of patients with at least one serum potassium, one serum creatinine, and a serum digoxin therapeutic monitoring test in the measurement year.

For annual monitoring for patients on diuretics: the number of patients with at least one serum potassium and serum creatinine therapeutic monitoring test in the measurement year.

For the total rate: sum of the 3 numerators.

Denominator Statement: Patients age 18 and older as of the end of the measurement year (e.g., December 31) who are on selected persistent medications (ACE Inhibitors/ARB, Digoxin or Diuretics.)

Exclusions: Exclude patients who had an inpatient (acute or nonacute) claim or encounter during the measurement year.

Adjustment/Stratification:

Level of Analysis: Health Plan, Integrated Delivery System **Setting of Care:** Ambulatory Care: Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Laboratory,

Electronic Clinical Data: Pharmacy

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-17**; N**-0**; 1b. Performance Gap: **H-9**; **M-7**; **L-0**; 1c. Impact: **H-10**; **M-7**; **L-0**; I-0 Rationale:

- Committee members noted that there are varying levels of evidence supporting annual monitoring for the different medications covered by this measure, but found the overall evidence for the measure to be strong.
- The Committee discussed the possibility of measuring outcomes related to this issue (e.g., adverse events), rather than measuring adherence to the process of annual monitoring.
- The developer indicated that a lack of data limits the ability to measure outcomes in this area—this measure is based on administrative claims, which do not provide sufficient information to determine, for example, if a hospitalization or ED visit resulted from the negative effects of a lack of monitoring. However, the developer expressed hope that such information would become more available with increased adoption of electronic health records.
- Committee members observed that there appears to be relatively high performance on this
 measure in general, but that variation remains and there is still considerable room for
 improvement.
- The Committee agreed that this is a high-priority area for measurement.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-7; M-12; L-0; I-0 2b. Validity: H-16; M-3; L-0; I-0

Rationale:

- The Committee was satisfied with the results of reliability testing for this measure.
- Committee members noted that testing showed lower reliability for rates of Digoxin monitoring
 in the Medicaid population; however, this result was explained by the low number of Medicaid
 plans meeting the minimum sample size of patients with a Digoxin prescription and the small
 sample size of Medicaid plans in general.
- Validity testing at the data element level showed high levels of sensitivity and specificity for each of the critical data elements, indicating that the measure accurately reflects provider behavior.
- Testing also showed that organizations performing well on one aspect of the measure also performed well on the other aspects of the measure, which suggests the measure is a valid indicator of provider quality.
- The developer's Technical Expert Panel gave the measure high face validity ratings, and an analysis of variation in performance across health plans demonstrated that the measure is able to identify significant differences in performance.

3. Feasibility: H-17; M-0; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

• The Committee agreed that the measure is feasible, noting its use of administrative data that are gathered routinely by health plans and provider groups.

4. Use and Usability: H-12; M-6; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

 The Committee noted that the measure is currently in use in various applications, including public reporting through NCQA and use in the Medicaid Adult Core Measure Set.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-17; N-0

6. Public and Member Comment

Post Draft Comments Received:

• Commenters expressed concerns about variations in prescribing practice resulting in inconsistent claims data, and suggested that the measure should monitor testing for therapeutic levels not just documentation of a prescription being filled.

Developer Response:

- The developer noted that the intent of this measure is to monitor for side effects of certain medications rather than to monitor the therapeutic levels of those medications. The developers also recognized that pharmacy claims data may not capture all medications prescribed or given to a patient, but stated that in order for this measure to be easily collected and reported by health plans, it is based solely on data found in administrative claims.
- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0
- 8. Board of Directors Vote: Yes (November, 2014)

2337 Antipsychotic Use in Children Under 5 Years Old

<u>Submission</u> | <u>Specifications</u>

Description: The percentage of children under age 5 who were dispensed antipsychotic medications during the measurement period.

Numerator Statement: The number of patients under 5 years of age with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.

Denominator Statement: Children who are less than 5 years old at any point during the measurement period, and also enrolled in a health plan for one month or longer during the measurement period.

Exclusions: None.

Adjustment/Stratification:

Level of Analysis: Health Plan, Population: State

Setting of Care: Other **Type of Measure**: Process

Data Source: Administrative claims

Measure Steward: Pharmacy Quality Alliance (PQA, Inc.)

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-14**; **N-5**; 1b. Performance Gap: **H-10**; **M-10**; **L-0**; **I-0**; 1c. Impact: **H-14**; **M-6**; **L-0**; **I-0**; **Rationale**:

• Committee members recognized that there are virtually no FDA-approved indications for the medications addressed by this measure in children under five, but that there is increasing use of those medications in this population as well as wide regional variations in their use under the

Medicaid program. In addition, there are significant metabolic and other side effects associated with antipsychotic use.

- It was noted that children in foster care are most impacted by this issue.
- Some Committee members argued that there may be instances in which use of antipsychotics could be appropriate for children under five, cautioning against excessively rigid mandates.
- Ultimately, the Committee agreed that this is a high-priority and high-impact area of measurement, particularly considering the vulnerable population it addresses.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-3; M-10; L-3; I-4 2b. Validity: H-2; M-13; L-3; I-1

Rationale:

- Some Committee members expressed concerns about the lack of inter-rater reliability for the measure.
- However, the Committee was satisfied that the critical data elements of age and prescription documentation could be reliably collected through prescription claims data.
- The developer provided results of an assessment of face validity by a technical expert panel; the Committee was satisfied with the measure's validity.

3. Feasibility: H-7; M-11; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

• The Committee agreed that the data required for the measure could be generated feasibly and without undue burden through prescription claims.

3. Use and Usability: H-5; M-10; L-3; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The developer is working to generate support for use of the measure in state Medicaid programs, as well as inclusion in the federal core set of measures for children in Medicaid programs.
- The Committee was satisfied with the current and planned use of the measure.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-14; N-5

6. Public and Member Comment

Post Draft Comments Received:

- Comments on this measure were generally supportive of the Committee's decision, but raised cautions about the strength of evidence supporting the measure and the potential need for exclusions.
- 7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0
- 8. Board of Directors Vote: Yes (November, 2014)

0740 Participation in a Systematic National Dose Index Registry

<u>Submission</u> | <u>Specifications</u>

Description: Participation in a multi-center, standardized data collection and feedback program that will establish national dose index benchmarks for designated examinations. The registry will eventually provide a comparison of practice or facility dose indices such as CTDIvol and DLP for specified examinations relative to national and regional benchmarks. Data is captured electronically from the images of CT examinations using Digital Imaging and Communications in Medicine (DICOM) standards and the Integrating the Healthcare Enterprise (IHE) Radiation Exposure Monitoring (REM) profile.

Numerator Statement: Participation in a systematic national dose index registry.

Denominator Statement: The measure does not have a numerator/denominator. It is strictly an attestation – Yes or No.

Exclusions: No exclusions **Adjustment/Stratification**:

Level of Analysis: Facility, Clinician : Group/Practice, Population : National, Population : Regional

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility,

Other

Type of Measure: Structure

Data Source: Electronic Clinical Data : Registry **Measure Steward**: American College of Radiology

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: Consensus was not reached on the Importance criterion

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: H-0; M-7; L-11; IE-0; I-8; 1b. Performance Gap: NA 1c. High Priority: NA;

Rationale:

- The Committee questioned the research for this measure and agreed that the evidence linking radiation doses from CT scan to later cancers is vague. This measure was previously NQF endorsed in 2011 yet very little evidence on improvements has been collected since then. Committee members wanted more information on the use of this registry in promoting accountability. Although the developer explained that there was a trend in the early phase with a decrease in dose usage among participating facilities, there was no comparison with facilities that did not participate in the registry and that there were many gaps in the evidence.
- The Committee did not agree with the caveat that there is a fee associated with participating in the ACR registry.
- Overall, the Committee agreed that there was not enough evidence to support the measure and the belief that this measure came to the Committee too soon for endorsement.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: NA 2b. Validity: NA

Rationale:

No discussion on scientific acceptability of measure properties noted.

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

• No discussion on feasibility noted.

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

No discussion on use and usability noted.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: NA

6. Public and Member Comment

Post Draft Comments Received

• Commenters agreed with the Committee's decision to not recommend this measure for NQF endorsement, stating that participation in a registry alone is not sufficient to demonstrate a safety component or to directly improve outcomes.

0739 Radiation Dose of Computed Tomography (CT)

Submission | Specifications

Description: The measure requires hospitals and output facilities that conduct Computed Tomography (CT) studies to assess the radiation dose associated with the most frequently conducted examination types – CT's of the head, chest, abdomen/pelvis obtained in children and adults. The measure provides a simple framework for how facilities can assess their dose, a framework that currently does not exist. By assessing their doses, facilities can monitor the doses they use over time and compare their doses to benchmarks. The creation of benchmarks is not part of this measure per se. However, if facilities use this measure, I believe professional societies, researchers, and oversight organizations can separately create their benchmarks. Several research groups, including my own, have published benchmarks and

published manuscripts that have used the framework of this measure to assess changes in radiation dose over time (Keagan, JACR, 2014) and to assess the impact of an educational intervention on doses, using the specifications of the measure to assess the results of a randomized trial (Miglioretti, JACR, 2014).

This measure was initially developed for diagnostic CT, but can equally be used for CT used in conjunction with radiation therapy for cancer. Professional organizations within various medical specialties can create appropriate benchmarks depending on the application.

Numerator Statement: Radiation Dose, quantified using the distribution in four dose metrics (DLP, CTDIvol, SSDE, ED); within anatomic area, age, and machine-type strata. SSDE only pertains to abdomen scans.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only generates dose metrics for a single metric, there is a lot of information and performance information to be gleaned.

CTDIvol will reveal the settings used per small scan length. This is directly generated by most modern CT scanners.

DLP reflects both the dose per small scan length, but also the length of scan that is conducted, and is defined as CTDIvol x scan length. This is directly generated by most modern CT scanners.

Effective dose takes into account the total amount of radiation emitted from the machine as well the radio-sensitivity to developing cancer in the area radiated. The measure thus combines both radiation dose and future cancer risk. The metric is the only one that can be combined across types of studies and anatomic areas and is thus useful for dose monitoring dose surveillance and facility performance (see Smith-Bindman, Radiology, 2011).

While there are many different ways to calculate Effective Dose, and many current dose monitoring software products can do this automatically, a simple rule of thumb can be used to convert DLP to Effective dose in adults (see Huda, below). In the brain, given typical machine settings that are used, the DLP can be converted to Effective Dose by multiplying DLP measured in mGy-Cm by 0.002 to yield Effective Dose measured in milli-Sieverts. Effective Dose of CT scans though the chest can be estimated by multiplying the DLP measured in mGy-cm by .017 to yield Effective Dose measurements in mSv; and Effective Dose of abdominal and pelvis CT can be estimated by multiplying DLP by 0.18. It is not clear that using greater precision in the quantification of effective dose is necessary for the quality improvement purposes outlined in this measure.

Additional relevant citations for effective dose

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

Denominator Statement: Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis **Exclusions**: CT examinations conducted in anatomic areas not included above (such as CTs of the

extremities or lumbar spine). In adults approximately 16% of CT scans fall in these excluded areas. In children, approximately 23% of CT examinations fall into excluded areas.

Further, combined areas, such as head and chest, should not be included in the scans collected.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category.

Adjustment/Stratification:

Level of Analysis: Facility, Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care: Outpatient Rehabilitation,

Ambulatory Care : Urgent Care **Type of Measure**: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic

Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry

Measure Steward: University of California San Francisco

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: Consensus was not reached on the Importance criterion

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: H-0; M-7; L-11X; IE-0; I-8; 1b. Performance Gap: NA 1c. High Priority: NA;

Rationale:

- This outcomes measure is to provide a simple way for facilities to summarize the doses they have used in their population and compare it to other populations. Developers stated that the clinical problem this measure addresses is that the current status of radiation dose for CT in the US is very non-standardized so doses are much higher than needed for diagnosis. The doses are highly variable between institutions and they're in the range where the doses have been shown in several recent large cohort studies to have significant and real increased risk of cancer.
- The Committee discussed the importance of radiation safety and monitoring dosage levels to
 prevent the potential onset of later cancers however, evidence supporting the link between the
 two was ambiguous particularly, in reducing mortality or development of a disease. They
 debated whether this was an outcomes measure and emphasized the lack of maturity in the
 science depending on what sector you are in and then the maturity of the measure itself.
 Although there were some references to benchmarks in testing, most of them were based on
 small studies.
- The developers stated that there are many international benchmarks that support the evidence
 of this measure. In addition, CMS, The Joint Commission, and four states including California are
 all in support of monitoring radiation dose levels in hospitals. Thus, NQF endorsement would
 greatly advance the use of this measure and increase data collection.
- This measure did not pass the evidence criterion however, the Committee suggested that the developers come back to NQF when there is more data.

2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific</u> Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: NA 2b. Validity: NA

Rationale:

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: NA

6. Public and Member Comment

Post Draft Comments Received

Comments received on this measure were both supportive of and opposed to the Committee's
decision to not recommend it for NQF endorsement. One commenter emphasized the
importance of acknowledging the usefulness of process measures in capturing the data
necessary for benchmarking radiation exposure. Commenters noted that measuring radiation
exposure is a new endeavor and suggested that CT metrics are evolving as are the methods of
linking these measures in selected settings. Commenters also noted that the need to optimize
radiation exposure for patient safety has prompted the development of both quality and safety
improvement programs for CT. In addition, one commenter suggested development of a
composite radiation measure data.

Committee Response

 The Committee agrees that optimizing radiation exposure is an important safety goal, and supports continued measure development in this area. However, Committee members suggested that current evidence linking higher CT doses to poorer outcomes was not conclusive, and as a consequence, measure 0739 did not pass a vote on the Evidence sub-criterion. The Committee expressed an interest in re-evaluating the measure once more data was available, and encouraged further development of radiation safety measures.

2564 Documenting the Radiation Dose of Computed Tomography in the Patient Medical Record

<u>Submission</u> | <u>Specifications</u>

Description: The measure is a process measure. The measure records the proportion of consecutive CT examinations conducted at an institution (facility, health plan, etc.) where one or more measures of CT radiation dose are included in the radiology report, other imaging report or electronic medical record.

Numerator Statement: The proportion of CT scans of one of the included anatomic areas with a measure of radiation dose reported in the final approved report. (The reported measure can be DLP, CTDIvol, Effective Dose, SSDE, or any combination of these).

Denominator Statement: Consecutive sample of CTs

Exclusions: None

Adjustment/Stratification:

Level of Analysis: Facility, Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care: Outpatient Rehabilitation,

Ambulatory Care: Urgent Care

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic

Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry

Measure Steward: University of California San Francisco

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: Consensus was not reached on the Importance criterion

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: H-0; M-7; L-8; IE-0; I-10; 1b. Performance Gap: NA 1c. High Priority: NA

Rationale:

- The Committee noted that this measure would increase dose awareness and permit tracking of
 radiation dose over time. Patients who undergo any CT undergo an average of two CTs a year, so
 there's concern not just with the doses per exam, but with the cumulative doses. However, the
 evidence presented linking dose awareness and documentation to the outcome of safer CT
 scans was considered to be weak.
- One Committee member noted a study that showed a 20 to 50-fold variation in radiation doses
 within the same institution, indicating an opportunity for physicians, radiologists to reduce the
 scan radiation exposure. Although the Committee agreed that documentation of dose
 information in the medical record may force institutions to pay attention to dosing for the
 various radiologic procedures, the question remained if this more of a practice as opposed to a
 quantifiable performance measure.
- The Committee identified radiation safety as a gap area in terms of NQF endorsed measures.
 Practices around evidence-based quality improvement strategies and performance metrics with the supporting evidence are critical to have. However, the majority of the Committee rated the evidence as low or insufficient for this measure as presented.

2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific</u> Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: NA 2b. Validity: NA

Rationale:

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: NA

6. Public and Member Comment

Post Draft Comments Received

 One comment was submitted reiterating the importance of this area and suggesting development of a composite radiation measure.

Committee Response

 The Committee agrees that optimizing radiation exposure is an important safety goal, and supports continued measure development in this area. However, Committee members suggested that current evidence linking higher CT doses to poorer outcomes was not conclusive, and as a consequence, measure 0739 did not pass a vote on the Evidence subcriterion. The Committee expressed an interest in re-evaluating the measure once more data was available.

0510 Exposure time reported for procedures using fluoroscopy

<u>Submission</u> | <u>Specifications</u>

Description: Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time

Numerator Statement: Final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time

Denominator Statement: All final reports for procedures using fluoroscopy

Exclusions: No exclusions **Adjustment/Stratification**:

Level of Analysis: Clinician: Group/Practice, Clinician: Individual

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health

Record, Electronic Clinical Data: Imaging/Diagnostic Study, Paper Medical Records

Measure Steward: American College of Radiology

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: Consensus was not reached on the Importance criterion

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: H-1; M-8; L-7; IE-5; I-4; 1b. Performance Gap: NA 1c. High Priority: NA

Rationale:

- The Committee questioned whether or not documentation of radiation exposure is directly linked to a clinical outcome such as reducing patient harm or decreasing radiation exposure.
 Although a clinical practice guideline, the Committee noted that direct quality-related evidence to support the measure was lacking.
- Many Committee members struggled with the fact that the data is important for developing
 programs around safety and radiation exposure. Members felt that collecting the data is an
 important foundation for developing outcomes analyses, quality improvement, and reducing
 injury from radiation for patients.
- Overall the Committee agreed this was an important measure, however the measure did not
 pass the Evidence criterion. Although there was evidence presented that greater fluoroscopic
 use and length of time does result in higher patient harm, evidence for other modalities, such as
 CT, there was not enough evidence that supported documentation to improve the use of
 fluoroscopy time.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: NA 2b. Validity: NA

Rationale:

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: NA

6. Public and Member Comment

Post Draft Comments Received

Comments on this measure were generally supportive of efforts to measure radiation safety,
with some expressing concern over the Committee's decision to not recommend this measure
for endorsement. One commenter noted NQF's inclination towards outcomes measures but
stated that there is often a long lag period between exposure and outcomes, which will make
the development of outcome measures for radiation exposure a measurement challenge. Thus,
process measures are needed to help prevent risks. Additionally, commenters expressed
concern that lack of radiation exposure measures in NQF's Patient Safety Portfolio could suggest
that this is not an important patient safety issue.

Committee Response

 The Committee agrees that optimizing radiation exposure is an important safety goal, and supports continued measure development in this area. However, Committee members suggested that the radiation safety measures under consideration in this project needed additional evidentiary support and testing to warrant endorsement.

2426 Elder Maltreatment Screening and Follow-Up Plan

<u>Submission</u> | <u>Specifications</u>

Description: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen

Numerator Statement: Patients with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of the encounter and follow-up plan documented on the date of the positive screen

Denominator Statement: All patients aged 65 years and older

Exclusions: A patient is not eligible if one or more of the following reasons is documented: Patient refuses to participate; Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status

Adjustment/Stratification:

Level of Analysis: Clinician: Group/Practice, Clinician: Individual

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Behavioral Health/Psychiatric: Outpatient

Type of Measure: Process

Data Source: Administrative claims, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: Consensus was not reached on the Importance criterion

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-1**; **M-3**; **L-3**; **IE-12**; **I-4**; 1b. Performance Gap: **H-3**; **M-6**; **L-4**; **I-10** 1c. High Priority: **NA** Rationale:

- This process measure has been included in the Physician Quality Reporting System since 2009; the measure submitted has been revised based on the recommendations of stakeholders and experts and is new in 2014. A broader range of providers is now included.
- The developer stated that the prevalence of elder abuse is between 3.2% and 27.5%, with the
 higher rates among vulnerable older adults, and that these numbers are likely underestimates.
 Elder abuse is associated with increased morbidity and mortality and an increased rate of
 hospitalizations and emergency department utilizations, and is estimated to cost tens of billions
 of healthcare dollars annually.
- The Committee agreed that assisting eligible providers to identify cases of suspected elder maltreatment is conceptually important; however, the USPSTF currently rates the evidence for screening all adults over the age of 65 as an insufficient because it is not routinely done, even when weighting the balance of evidence vs harm.
- Committee members also noted that providers have a legal, ethical, and moral responsibility to look for and report signs of neglect, abuse, and exploitation, but that there is a lack of tools provided for elder abuse as compared to pediatric abuse.
- Committee members inquired if there was demonstrable impact from this measure; the developer explained that it was too soon to show improvements but that the population that is being screened was receiving what would be perceived as better quality care; they noted that this measure would help collect data that would improve the evidence available.
- Committee members also asked if there was anything in the evidence base that would provide
 more detail as to the appropriate components of the follow up plan; the developer stated that
 there was no specific evidence at this time but that experts felt that making the referral was
 very important in response to a positive screen. The Committee noted that a referral to a state
 agency does not link to a positive outcome.
- Committee members asked if this measure would qualify for the evidence exception (invoked when the evidence is insufficient but the benefits would exceed the risks), and NQF staff stated that it would. The measure passed sub-criterion 1A on an evidence exception.
- The Committee noted that the performance gap is unknown, especially since the actual incidence of elder abuse is unknown. They noted that there is not a good way to collect the data since there is no electronic medical record or template for reporting; it's all done on paper. However, they also noted that behavioral health issues are not well integrated into the healthcare environment in general and that this measure may be suffering from that challenge.
- The developer stated that this measure is also an opportunity to highlight a broadly applicable issue that could get providers engaged and starting to screen for elder abuse.
- Committee members asked if there were differences in practice types, and the developer stated
 that the first version of the measure had only targeted psychologists and psychiatrists and was
 not broadly available to other providers; however, the new version is more widely applicable
 and while they hope there will be increased uptake, they do not have the data yet.
- The measure did not pass the performance gap sub-criterion, but the Committee stated that this
 is an important idea and encouraged the developers to return with a stronger measure if they
 can in the future.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: NA 2b. Validity: NA

Rationale:

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: NA

6. Public and Member Comment

Post Draft Comments Received

N/A

0531 Patient Safety for Selected Indicators (PSI 90)

Submission | Specifications

Description: PSI measure specifications: http://qualityindicators.ahrq.gov/modules/psi_resources.aspx;

Data source upon which developed and tested: www.hcup-us.ahrq.gov/sidoverview.jsp

Numerator Statement: Senior Care

Denominator Statement: See Patient Safety Indicators: Technical Specifications for additional details

(available at

http://www.qualityindicators.ahrq.gov/Modules/PSI TechSpec.aspx) and in the supporting information.

Exclusions:

Adjustment/Stratification:

Level of Analysis: PSI 90 Supporting Docs Specs Evidence Test.pdf

Setting of Care: The patient safety composite measure was developed to summarize patient safety across multiple indicators to monitor performance over time or across regions and populations using a

methodology that can be applied at the national, regional, State and provider level. Practically, a composite was constructed to increase statistical precision due to an increase in the effective sample size and to address the issue of competing priorities where more than one component measure may be important; and to assist consumers in selecting healthcare, providers allocating resources, and payers assessing performance.

Type of Measure:

Data Source: Hospital/Acute Care Facility

Measure Steward: Agency for Healthcare Research and Quality

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: Y-18; N-5; 1b. Performance Gap: H-17; M-6; L-0; I-0 1c. High Priority: H-9; M-6; L-7; I-0 1d.

Composite: H-3; M-7; L-10; I-1

Rationale:

- Committee members asked whether AHRQ's experience with the patient safety indicators (PSIs)
 had offered any insight into clinical interventions associated with improvement on the
 measures. The developer noted that the University Healthsystem Consortium had observed
 improvements in quality through use and reporting of the PSIs and implementation of the AHRQ
 QI Toolkit.
- The Committee discussed the extent to which the outcomes in the composite are preventable and represent lapses in the quality of care; overall, the Committee agreed that there was sufficient rationale to support each individual component in the measure.
- The Committee questioned whether the weighting of the composite components reflected the relative importance of each component; some suggested that the item related to accidental puncture or laceration (PSI 15) seemed to be weighted too heavily. The developer explained that there are several ways to measure and weight the components of this measure, and there was discussion among the Committee that approaches that include other PSI components that were not included in this measure, including Perioperative Hemorrhage or Hematoma Rate (PSI 9), Postoperative Physiologic and Metabolic Derangement Rate (PSI 10), and Postoperative Respiratory Failure Rate (PSI 11) may be more desirable.
- In addition the Committee felt that there should be additional consideration should be given to the weights and whether each of the PSIs may be associated with a criterion standard, such as mortality, and the degree of preventability or actionability by a health system to reduce it.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-7; M-11; L-3; I-1 2b. Validity: H-5; M-11; L-7; I-0 2d. Composite: H-3; M-6; L-12; I-1

Rationale:

• The developer explained that one of the main reasons to develop a composite measure is to enhance reliability. Aggregating a number of individual measures into a single composite can

generate an overall performance score that is more reliable than the individual measure scores would be if taken in isolation.

- The Committee found the measure to be sufficiently reliable.
- The Committee noted that based on the composite guidance, empirical validity testing for the overall composite as opposed to the individual components. Some expressed concern about the validity scores provided for the components; however, the developer explained that the analyses were done using older data, before the incorporation of 'present on admission' status and increased specificity in claims data, which were expected to increase the measures' validity.
- Some Committee members voiced concerns about the ability of administrative claims to
 accurately identify safety events it was noted that some of the events appeared to be
 significantly underreported.
- The Committee continued to express concerns about the aggregation and relative weighting of
 the composite components. The developer noted that three additional components had been
 kept out of the measure when it was submitted for endorsement review, and that including
 those additional components could even out the weighting to some degree.

3. Feasibility: H-10; M-7; L-5; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

• The Committee was satisfied with the measure's feasibility, given its use of readily available and widely used administrative data.

4. Use and Usability: H-5; M-5; L-13; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is used to monitor performance in national and regional reporting. It was also developed to enable comparative reporting and quality improvement at the provider or the hospital level.
- The Committee expressed apprehension about use of the measure in payment applications.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-8; N-15

• The Committee suggested that the developer include three additional components that are part of the AHRQ PSI composite in the measure, specifically PSI 9, 10, and 11, noting that doing so could improve the balance of the weighting scheme. The developer agreed to address the Committee's concerns, and confirmed that the measure would be revised and submitted for reconsideration by the Committee after the public comment period.

6. Public and Member Comment

Post Draft Comments Received

A number of comments were submitted on measure 0531. One commenter expressed concerns about several of the components of the composite measure; these included concerns about PSI-6 (jatrogenic pneumothorax rate), which the commenter argued could create unintended consequences such as inappropriate avoidance of central line placement; PSI-7 (central venous catheter-related bloodstream infection rate), which the commenter suggested should have exclusions for trauma; PSI-12 (postoperative PE or DVT rate), which the commenter suggested could discourage early diagnosis of PE or DVT or contribute to increased rates of bleeding events; and PSI-14 (wound dehiscence rate), which the commenter recommended should exclude trauma cases and patients in shock. Another commenter supported re-endorsement of measure 0531, noting that it is one of the only NQF-endorsed complications measure not focused on infections. The commenter further suggested that the component related to accidental puncture and laceration (PSI-15) is in fact a common and relevant patient safety event of great concern to patients and one that can be can be improved through increases in surgical proficiency. Finally, another commenter supported the Committee's decision to not recommend measure 0531 for continued endorsement, arguing that the measure's use of retrospective claims data may contribute to underreporting of safety events and expressing support for clinically-enriched electronic measures of healthcare-acquired conditions.

Developer Response

• As a follow-up to the Steering Committee meeting held on April 17 and April 18, 2014, AHRQ submitted additional materials related to PSI 90 – Patient Safety for Selected Indicators on June 30, 2014. Reviewers asked to see additional measure information related to the re-weighting of PSI 90 with three additional components (i.e., PSI 90 with 11-item composite). AHRQ believes that the revised reweighting approach achieves a better balance across various hospital-acquired, safety-related events, provides a more reliable and valid signal to users, and is more consistent with the original conception and design of the PSI 90 composite. (See submitted memo to NQF on June 30, 2014).

Supplemental Comment Period Comments Received

- Multiple commenters in support of the measures expressed concern that removing endorsement would lead to serious patient safety implications. Commenters emphasized that this measure provides critical information about unsafe practices taking place in hospitals, thereby holding hospitals accountable for these adverse events through transparency.
- Commenters stated that this is a robust measure and currently being used in three hospital
 quality programs for Medicare therefore, encouraged the committee to consider the strengths
 and strong predictive value. Various concerns were expressed regarding this measures' loss of
 endorsement resulting in it being removed from current federal programs.
- Some commenters expressed concerns that removing endorsement from this measure would communicate a negative message about NQF's dedication to patient safety.

Committee Response

Upon further review of the updated measure, the Committee determined that an immediate
revote would be premature, agreeing that additional review and discussion of the measure was
warranted. Consequently, a final decision on measure 0531 will be deferred to the next cycle of
measure evaluation by the Patient Safety Standing Committee, which is expected to occur in

early 2015. This will also enable the developer to provide additional analyses for the Committee's review. In the interim, the measure will remain endorsed as currently specified. To ensure that comments from the supplemental period are given proper and timely consideration, these comments will be provided to the Committee in advance of and during their full evaluation of the measure in the next cycle. Additional opportunities for public comment will also be available throughout the phase of that project.

0532 Pediatric Patient Safety for Selected Indicators (PDI 19)

<u>Submission</u> | <u>Specifications</u>

Description: indicator information: http://qualityindicators.ahrq.gov/modules/pdi_resources.aspx; data

source: www.hcup-us.ahrq.gov/sidoverview.jsp

Numerator Statement: Children's Health

Denominator Statement: See Pediatric Quality Indicators: Technical Specifications for additioinal details

(available at

http://www.qualityindicators.ahrq.gov/downloads/pdi/pdi_technical_specs_v32.pdf)

Exclusions:

Adjustment/Stratification:

Level of Analysis: PDI_19_Supporting_Docs_Specs_Evidence_Tests.pdf

Setting of Care: Not applicable

Type of Measure:

Data Source: Hospital/Acute Care Facility

Measure Steward:

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: Y-16; N-7; 1b. Performance Gap: H-9; M-12; L-1; I-0 1c. High Priority: H-9; M-9; L-4; I-0 1d.

Composite: H-1; M-12; L-7; I-0

Rationale:

- The Committee was satisfied that the outcomes assessed by this measure could be influenced by healthcare processes or interventions, that the measure addresses a high-priority area, and that there is a performance gap warranting measurement.
- Committee members noted that the developer had provided good information on disparities relevant to this measure.
- The Committee observed that the methodology for the pediatric safety indicator composite
 measure was essentially the same as the adult composite; Committee members remained
 concerned about the weighting scheme used in the composites.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-4**; **M-12**; **L-7**; **I-0** 2b. Validity: **H-0**; **M-15**; **L-8**; **I-0** 2d. Composite: **H-2**; **M-7**; **L-14**; **I-0** Rationale:

- Committee members were satisfied with the measure's reliability, again noting that the measure has higher reliability at the composite level than at the component level.
- The Committee discussed the currency of validity testing for the measure, observing that there is a need for updated testing results.
- The measure failed on the composite subcriterion; Committee members again expressed concerns about the weighting methodology.
- Committee members agreed that they would be amenable to reconsidering the measure if AHRQ revisited the weighting of components within the composite.

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: N/A

6. Public and Member Comment

Post Draft Comments Received

Comments about this measure were both supportive and in opposition to the committee's
decision to not recommend it for NQF endorsement. One commenter suggested that the voting
results were inconclusive and requested continued review of the measure. Another comment
supported the Committee's decision to not recommend this measure, arguing that its weighting
scheme poses threats to validity. However, the commenter also stated that revisions to the
composite's weighting methodology would strengthen this measure and strongly recommended
endorsing the measure once this has been resolved.

NQF Response

• It is NQF policy that a measure may be recommended for endorsement by the Standing Committee when the vote margins on all must-pass criteria (Importance, Scientific Acceptability)

and overall suitability for endorsement are greater than 60% of voting members in favor of endorsement. A measure is not recommended for endorsement when the vote margin on any major criteria or overall is less than 40% of voting members in favor of endorsement. The Standing Committee has not reached consensus if the vote margin on any major criterion or overall is between 40%-60% in favor of endorsement. Because fewer than 40% of voting Committee members found this measure to have passed the Scientific Acceptability criterion, the measure was not evaluated further and will not be recommended for endorsement.

0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI) – Central Venous Catheter (CVC)

<u>Submission</u> | <u>Specifications</u>

Description: Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed

Numerator Statement: Patients for whom CVC was inserted with all elements of maximal sterile barrier technique*, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques** followed

Definitions:

- *Maximal sterile barrier technique includes ALL of the following elements:
- cap
- mask
- sterile gown
- sterile gloves
- sterile full body drape
- ** Sterile ultrasound techniques require sterile gel and sterile probe covers

NOTE: For purposes of this measure, maximal sterile barrier technique during CVC insertion is defined to include use of:

cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis.

Denominator Statement: All patients, regardless of age, who undergo CVC insertion

Exclusions: Denominator Exceptions: Documentation of medical reason(s) for not following all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques during CVC insertion (including increased risk of harm to patient if adherence to aseptic technique would cause delay in CVC insertion)

Adjustment/Stratification:

Level of Analysis: Facility, Clinician: Group/Practice, Clinician: Individual, Clinician: Team

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Registry

STANDING COMMITTEE MEETING [04/17/2014-04/18/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: H-4; M-16; L-2; IE-0; I-0; 1b. Performance Gap: H-6; M-18; L-1; I-0 1c. High Priority: H-8; M-

11; L-4; I-1;

Rationale:

- This process measure was acquired from the American Medical Association by the American Society of Anesthesiologists and was developed to drive accountability among anesthesia providers and to reduce CRBSI's. This measure requires the use of a sterile bundle when placing a central venous catheter which includes the use of maximum barrier precautions, drapes, gown mask, hand washing, appropriate skin preparation and the use of sterile technique for ultrasound. The developers stated that for those who report this measure, performance is high however, there is a substantial gap in who reports it and how often it is reported. Still, it has driven documentation systems to record this important information and to get it transmitted either nationally to CMS or to ASA registry.
- The Committee discussed the possible medical reasons for not following all the elements of
 maximal sterile barrier technique including emergency situations where there is not enough
 time to take such precautions. The developers agreed that this would be an appropriate
 exception to the rule and would be documented in the administrative codes.
- The Committee identified that the data sources for this measure are administrative claims, electronic clinical data, and registry data. In addition, the developers used four randomized control trials, three series cohort studies, and on cross sectional study for testing yet there was no systemic grading of the evidence. Therefore, according to NQF's algorithm, this measure would be insufficient or insufficient with exception.
- The Committee noted that the evidence for maximum barrier over time in terms of prevention
 of CRBSI has decreased in terms of the science. They inquired whether insertion was more
 important or maintenance. The developers responded by stating that there is a strong
 correlation between the duration a line is in and the risk of an infection and therefore,
 maintenance is more important.
- The Committee addressed concern about National Anesthesia Clinical Outcomes Registry in its infancy and performing effectively with only a quarter of the practices reporting on the measure. There is very little representation and there appears to be lack of evidence but not sure that there is an actual gap. The developer responded by stating that in order to provide documentation one would have to chart that they followed the maximum barrier precautions. That has to get turned into a code or a direct checked box in an electronic record. Currently, there is data that shows the measure is being reported in about four percent of all the central lines placed (approximately 200,000 central lines). In addition, there are financial incentives reporting on the measure and how data is transmitted. Committee member addressed the incentive comment saying that that will only lead to more documentation but not necessarily done so properly (e.g., give CT to someone pregnant and checked "not pregnant").

2. Scientific Acceptability of Measure Properties: <u>Consensus was not reached on the Scientific</u> Acceptability criterion

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-0; M-3; L-1; I-20 2b. Validity: NA

Rationale:

• The Committee noted that neither reliability nor validity had been systematically tested; therefore, the measure did not pass the reliability criterion and was not evaluated further.

3. Feasibility: NA

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

4. Use and Usability: NA

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

5. Related and Competing Measures

• No related or competing measures noted.

Standing Committee Recommendation for Endorsement: NA

6. Public and Member Comment

Post Draft Comments Received

• Comments were submitted both in support of and in opposition to the Committee's recommendation to remove endorsement from this measure. The developer submitted a request for reconsideration of the measure, citing the reductions in central line-associated bloodstream infection rates since the measure has been endorsed and reported by anesthesiologists, as well as the remaining gap in adherence to the measure. The Association of Professionals in Infection Control and Epidemiology (APIC) submitted a comment supporting the Committee's decision, suggesting that the measure does not provide reliable data for prevention and benchmarking purposes.

Committee Response

- Committee members remained concerned about the lack of systematic testing for reliability and validity, and also expressed a preference for CLABSI outcome measures over process measures.
- The Committee discussed ASA's reconsideration request on the July 14 post-comment call, and reaffirmed its initial decision to not recommend the measure for endorsement.

Measures Withdrawn from consideration

Three measures previously endorsed by NQF have not been re-submitted or withdrawn from maintenance of endorsement. The following measures are being retired from endorsement:

Measure	Reason for retirement
0612: Warfarin - INR	The developer did not resubmit this measure for maintenance review.
0586: Warfarin PT/INR Test	The developer did not resubmit this measure for maintenance review.
0542 Adherence to Chronic Medications	The specifications of this measure were harmonized with measure 0541 to the extent possible, and 0542 was withdrawn from consideration.

One additional new measure was withdrawn after initial submission.

Measure	Reason for withdrawal
2410: Bleeding Outcomes Related to Oral Anticoagulants	Withdrawn at request of developer in response to testing results.

Appendix B: NQF Patient Safety Portfolio and related measures

General

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0510	Percentage of final reports for procedures using fluoroscopy that	Process	Maintenance	Competing
Exposure time	include documentation of radiation exposure or exposure time		Measure –	N/A
reported for	Level of Analysis: Clinician : Group/Practice, Clinician : Individual		Currently Under	Related
procedures using	Care Setting: Ambulatory Care: Clinician Office/Clinic,		Review	0739:
fluoroscopy	Hospital/Acute Care Facility, Imaging Facility			Radiation Dose
	Data Source: Administrative claims, Electronic Clinical Data,			of Computed
	Electronic Clinical Data : Electronic Health Record, Electronic Clinical			Tomography
	Data: Imaging/Diagnostic Study, Paper Medical Records			(CT)

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
O531 Patient Safety for Selected Indicators (PSI 90)	Patient Safety for Selected Indicators (PSI 90) is a weighted average of the observed-to-expected ratios for the following component indicators: PSI 03 Pressure Ulcer Rate, PSI 06 latrogenic Pneumothorax Rate, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, PSI 08 Postoperative Hip Fracture Rate, PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate, PSI 13 Postoperative Sepsis Rate, PSI 14 Postoperative Wound Dehiscence Rate, and PSI 15 Accidental Puncture or Laceration Rate. The weights include component weights and shrinkage weights. The component weights are numerator weights, defined as the relative frequency of the numerators for the component indicators in the reference population. The shrinkage weights are the signal-to-noise ratio, where the signal variance is estimated from the reference population, and the noise variance is estimated from the user's data and is unique to each provider in the user's data. For more information, see Quality Indicator Empirical Methods, PSI Composite Measure Workgroup Final Report, and AHRQ QI User Guide: PSI Composite available online at www.qualityindicators.ahrq.gov Level of Analysis: Facility Care Setting: Hospital/Acute Care Facility Data Source: Administrative claims	Composite	Maintenance Measure – Currently Under Review	Competing N/A Related 0532: Pediatric Patient Safety for Selected Indicators (PDI 19)

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
Pediatric Patient Safety for Selected Indicators (PDI 19)	Pediatric Patient Safety for Selected Indicators (PDI 19) is a weighted average of the observed-to-expected ratios for the following component indicators: PDI 01 Accidental Puncture or Laceration Rate, PDI 02 Pressure Ulcer Rate, PDI 05 latrogenic Pneumothorax Rate, PDI 10 Postoperative Sepsis Rate, PDI 11 Postoperative Wound Dehiscence Rate, and PDI 12 Central Venous Catheter-Related Blood Stream Infection Rate. The weights include component weights and shrinkage weights. The component weights are numerator weights, defined as the relative frequency of the numerators for the component indicators in the reference population. The shrinkage weights are the signal-to-noise ratio, where the signal variance is estimated from the reference population, and the noise variance is estimated from the user's data and is unique to each provider in the user's data. For more information, see Quality Indicator Empirical Methods, PDI Composite Measure Workgroup Final Report, and AHRQ QI User Guide: PDI Composite available online at www.qualityindicators.ahrq.gov Level of Analysis: Facility Care Setting: Hospital/Acute Care Facility Data Source: Administrative claims	Composite	Maintenance Measure – Currently Under Review	Competing N/A Related 0531: Patient Safety for Selected Indicators (PSI 90)

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0739 Radiation Dose of Computed Tomography (CT)	The measure has two components. Part A is an outcome measure; Part B is a process measure. Both would work together towards improving quality and allowing hospitals and imaging facilities to conduct ongoing quality improvement. Part A: radiation dose associated with computed tomography (CT) examinations of the head, neck, chest, abdomen/pelvis and lumbar spine, obtained in children and adults. Part B: The proportion of CT examinations where a measure of dose is included in the final medical report. Level of Analysis: Facility Care Setting: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care: Outpatient Rehabilitation, Ambulatory Care: Urgent Care Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Registry	Outcome	Maintenance Measure – Currently Under Review	Competing N/A Related 0510: Exposure time reported for procedures using fluoroscopy

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0740 Participation in a Systematic National Dose Index Registry	Participation in a multi-center, standardized data collection and feedback program that will establish national dose index benchmarks for designated examinations. The registry will eventually provide a comparison of practice or facility dose indices such as CTDIvol and DLP for specified examinations relative to national and regional benchmarks. Data is captured electronically from the images of CT examinations using Digital Imaging and Communications in Medicine (DICOM) standards and the Integrating the Healthcare Enterprise (IHE) Radiation Exposure Monitoring (REM) profile. Level of Analysis: Facility, Clinician: Group/Practice, Population: National, Population: Regional Care Setting: Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Other Data Source: Electronic Clinical Data: Registry	Structure	Maintenance Measure – Currently Under Review	Competing N/A Related N/A
2426 Elder Maltreatment Screening and Follow-Up Plan	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen Level of Analysis: Clinician: Group/Practice, Clinician: Individual Care Setting: Ambulatory Care: Clinician Office/Clinic, Behavioral Health/Psychiatric: Outpatient Data Source: Administrative claims, Paper Medical Records	Process	New Measure Submission – Currently Under Review	Competing N/A Related N/A

Healthcare-Associated Infection (HAI)

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0138	Standardized Infection Ratio (SIR) of healthcare-associated,	Outcome	Maintenance	Competing
National	catheter-associated urinary tract infections (UTI) will be calculated		Measure –	N/A
Healthcare Safety	among patients in bedded inpatient care locations, except level II or		Currently Under	Related
Network (NHSN)	level III neonatal intensive care units (NICU.		Review	N/A
Catheter-	This includes acute care general hospitals, long-term acute care			
associated Urinary	hospitals, rehabilitation hospitals, oncology hospitals, and behavior			
Tract Infection	health hospitals.			
(CAUTI) Outcome	Level of Analysis : Facility, Population : National, Population :			
Measure	Regional, Population : State			
	Care Setting: Hospice, Hospital/Acute Care Facility, Behavioral			
	Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility:			
	Long Term Acute Care Hospital, Post Acute/Long Term Care Facility:			
	Nursing Home/Skilled Nursing Facility, Other			
	Data Source: Electronic Clinical Data, Electronic Clinical Data:			
	Electronic Health Record, Electronic Clinical Data: Laboratory,			
	Other, Paper Medical Records			

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0139 National Healthcare Safety Network (NHSN) Central line- associated Bloodstream Infection (CLABSI) Outcome Measure	Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in bedded inpatient care locations. This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavioral health hospitals. Level of Analysis: Facility, Population: National, Population: Regional, Population: State Care Setting: Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Other Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Laboratory, Other, Paper Medical Records	Outcome	Maintenance Measure – Currently Under Review	Competing N/A Related N/A
0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI) – Central Venous Catheter (CVC)	Other, Paper Medical Records Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed Level of Analysis: Facility, Clinician: Group/Practice, Clinician: Individual, Clinician: Team Care Setting: Hospital/Acute Care Facility Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Registry		Maintenance Measure – Currently Under Review	Competing N/A Related N/A

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
O684 Percent of Residents with a Urinary Tract Infection (Long- Stay)	This Minimum Data Set (MDS) 3.0 based measure estimates the percentage of long-stay residents who have a urinary tract infection on the target MDS assessment (OBRA, PPS, or discharge). In order to address seasonal variation, the proposed measure uses a 6-month average for the facility. Long-stay nursing facility residents are those with more than 100 cumulative days in the facility. Level of Analysis: Facility Care Setting: Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility Data Source: Electronic Clinical Data	Outcome	Maintenance Measure – Currently Under Review	Competing N/A Related N/A

Medication Safety

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0541 Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category	The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year. A performance rate is calculated seperately for the following medication categories: Renin Angiotensin System (RAS) Antagonists, Diabetes Medications, Statins. A higher score indicates better quality. Level of Analysis: Clinician: Group/Practice, Health Plan Care Setting: Ambulatory Care: Clinician Office/Clinic, Pharmacy Data Source: Administrative claims	Process	Maintenance Measure – Currently Under Review	Competing N/A Related N/A
0555 INR Monitoring for Individuals on Warfarin	Percentage of individuals 18 years of age and older with at least 56		Maintenance Measure – Currently Under Review	Competing N/A Related 0556: INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications
0556 INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications	Percentage of episodes with an International Normalized Ratio (INR) test performed three to seven days after a newly started interacting anti-infective medication for individuals receiving warfarin Level of Analysis: Health Plan, Integrated Delivery System, Population: State Care Setting: Ambulatory Care: Clinician Office/Clinic Data Source: Administrative claims, Electronic Clinical Data: Pharmacy	Process	Maintenance Measure – Currently Under Review	Competing N/A Related 0555: INR Monitoring for Individuals on Warfarin

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
2337 Antipsychotic Use	The percentage of children under age 5 who were dispensed antipsychotic medications during the measurement period.	Process	New Measure Submission –	Competing N/A
in Children Under 5 Years Old	Level of Analysis: Health Plan, Population: State Care Setting: Other Data Source: Administrative claims		Currently Under Review	Related N/A
2371 Annual Monitoring for Patients on Persistent Medications	This measure assesses the percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. - Angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB): At least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year. - Digoxin: At least one serum potassium, one serum creatinine and a serum digoxin therapeutic monitoring test in the measurement year. - Diuretics: At least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year. - Total rate (the sum of the three numerators divided by the sum of the three denominators) Level of Analysis: Health Plan, Integrated Delivery System Care Setting: Ambulatory Care: Clinician Office/Clinic Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Pharmacy	Process	New Measure Submission – Currently Under Review	Competing N/A Related N/A

Other Measures in the NQF Patient Safety Portfolio – Not Currently Under Review

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0022	There are two rates for this measure:	Process	Endorsed	Competing
Use of High-Risk	- The percentage of patients 65 years of age and older who received	N/A		
Medications in the	at least one high-risk medication.			Related
Elderly (DAE)	- The percentage of patients 65 years of age and older who received			N/A
	at least two different high-risk medications.			
	For both rates, a lower rate represents better performance.			
	Level of Analysis: Health Plan, Integrated Delivery System			
	Care Setting: Ambulatory Care: Clinician Office/Clinic, Pharmacy			
	Data Source: Administrative claims, Electronic Clinical Data,			
	Electronic Clinical Data : Pharmacy			
0035	Assesses different facets of fall risk management:	Process	Endorsed	Competing
Fall Risk	Discussing Fall Risk. The percentage of adults 75 years of age and		Measure	N/A
Management	older, or 65–74 years of age with balance or walking problems or a			Related
(FRM)	fall in the past 12 months, who were seen by a practitioner in the			N/A
	past 12 months and who discussed falls or problems with balance or walking with their current practitioner.			
	Managing Fall Risk. The percentage of adults 65 years of age and			
	older who had a fall or had problems with balance or walking in the			
	past 12 months, who were seen by a practitioner in the past 12			
	months and who received fall risk intervention from their current			
	practitioner.			
	Level of Analysis : Health Plan, Integrated Delivery System			
	Care Setting: Ambulatory Care: Clinician Office/Clinic,			
	Hospital/Acute Care Facility			
	Data Source: Patient Reported Data/Survey			

Measure Title and Steward	Description Level of Analysis Target Population		Status	Related and Competing Measures
0097 Medication Reconciliation	Percentage of patients aged 18 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days of discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist who had reconciliation of the discharge medications with the current medication list in the outpatient medical record documented. This measure is reported as two rates stratified by age group: 18-64 and 65+. Level of Analysis: Clinician: Group/Practice, Clinician: Individual Care Setting: Ambulatory Care: Clinician Office/Clinic, Pharmacy, Ambulatory Care: Urgent Care Data Source: Administrative claims, Electronic Clinical Data	Process	Endorsed Measure	Competing N/A Related N/A

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
O101 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls	This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates: A) Screening for Future Fall Risk: Percentage of patients aged 65 years of age and older who were screened for future fall risk at least once within 12 months B) Falls: Risk Assessment: Percentage of patients aged 65 years of age and older with a history of falls who had a risk assessment for falls completed within 12 months C) Plan of Care for Falls: Percentage of patients aged 65 years of age and older with a history of falls who had a plan of care for falls documented within 12 months. Level of Analysis: Clinician: Group/Practice, Clinician: Individual Care Setting: Ambulatory Care: Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Ambulatory Care: Urgent Care Data Source: Administrative claims, Electronic Clinical Data, Paper	Process	Endorsed Measure	Competing N/A Related N/A
0141 Patient Fall Rate	All documented falls, with or without injury, experienced by patients on eligible unit types in a calendar quarter. Reported as Total Falls per 1,000 Patient Days and Unassisted Falls per 1000 Patient Days. (Total number of falls / Patient days) X 1000 Measure focus is safety. Target population is adult acute care inpatient and adult rehabilitation patients. Level of Analysis: Clinician: Team Care Setting: Hospital/Acute Care Facility, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility Data Source: Electronic Clinical Data, Other, Paper Medical Records	Outcome	Endorsed Measure	Competing N/A Related N/A

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0181 Increase in number of pressure ulcers	Percentage of patients who had an increase in the number of pressure ulcers Level of Analysis: Facility/Agency, Clinicians: Other Care Setting: Home		Endorsed Measure	Competing N/A Related N/A
0201 Pressure ulcer prevalence (hospital acquired)	The total number of patients that have hospital-acquired (nosocomial) category/stage II or greater pressure ulcers on the day of the prevalence measurement episode. Level of Analysis: Facility, Clinician: Team Care Setting: Hospital/Acute Care Facility, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility Data Source: Electronic Clinical Data, Other, Paper Medical Records		Endorsed Measure	Competing N/A Related N/A
0202 Falls with injury	All documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter. Reported as Injury falls per 1000 Patient Days. (Total number of injury falls / Patient days) X 1000 Measure focus is safety. Target population is adult acute care inpatient and adult rehabilitation patients. Level of Analysis: Clinician: Team Care Setting: Hospital/Acute Care Facility, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility Data Source: Electronic Clinical Data, Other, Paper Medical Records	Outcome	Endorsed Measure	Competing N/A Related N/A

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
O204 Skill mix (Registered Nurse [RN], Licensed Vocational/Practic al Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)	NSC-12.1 - Percentage of total productive nursing hours worked by RN (employee and contract) with direct patient care responsibilities by hospital unit. NSC-12.2 - Percentage of total productive nursing hours worked by LPN/LVN (employee and contract) with direct patient care responsibilities by hospital unit. NSC-12.3 - Percentage of total productive nursing hours worked by UAP (employee and contract) with direct patient care responsibilities by hospital unit. NSC-12.4 - Percentage of total productive nursing hours worked by contract or agency staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities by hospital unit. Note that the skill mix of the nursing staff (NSC-12.1, NSC-12.2, and NSC-12.3) represent the proportions of total productive nursing hours by each type of nursing staff (RN, LPN/LVN, and UAP); NSC-12.4 is a separate rate. Measure focus is structure of care quality in acute care hospital units. Level of Analysis: Clinician: Team Care Setting: Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility Data Source: Management Data, Other	Structure	Endorsed Measure	Competing N/A Related N/A

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0205 Nursing Hours per Patient Day	NSC-13.1 (RN hours per patient day) – The number of productive hours worked by RNs with direct patient care responsibilities per patient day for each in-patient unit in a calendar month. NSC-13.2 (Total nursing care hours per patient day) – The number of productive hours worked by nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities per patient day for each in-patient unit in a calendar month. Measure focus is structure of care quality in acute care hospital units. Level of Analysis: Clinician: Team Care Setting: Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility Data Source: Management Data, Other		Endorsed Measure	Competing N/A Related N/A
O239 Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis	Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time Level of Analysis: Clinician: Group/Practice, Clinician: Individual Care Setting: Ambulatory Care: Ambulatory Surgery Center (ASC), Hospital/Acute Care Facility Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Paper Medical Records, Electronic Clinical Data: Registry	Process	Endorsed Measure	Competing N/A Related N/A
0263 Patient Burn	Percentage of ASC admissions experiencing a burn prior to discharge Level of Analysis: Facility Care Setting: Ambulatory Care: Ambulatory Surgery Center (ASC) Data Source: Paper Records	Outcome	Endorsed Measure	Competing N/A Related N/A

Measure Title and Steward	Description Level of Analysis Target Population	Measure Type	Status	Related and Competing Measures
0266 Patient Fall	Percentage of ASC admissions experiencing a fall in the ASC. Level of Analysis: Facility Care Setting: Ambulatory Care: Ambulatory Surgery Center (ASC) Data Source: Paper Records	Outcome	Endorsed Measure	Competing N/A Related N/A

Appendix C: Patient Safety Portfolio—Use In Federal Programs

NQF#	Title	Federal Programs: Currently Finalized as 2013-2014
0510	Exposure Time Reported for Procedures Using Fluoroscopy (ACR)	Physician Feedback; Physician Quality Reporting System (PQRS)
0531	Patient Safety for Selected Indicators (PSI 90)	Hospital Acquired Condition Reduction Program; Hospital Inpatient Quality Reporting; Hospital Value-Based Purchasing
0532	Pediatric Patient Safety for Selected Indicators (PDI 19)	Not Currently Finalized in Federal Program
0739	Radiation Dose of Computed Tomography (CT)	Not Currently Finalized in Federal Program
0740	Participation in a Systematic National Dose Index	Not Currently Finalized in Federal Program
2426	Elder Maltreatment Screening and Follow Up Plan	Not Currently Finalized in Federal Program
0138	National Healthcare Safety Network (NHSN) Catheter- Associated Urinary Tract Infection (CAUTI) Outcome Measure	Hospital Acquired Condition Reduction Program; Hospital Inpatient Quality Reporting; Hospital Value-Based Purchasing; Inpatient Rehabilitation Facilities Quality Reporting; Long-term Care Hospital Quality Reporting; PPS-Exempt Cancer Hospital Quality Reporting
0139	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	Children's Health Insurance Program Reauthorization Act Quality Reporting; Hospital Acquired Condition Reduction Program; Hospital Inpatient Quality Reporting; Hospital Value-Based Purchasing; Long-term Care Hospital Quality Reporting; PPS- Exempt Cancer Hospital Quality Reporting

NQF#	Title	Federal Programs: Currently Finalized as 2013-2014
0464	Prevention of Catheter-Related Bloodstream infections (CRBSI) Central Venous Catheter (CVC)	Physician Feedback; Physician Quality Reporting System (PQRS)
0684	Percent of Residents with Urinary Tract Infection (Long Stay)	Nursing Home Quality Initiative and Nursing Home Compare
0541	Proportion of Days Covered (PDC) 3 Rates by Therapeutic Category	Medicare Part D Plan Rating
0555	INR Monitoring for Individuals on Warfarin	Not Currently Finalized in Federal Program
0556	INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications	Physician Feedback
2337	Antipsychotic Use in Children Under 5 Years Old	Not Currently Finalized in Federal Program
2371	Management of Patients on Persistent Medication	Not Currently Finalized in Federal Program
0022	Use of High-Risk Medications in the Elderly (DAE)	Meaningful Use (EHR Incentive Program) - Eligible Professionals; Medicare Part D Plan Rating; Physician Feedback; Physician Quality Reporting System (PQRS)
0035	Fall Risk Management (FRM)	Medicare Part C Plan Rating
0097	Medication Reconciliation	Medicare Shared Savings Program; Physician Feedback; Physician Quality Reporting System (PQRS)

NQF#	Title	Federal Programs: Currently Finalized as 2013-2014
0101	Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls	Meaningful Use (EHR Incentive Program) - Eligible Professionals; Medicare Shared Savings Program; Physician Quality Reporting System (PQRS)
0141	Patient Fall Rate	Not Currently Finalized in Federal Program
0181	Increase in number of pressure ulcers	Home Health Quality Reporting
0201	Pressure ulcer prevalence (hospital acquired)	Not Currently Finalized in Federal Program
0202	Falls with injury	Not Currently Finalized in Federal Program
0204	Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)	Not Currently Finalized in Federal Program
0205	Nursing Hours per Patient Day	Not Currently Finalized in Federal Program
0239	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis	Physician Feedback; Physician Quality Reporting System (PQRS)
0263	Patient Burn	Ambulatory Surgical Center Quality Reporting
0266	Patient Fall	Ambulatory Surgical Center Quality Reporting
2564	Documenting the Radiation Dose of Computed Tomography (CT)	Not Currently Finalized in Federal Program

Appendix D: Patient Safety Standing Committee and NQF Staff

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Appendix E: Implementation Comments

Comments received as of March 6, 2014

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Hazel Thomas	I serve as Chaplain Manager at TIRR Memorial Hermann, a model systems inpatient rehab hospital currently ranked #3 in the nation. Even though I do not speak from the medical (physician or nurse) perspective, I have heard from many of our spinal cord injured patients as well as the staff, the need for catheters to stay in place during hospitalization. Patients with spinal cord injury, especially at the tetraplegic level but also at the paraplegic level, cannot always feel or know when their bladder is full or needs to be emptied. The foley catheter is safe, and patients and/or support persons can be taught how to clean and/or change as necessary.
		A person dealing with spinal cord injury for the first time has lots of information and new ways of completing simple task to learn each day. This can be daunting and can overwhelm a patient, spiritually, emotionally, and physically. Patients who acquire infections during their rehab stay because a catheter was removed prior to teaching proper cathing protocol are less likely to complete their rehab well or willing to participate fully. This can prolong their length of stay and possibly cause a re-admission to acute care to address the infection issue, especially if it leads to renal failure. All of this can cause setbacks in their medical recovery, as well as their emotional recovery and adjustment. I feel it needs to be re-evaluated to NOT remove catheters during hospitalization without ensuring patients are correctly voiding on their own or have learned a proper cathing protocol.

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated	Submitted by Dr. Sarah E. Lake- Wallace,	In our aim to achieve a highly reliable healthcare system, it is important to not let the needs of special populations to be overshadowed. A negative impact on changes in clinical care in the attempt to reduce the use of indwelling catheters is starting to appear.
Urinary Tract Infection (CAUTI) Outcome Measure	Pharm.D.	One primary focus of the measure is to reduce the number of unnecessary indwelling catheters. Many guidelines start with the premise that most indwelling catheters are unnecessary. Add to this the issue that many healthcare providers have limited experience with SCI patients, and they are not effectively evaluating the justification for an indwelling catheter. The impact on these guidelines is pressure on clinicians to remove all indwelling catheters regardless of indication. In the recent months our rehabilitation hospital has seen several SCI patients transitioned to condom catheters in the acute care setting resulting in urinary retention and acute renal injury due the physiological inability to empty the bladder.
		The appropriate use of indwelling catheters in the SCI patients was specifically addressed in the 2009 CDC CAUTI guidelines (Gould 2009) which stated "for patients with spinal cord injury, very low-quality evidence suggested a benefit of avoiding indwelling urinary catheters"
		It should be noted in the above statement that the group of patients "without indwelling catheters" included patients who could spontaneously void, as well as those who had had sphincterotomy with condom catheter drainage. In the acute stage of SCI neither of these options are possible or feasible. Instead, the choice is simply between indwelling catheterization and CIC. Studies comparing rates of UTI in CIC versus indwelling catheterization show mixed results, but no marked decrease in UTI risk with CIC. Furthermore, CIC must be done according to a strict protocol in order to avoid obstructive uropathy. Unfortunately, acute care hospitals are not well-versed in implementing this protocol due to a low incidence of SCI patients in most hospital settings.
		The use of indwelling catheters in SCI patients may actually represent the safest alternative and highest quality of life possible. Patients with limited dexterity or high level injuries have to rely on caregivers to provide CIC every 4 hours which may not be feasible or a deterrent to returning to outside activities. The evidence on SPT is not clear as an infection prevention strategy. Additionally SPT are not appropriate in the early stages of rehabilitation and recovery of patients with SCI. This leaves limited options for this patient population. Many SCI patients will have an indwelling catheter for many years or a lifetime because it is the only way to assure appropriate bladder health.

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated	Submitted by Dr. Sarah E. Lake- Wallace,	The use of evidence to improve practice and outcomes for patients has been one of the major improvements in the last decade to improve public health; however the current definition for SUTI is inadequate for the SCI population.
Urinary Tract Infection (CAUTI) Outcome Measure	Pharm.D.	The recent operational clarification of the SUTI definition in using fever as a symptom regardless of whether it can be attributed to another cause, has led to an over calculation of the incidence of CAUTIs. In the current reporting process if a patient has a fever, an indwelling catheter and a colony count greater than 105 cfu/ml in the urine, it is automatically counted as a CAUTI. This criterion is not specific enough to capture just CAUTIs. Fever can often be related directed to the spinal cord injury by means of storming events or autonomic dysreflexia, or it can be attributed to other acute events, such as pneumonia. The CDC definition has recognized other populations that fever is a non-specific symptom (specifically patients >65 years). Patients with a high colony count of bacteria (>100,000 cfu) in the urine is not always indicative of a UTI, as they can have high colony counts representing colonization, especially seen in patients with catheters(Hull, et al., 2000). The 2009 CDC CAUTI guidelines (Gould, et al., 2009) specifically recognized that 100% of patients with an indwelling catheter for more than 30 days will have bacteriuria; therefore, it would be expected for all long term catheter patients to have a colony count in the urine. Additionally, the UA criteria being used currently by NHSN are too sensitive for a spinal cord patient who has a chronic indwelling catheter. These patients often have a pyuria count of >10WBC/high spun field. In a study by Hull et al, they found that bacteriuria was associated with pyuria and that it continued as long as the bacteriuria remained in their test subjects (Hull, et al., 2000).
		The incidence rate of CAUTI in the spinal cord injury population has likely been under-reported based on current surveillance data. Most facilities use the CDC/NHSN definition for defining infections. The symptoms included in this definition of catheter-associated UTIs does not take into account the lack of sensation or the change in physiological response seen in spinal cord injury patients. Patients will often not have suprapubic pain or costovertebral angle pain, but rather an increase in spasticity, urinary leakage or hematuria. Our internal research has found that spasticity and hematuria are the most common symptoms associated with UTI in the SCI population. Therefore our specific request is
		Exclude SCI patients from the numerator of NQF #0138
		Develop a SCI specific definition of SUTI to better reflect the events in this population

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Dr. Sarah E. Lake- Wallace, Pharm.D.	In our aims to achieve a highly reliable healthcare system, it is important to not let the needs of special populations to be overshadowed. This concern for special populations is the reason for our request to modify NQF #0138 (NHSN Catheter-Associated Urinary Tract Infection (CAUTI) outcome measure) to specifically exclude patients with spinal cord injuries (SCI) due to the unequal distributions of SCI patients in hospitals and rehabilitation settings without any risk adjustment.
		The current proposal allows for stratification by bed size, location type and medical school affiliation. None of these categories address the SCI population. The current reporting tools do not collect any diagnostic information about the patient and location alone is inadequate.
		The distribution of SCI patients is not equal among hospitals or rehabilitation settings. The current measure has no risk adjustment for this population despite the knowledge that the risk of CAUTI is different. The use of SIR as the comparison then unfairly impacts those facilities that care for patients with SCI.
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Carolyn Tillquist	Regarding measure #0138 As an Infectious Diseases specialist practicing at Craig Hospital for sci and brain injury patients, I deal with bacteriuria and utis on a daily basis. We have been working at Craig to study these measures in this population so as to better understand what best practices may be. Although studies are in progress, both here and at other centers across the nation, guidelines appropriate for these unique patients have not been established. We know that the guidelines used to address the acute care population, that are represented in measure #0138, do not apply. Please exclude this population from this measure; including them in the current measure would be a disservice to the patients and to those of us who have dedicated our expertise to providing them with the best care possible.
		Thank-you, Carolyn Tillquist,MD

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by William Carter, III, MD	I am relatively new to exposure to larger spinal cord injury/ trauma centers. Prior to working in one, I had no concept of how to manage bladder function in SCI. Afterwards, as mentioned by others, there is a struggle even without such a policy for their bladder management to be appropriate. In addition to spinal cord injury, this measure could also adversely impact other populations such as multiple sclerosis, polytrauma, and others. When transitioning from an indwelling catheter we almost invariably place patients on fluid restriction of 2L/day. Without this restriction, to maintain a safe bladder volume in someone unable to void, intermittent catheterization would need to be performed more frequently and there is no study that shows that doing intermittent catheterization every 3 hours is safer than an indwelling catheter. Furthermore, in the acute care setting almost invariably patients are continued on IV fluids, IV antibiotics, etc, contributing to more rapid bladder filling. Catheters are placed for multiple reasons and if there is good documentation for why it needs to be continued (too high fluid intake, inability to self cath, reasons that bladder accidents can't be risked such as sacral pressure sores (not unique to SCI population), etc) that should ideally suffice. I can recall from my internal medicine training that all patients with heart failure were supposed to be discharged on an ACE-I or ARB as a quality standard. However, if documentation suggesting a contraindication was provided, there was no penalty. What is the best way to make exceptions to the rule?
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Monica Verduzco- Gutierrez, MD	The CAUTI Outcome measure is an excellent quality guideline in the abled body population. I take care of patients with catastrophic injuries (spinal cord injuries and severe acquired brain injuries) and in this patient population with neurogenic bladder, the discontinuation of a foley can be injurious or deadly. Some centers are not aware or able to manage a patient that necessitates a intermittent catheterization program. These patients can be harmed by hydronephrosis, renal failure, bladder rupture when a necessary foley is removed. I urge you to consider excluding SCI patients from these guidelines or excluding speciality rehabilitation hospitals from this measure. Thank you.

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Stephen Burns, MD	I agree with the comments of Drs. Alander, Stampas, Francisco, Gershkoff, Berliner, and Davis. Indwelling catheters are the most appropriate management option for many patients with neurogenic bladder dysfunction secondary to spinal cord injury. They have been recommended as an option in the Consortium for Spinal Cord Medicine's clinical practice guideline on management of neurogenic bladder. They are usually the best choice for patients who lack hand function (or cognitive function) to reliably perform self-intermittent catheterization. There is no significant difference in the rate of symptomatic urinary tract infections with indwelling catheters compared to other options in patients with severe neurogenic bladder dysfunction. I have personally seen adverse outcomes when Foley catheters are inappropriately discontinued in patients with SCI. A patient currently hospitalized on my service had this occur when he was at an outside hospital. He was returned to his nursing home without a catheter and was required to have a urinal balanced between his thighs 24 hours per day, since he had no ability to control urination. When we admitted him, he had a post-void residual of 400ml. We immediately replaced the Foley catheter and educated the patient on the appropriateness of this for managing his bladder. It is not reasonable to expect providers outside of tertiary care centers to have the knowledge to select optimal management for this condition. I fear that encouraging them to discontinue catheter management will have a negative impact on quality of life in this population with no health benefit gained. For these reasons, exclusion of SCI patients from the numerator of NQF #0138 is therefore justified.
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Dirk H. Alander, MD	I work in at a level one trauma center (ACS, Illinois, Missouri) serving both the inner city and large rural areas. I would move to avoid the inclusion of the SCI patient into the population of patients using catheters. The SCI patient population has a diverse range of injury patterns, associated injuries, and social issues that do not lend themselves to the average patient with a short term need of a catheter. Lack of adequate care outside of the acute and rehabilitation hospitals is a real concern when patients are unable to complete serial catheterizations and have little or no resources for assistance. There needs to be much stronger evidence to support one method or another before penalizing physicians, institutions and patients for urinary tract infections after catheter use in this challenging patient population.

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Argyrios Stampas, MD	Urinary tract infections are an unfortunate risk when maintaining an indwelling catheter. However, they are a necessity for many patients with spinal cord injury or disease secondary to the risk of high bladder pressures and the subsequent kidney damage that will ensue. Ideally, these patients would have an intermittent catheter schedule, which is well known to reduce the amount of UTIs. However, for many patients, they cannot self cath, nor can their loved ones or caregivers. They must rely on health care providers. That said, a skilled nursing facility is ill-equipped to catheterize patients every 4 - 6 hours. Without the bladder being intermittently decompressed, the pressures can elevate leading to kidney damage and/or infection.
		Thus, facilities must continue to use indwelling catheters and treat the potential UTI, versus the alternative of renal failure, pyelonephritis, and other far worse morbidities that may occur, compared to a UTI.
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Lance Goetz	I concur with the cements from other spinal cord injury (SCI) professionals. Indwelling catheters (urethral or suprapubic) are sometimes the only viable option for persons with SCI and some other causes of neurogenic bladder dysfunction. Removal of an indwelling catheter and placement of an external catheter could put such persons at risk for a number of serious complications, including vesicoueretral reflux due to outlet obstruction, leading to stone disease and/or kidney damage.
		Further, insistence on intermittent catheterization could cause persons with SCI to be denied admission to certain facilities.
		I recommend allowing justification of indwelling catheter use or making other accommodations for these persons.

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Gerard Francisco	The use of indwelling catheters in SCI patients may actually represent the safest alternative and highest quality of life possible. This was specifically addressed in the 2009 CDC CAUTI guidelines (Gould 2009): "For patients with spinal cord injury, very low-quality evidence suggested a benefit of avoiding indwelling urinary catheters. This was based on a decreased risk of UTI and bacteriuria in those without indwelling catheters (including patients managed with spontaneous voiding, clean intermittent catheterization [CIC], and external striated sphincterotomy with condom catheter drainage), as well as a lower risk of urinary complications, including hematuria, stones, and urethral injury (fistula, erosion, stricture)."
		Patients with limited dexterity or high level injuries have to rely on caregivers to provide intermittent catherization every 4 hour which may not be feasible or a deterent to returning to work or other activities. The evidence on suprapubic tubes is not clear as a infection prevention strategy. Over the course of time, these patients become naturally colonized with benign organism(s) that does not represent an acute infection and likely should not be treated with antibiotics. This colonization most likely helps protect the patient from developing a UTI from pathogenic organisms, such as those that are antibiotic resistant. Thus, I have concerns that the current CDC definition and implementation by NHSN for CAUTI is currently overestimating events in the SCI population and does not adequately address the symptomology seen in these patients. The 2009 CDC CAUTI guidelines (Gould, et al. , 2009) specifically recognized that 100% of patients with an indwelling catheter for more than 30 days will have bacteriuria; therefore, it would be expected for all long term catheter patients to have a colony count in the urine. The preventative efforts outlined in NQF #0138 are appropriate for the care of any indwelling catheter and we fully support the implementing securing catheters to the leg, keeping collection bags below the level of the bladder, and utilizing aseptic techniques for insertions. Our organization is implementing programs to address these issues. Our concern is that these efforts will only minimally impact infections because of the unique issues for SCI patients as adequate research and evidence is lacking.
		Thus, I strongly recommend: 1) Excluding SCI patients from the numerator of NQF #0138; 2) Developing a SCI specific definition of CAUTI to better reflect the events in this population; 3) Developing a specific measure on CAUTI for this population to further the knowledge and advance the preventative efforts that are likely to have a clinical impact for patients (ex: use of leg bags, closed vs open symptoms, managing colonizations).
		Thank you.

Topic	Commenter	Comment
O138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Arthur Maurice Gershkoff, M.D.	l am concerned that the outcome measure related to catheter associated urinary tract infections may impact adversely on the medical care received by persons with spinal cord injuries and other severe physical disabilities. Such patients may be at risk for urinary incontinence with complications(such as skin irritation and impeding of the healing of skin ulcers) or for urinary retention. The policy threatens financial repercussions to hospitals with above-average rates of catheter-associated urinary tract infections (CAUTIs). In response, many facilities are making efforts to remove indwelling catheters in all patients – often including SCI patients and other patients with severe physical disabilities. These facilities may not be adequately educated or equipped to successfully implement an intermittent catheterization program, and I have been told that some patients are simply having condom catheters placed — putting them at risk for obstructive uropathy and renal failure. While the incentive to move to intermittent catheterizaton is admirable for most patients, some patients are completely unable to tolerate this because of pain or anatomic problems. For some patients, a hypertonic bladder or lower motor neuron type bladder with a flaccid urinary sphincter and incontinence between catheterizations, may also not be tolerable. For those patients, intermittent catheterization is not an option, and indwelling Foley catheterization may be required. It is inevitable that patients with long term indwelling Foley catheters will eventually become colonized, and that some of these will go on to develop infection. It would be important in the evaluation of CAUTI's, to make sure that hospitals that have a large number of severely physically disabled patients, such as rehabilitation hospitals, not be compared with other hospitals that do not admit such patients (and instead, refer them elsewhere.) If all hospitals are lumped together, there needs to be some risk adjustment based on the percentage of severely disabled pers

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Jeff Berliner, DO	Dear NHSN- I am from Craig Hospital, a mosel Spinal Cord System that specializes in the delivery of outstanding care to those with spinal cord and traumatic brain injuries. CAUTI's are a formidable opponent in those living with spinal cord injury that rely on Foley or Intermittent Catheterization Programs to drain the bladder. In acute inpatient rehabilitation a team approach is used to teach those with either full or poor hand function to use an intermittent catheter program to drain the bladder every four hours. Even with the best of hygiene, CAUTI's are unavoidable in many of these patients. They are learning to manipulate a catheter into their meatus to drain their bladder and are repeatedly performing this action with-in a hospital setting every four hours to learn to become independent. We use gloves, sterile catheters and iodine every time but still to no avail as many come down with UTI's. If a person has poor hand function then a catheter must remain in the bladder and a caregiver must learn how to change and flush the Foley. What I am asking for is an exclusion for this unique patient population. They, their bladders and their means of elimination of urine do not fit the mold or the spirit of the very people that this new guideline is trying to protect. This new law may force clinicians in spinal cord injury to prescribe unneeded antiobiotic prophylaxis for all patients to protect against a CAUTI. I will ask our research department to come with facts about the frequency of UTI's in this patient population. Thank you for this consideration- Dr. Berliner

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Matthew Davis, MD	While seeking to achieve a highly reliable healthcare system, it is important not to overlook the needs of special populations. One such population is that of people with disabilities – which has been designated as a minority group with protection under items of legislation such as the Americans with Disabilities Act.
		This concern leads me to request a modification of NQF #0138 (NHSN Catheter-Associated Urinary Tract Infection (CAUTI) outcome measure) to specifically exclude patients with spinal cord injuries (SCI). Specific considerations include:
		1) A thorough review of studies measuring UTI rates in SCI patients with indwelling catheters versus other means of bladder management fails to demonstrate a consistent, clear, and statistically significant benefit to removing indwelling catheters.
		2) In an effort to reduce CAUTI rates, acute care hospitals have been removing indwelling catheters while failing to implement an adequate alternative form of bladder management. This puts SCI patients at risk for obstructive uropathy and renal failure.
		In the 2009 CDC CAUTI guidelines, Gould, et al, admits "For patients with spinal cord injury, very low-quality evidence suggested a benefit of avoiding indwelling urinary catheters." Likewise, the Clinical Practice Guidelines prepared by the Consortium for Spinal Cord Medicine in 2006 acknowledge that the data regarding rates of UTI in SCI patients with indwelling catheters versus those using intermittent catheterization is conflicting. In other words, there is not a clear, unequivocal benefit from removing indwelling catheters in terms of reducing UTI risk.
		What is clear and unequivocal, however, is that patients with acute SCI require adequate bladder drainage – either through indwelling catheterization or through intermittent catheterization. Intermittent catheterization must be done according to a strict protocol in order to avoid obstructive uropathy and risk for renal failure. Unfortunately, acute care hospitals are not well-versed in implementing this protocol due to a low incidence of SCI patients in most hospital settings. In the past few weeks, presumably due to concerns about CAUTI rates, TIRR rehabilitation hospital has seen increasing numbers of patients referred from acute care hospitals who have been transitioned to diapers or condom catheters, a practice which puts patients at risk for obstructive uropathy and acute renal failure.
		Our specific requests are:
		1) Exclude SCI patients from the numerator of NQF #0138
		2) Develop a SCI-specific definition of UTI to better reflect events in this population. This should be done with input from board-certified specialists in spinal cord medicine.

Topic	Commenter	Comment
0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Submitted by Stephen Burns, MD	I agree with the comments of Drs. Alander, Stampas, Francisco, Gershkoff, Berliner, and Davis. Indwelling catheters are the most appropriate management option for many patients with neurogenic bladder dysfunction secondary to spinal cord injury. They have been recommended as an option in the Consortium for Spinal Cord Medicine's clinical practice guideline on management of neurogenic bladder. They are usually the best choice for patients who lack hand function (or cognitive function) to reliably perform self intermittent catheterization. There is no significant difference in the rate of symptomatic urinary tract infections with indwelling catheters compared to other options in patients with severe neurogenic bladder dysfunction. I have personally seen adverse outcomes when Foley catheters are inappropriately discontinued in patients with SCI. A patient currently hospitalized on my service had this occur when he was at an outside hospital. He was returned to his nursing home without a catheter and was required to have a urinal balanced between his thighs 24 hours per day, since he had no ability to control urination. When we admitted him, he had a post-void residual of 400ml. We immediately replaced the Foley catheter and educated the patient on the appropriateness of this for managing his bladder. It is not reasonable to expect providers outside of tertiary care centers to have the knowledge to select optimal management for this condition. I fear that encouraging them to discontinue catheter management will have a negative impact on quality of life in this population with no health benefit gained.
		For these reasons, exclusion of SCI patients from the numerator of NQF #0138 is therefore justified.
0532: Pediatric Patient Safety for Selected Indicators (PDI 19)	Submitted by Ms. Vipra Ghimire, MPH	The following comment is from the Johns Hopkins University Armstrong Institute for Patient Safety and Quality: The Armstrong Institute does not support the re-endorsement of the AHRQ Pediatric Patient Safety composite measure. A 2008 study and opinion piece by Scanlon et al. found that in their present form, true preventability of these PDIs is relatively low; therefore, the indicators are not useful for public hospital comparison. Identifying complications, or set of complications, that were not present on admission is made more difficult by the fact that data gleaned from admission records are not always reliable.

Topic	Commenter	Comment
2371: Annual Monitoring for Patients on Persistent Medications	Kelly Robberson, Providence Health & Services; Submitted by Kelly Robberson, JD	We support this measure and believe it is very important, however are concerned it will require a much more sophisticated tracking and reporting capability than currently available. There is also the issue of patient adherence that may not be considered effectively through this measure as written.
0556: INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications	Kelly Robberson, Providence Health & Services; Submitted by Kelly Robberson, JD	We fully support this measure; reducing the risk of preventable bleeds due to drug-induced prolongation of the PT/INR remains critically important
0555: INR Monitoring for Individuals on Warfarin	Kelly Robberson, Providence Health & Services; Submitted by Kelly Robberson, JD	We support this measure, however would appreciate more detailed rationale on how the 56 day timeframe for warfarin treatment was determined.

Topic	Commenter	Comment
0541: Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category	Kelly Robberson, Providence Health & Services; Submitted by Kelly Robberson, JD	This measure would be difficult to meet without an integrated outpatient pharmacy system capable of providing data back to providers. Additional questions to be answered are whether this measure is calculated based on pharmacy claims, and how it is managed in cases where patients do not fill a prescription that is provided. Measure Submitter Response: The measure uses prescription claims data from a health plan to calculate the rate. For example, the measure is calculated for Medicare Part D health plans providing prescription drug coverage to Medicare beneficiaries. To be included in the measure denominator, the patient must have two prescription claims for the target medication. If a patient does not get the prescription filled (primary medication non-adherence), they would not be included in this particular measure.
0510: Exposure time reported for procedures using fluoroscopy	Kelly Robberson, Providence Health & Services; Submitted by Kelly Robberson, JD	Most providers that utilize fluoroscopy do not currently include this in their final report because it is noted in the procedure log. This would require only a modest change in workflow with specific communication to providers to achieve.

Topic	Commenter	Comment
0739: Radiation Dose of Computed Tomography (CT)	ASTRO Subcommittee ASTRO Subcommittee, American Society for Radiation Oncology (ASTRO); Submitted by Mrs. Caitlin Drumheller	Section 4c.1: CT PROTOCOLS I agree with the premise that it would be too difficult to gather the data based on protocols, and therefore gathering single anatomic area. However, the question remains how institution B would be able to do a meaningful root cause analysis of their higher doses if the data just provides average doses by site. The pitfall scenario would be for Institution B to cite their higher incidents of multi-phase head CT (based on their own estimate of patient populations across hospitals), thereby potentially missing a systematically higher dose in their routine CTs. A more serious issue with this overall excellent Measure is that seems to address Radiology exclusively. A large number of CT studies are conducted in Radiation Oncology Departments for treatment planning purposes. >60% of all cancer patients receive radiation. Some of these studies, e.g. 4D-CT conducted for lung and breast cancer, have 10x as much dose as a free breathing scan. With the increased survival rate of many cancer patients, imaging dose and long-term toxicity such as secondary cancers are a concern. In addition, the quality assurance and protocol development for CT machines installed in Radiation Oncology are often not performed by diagnostic medical physicists, but by medical physicists trained in therapy physics. All this factors lead me to the conclusion that inclusion of CT dose from Radiation Oncology Departments should be much more emphasized in the language of this Measure.

Appendix F: Measure Specifications

O138 National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAU Outcome Measure	-
0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CL Outcome Measure	-
0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI) – Central Venous Catheter (CV	/C)
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0531 Patient Safety for Selected Indicators (PSI 90)	123
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0684 Percent of Residents with a Urinary Tract Infection (Long-Stay)	144
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2426 Elder Maltreatment Screening and Follow-Up Plan	159
2564 Documenting the Radiation Dose of Computed Tomography in the Patient Medical Record	163

0138 National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

STATUS

Submitted

STEWARD

Centers for Disease Control and Prevention

DESCRIPTION

Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (UTI) will be calculated among patients in bedded inpatient care locations, except level II or level III neonatal intensive care units (NICU.

This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavior health hospitals.

TYPE

Outcome

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Laboratory, Other, Paper Medical Records NHSN Urinary Tract Infection form; NHSN Denominators for Intensive Care Unit (ICU)/Other Locations (not NICU or SCA) form; NHSN Denominators for Specialty Care Areas/Oncology form.

Available at measure-specific web page URL identified in S.1 Attachment NHSN Data Dictionary 7.2-635228834519586683.xlsx

LEVEL

Facility, Population: National, Population: Regional, Population: State

SETTING

Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Other Oncology hospital

TIME WINDOW

Cases are included if they are healthcare-associated and their infection dates are during a month in which a patient care area (location) was selected for surveillance. With low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs, thus the time window may be a period greater than monthly.

NUMERATOR STATEMENT

Total number of observed healthcare-associated CAUTI among patients in bedded inpatient care locations (excluding patients in Level II or III neonatal ICUs).

NUMERATOR DETAILS

- . Definition of Infection that is Present on Admission (POA): An infection where all of the elements of an infection definition are present during the two calendar days before the day of admission, the first day of admission (day 1) and/or the day after admission (day 2) and are documented in the medical chart. Infections that are POA should not be reported as healthcare-associated infections (HAI) and are not reported as CAUTI. Acceptable documentation does not include self-reported symptoms by the patient (e.g., patient reporting having a fever prior to arrival to the hospital). Instead, symptoms must be documented in the chart by a healthcare professional during the POA time frame (e.g., nursing home documents fever prior to arrival to the hospital). Physician diagnosis alone cannot be accepted as evidence of a urinary tract infection that is POA. NOTE: For POA, the temperature value does not need to be known to establish the presence of a fever.
- 2. Definition of Healthcare-associated Infection (HAI): Any infection reported to NHSN must meet the definition of an NHSN HAI, that is, a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that was not present on admission to the acute care facility. An infection is considered an HAI if all elements of a CDC/NHSN site-specific infection criterion were not present during the POA time period but were all present on or after the 3rd calendar day of admission to the facility (the day of hospital admission is calendar day 1). All elements used to meet the CDC/NHSN site-specific infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between any two adjacent elements. The definition of a gap day is a calendar day during which no infection criterion elements are present. If all elements of a CDC/NHSN site-specific infection criterion are present on the day of transfer or the next day from one inpatient location to another in the same facility or a new facility, the infection is attributed to the transferring location or facility. Likewise, if all elements of a CDC/NHSN site-specific infection criterion are present on the day of discharge or the next day, the infection is attributed to the discharging location. Clinical evidence may be derived from direct observation of the infection site or review of information in the patient chart or other clinical records.
- 2.Definition of CAUTI: A UTI (either a Symptomatic Urinary Tract Infection [SUTI], or an asymptomatic bacteremic urinary tract infection [ABUTI]) where an indwelling urinary catheter was in place for >2 calendar days on the date of event, with day of device placement being Day 1,AND an indwelling urinary catheter was in place on the date of event or the day before. If an indwelling urinary catheter was in place for > 2 calendar days and then removed, the UTI criteria must be fully met on the day of discontinuation or the next day to be catheter-associated.
- 3.Definition of indwelling catheter: A drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag (including leg bags). These devices are also called Foley catheters. Condom or straight in-and-out catheters are not included nor are nephrostomy tubes or suprapubic catheters unless a Foley catheter is also present. Indwelling urethral catheters that are used for intermittent or continuous irrigation are included in CAUTI surveillance.
- 4.UTI criteria meets either the Symptomatic Urinary Tract Infection, criteria or the Asymptomatic Bacteremic Urinary Tract Infection criteria:
- A Symptomatic Urinary Tract Infection (SUTI) that is catheter associated must meet at least 1 of A,) B), C), D), E), or F) below:
- A) Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place on the date of event AND

- at least 1 of the following signs or symptoms: fever (>38°C); suprapubic tenderness*; costovertebral angle pain or tenderness* AND
- a positive urine culture of =105 colony-forming units (CFU)/ml and with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.
- *With no other recognized cause
- B) Patient had an indwelling urinary catheter in place for >2 calendar days and had it removed the day of or the day before the date of event AND
- at least 1 of the following signs or symptoms: fever (>38°C); urgency*; frequency*; dysuria*; suprapubic tenderness*; costovertebral angle pain or tenderness* AND
- a positive urine culture of =105 colony-forming units (CFU)/ml and with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.
- *With no other recognized cause
- C) Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place on the date of event AND
- at least 1 of the following signs or symptoms: fever (>38°C); suprapubic tenderness*; costovertebral angle pain or tenderness* AND
- at least 1 of the following findings:
- i. positive dipstick for leukocyte esterase and/or nitrite
- ii. pyuria (urine specimen with =10 white blood cells [WBC]/mm3 of unspun urine or >5 WBC/high power field of spun urine)
- iii. microorganisms seen on Gram's stain of unspun urine

AND

- a positive urine culture of =103 and <105 CFU/ml and with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.
- *With no other recognized cause
- D) Patient with an indwelling urinary catheter in place for > 2 calendar days and had it removed the day of or the day before the date of event AND at least 1 of the following signs or symptoms: fever (>38°C); urgency*; frequency*; dysuria*; suprapubic tenderness*; costovertebral angle pain or tenderness* AND at least 1 of the following findings:
- i. positive dipstick for leukocyte esterase and/or nitrite
- ii. pyuria (urine specimen with =10 WBC/mm3 of unspun urine or >5 WBC/high power field of spun urine
- iii. microorganisms seen on Gram's stain of unspun urine

AND

- a positive urine culture of =103 and <105 CFU/ml and with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.
- *With no other recognized cause

E) Patient =1 year of age with or without** an indwelling urinary catheter has at least 1 of the following signs or symptoms: fever (>38°C core); hypothermia (<36°C core); apnea*; bradycardia*; dysuria*; lethargy*; vomiting*

and

a positive urine culture of =105 CFU/ml and with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.

- *With no other recognized cause
- ** Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1 and catheter was in place on the date of event or removed the day before.
- F) Patient =1 year of age with or without** an indwelling urinary catheter has at least 1 of the following signs or symptoms: fever (>38°C core); hypothermia (<36°C core); apnea*; bradycardia*; dysuria*; lethargy*; vomiting*

and

at least 1 of the following findings:

- a. positive dipstick for leukocyte esterase and/or nitrite
- b. pyuria (urine specimen with =10 WBC/mm3 of unspun urine or >5 WBC/high power field of spun urine
- c. microorganisms seen on Gram's stain of unspun urine

and

- a positive urine culture of between =103 and <105 CFU/ml and with no more than two species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.
- *With no other recognized cause
- ** Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1 and catheter was in place on the date of event or removed the day before.

An Asymptomatic Bacteremic Urinary Tract Infection (ABUTI) that is catheter associated must meet the following:

Patient with or without* an indwelling urinary catheter has no signs or symptoms (i.e., for any age patient, no fever (>38°C); urgency; frequency; dysuria; suprapubic tenderness; costovertebral angle pain or tenderness OR for a patient =1 year of age; no fever (>38°C core); hypothermia (<36°C core); apnea; bradycardia; dysuria; lethargy; or vomiting)

a positive urine culture of =105 CFU/ml and with no more than 2 species of uropathogen microorganisms** (see Comments section below)

and

a positive blood culture with at least 1 matching uropathogen microorganism to the urine culture, or at least 2 matching blood cultures drawn on separate occasions if the matching pathogen is a common skin commensal. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.

- *Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place on the date of event, or removed that day or the day before.
- **Uropathogen microorganisms are: Gram-negative bacilli, Staphylococcus spp., yeasts, betahemolytic Streptococcus spp., Enterococcus spp., G. vaginalis, Aerococcus urinae, and Corynebacterium (urease positive)+.
- 5. Definition of Adjacent Elements: "Adjacent" elements are elements of an infection criteria that occur in chronological order during the course of an infection.
- 6. Definition of Location of Attribution: The location to which the CAUTI is attributed.
- 7. Definition of Date of Event: The date when the last element used to meet the UTI criterion occurred.
- 8. Definitions for Facility Physician Education Status: Teaching statuses: major, graduate, undergraduate Major: Facility has a program for medical students and post-graduate medical training; Graduate: Facility has a program for post-graduate medical training (i.e., residency and/or fellowships); Undergraduate: Facility has a program for medical students only.

DENOMINATOR STATEMENT

Total number of indwelling urinary catheter days for each location under surveillance for CLABSI during the data period.

DENOMINATOR DETAILS

Numbers of indwelling urinary catheter days attributed to each location are counted for each data period utilizing the following definitions and guidelines. All CL days for each location and data period are summed.

1. Definition of indwelling catheter day: For each patient, a day that an indwelling urinary catheter was present at the time of the CL day count

EXCLUSIONS

The following are not considered indwelling catheters by NHSN definitions:

- 1. Suprapubic catheters
- 2.Condom catheters
- 3."In and out" catheterizations
- 4. Nephrostomy tubes

Note, that if a patient has either a nephrostomy tube or a suprapubic catheter and also has an indwelling urinary catheter, the indwelling urinary catheter will be included in the CAUTI surveillance.

EXCLUSION DETAILS

See S. 10

RISK ADJUSTMENT

Stratification by risk category/subgroup

Standardized Infection Ratio (annual and quarter aggregation)

The SIR is constructed by using an indirect standardization method for summarizing HAI experience across any number of stratified groups of data. CAUTI incidence rates stratified by

patient care location type and in some instances, location bed size and type of physician education affiliation which form the basis of the population standardization. Example: predicted numbers of CAUTI (and CAUTI rates) in a medical ICU are not the same as in an NICU.

See also Scientific Validity section for further information on risk adjustment and variables.

Adjusted Ranking Metric (annual aggregation)

The adjusted ranking metric (ARM) combines the method of indirect standardization with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR mentioned above. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator.

URL

STRATIFICATION

CAUTI data is stratified by facility-specific and individual patient location data (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, undergraduate, not affiliated - See definitions S.6. above.

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

Standardized Infection Ratio (annual and quarter aggregation)

The SIR is calculated as follows:

- 1. Identify the number of CAUTI in each location
- 2. Total these numbers for an observed number of CAUTIS
- 3. Obtain the predicted number of CAUTIs in the same locations by multiplying the observed indwelling urinary catheter days by the corresponding CAUTI rates in specific location types from a standard population (i.e., see most recent NHSN Report at Available at:http://www.sciencedirect.com/science/article/pii/S019665531301153X This report included device-associated infection data for 4444 facilities, for the year of 2012.
- 4. Sum the number of predicted CAUTIs from all locations in the annual period.
- 5. Divide the total number of observed CAUTI events ("2" above) by the "predicted" number of CAUTIS ("4" above).
- 6. Result = SIR

(The NHSN analysis tool will perform the calculations once the patient infection data and denominator information are entered into the system.)

Adjusted ranking metric annual aggregation)

The ARM is calculated as follows:

- 1. Identify the number of CAUTI in each location
- 2. Obtain the adjusted number of observed CAUTIs by using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
- 3. Total these numbers for an observed number of CAUTIS

- 4. Obtain the predicted number of CAUTIs in the same locations by multiplying the observed indwelling urinary catheter days according to the factors significantly associated with predicting CAUTI incidence as identified through a Log-linear Negative Binomial Regression Model.
- 6. Divide the total number of adjusted CAUTI events ("3" above) by the predicted number of CAUTIS ("4" above).
- 7. Result = ARM.

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact:
- 5b.1 If competing, why superior or rationale for additive value:

0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

STATUS

Submitted

STEWARD

Centers for Disease Control and Prevention

DESCRIPTION

Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in bedded inpatient care locations.

This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavioral health hospitals.

TYPE

Outcome

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical

Data: Laboratory, Other, Paper Medical Records NHSN Primary BSI collection form

NHSN Denominator for ICU form

NHSN Denominator for NICU form

NHSN Denominator for Specialty Care Area/Oncology Form

Available at measure-specific web page URL identified in S.1 Attachment

NHSN_Data_Dictionary_7.2.xlsx

LEVEL

Facility, Population: National, Population: Regional, Population: State

SETTING

Hospice, Hospital/Acute Care Facility, Behavioral Health/Psychiatric: Inpatient, Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Other Oncology Hospital

TIME WINDOW

Cases are included if they are healthcare-associated and their infection dates are during a month in which a patient care area (location) was selected for surveillance. With low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs, thus the time window may be a period greater than monthly.

NUMERATOR STATEMENT

Total number of observed healthcare-associated CLABSI among patients in bedded inpatient care locations.

NUMERATOR DETAILS

Numbers of CLABSIs attributed to each location are counted for each month utilizing the definitions below. CLABSIs attributed to neonatal ICUs are stratified by birthweight category. CLABSIs attributed to Special Care Areas (inpatient dialysis locations) or Oncology Locations are stratified by association with temporary vs. permanent central line.

- 1. Definition of infection that is Present on Admission (POA): An infection where all of the elements of an infection definition are present during the two calendar days before the day of admission, the first day of admission (day 1) and/or the day after admission (day 2) and are documented in the medical chart. Infections that are POA should not be reported as healthcare-associated infections (HAI) and are not reported as CLABSI. Acceptable documentation does not include self-reported symptoms by the patient (e.g., patient reporting having a fever prior to arrival to the hospital). Instead, symptoms must be documented in the chart by a healthcare professional during the POA time frame (e.g., nursing home documents fever prior to arrival to the hospital). Physician diagnosis alone, cannot be accepted as evidence of a laboratory confirmed bloodstream infection. NOTE: For POA, the temperature value does not need to be known to establish the presence of a fever.
- 2. Definition of Healthcare-associated Infection (HAI): Any infection reported to NHSN must meet the definition of an NHSN HAI, that is, a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that was not present on admission to the acute care facility. An infection is considered an HAI if all elements of a CDC/NHSN site-specific infection criterion were not present during the POA time period but were all present on or after the 3rd calendar day of admission to the facility (the day of hospital admission is calendar day 1). All elements used to meet the CDC/NHSN site-specific infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between any two adjacent elements. The definition of a gap day is a calendar day during which no infection criterion elements are present. Adjacent elements are elements that occur next to each other chronologically over the course of an infection. If all elements of a CDC/NHSN site-specific infection criterion are present on the day of transfer or the next day from one inpatient location to another in the same facility or a new facility, the infection is attributed to the transferring location or facility. Likewise, if all elements of a CDC/NHSN site-specific infection criterion are present on the day of discharge or the next day, the infection is attributed to the

discharging location. Clinical evidence may be derived from direct observation of the infection site or review of information in the patient chart or other clinical records.

- 3. Definition of CLABSI: A laboratory-confirmed bloodstream infection (LCBI) where central line (CL) or umbilical catheter (UC) was in place for >2 calendar days on the date of event, with day of device placement being Day 1, and a CL or UC was in place on the date of event or the day before. If a CL or UC was in place for >2 calendar days and then removed, the LCBI criteria must be fully met on the day of discontinuation or the next day. If the patient is admitted or transferred into a facility with a central line in place (e.g., tunneled or implanted central line), and that is the patient's only central line, day of first access as an inpatient is considered Day1. "Access" is defined as line placement, infusion or withdrawal through the line.
- 4. Definition of Central line: An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central-line BSI and counting central-line days in the NHSN system: Aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common femoral veins, and in neonates, the umbilical artery/vein. NOTE: Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. Pacemaker wires and other non-lumened devices inserted into great vessels or the heart, peripheral intravenous lines, extracorporeal membrane oxygenation (ECMO), intraaortic balloon pump (IABP) devices, and hemodialysis reliable outflow (HeRO) catheters are among those excluded as central lines.
- 5. Definition of Infusion: The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes or IV antimicrobial administration, or blood, in the case of transfusion or hemodialysis.
- 6. Definition of Umbilical Catheter: A central vascular device inserted through the umbilical artery or umbilical vein in a neonate.
- 7. Definition of Temporary Central Line: A non-tunneled, non-implanted catheter.
- 8. Definition of Permanent Central Line: Tunneled catheters, (including certain dialysis catheters) and implanted catheters (including ports)
- 9. Definition of Laboratory Confirmed Bloodstream Infection (LCBI): LCBI must meet one of the following criteria:
- LCBI Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures and organism cultured from blood is not related to an infection at another site (See Appendix 1 Secondary BSI Guide available at http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf)
- LCBI Criterion 2: Patient has at least one of the following signs or symptoms: fever (>38 degrees C), chills, or hypotension and positive laboratory results are not related to an infection at another site (See Appendix 1 Secondary BSI Guide) and the same common commensal (i.e., diphtheroids [Corynebacterium spp. not C. diphtheriae], Bacillus spp. [not B. anthracis], Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., and Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions. Criterion elements must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements. (NOTE: The matching common commensals represent a single element; therefore, the collection date of the first common commensal is the date of the element used to determine the Date of Event).

- LCBI Criterion 3: Patient 1 year of age or less has at least one of the following signs or symptoms: fever (>38 degrees C core), hypothermia (<36 degrees C core), apnea, or bradycardia and positive laboratory results are not related to an infection at another site (See Appendix 1 Secondary BSI Guide) and the same common commensal (i.e., diphtheroids [Corynebacterium spp. not C. diphtheriae], Bacillus spp. [not B. anthracis], Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on the same or consecutive days and separate occasions. Criterion elements must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements. (NOTE: The matching common commensals represent a single element; therefore, the collection date of the first common commensal is the date of the element.)
- MBI-LCBI Criterion1: Patient of any age meets criterion 1 for LCBI with at least one blood culture growing any of the following intestinal organisms with no other organisms isolated: Bacteroides spp., Candida spp., Clostridium spp., Enterococcus spp., Fusobacterium spp., Peptostreptococcus spp., Prevotella spp., Veillonella spp., or Enterobacteriaceae* AND patient meets at least one of the following (a or b):
- a)Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood culture:
- i.) Grade III or IV gastrointestinal graft versus host disease [GI GVHD]
- ii.)1 liter or more diarrhea in a 24-hour period (or 20 or more mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the positive blood culture was collected.
- b)Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm3 within a seven-day time period which includes the date the positive blood culture was collected (Day 1), the 3 calendar days before and the 3 calendar days after.
- MBI-LCBI Criterion 2: Patient of any age meets criterion 2 for LCBI when the blood cultures are growing only viridans group streptococci with no other organisms isolated AND patient meets at least one of the following (a or b):
- a)Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood culture:
- i.)Grade III or IV gastrointestinal graft versus host disease [GI GVHD]
- ii.)1 liter or more diarrhea in a 24-hour period (or 20 or more mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the first positive blood culture was collected.
- b)Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm3 within a seven-day time period which includes the date the positive blood culture was collected (Day 1), the 3 calendar days before and the 3 calendar days after.
- MBI-LCBI Criterion 3: Patient 1 year of age or less meets criterion 3 for LCBI when the blood cultures are growing only viridans group streptococci with no other organisms isolated AND patient meets at least one of the following (a or b):
- a)Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood culture:
- i.) Grade III or IV gastrointestinal graft versus host disease [GI GVHD]

ii.)20 mL or more/kg diarrhea in a 24-hour period with onset on or within 7 calendar days before the date the first positive blood culture is collected.

b)Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm3 on or within a seven-day time period which includes the date the positive blood culture was collected (Day 1), the 3 calendar days before and the 3 calendar days after.

- 10. Definition of CDC Location: The patient care area to which a patient is assigned while receiving care in the healthcare facility. NOTE: Only locations where patients are housed overnight (i.e., inpatient locations) and where denominator data are collected can be used for reporting CLABSI data. Operating rooms (including cardiac cath labs, c-section rooms, and interventional radiology) and outpatient locations are not valid locations for this type of surveillance. See attached list of CDC/NHSN Location Types to identify Special Care Areas or Oncology Locations.
- 11. Definition of Adjacent Elements: "Adjacent" elements are elements of an infection criteria that occur in chronological order in the course of an infection.
- 12. Definition of Location of Attribution: The location to which the CLABSI is attributed.
- 13. Definition of Date of event: The date when the last element used to meet the LCBI criterion occurred.
- 14. Definition of birthweight: Birthweight is the weight of the infant at the time of birth and should not be changed as the infant gains weight. The birthweight categories are as follows:
- A = 750 g or less; B = 751-1000 g; C = 1001-1500 g; D = 1501-2500 g; E = >2500 g.
- 15. Definitions for facility physician education status: Teaching statuses: major, graduate, undergraduate Major: Facility has a program for medical students and post-graduate medical training; Graduate: Facility has a program for post-graduate medical training (i.e., residency and/or fellowships); Undergraduate: Facility has a program for medical students only.

DENOMINATOR STATEMENT

Total number of central line days for each location under surveillance for CLABSI during the data period.

DENOMINATOR DETAILS

Methodologies for counting central line days differ according to the location of the patients being monitored. Numbers of central line days attributed to each location are counted for each data period utilizing the following definitions and guidelines. In locations that are not neonatal ICUs, SCA or oncology locations, all CL days for that location and data period are summed. For neonatal ICU central line days counts are stratified by birthweight category. CL day counts for Special Care Areas or Oncology Locations are stratified by temporary vs. permanent central line type.

1. Definition of central line day: For each patient, a day that at least one central line was present at the time of the CL day count.

EXCLUSIONS

1. Pacemaker wires and other non-lumened devices inserted into central blood vessels or the heart are excluded as CLs.

- 2. Extracoporeal membrane oxygenation lines, femoral arterial catheters, intraaortic balloon pump devices, and hemodialysis reliable outflow catheters (HeRO) are excluded as CLs.
- 3. Peripheral intravenous lines are excluded as CLs.

EXCLUSION DETAILS

See S.10

RISK ADJUSTMENT

Statistical risk model

Standardized Infection Ratio (annual and quarter aggregation)

The SIR is constructed by using an indirect standardization method for summarizing HAI experience across any number of stratified groups of data. CLABSI incidence rates stratified by patient care location type and in some instances, location bed size and type of medical school affiliation which form the basis of the population standardization. Example: predicted numbers of CLABSI (and CLABSI rates) in a medical ICU are not the same as in an NICU.

See also Scientific Validity section for further information on risk adjustment and variables.

Adjusted Ranking Metric (annual aggregation)

The adjusted ranking metric (ARM) combines the method of indirect standardization with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR mentioned above. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator.

URL

STRATIFICATION

- 1. CLABSI data is stratified by facility-specific and individual patient location data (i.e., bedsize of location, affiliation and level of affiliation with physician education program [Teaching statuses: major, graduate, undergraduate, not affiliated See definitions S.6. above
- 2. NICU CLABSI data is stratified by five birthweight categories (see S. 6. above.
- 3. CLABSI data for SCA/Oncology location central lines are stratified by two types, temporary and permanent. See definitions in S.6 above.

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

Standardized Infection Ratio (annual and quarter aggregation)

The SIR is calculated as follows:

- 1. Identify the number of CLABSI in each location
- 2. Total these numbers for an observed number of CLABSIs
- 3. Obtain the predicted number of CLABSIs in the same locations by multiplying the observed central line days by the corresponding CLABSI rates in specific location types from a standard population (i.e., see most recent NHSN Report at

http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF).

4. Sum the number of predicted CLABSIs from all locations in the annual period.

- 5. Divide the total number of observed CLABSI events ("2" above) by the "predicted" number of CLABSIs ("4" above).
- 6. Result = SIR

(The NHSN analysis tool will perform the calculations once the patient infection data and denominator information are entered into the system.)

Adjusted ranking metric annual aggregation)

The ARM is calculated as follows:

- 1. Identify the number of CLABSI in each location
- 2. Obtain the adjusted number of observed CLABSIs by using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
- 3. Total these numbers for an observed number of CLABSIs
- 4. Obtain the predicted number of CLABSIs in the same locations by multiplying the observed central line days according to the factors significantly associated with predicting CLABSI incidence as identified through a Log-linear Negative Binomial Regression Model.
- 6. Divide the total number of adjusted CLABSI events ("3" above) by the predicted number of CLABSIs ("5" above).
- 7. Result = ARM

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact:
- 5b.1 If competing, why superior or rationale for additive value:

0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI) – Central Venous Catheter (CVC)

STATUS

Submitted

STEWARD

American Society of Anesthesiologists

DESCRIPTION

Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed

TYPE

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Registry Data is gathered by the Anesthesia Quality Institute and the National Anesthesia Clinical Outcomes Registry. Data source for reporting also includes the Medicare Limited Data Set.

No data collection instrument provided No data dictionary

LEVEL

Facility, Clinician: Group/Practice, Clinician: Individual, Clinician: Team

SETTING

Hospital/Acute Care Facility

TIME WINDOW

The time period for data includes at least five years (2008-2012) of Medicare Limited Data Set. We have also used three years of data from the National Anesthesia Clinical Outcomes Registry (NACOR; 2010-2012). There is no difference in time periods for the numerator or denominator.

NUMERATOR STATEMENT

Patients for whom CVC was inserted with all elements of maximal sterile barrier technique*, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques** followed

Definitions:

- *Maximal sterile barrier technique includes ALL of the following elements:
- cap
- mask
- sterile gown
- sterile gloves
- sterile full body drape
- ** Sterile ultrasound techniques require sterile gel and sterile probe covers

NOTE: For purposes of this measure, maximal sterile barrier technique during CVC insertion is defined to include use of:

cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis.

NUMERATOR DETAILS

Report the following CPT Category II code:

6030F: All elements of maximal sterile barrier technique including: cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous asepsis (or acceptable alternative antiseptics, per current guideline)

DENOMINATOR STATEMENT

All patients, regardless of age, who undergo CVC insertion

DENOMINATOR DETAILS

CPT® codes for:

Central Venous Access Device Insertion Procedures – 36555, 36556, 36557, 36558, 36560, 36561, 36563, 36565, 36566, 36568, 36569, 36570, 36571

Central Venous Access Device Replacement Procedures – 36578, 36580, 36581, 36582, 36583, 36584, 36585

Cardiac Catheterization Procedure: 93503 (placement of a pulmonary artery catheter)

EXCLUSIONS

Denominator Exceptions: Documentation of medical reason(s) for not following all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques during CVC insertion (including increased risk of harm to patient if adherence to aseptic technique would cause delay in CVC insertion)

EXCLUSION DETAILS

For cases with a documented reason for exception: Append modifier to CPT Category II code: 6030F-1P

RISK ADJUSTMENT

No risk adjustment or risk stratification

This question does not apply to this measure. The measure is not risk adjusted.

STRATIFICATION

This question does not apply to this measure. The measure is not risk adjusted.

TYPE SCORE

Ratio better quality = higher score

ALGORITHM

This question does not apply to this measure. The measure is not risk adjusted. No diagram provided

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5.1 Identified measures:

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: This question does not apply to the measure.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

0510 Exposure time reported for procedures using fluoroscopy

STATUS

Submitted

STEWARD

American College of Radiology

DESCRIPTION

Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time

TYPE

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Paper Medical Records Claims

No data collection instrument provided No data dictionary

LEVEL

Clinician: Group/Practice, Clinician: Individual

SETTING

Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility

TIME WINDOW

NUMERATOR STATEMENT

Final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time

NUMERATOR DETAILS

Radiation exposure or exposure time in final report for procedure using fluoroscopy, documented

CPT Category II code: 6045F

DENOMINATOR STATEMENT

All final reports for procedures using fluoroscopy

DENOMINATOR DETAILS

All final reports for procedures using fluoroscopy (codes where fluoroscopy is not always used are not included)

CPT® Procedure Code OR HCPCS G-Code: 0075T, 0234T, 0235T, 0238T, 25606, 25651, 26608, 26650, 26676, 26706, 26727, 27235, 27244, 27245, 27509, 27756, 27759, 28406, 28436, 28456, 28476, 36147, 36221, 36222, 36223, 36224, 36225, 36226, 36252, 36253, 36254, 36598, 37182, 37183, 37184, 37187, 37188, 37211, 37212, 37213, 37214, 37217, 37220, 37221, 37222, 37223, 37224, 37225, 37226, 37227, 37228, 37229, 37230, 37231, 37232, 37234, 37235, 37236, 37238, 37241, 37242, 37243, 37244, 43260, 43261, 43262, 43263, 43264, 43265, 43275, 43276, 43277, 43278, 43752, 44500, 49440, 49441, 49442, 49446, 49450, 49451, 49452, 49460, 49465, 50382, 50384, 50385, 50386, 50387, 50389, 50590, 61623, 62263, 62264, 62280, 62281, 62282, 63610, 64610, 64620, 70010, 70015, 70170, 70332, 70370, 70371, 70373, 70390, 71023, 71034, 72240,

72255, 72265, 72270, 72275, 72285, 72291, 72295, 73040, 73085, 73115, 73525, 73580, 73615, 74190, 74210, 74220, 74230, 74235, 74240, 74241, 74245, 74246, 74247, 74249, 74250, 74251, 74260, 74270, 74280, 74283, 74290, 74291, 74300, 74305, 74320, 74327, 74328, 74329, 74330, 74340, 74355, 74360, 74363, 74425, 74430, 74440, 74445, 74450, 74455, 74470, 74475, 74480, 74485, 74740, 74742, 75600, 75605, 75625, 75630, 75658, 75705, 75710, 75716, 75726, 75731, 75733, 75736, 75741, 75743, 75746, 75756, 75791, 75801, 75803, 75805, 75807, 75809, 75810, 75825, 75827, 75831, 75833, 75840, 75842, 75860, 75870, 75872, 75880, 75885, 75887, 75889, 75891, 75893, 75894, 75896, 75898, 75901, 75902, 75952, 75953, 75954, 75956, 75957, 75958,75959, 75962, 75966, 75970, 75978, 75980, 75982, 75984, 76000, 76001, 76080, 76120, 76496, 77001, 77002, 77003, 92611, 93565, 93566, 93567, 93568, G0106, G0120, G0278

EXCLUSIONS

No exclusions

EXCLUSION DETAILS

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

The measure is not stratified.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Calculation for Performance

For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator,

Denominator.

Numerator (A) Includes:

Number of patients/reports meeting numerator criteria

Performance Denominator (PD) Includes:

Number of reports meeting criteria for denominator inclusion

To calculate performance rates:

- 1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).
- 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.
- 3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4) If the measure does not have exceptions, STOP. If the measure does have exceptions, proceed with the following steps. From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception, when exceptions have been specified. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. Available at measure-specific web page URL identified in S.1

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5.1 Identified measures: 0739: Radiation Dose of Computed Tomography (CT)

0740: Participation in a Systematic National Dose Index Registry

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact: These measures are similar in that the focus is collection and tracking of dose information, however the imaging modality is limited to computed tomography (CT).

5b.1 If competing, why superior or rationale for additive value:

0531 Patient Safety for Selected Indicators (PSI 90)

STATUS

Submitted/Composite Measure

STEWARD

Agency for Healthcare Research and Quality

DESCRIPTION

Patient Safety for Selected Indicators (PSI 90) is a weighted average of the observed-to-expected ratios for the following component indicators: PSI 03 Pressure Ulcer Rate, PSI 06 latrogenic Pneumothorax Rate, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, PSI 08 Postoperative Hip Fracture Rate, PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate, PSI 13 Postoperative Sepsis Rate, PSI 14 Postoperative Wound Dehiscence Rate, and PSI 15 Accidental Puncture or Laceration Rate.

The weights include component weights and shrinkage weights. The component weights are numerator weights, defined as the relative frequency of the numerators for the component indicators in the reference population. The shrinkage weights are the signal-to-noise ratio, where the signal variance is estimated from the reference population, and the noise variance is estimated from the user's data and is unique to each provider in the user's data.

For more information, see Quality Indicator Empirical Methods, PSI Composite Measure Workgroup Final Report, and AHRQ QI User Guide: PSI Composite available online at www.qualityindicators.ahrq.gov

TYPE

Composite

DATA SOURCE

Administrative claims All analyses were completed using data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID), 2007-2011.HCUP is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP databases bring together the data collection efforts of State data organizations, hospital associations, private data organizations, and the Federal government to create a national information resource of encounter-level health care data. The HCUP SID contain the universe of the inpatient discharge abstracts in participating States, translated into a uniform format to facilitate multi-State comparisons and analyses. Together, the SID encompass about 97 percent of all U.S. community hospital discharges (in 2011, 46 states participated for a total of more than 38.5 million hospital discharges). As defined by the American Hospital Association, community hospitals are all non-Federal, short-term, general or other specialty hospitals, excluding hospital units of institutions. Veterans hospitals and other Federal facilities are excluded. Taken from the Uniform Bill-04 (UB-04), the SID data elements include ICD-9-CM coded principal and secondary diagnoses and procedures, additional detailed clinical and service information based on revenue codes, admission and discharge status, patient demographics, expected payment source (Medicare, Medicaid, private insurance as well as the uninsured), total charges and length of stay (www.hcup-us.ahrq.gov).

Available at measure-specific web page URL identified in S.1 Attachment Patient_Safety_for_Selected_Indicators___PSI_90.xlsx

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

TIME WINDOW

The time window can be determined by user, but is generally a calendar year.

NUMERATOR STATEMENT

Not applicable for the composite. The numerator for component indicators is the number of potentially preventable adverse events (i.e., pressure ulcer rate, iatrogenic pneumothorax rate, central venous catheter-related blood stream infection rate, postoperative hip fracture rate, perioperative pulmonary embolism or deep vein thrombosis rate, postoperative sepsis rate, postoperative wound dehiscence rate, and accidental puncture or laceration rate).

NUMERATOR DETAILS

See Patient Safety Indicators: Technical Specifications for additional details (available at http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx) and in the supporting information.

DENOMINATOR STATEMENT

Not applicable for the composite. The denominator for component indicators is the number of eligible discharges (all indicators limited to the adult population)

DENOMINATOR DETAILS

See Patient Safety Indicators: Technical Specifications for additional details (available at http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx) and in the supporting information.

EXCLUSIONS

Not applicable for the composite. The denominator for specific component indicators has exclusion criteria as shown in the technical specifications.

EXCLUSION DETAILS

See Patient Safety Indicators: Technical Specifications for additional details (available at http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx) and in the supporting information.

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not applicable for the composite. Component measures are risk adjusted.

For more information on risk adjustment models for the component measures, see supporting materials including the Quality Indicator Empirical Methods and Patient Safety Indicators Parameter Estimates, Version 4.5 (with corrected PSI #90). The information is also available on the AHRQ Quality Indicator website at www.qualityindicators.ahrq.gov.

Available in attached Excel or csv file at S.2b

STRATIFICATION

Not applicable.

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

The composite performance score is a weighted average of reliability-adjusted observed to expected ratios. No diagram provided

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact: Not applicable.
- 5b.1 If competing, why superior or rationale for additive value: Not applicable

0532 Pediatric Patient Safety for Selected Indicators (PDI 19)

STATUS

Submitted/Composite Measure

STEWARD

Agency for Healthcare Research and Quality

DESCRIPTION

Pediatric Patient Safety for Selected Indicators (PDI 19) is a weighted average of the observed-to-expected ratios for the following component indicators: PDI 01 Accidental Puncture or Laceration Rate, PDI 02 Pressure Ulcer Rate, PDI 05 Iatrogenic Pneumothorax Rate, PDI 10 Postoperative Sepsis Rate, PDI 11 Postoperative Wound Dehiscence Rate, and PDI 12 Central Venous Catheter-Related Blood Stream Infection Rate.

The weights include component weights and shrinkage weights. The component weights are numerator weights, defined as the relative frequency of the numerators for the component indicators in the reference population. The shrinkage weights are the signal-to-noise ratio, where the signal variance is estimated from the reference population, and the noise variance is estimated from the user's data and is unique to each provider in the user's data.

For more information, see Quality Indicator Empirical Methods, PDI Composite Measure Workgroup Final Report, and AHRQ QI User Guide: PDI Composite available online at www.qualityindicators.ahrq.gov

TYPE

Composite

DATA SOURCE

Administrative claims All analyses were completed using data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID), 2007-2011.HCUP is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP databases bring together the data collection efforts of State data organizations, hospital associations, private data organizations, and the Federal government to create a national information resource of encounter-level health care data. The HCUP SID contain the universe of the inpatient discharge abstracts in participating States, translated into a uniform format to facilitate multi-State comparisons and analyses. Together, the SID encompass about 97 percent of all U.S. community hospital discharges (in 2011, 46 states participated for a total of more than 38.5 million hospital discharges with approximately 5 million pediatric (including births) hospital discharges). As defined by the American Hospital Association, community hospitals are all non-Federal, short-term, general or other specialty hospitals, excluding hospital units of institutions. Veterans hospitals and other Federal facilities are excluded. General and speciality children's hospitals are included in the hospital universe. Taken from the Uniform Bill-04 (UB-04), the SID data elements include ICD-9-CM coded principal and secondary diagnoses and procedures, additional detailed clinical and service information based on revenue codes, admission and discharge status, patient demographics, expected payment source (Medicare, Medicaid, private insurance as well as the uninsured), total charges and length of stay (www.hcup-us.ahrq.gov)

HCUP State Inpatient Databases (SID). Healthcare Cost and Utilization Project (HCUP). 2007-2011. Agency for Healthcare Research and Quality, Rockville, MD. www.ahrq.gov/sidoverview.jsp (AHRQ QI Software Version 4.5, www.qualityindicators.ahrq.gov) Available at measure-specific web page URL identified in S.1 Attachment Pediatric_Safety_for_Selected_Indicators___PDI_19.xlsx

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

TIME WINDOW

The time window can be determined by user, but is generally a calendar year.

NUMERATOR STATEMENT

Not applicable for the composite. The numerator for component indicators is the number of potentially preventable adverse events (i.e., PDI 01 Accidental Puncture or Laceration Rate, PDI 02 Pressure Ulcer Rate, PDI 05 latrogenic Pneumothorax Rate, PDI 10 Postoperative Sepsis Rate, PDI 11 Postoperative Wound Dehiscence Rate, and PDI 12 Central Venous Catheter-Related Blood Stream Infection Rate).

NUMERATOR DETAILS

See Pediatric Quality Indicators: Technical Specifications for additional details (available at: http://www.qualityindicators.ahrq.gov/Modules/PDI_TechSpec.aspx and in supporting documentation

DENOMINATOR STATEMENT

Not applicable for the composite. The denominator for component indicators is the number of eligible discharges (all indicators limited to the pediatric population)

DENOMINATOR DETAILS

See Pediatric Quality Indicators: Technical Specifications for additional details (available at: http://www.qualityindicators.ahrq.gov/Modules/PDI_TechSpec.aspx and in supporting documentation

EXCLUSIONS

Not applicable for the composite. The denominator for component indicators has exclusion criteria as shown in the technical specifications.

EXCLUSION DETAILS

See Pediatric Quality Indicators: Technical Specifications for additioinal details (available at http://www.qualityindicators.ahrq.gov/downloads/pdi/pdi_technical_specs_v32.pdf)

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not applicable for the composite. Component measures are risk adjusted.

For more information on risk adjustment models for the component measures, see supporting materials including the Quality Indicator Empirical Methods and Pediatric Quality Indicators Parameter Estimates, Version 4.5. The information is also available on the AHRQ Quality Indicator website at www.qualityindicators.ahrq.gov

Available in attached Excel or csv file at S.2b

STRATIFICATION

Not applicable

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

The composite performance score is a weighted average of reliability-adjusted observed to expected ratios No diagram provided

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact: Not applicable.
- 5b.1 If competing, why superior or rationale for additive value: Not applicable.

0541 Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category

STATUS

Submitted

STEWARD

Pharmacy Quality Alliance (PQA, Inc.)

DESCRIPTION

The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year. A performance rate is calculated seperately for the following medication categories: Renin Angiotensin System (RAS) Antagonists, Diabetes Medications, Statins.

A higher score indicates better quality.

TYPE

Process

DATA SOURCE

Administrative claims Health plan prescription claims data and enrollment data (e.g. Medicare Part D)

No data collection instrument provided No data dictionary

LEVEL

Clinician: Group/Practice, Health Plan

SETTING

Ambulatory Care: Clinician Office/Clinic, Pharmacy

TIME WINDOW

The numerator time window should match the denominator window (see denominator window description).

NUMERATOR STATEMENT

The number of patients who met the PDC threshold during the measurement year for each therapeutic category separately. Follow the steps below for each patient to determine whether the patient meets the PDC threshold.

Step 1: Determine the patient's measurement period, defined as the index prescription date (date of the first fill of the target medication) to the end of the calendar year, disenrollment, or death.

Step 2: Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3: Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4: Count the number of patients who had a PDC 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of combination product to another combination product where a least one of the drugs from the target therapeutic class is common.

NUMERATOR DETAILS

The number of patients who met the PDC threshold during the measurement year for each therapeutic category separately. Follow the steps below for each patient to determine whether the patient meets the PDC threshold.

Step 1: Determine the patient's measurement period, defined as the index prescription date (date of the first fill of the target medication) to the end of the calendar year, disenrollment, or death.

Step 2: Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3: Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4: Count the number of patients who had a PDC 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of combination product to another combination product where a least one of the drugs from the target therapeutic class is common.

RENIN ANGIOTENSIN SYSTEM (RAS) ANTAGONISTS: aliskiren, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan, azilsartan, benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, trandolopril, amlodipine & benazepril, benazepril & HCTZ, captopril & HCTZ, enalapril & HCTZ, fosinopril & HCTZ, lisinopril & HCTZ, moexipril & HCTZ, quinapril & HCTZ, trandolopril & verapamil HCL, candesartan & HCTZ, eprosartan & HCTZ, telmisartan & amilodipine, irbesartan & HCTZ, losartan & HCTZ, amlodipine & olmesartan, azlisartan & chlorthalidone, olmesartan & HCTZ, telmisartan & HCTZ, aliskiren & valsartan, olmesartan & amlodipine & HCTZ, valsartan & HCTZ, amlodipine & valsartan, amlodipine & valsartan & HCTZ, aliskiren & amlodipine & molodipine & HCTZ, aliskiren & HCTZ, aliskiren & HCTZ, aliskiren & WCTZ, aliskiren & WCTZ, aliskiren & Valsartan

DIABETES MEDICATIONS: (Biguanides, Sulfonylureas, Thiazolidinediones, DPP-IV Inhibitors, Incretin Mimetic Agents, Meglitinides, Sodium glucose co-transporter2 (SGLT2) inhibitors and combination products that include these medications)

metformin, glipizide & metformin, glyburide & metformin, chlorpropamide, glimepiride, glipizide, glyburide, tolazamide, tolbutamide, pioglitazone, rosiglitazone, rosiglitazone & metformin, rosiglitazone & glimepiride, pioglitazone & metformin, pioglitazone & glimepiride, alogliptin & pioglitazone, sitagliptin, linagliptin, saxagliptin, alogliptin, sitagliptin & metformin, saxagliptin & metformin SR, sitagliptin & simvastatin, linagliptin & metformin, alogliptin & metformin, exenatide, liraglutide, nateglinide, repaglinide, repaglinide & metformin, canagliflozin

STATINS: lovastatin, rosuvastatin, fluvastatin, atorvastatin, pravastatin, pitavastatin, simvastatin, niacin & lovastatin, atorvastatin & amlodipine, niacin & simvastatin, sitagliptin & simvastatin, ezetimibe & simvastatin, ezetimibe & atorvastatin

DENOMINATOR STATEMENT

Patients age 18 years and older who were dispensed at least two prescriptions in a specific therapeutic category on two unique dates of service during the measurement year.

For the Diabetes rate only: Exclude any patient with one or more prescriptions fo

DENOMINATOR DETAILS

Patients age 18 years and older who were dispensed at least two prescriptions in a specific therapeutic category on two unique dates of service during the measurement year.

(For the Diabetes rate only: Exclude any patient with one or more prescriptions for insulin in the measurement period - See S.10)

RENIN ANGIOTENSIN SYSTEM (RAS) ANTAGONISTS: aliskiren, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan, azilsartan, benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, trandolopril, amlodipine & benazepril, benazepril & HCTZ, captopril & HCTZ, enalapril & HCTZ, fosinopril & HCTZ, lisinopril & HCTZ, moexipril & HCTZ, quinapril & HCTZ, trandolopril & verapamil HCL, candesartan & HCTZ, eprosartan & HCTZ, telmisartan & amilodipine, irbesartan & HCTZ, losartan & HCTZ, amlodipine & olmesartan, azlisartan & chlorthalidone, olmesartan & HCTZ, telmisartan & HCTZ, aliskiren & valsartan, olmesartan & amlodipine & HCTZ, valsartan & HCTZ, amlodipine & valsartan,

amlodipine & valsartan & HCTZ, aliskiren & amlodipine, aliskiren & amlodipine & HCTZ, aliskiren & HCTZ, aliskaren & valsartan

DIABETES MEDICATIONS: (Biguanides, Sulfonylureas, Thiazolidinediones, DPP-IV Inhibitors, Incretin Mimetic Agents, Meglitinides, Sodium glucose co-transporter2 (SGLT2) inhibitors and combination products that include these medications)

metformin, glipizide & metformin, glyburide & metformin, chlorpropamide, glimepiride, glipizide, glyburide, tolazamide, tolbutamide, pioglitazone, rosiglitazone, rosiglitazone & metformin, rosiglitazone & glimepiride, pioglitazone & metformin, pioglitazone & glimepiride, alogliptin & pioglitazone, sitagliptin, linagliptin, saxagliptin, alogliptin, sitagliptin & metformin, saxagliptin & metformin SR, sitagliptin & simvastatin, linagliptin & metformin, alogliptin & metformin, exenatide, liraglutide, nateglinide, repaglinide, repaglinide & metformin, canagliflozin

STATINS: lovastatin, rosuvastatin, fluvastatin, atorvastatin, pravastatin, pitavastatin, simvastatin, niacin & lovastatin, atorvastatin & amlodipine, niacin & simvastatin, sitagliptin & simvastatin, ezetimibe & simvastatin, ezetimibe & atorvastatin

EXCLUSIONS

Exclusion criteria for the PDC category of Diabetes medications:

Patients who have one or more prescriptions for insulin in the measurement period.

EXCLUSION DETAILS

Exclusion details for PDC category of Diabetes medications (one or more prescriptions for insulin):

INSULINS: insulin aspart, insulin aspart Protamine & Aspart, insulin detemir, insulin glargine, insulin glulisine, insulin isophane & regular human insulin, insulin isophane (human N), insulin lispro, insulin lispro Protamine & Insulin lispro, insulin regular (human R)

RISK ADJUSTMENT

No risk adjustment or risk stratification

N/A

STRATIFICATION

None

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

For EACH PDC rate identify the Denominator:

Step 1: Identify the eligible population that is 18 years and older as of the last day of the measurement year and that are continuously enrolled in the drug plan.

Step 2: Identify those patients in Step 1 that have filled at least two prescriptions for the target class of medication (either RAS Antagonist, Diabetes medication or Statin)

For the Diabetes rate only:Step 3: Exclude any patient with one or more prescriptions for insulin in the measurement period

For EACH PDC rate calculate the Numerator:

Step 1: Determine the patient's measurement period, defined as the index prescription date (first fill of the target medication) to the end of the calendar year, disenrollment, or death.

Step 2: Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days supply. If prescriptions for the same drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3: Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4: Count the number of patients who had a PDC greater than 80% and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the drugs is common. No diagram provided

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact:
- 5b.1 If competing, why superior or rationale for additive value:

0555 INR Monitoring for Individuals on Warfarin

STATUS

Submitted

STEWARD

Centers for Medicare & Medicaid

DESCRIPTION

Percentage of individuals 18 years of age and older with at least 56 days of warfarin therapy who receive an International Normalized Ratio (INR) test during each 56-day interval with warfarin

TYPF

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data: Pharmacy For measure calculation, the following Medicare files were required:

- Denominator tables
- Prescription drug benefit (Part D) coverage tables
- Beneficiary file

- Institutional claims (Part A)
- Non-institutional claims (Part B)—physician carrier/non-DME
- Prescription drug benefit (Part D) claims
- Minimum Dataset (MDS)

For ACO attribution, the following were required:

- Denominator tables for Parts A and B enrollment
- Prescription drug benefit (Part D) coverage tables
- Beneficiary file
- Institutional claims (Part A)
- Non-institutional claims (Part B)—physician carrier/non-DME
- Prescription drug benefit (Part D) claims

For physician group attribution, the following were required:

- Non-institutional claims (Part B)—physician carrier/non-DME
- Denominator tables to determine individual enrollment
- Beneficiary file or coverage table to determine hospice benefit and Medicare as secondary payer status
- CMS physician and physician specialty tables
- National Plan & Provider Enumeration System (NPPES) database

No data collection instrument provided Attachment NQF0555_-_Codes_Table-635252999765982739.xls

LFVFL

Clinician: Group/Practice, Health Plan, Integrated Delivery System, Population: State

SETTING

Ambulatory Care: Clinician Office/Clinic

TIME WINDOW

The time period of the data is defined as any time during the measurement period (12 consecutive months).

NUMERATOR STATEMENT

The number of individuals in the denominator who have at least one INR monitoring test during each 56-day interval with active warfarin therapy.

NUMERATOR DETAILS

Individuals in the denominator who have at least one INR test performed during each 56-day interval with warfarin therapy, or 100% INR monitoring compliance, will be counted in the numerator. Each 56-day interval with an INR test is used to calculate the INR compliance rate for the individual. An interval with a hospitalization of more than 48 hours is considered an interval with an INR test.

INR Test: Prothrombin time, CPT 85610

"Warfarin usage" or "warfarin therapy" is determined by the start date of the first prescription for warfarin up through the start date of the last prescription for warfarin plus the days' supply from the last claim.

Interval: 56 days

The first day of the first 56-day interval is the start date of the first warfarin prescription, and the last day of the first 56-day interval is the start date of the first warfarin prescription + 55. The subsequent 56-day interval starts on the day after the first 56-day interval and ends 56 days following the first 56-day interval, as long as this end date occurs within the warfarin therapy time frame. This process continues until a calculated 56-day interval end date does not occur within the warfarin therapy time frame. If there are fewer than 56 days of warfarin therapy remaining, those remaining days are not counted in any interval in determining the numerator. Only full 56-day intervals are used for calculating the numerator.

DENOMINATOR STATEMENT

Individuals at least 18 years of age as of the beginning of the measurement period with warfarin therapy for at least 56 days during the measurement period.

DENOMINATOR DETAILS

Target population meets the following conditions:

- 1. Continuously enrolled in Part D with no more than a one-month gap in enrollment during the measurement year;
- 2. Continuously enrolled in Part A and Part B with no more than a one-month gap in Part A enrollment and no more than a one-month gap in Part B enrollment during the measurement year; and,
- 3. No more than one month of HMO (Health Maintenance Organization) enrollment during the measurement year.

Active Ingredients by Class

Anticoagulants: warfarin

Note: The active ingredient is limited to oral formulations only.

EXCLUSIONS

Individuals who are monitoring INR at home.

Optional Exclusion Criteria

Individuals who are in long-term care (LTC) during the measurement period.

EXCLUSION DETAILS

INR Monitoring at Home: HCPCS Codes

G0248 - DEMONSTRATE USE HOME INR MON

G0249 - PROVIDE TEST MATS & EQUIP HOME INR

G0250 - MD INR TEST REVIEW INTER MGMT

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not applicable

STRATIFICATION

Depending on the operational use of the measure, measure results may be stratified by:

- State
- Plan
- Accountable Care Organizations (ACOs)
- Physician Group
- Age- Divided into 6 categories: 18-24, 25-44, 45-64, 65-74, 75-84, and 85+ years
- Race/Ethnicity
- Dual Eligibility Status
- New Warfarin User vs. Continuous Warfarin User: "New" users are defined as those individuals with no warfarin prescriptions during the 180 days prior to the first warfarin prescription in the current measurement period.
- Diagnosis Indications for Warfarin: Atrial Fibrillation, Acute Myocardial Infarction, Venous Thromboembolism, Stroke, Mechanical Heart Valve

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Denominator: Individuals at least 18 years of age as of the beginning of the measurement period with warfarin therapy for at least 56 days during the measurement period.

Create Denominator

- 1. Pull individuals who are 18 years of age or older as of January 1st of the measurement period.
- 2. Include individuals who were continuously enrolled in Part D coverage during the measurement year, with no more than a one-month gap in enrollment during the measurement year.
- 3. Include individuals who had no more than a one-month gap in Part A enrollment, no more than a one-month gap in Part B enrollment, and no more than one month of HMO (Health Maintenance Organization) enrollment during the current measurement year (fee-for-service [FFS] individuals only).
- 4. Of the individuals identified in Step 3, include those who had warfarin claims during the measurement period.
- 5. Of the individuals identified in Step 4, calculate the start date and end date of warfarin therapy for each individual and count the days between the start date and the end date inclusive. For individuals who die during the measurement period and prior to the calculated end date of warfarin therapy, reset the end date of warfarin therapy to be the death date.
- 6. Keep individuals who have at least 56 days of warfarin therapy during the measurement period and calculate the number of 56-day intervals for each individual.
- 7. Exclude individuals who are monitoring their INR at home during the current measurement period.
- 8. Calculate using optional denominator exclusion: Identify and delete individuals who were in long-term care during the measurement period.

Long-Term Care

The proportion of beneficiaries in the measure denominator with a target Omnibus Budget Reconciliation Act (OBRA) assessment in 2008 and an assessment 45-165 days prior to the target assessment (i.e., the latest MDS assessment with qualifying reasons for assessment), were identified. This method of identifying patients in LTC was adapted from the selection criteria for the national nursing home quality measures, which are endorsed by NQF. [1]

[1]. ABT Associates. National Nursing Home Quality Measures User's Manual. Cambridge, MA: Centers for Medicare & Medicaid Services; 2004.

Numerator: The number of individuals in the denominator who have at least one INR monitoring test during each 56-day interval with warfarin.

Create Numerator

- 1. Pull all INR test claims from Part A and Part B claims data for the current measurement period.
- 2. From the claims identified in Step 1, keep only those INR test claims for the individuals who are included in the denominator.
- 3. From Part A claims data, identify and pull all inpatient stays of more than 48 hours during the measurement period (calculate and keep stays of at least three days). Note: To identify inpatient stays in the Part A claims data, confirm the third character in the hsp_id field is a "0" and the nch_clm_type_cd field is either "60" or "61."
- 4. From the claims identified in Step 3, keep those that are also included in the denominator.
- 5. Combine the INR test claims dataset from Step 2 and the hospitalizations of more than 48 hours dataset from Step 4.
- 6. Using the start date of warfarin therapy identified in the denominator, determine the subsequent start dates for each of the calculated 56-day interval(s) of warfarin therapy and determine the number of the 56-day intervals designated in the denominator for each individual.
- 7. From the dataset created in Step 5, create a dataset containing INR test performed/48-hour hospitalizations by unique individual and date of service (hse_clm_from_dt in the Part A claims hospitalizations).
- 8. Determine which 56-day intervals have an INR test completed or have a 48-hour inpatient stay by comparing each date of service from Step 7 to each 56-day interval for each individual designated in Step 6.
- 9. From the dataset created in Step 8, calculate the individual's INR monitoring compliance rate as the sum of 56-day intervals with an INR test divided by the total number of 56-day intervals.
- 10. From the dataset created in Step 9, calculate the measure numerator by counting the number of individuals with a 100% INR monitoring rate.

A measure logic diagram is provided in the Appendix section of the NQF Submission Form. Available in attached appendix at A.1

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5.1 Identified measures: 0556: INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The measure under review (NQF 0555) is related to NQF 0556 (INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications). They both have the same measure focus, which is INR testing, and their specifications for INR testing are harmonized. However, the two measures have different target populations.

5b.1 If competing, why superior or rationale for additive value: The measure under review (i.e., NQF 0555 INR Monitoring for Individuals on Warfarin) addresses the same measure focus (i.e., INR monitoring) and the same target population (i.e., individuals on warfarin) as one current NQF-endorsed measures listed below:

• NQF 0586: Warfarin PT/ INR Test (Resolution Health, Inc.): This measure identifies the percentage of patients taking warfarin during the measurement year who had at least one PT/INR test within 30 days after the first warfarin prescription in the measurement year.

NQF 0555 vs. NQF 0586

NQF 0555, the measure under review, is superior to NQF 0586 because NQF 0555 offers more comprehensive information about the INR monitoring of the patient during the measurement period (up to 12 months). For the period during which the patient is on warfarin, NQF 0555 reports the percentage patients who have an INR test every 56 days while on warfarin therapy. In contrast, NQF 0586 reports whether the patient had at least one INR test within 30 days following the first prescription of warfarin during the measurement year. NQF 0586 does not report any information about INR monitoring during the rest of the year.

0556 INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications

STATUS

Submitted

STEWARD

Centers for Medicare & Medicaid

DESCRIPTION

Percentage of episodes with an International Normalized Ratio (INR) test performed three to seven days after a newly started interacting anti-infective medication for individuals receiving warfarin

TYPE

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data: Pharmacy For measure calculation, the following Medicare files were required:

- Denominator tables
- Prescription drug benefit (Part D) coverage tables
- Beneficiary file
- Institutional claims (Part A)

- Non-institutional claims (Part B) —physician carrier/non-DME
- Prescription drug benefit (Part D) claims

For ACO attribution, the following were required:

- Denominator tables for Parts A and B enrollment
- Prescription drug benefit (Part D) coverage tables
- Beneficiary file
- Institutional claims (Part A)
- Non-institutional claims (Part B)—physician carrier/non-DME
- Prescription drug benefit (Part D) claims

No data collection instrument provided Attachment NQF0556_-_Codes_Table-635254586561790739.xls

LEVEL

Health Plan, Integrated Delivery System, Population: State

SETTING

Ambulatory Care: Clinician Office/Clinic

TIME WINDOW

Numerator Time Window: Three to seven days after the start of an anti-infective medication Denominator Time Window: The first 358 days of the measurement period

NUMERATOR STATEMENT

Number of episodes in the denominator with an INR test performed three to seven days after the start date of an anti-infective medication

NUMERATOR DETAILS

Hospitalizations of more than 48 hours are counted as an INR test.

Table 1. Codes Used to Identify INR Monitoring

Prothrombin Time CPT: 85610

Source: American Medical Association (AMA) (2006). Updated: AMA (2009).

DENOMINATOR STATEMENT

Number of episodes with a newly started interacting anti-infective medication with an overlapping days' supply of warfarin.

DENOMINATOR DETAILS

Target population meets the following conditions:

- 1. Continuously enrolled in Part D with no more than a one-month gap in enrollment during the measurement year;
- 2. Continuously enrolled in Part A and Part B with no more than a one-month gap in Part A enrollment and no more than a one-month gap in Part B enrollment during the measurement year;

- 3. No more than one month of HMO (Health Maintenance Organization) enrollment during the measurement year; and,
- Individuals must have at least two claims for warfarin on different dates of service.
- a. If more than one prescription for warfarin with the same date of service overlaps an interacting anti-infective medication, then keep the prescription with the greatest days' supply.
- b. If more than one prescription for warfarin with different dates of service overlaps an interacting anti-infective medication, then keep the episode with the greatest number of overlapping days.

Table 2. Anti-Infective Medications

Aminoglycosides

Active ingredients: neomycin, paromomycin

Anticoagulant effect: Increased

Antifungal Agents

Active ingredients: fluconazole, voriconazole, miconazole

Anticoagulant effect: Increased Active ingredients: griseofulvin Anticoagulant effect: Decreased

Active ingredients: itraconazole, ketoconazole

Anticoagulant effect: Increased Active ingredients: terbinafine

Anticoagulant effect: Increased/decreased

Antiviral

Active ingredients: interferon-alfa, interferon-beta

Anticoagulant effect: Increased
Active ingredients: ribavirin
Anticoagulant effect: Decreased
Active ingredients: oseltamivir
Anticoagulant effect: Increased

Active ingredients: atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir,

saquinavir, tipranavir

Anticoagulant effect: Increased/decreased

Active ingredients: nevirapine
Anticoagulant effect: Decreased

Cephalosporins

Active ingredients: cefotetan
Anticoagulant effect: Increased

Fluoroquinolones

Active ingredients: ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin,

Anticoagulant effect: Increased

Macrolides

Active ingredients: azithromycin, clarithromycin, erythromycin

Anticoagulant effect: Increased

Penicillin

Active ingredients: nafcillin, dicloxacillin

Anticoagulant effect: Decreased

Active ingredients: ampicillin, oxacillin, penicillin G, piperacillin, ticarcillin, amoxicillin,

amoxicillin/clavulanic acid

Anticoagulant effect: Increased

Tetracycline

Active ingredients: demeclocycline, doxycycline, minocycline, tetracycline, oxytetracycline

Anticoagulant effect: Increased

Others

Active ingredients: rifabutin, rifapentine

Anticoagulant effect: Decreased Active ingredients: rifampin Anticoagulant effect: Decreased Anti-Infective Agents – Misc

Active ingredients: sulfamethoxazole, chloramphenicol, telithromycin, metronidazole, tinidazole

Anticoagulant effect: Increased

Active ingredients: sulfisoxazole, isoniazid

Anticoagulant effect: Increased Active ingredients: rifaximin Anticoagulant effect: Decreased

Anti-Malarial

Active ingredients: atovaquone, mefloquine, proguanil

Anticoagulant effect: Increased Active ingredients: quinine Anticoagulant effect: Increased

Note: Drugs listed were selected based on a severity rating of either "severe or moderate" and a documentation rating of "Probable, Possible, or Suspected" according to Drug Interaction Facts; excludes the following routes of administration: external (EX), inhalation (IN), irrigation (IR), ophthalmic (OP), otic (OT), mouth/throat preparations (MT), and route does not apply (XX) unless otherwise noted. All other formulations and combination products of the active ingredients listed are included unless otherwise noted. Obsolete drug products are excluded from NDCs with an inactive date more than three years prior to the beginning of the measurement period or look-back period, if applicable. Updated: First Databank and Medi-Span, 2013.

Citations

Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc.; December 2013. Accessed December 13, 2013.

EXCLUSIONS

We excluded the following individuals from the denominator:

- Individuals with a diagnosis of cancer
- Individuals who are monitoring INR at home

EXCLUSION DETAILS

Exclusion One

Table 3. Codes Used to Identify Cancer

ICD-9-CM: 210.0-228.1, 273.3, 288.3, V10.00-V10.89, V10.90, V10.91, V87.41

ICD-10-CM: C88.0, D10.0, D10.1, D10.2, D10.30, D10.39, D10.4, D10.5, D10.6, D10.7, D10.9, D11.0, D11.7, D11.9, D12.0, D12.1, D12.2, D12.3, D12.4, D12.5, D12.6, D12.7, D12.8, D12.9, D13.0, D13.1, D13.2, D13.30, D13.39, D13.4, D13.5, D13.6, D13.7, D13.9, D14.0, D14.1, D14.2, D14.30, D14.31, D14.32, D14.4, D15.0, D15.1, D15.2, D15.7, D15.9, D16.00, D16.01, D16.02, D16.10, D16.11, D16.12, D16.20, D16.21, D16.22, D16.30, D16.31, D16.32, D16.4, D16.5, D16.6, D16.7, D16.8, D16.9, D17.0, D17.1, D17.20, D17.21, D17.22, D17.23, D17.24, D17.30, D17.39, D17.4, D17.5, D17.6, D17.7, D17.9, D18.00, D18.01, D18.02, D18.03, D18.09, D18.1, D19.0, D19.1, D20.0, D20.1, D21.0, D21.10, D21.11, D21.12, D21.20, D21.21, D21.22, D21.3, D21.4, D21.5, D21.6, D21.9, D22.0, D22.10, D22.11, D22.12, D22.20, D22.21, D22.22, D22.30, D22.39, D22.4, D22.5, D22.60, D22.61, D22.62, D22.70, D22.71, D22.72, D22.9, D23.0, D23.10, D23.11, D23.12, D23.20, D23.21, D23.22, D23.30, D23.39, D23.4, D23.5, D23.60, D23.61, D23.62, D23.70, D23.71, D23.72, D23.9, D24.1, D24.2, D24.9, D25.0, D25.1, D25.2, D25.9, D26.0, D26.1, D26.7, D26.9, D27.0, D27.1, D27.9, D28.0, D28.1, D28.2, D28.7, D28.9, D29.0, D29.1, D29.20, D29.21, D29.22, D29.30, D29.31, D29.32, D29.4, D29.8, D29.9, D30.00, D30.01, D30.02, D30.10, D30.11, D30.12, D30.20, D30.21, D30.22, D30.3, D30.4, D30.8, D30.9, D31.00, D31.01, D31.02, D31.10, D31.11, D31.12, D31.20, D31.21, D31.22, D31.30, D31.31, D31.32, D31.40, D31.41, D31.42, D31.50, D31.51, D31.52, D31.60, D31.61, D31.62, D31.90, D31.91, D31.92, D32.0, D32.1, D32.9, D33.0, D33.1, D33.2, D33.3, D33.4, D33.7, D33.9, D34, D35.00, D35.01, D35.02, D35.1, D35.2, D35.3, D35.4, D35.5, D35.6, D35.7, D35.9, D36.10, D36.11, D36.12, D36.13, D36.14, D36.15, D36.16, D36.17, D72.1, K31.7, K63.5, Z85.00, Z85.01, Z85.020, Z85.028, Z85.030, Z85.038, Z85.040, Z85.048, Z85.05, Z85.060, Z85.068, Z85.07, Z85.09, Z85.110, Z85.118, Z85.12, Z85.20, Z85.21, Z85.22, Z85.230, Z85.238, Z85.29, Z85.3, Z85.40, Z85.41, Z85.42, Z85.43, Z85.44, Z85.45, Z85.46, Z85.47, Z85.48, Z85.49, Z85.50, Z85.51, Z85.520, Z85.528, Z85.53, Z85.59, Z85.6, Z85.71, Z85.72, Z85.79, Z85.810, Z85.818, Z85.819, Z85.820, Z85.821, Z85.828, Z85.830, Z85.831, Z85.840, Z85.841, Z85.848, Z85.850, Z85.858, Z85.89, Z85.9, Z92.21

Exclusion Two

Table 4. INR Monitoring at Home: HCPCS Codes

G0248 - DEMONSTRATE USE HOME INR MON

G0249 - PROVIDE TEST MATS & EQUIP HOME INR

G0250 - MD INR TEST REVIEW INTER MGMT

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not applicable

STRATIFICATION

Depending on the operational use of the measure, measure results may be stratified by:

- State
- Plan
- Accountable Care Organizations (ACOs)
- Age- Divided into six categories: 18-24, 25-44, 45-64, 65-74, 75-84, and 85+ years
- Race/Ethnicity
- Dual Eligibility Status

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Create Denominator

- 1. Pull individuals who are 18 years of age or older as of January 1 of the measurement period.
- 2. Include individuals who were continuously enrolled in Part D coverage during the measurement year, with no more than a one-month gap in enrollment during the measurement year.
- 3. Include individuals who had no more than a one-month gap in Part A enrollment, no more than a one-month gap in Part B enrollment, and no more than one month of HMO enrollment during the current measurement year (FFS individuals only).
- 4. Identify and delete individuals with cancer, based on Part A and B claims.
- 5. Identify and delete individuals who are monitoring INR at home, based on Part A and B claims.
- 6. Pull all warfarin claims from the Part D claims data for the individuals still eligible in Step 4.
- 7. From the dataset created in Step 5, include those individuals with at least two claims for warfarin on different dates of service.
- 8. Using the dataset from Step 6, calculate the warfarin start date and warfarin end date.
- 9. Pull all anti-infective claims from the Part D claims data.
- 10. From the dataset in Step 8, keep the anti-infective prescription with the highest days' supply for each unique date for each individual.
- 11. From the dataset in Step 9, keep only the "newly-started" anti-infectives (no other anti-infective in the prior 30 days).
- 12. Using the dataset from Step 10, calculate the anti-infective start date and anti-infective end date.
- 13. Merge the warfarin claims dataset from Step 7 and the anti-infective dataset from Step 11, keeping only the individuals' episodes where there are overlapping days' supply of warfarin therapy and anti-infective therapy. If there is more than one anti-infective started on the same date, keep the overlap episode with the largest overlapping period.

Create Numerator

- 1. Pull all individuals who had an INR test performed, identified using a CPT code, or who had a hospitalization of more than 48 hours during the measurement period from the Part A and Part B claims data.
- 2. Of the individuals identified in Step 1, keep those who are also included in the denominator.
- 3. Compare start date of anti-infective medication with the INR/hospitalization date.
- 4. Keep only the claims where the INR/hospitalization date occurred at least three days after the start of the anti-infective therapy.
- 5. Keep unique episodes of anti-infective date and first occurring INR test/hospitalization.
- 6. Keep the episodes in which the first INR/hospitalization occurred within three to seven days after the start of the anti-infective. Available in attached appendix at A.1

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5.1 Identified measures: 0555: INR Monitoring for Individuals on Warfarin

0586: Warfarin PT/INR Test

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The measure under review (NQF 0556) is related to two NQF-endorsed measures: • NQF 0555: Lack of Monthly INR Monitoring for Individuals on Warfarin (Centers for Medicare & Medicaid Services): Average percentage of monthly intervals in which individuals with claims for warfarin do not receive an International Normalized Ratio (INR) test during the measurement period; and, • 0586: Warfarin PT/INR Test (Resolution Health, Inc.): This measure identifies the percentage of patients taking warfarin during the measurement year who had at least one PT/INR test within 30 days after the first warfarin prescription in the measurement year. These two related measures address the same measure focus (i.e., INR monitoring) as NQF 0556. However, the measures use a different denominator (i.e., individuals on warfarin) than NQF 0556 (i.e., individuals taking warfarin and interacting anti-infective medications). Below we describe the differences between NQF 0556 and the two related measures and the implications of those differences. Time Period for INR Test - Difference: NQF 0556 requires that the INR test be performed within three to seven days of the interacting anti-infective prescription. NQF 0555 requires monthly INR tests and NQF 0586 requires one INR test within 30 days of the first warfarin prescription of the measurement year. Rationale: Patients on warfarin who start an interacting anti-infective medication are at higher risk of a warfarin-related adverse event. The INR test must be performed shortly after the interacting anti-infective prescription is started to assess the effect on the INR value and to adjust the warfarin dose if necessary. Impact on interpretability: The narrow time window for the INR test is a logical way to track the impact of the interacting anti-infective medication. Data collection burden: Because NQF 0556 and the two related measures are based on administrative claims data, identifying the INR test should require approximately the same resources. Definition of Denominator - Difference: The denominator of NQF 0556 includes patients on warfarin who start an interacting anti-infective medication. The denominators of the two related measure include all patients on warfarin. Rationale: The denominator definition used in NQF 0556 adds value because it restricts the measure to patients at higher risk of an adverse event due to warfarin to capture an acute event. Impact on interpretability: Because the rationale for restricting the denominator is clearly stated, NQF 0556 should be easy to interpret. Data collection burden: Because NQF 0556 and

the two related measures are based on administrative claims data, identifying individuals for the denominator should require about the same time and resources, regardless of the definition.

5b.1 If competing, why superior or rationale for additive value: There are no NQF-endorsed measures that compete (i.e., conceptually addresses both the same measure focus and the same target population) with NQF 0556.

0684 Percent of Residents with a Urinary Tract Infection (Long-Stay)

STATUS

Submitted

STEWARD

Centers for Medicare and Medicaid Services

DESCRIPTION

This Minimum Data Set (MDS) 3.0 based measure estimates the percentage of long-stay residents who have a urinary tract infection on the target MDS assessment (OBRA, PPS, or discharge). In order to address seasonal variation, the proposed measure uses a 6-month average for the facility. Long-stay nursing facility residents are those with more than 100 cumulative days in the facility.

TYPE

Outcome

DATA SOURCE

Electronic Clinical Data Minimum Data Set 3.0

See Minimum Data Set 3.0 item sets located as follows: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html

Available at measure-specific web page URL identified in S.1 No data dictionary

LEVEL

Facility

SETTING

Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility

TIME WINDOW

The measure time period is six months or two calendar quarters. The numerator is based on target assessments selected from the target quarter that indicate a urinary tract infection. The measure is adjusted for seasonal variation by calculating a simple average of two quarters by adding the QM score from the current and prior quarters and dividing by two.

NUMERATOR STATEMENT

The numerator is the number of long-stay nursing facility residents with a selected target assessment (OBRA, PPS or discharge) that indicates a urinary tract infection within the last 30 days (Item I2300= [1]).

NUMERATOR DETAILS

Residents are counted if they are long-stay residents, defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their day count reset to zero. Residents are counted if item I2300 of the MDS 3.0, urinary tract infection within the last 30 days = 1. This section of the MDS 3.0, "Active Diagnoses," asks that all applicable diagnoses be checked. The proposed measure targets all OBRA, PPS and discharge assessments (A0310A = 02, 03, 04, 05, 06; A0310B = 02, 03, 04, 05; A0310F = 10, 11), calculating a simple average by adding the QM value for each quarter and dividing by that number of quarters. The measure is adjusted for seasonal variation by calculating a simple average.

DENOMINATOR STATEMENT

All MDS target assessments (OBRA, PPS, and discharge) in a selected quarter are included, except those with exclusions.

DENOMINATOR DETAILS

Residents are counted if they are long-stay residents defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their day count reset to zero. The denominator includes target assessments (A0310A = 02, 03, 04, 05, 06; A0310B = 02, 03, 04, 05; A0310F = 10,11), except those with exclusions.

EXCLUSIONS

There are two exclusions applied to the denominator: one, the target assessment is an admission assessment ((A0310A = [01] or a PPS 5-day or readmission/return assessment (A0310B = [01, 06]), and two, the urinary tract infection value is missing (I2300 = [-]). Assessments of residents with only an admission assessment are excluded because these residents may have developed urinary tract infection in the hospital, rather than the nursing facility. It would be unfair to hold the nursing facility accountable for care received in the hospital.

EXCLUSION DETAILS

OBRA admission assessments (A0310A = [01]) and PPS 5-day or readmission/return assessment (A0310B = [01, 06]) are excluded. Nursing facilities are excluded from public reporting if their sample size is fewer than 30 residents.

RISK ADJUSTMENT

No risk adjustment or risk stratification Not applicable

Provided in response box S.15a

STRATIFICATION

Not applicable

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

Step 1: Determine the number of non-admission OBRA MDS 3.0 target assessments (A0310A=02, 03, 04, 05, 06; A0310B = 02, 03, 04, 05; A0310F = 10, 11) for long-stay residents who have had a urinary tract infection in the last 30 days (item I2300 is checked [=1] on the MDS 3.0) Step 2: Determine the total number of non-admission, OBRA MDS 3.0 assessments (exclude those with A0310A = [01] or A0310B = [01, 06] (admission assessment)) during the last two quarters. Step 3: Divide the result of Step 1 by the result of Step 2 and then divide the result by 2. Step 4: Sum the facility QM score derived in Step 3 for the current and prior quarters and divide the result by 2. No diagram provided

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5.1 Identified measures: 0751: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery

0138 : National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

0281: Urinary Tract Infection Admission Rate (PQI 12)

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Not applicable 5b.1 If competing, why superior or rationale for additive value: There are no competing measures for this QM. None of the measures listed in 5.1a or 5.1b have the same measure focus and the same measure target population. This measure is the most valid and efficient for capturing UTI among nursing home residents for purposes of reducing UTI.

0739 Radiation Dose of Computed Tomography (CT)

STATUS

Submitted

STEWARD

University of California San Francisco

DESCRIPTION

The measure requires hospitals and output facilities that conduct Computed Tomography (CT) studies to assess the radiation dose associated with the most frequently conducted examination types – CT's of the head, chest, abdomen/pelvis obtained in children and adults. The measure provides a simple framework for how facilities can assess their dose, a framework that currently does not exist. By assessing their doses, facilities can monitor the doses they use over time and compare their doses to benchmarks. The creation of benchmarks is not part of this measure per se. However, if facilities use this measure, I believe professional societies, researchers, and

oversight organizations can separately create their benchmarks. Several research groups, including my own, have published benchmarks and published manuscripts that have used the framework of this measure to assess changes in radiation dose over time (Keagan, JACR, 2014) and to assess the impact of an educational intervention on doses, using the specifications of the measure to assess the results of a randomized trial (Miglioretti, JACR, 2014).

This measure was initially developed for diagnostic CT, but can equally be used for CT used in conjunction with radiation therapy for cancer. Professional organizations within various medical specialties can create appropriate benchmarks depending on the application.

TYPF

Outcome

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry Electronic CT images (captured from the CT console at the time of scanning or harvested from the PACS (Picture Archiving Communication System - the computerized systems for reviewing and storing imaging data), Radiology Information System, EPIC, printed CT images, or information stored in the medical record. Further numerous software products are now available for capturing these data (Bayer, GE, etc.) and several free ware programs are also available. Of note, a recent California law requires the reporting of several of the dose metrics outlined in this measure in the patient medical record, and as a results, many software companies have provided techniques for collating these data.

LEVEL

Facility, Health Plan, Integrated Delivery System

SETTING

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care : Outpatient Rehabilitation, Ambulatory Care : Urgent Care

TIME WINDOW

The metric is based on cross sectional analyses, and the numerator and denominator have the same time period. The length of time needed to accrue a sufficient number of CT scans to generate sufficient precision will vary by the size of the facility, but for average sized practices, will include review of data from several months. The sample size to generate sufficient precision in the adult category is 100 CTs within each anatomic and machine type strata. More than this number can be included for example if data are automatically generated, they can be generated for a fixed time interval (see Keegan JACR 2014, Miglioretti JACR 2014). The sample size to generate sufficient precision in the child category is smaller, 50 in children within each strata. The sample sizes is lower in children (and can be lower still in the child categories if the facilities do not evaluate sufficient children within a year to meet this minimum of 50 per strata), because CT is used less often in children. Of not, facilities do not need to collate data in all categories, only ones relevant to their practice.

All of the data are stored with the CT images and stored electronic data (within DiCom Headers) and the dose data can be collected retrospectively for all patients at one time by reviewing existing records. Thus all of the data can be abstracted in a single time period of review.

NUMERATOR STATEMENT

Radiation Dose, quantified using the distribution in four dose metrics (DLP, CTDIvol, SSDE, ED); within anatomic area, age, and machine-type strata. SSDE only pertains to abdomen scans.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only generates dose metrics for a single metric, there is a lot of information and performance information to be gleaned.

CTDIvol will reveal the settings used per small scan length. This is directly generated by most modern CT scanners.

DLP reflects both the dose per small scan length, but also the length of scan that is conducted, and is defined as CTDIvol x scan length. This is directly generated by most modern CT scanners.

Effective dose takes into account the total amount of radiation emitted from the machine as well the radio-sensitivity to developing cancer in the area radiated. The measure thus combines both radiation dose and future cancer risk. The metric is the only one that can be combined across types of studies and anatomic areas and is thus useful for dose monitoring dose surveillance and facility performance (see Smith-Bindman, Radiology, 2011).

While there are many different ways to calculate Effective Dose, and many current dose monitoring software products can do this automatically, a simple rule of thumb can be used to convert DLP to Effective dose in adults (see Huda, below). In the brain, given typical machine settings that are used, the DLP can be converted to Effective Dose by multiplying DLP measured in mGy-Cm by 0.002 to yield Effective Dose measured in milli-Sieverts. Effective Dose of CT scans though the chest can be estimated by multiplying the DLP measured in mGy-cm by .017 to yield Effective Dose measurements in mSv; and Effective Dose of abdominal and pelvis CT can be estimated by multiplying DLP by 0.18. It is not clear that using greater precision in the quantification of effective dose is necessary for the quality improvement purposes outlined in this measure.

Additional relevant citations for effective dose

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

NUMERATOR DETAILS

Radiation dose distribution for the four metrics (CTDIvol, DLP, SSDE, Effective Dose) need to be recorded for a consecutive sample of CT examinations within anatomic area, age and machine type strata. The mean, median, and percentiles in dose distribution (min, 5%, 25%, 50%, 75%, 95%, max) for each measure need to be generated. Because these values can vary by the type of machine, these need to be recorded for each machine type within a facility. ED can be calculated using simple conversion factors for DLP as described above (a multiplication of DLP yields an effective dose) or using more sophisticated programs now readily available to do so within dose monitoring software programs.

These data can be extracted from the CT examinations in several ways. These numbers can written down directly from the CT scanner itself at the time of the examination; they can be written down from the PACS (computer terminal where images are reviewed and stored); or can be written down from the medical record if the facility stores these data as part of the medical record (a minority of facilities currently do this.) The CT manufacturers have agreed (through MITA, Medical Imaging and Technology Alliance, the professional trade association of imaging manufacturers) to make these data electronically available through export from the CT machines to a local server), and these data can also be collected electronically from the PACS, Radiology Information System, EPIC program if the data are exported there, or using any number of dose monitoring software programs allowing the collection and reporting of these dose data. The easiest way to collect these data is through one of the 6 or so commercial software programs, and several free-ware programs that enable directly extracting CT dose information from the PACS. We have published in a recent paper (Keegan, JACR 2014) several examples of techniques for dose extraction that can be completed even by even a small facility.

The strata for this measure include:

Anatomic area strata: head, chest, abdomen/pelvis

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

CT machine (manufacturer, type)

NOTE: The SSDE was developed as a metric for adjusting for size. However, it does not completely adjust for size and analysis within age strata are still needed among children to account for the different doses that are used and should be used for infants to obese children. Further, there have been no large-scale studies validating SSDE as a measure of quality and thus it is still import to assess dose within size strata in children to assure quality.

DENOMINATOR STATEMENT

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis

DENOMINATOR DETAILS

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis

EXCLUSIONS

CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine). In adults approximately 16% of CT scans fall in these excluded areas. In children, approximately 23% of CT examinations fall into excluded areas.

Further, combined areas, such as head and chest, should not be included in the scans collected.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category.

EXCLUSION DETAILS

Most abdominal/pelvis CT scans in adult patients include scanning of the abdomen and pelvis as one contiguous area. If examinations are conducted limited to one region, these should also be included, as it is difficult/impossible to define what areas would be considered limited.

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

Anatomic area strata: head, chest, abdomen/pelvis

These were chosen based on being the most common CT examination types conducted in the US, comprising >80% of all CT scans, and because dose varies by these groups.

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

These patient age groups were chosen based on the variation of CT settings and resulting radiation dose based on patient size (and age is frequently used as a marker for size.) The ICRU (International Commission on Radiation Units and Measurements) uses these child size categories, they correspond to available phantoms, and they are the ones found to be most reliable through the Image Gently Campaign

CT machine (manufacturer, type)

Geographic location where studies done (zip code or state)

Other strata are not needed

TYPE SCORE

ALGORITHM

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5.1 Identified measures: 0740: Participation in a Systematic National Dose Index Registry

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: The ACR Dose Index Registry and this measure each collect similar dose metrics - DLP, CTDIvol, SSDE are specified in each. I believe Effective Dose only specified in this measure.

The ACR provides benchmarking to organizations that belong to their registry (it is a fee based system) and do not publish benchmarks publicly. I do not believe they benchmark by anatomic area, but rather by protocol as described above, with the inherent weakness of not distinguishing organizations that use multiphase studies frequently or rarely.

The UCSF measures encourages facilities to analyze their own data using a simple standard, and benchmarks are currently being published using data from a large number of institutions using the measure specifications. Further, institutions can track their own performance over time using this measure. The ACR Dose Index Registry and this measure each collect similar dose metrics (DLP and CTDIvol are specified in each).

The ACR provides benchmarking to organizations that belong to their registry (it is a fee based system) and do not publish benchmarks publicly.

The UCSF measures encourages facilities to analyze their own data using a simple standard, and benchmarks are currently being published using data from a large number of institutions using the measure specifications. Further, institutions can track their own performance over time using this measure.

0740 Participation in a Systematic National Dose Index Registry

STATUS

Submitted

STEWARD

American College of Radiology

DESCRIPTION

Participation in a multi-center, standardized data collection and feedback program that will establish national dose index benchmarks for designated examinations. The registry will eventually provide a comparison of practice or facility dose indices such as CTDIvol and DLP for specified examinations relative to national and regional benchmarks. Data is captured electronically from the images of CT examinations using Digital Imaging and Communications in Medicine (DICOM) standards and the Integrating the Healthcare Enterprise (IHE) Radiation Exposure Monitoring (REM) profile.

TYPE

Structure

DATA SOURCE

Electronic Clinical Data: Registry The American College of Radiology Dose Index Registry Available at measure-specific web page URL identified in S.1 No data dictionary

LEVEL

Facility, Clinician: Group/Practice, Population: National, Population: Regional

SETTING

Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Other Imaging facility

TIME WINDOW

Variable. Can be reported monthly, quarterly, annually. The measure would best be reported on an annual basis.

NUMERATOR STATEMENT

Participation in a systematic national dose index registry.

NUMERATOR DETAILS

Dose Index registry collects dose indices in a standardized format using DICOM Radiation Dose Structured Report for CT as specified in DICOM Content Mapping Resource document PS 3.16-2009 (ftp://medical.nema.org/medical/dicom/2009/09_16pu.pdf)and the IHE (Integrating the Healthcare Enterprise) Radiation Exposure Monitoring profile. Data fields include CTDIvol in milligray (mGy) and Dose Length Product (DLP) by irradiation event for specified examinations, such as Adult Routine Head or Adult Routine Abdomen. Data are collected on all CT exams performed at a participating facility.

DENOMINATOR STATEMENT

The measure does not have a numerator/denominator. It is strictly an attestation – Yes or No.

DENOMINATOR DETAILS

EXCLUSIONS

No exclusions

EXCLUSION DETAILS

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

The measure is not stratified.

TYPE SCORE

Other Attestation - Yes/no measure passing score defines better quality

ALGORITHM

The measure is an attestation that the site participates in the registry. Y or N. No diagram provided

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5.1 Identified measures: 0739: Radiation Dose of Computed Tomography (CT)

0510: Exposure time reported for procedures using fluoroscopy

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: egarding measure #0739 UCSF Yes, the measures are completely harmonized.

The two measures have the same overarching goal of improving the safety of medical imaging with CT by improving the appropriateness of CT radiation exposures. The two measures are unique, although complimentary, and facilities can efficiently participate and comply with both measures if they so choose, without undue burden.

Because the two measures focus on similar radiation dose metrics, participation in one measure will facilitate participation in the other with minimal incremental effort and without undue burden to facilities. Data that will be collected through participation for the ACR dose registry measure can be used to generate the statistics that are called for in the UCSF measure through automatic data collection methods. (The ACR Dose Index registry has tested data collection from new and legacy scanners manufactured by four major vendors of CT scanners.) Site feedback reports can generate data that conforms to the specifications of the UCSF measure, including effective dose.

2337 Antipsychotic Use in Children Under 5 Years Old

STATUS

Submitted

STEWARD

Pharmacy Quality Alliance (PQA, Inc.)

DESCRIPTION

The percentage of children under age 5 who were dispensed antipsychotic medications during the measurement period.

TYPE

Process

DATA SOURCE

Administrative claims Health plan (e.g., Medicaid, other) enrollment data Health plan (e.g., Medicaid, other) prescription claims data No data collection instrument provided No data dictionary

LEVEL

Health Plan, Population: State

SETTING

Other Health plan

TIME WINDOW

The measurement period is the 12-month period (e.g., a calendar year) over which the antipsychotic medication use is to be observed.

NUMERATOR STATEMENT

The number of patients under 5 years of age with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.

NUMERATOR DETAILS

Numerator

Step 1: Of those included in the denominator, count the number of patients with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.

Step 2: Of those identified in Step 1, include only those patients for whom a prescription claim for an antipsychotic medication was generated when the patient was under the age of 5.

The number of patients remaining after completing Step 2 represents the numerator for this measure.

Antipsychotic Medications for this measure include: aripiprazole, asenapine, chlorpromazine, clozapine, fluphenazine, haloperidol, iloperidone, loxapine, lurasidone, olanzapine, paliperidone,

perphenazine, pimozide, quetiapine, risperidone, thioridazine, thiothixene, trifluoperazine, and ziprasidone.

(Note: Includes combination products that contain any of the above-listed medications. The active ingredients are limited to oral, sublingual, injectable, and intramuscular formulations only.)

DENOMINATOR STATEMENT

Children who are less than 5 years old at any point during the measurement period, and also enrolled in a health plan for one month or longer during the measurement period.

DENOMINATOR DETAILS

The denominator includes all patients who were under 5 years of age at any time during the measurement period, and also enrolled in a health plan for one month or longer during the measurement period.

Denominator Calculation:

Step 1: Identify patients that are less than 5 years of age at any point during the measurement period.

Step 2: Of those patients identified in Step 1, only include those patients that were enrolled in a health plan for one month or longer during the measurement period.

The number of patients identified in Step 2 is the denominator for the measure.

EXCLUSIONS

None.

EXCLUSION DETAILS

None.

RISK ADJUSTMENT

No risk adjustment or risk stratification

N/A

STRATIFICATION

None.

TYPE SCORE

Rate/proportion better quality = lower score

ALGORITHM

Denominator Calculation:

Step 1: Identify patients that are less than 5 years of age at any point during the measurement period.

Step 2: Of those patients identified in Step 1, only include those patients that were enrolled in a health plan for one month or longer during the measurement period.

The number of patients identified in Step 2 is the denominator for the measure.

Numerator Calculation:

Step 3: Of those patients identified in Step 2, count the number of patients with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.

Step 4: Of those patients identified in Step 3, include only those patients for whom a prescription claim for an antipsychotic medication was generated when the patient was under the age of 5.

The number of patients identified by completing Step 4 represents the numerator for this measure.

Step 5: Divide the numerator by the denominator and then multiply by 100 to obtain the rate (as a percentage) for the measure.

Antipsychotic Medications for this measure include: aripiprazole, asenapine, chlorpromazine, clozapine, fluphenazine, haloperidol, iloperidone, loxapine, lurasidone, olanzapine, paliperidone, perphenazine, pimozide, quetiapine, risperidone, thioridazine, thiothixene, trifluoperazine, and ziprasidone.

(Note: Includes combination products that contain any of the above-listed medications. The active ingredients are limited to oral, sublingual, injectable, and intramuscular formulations only.) No diagram provided

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact: N/A there are no related or competing NQF-endorsed measures.
- 5b.1 If competing, why superior or rationale for additive value: N/A. There are no related or competing NQF-endorsed measures.

2371 Annual Monitoring for Patients on Persistent Medications

STATUS

Submitted

STEWARD

National Committee for Quality Assurance

DESCRIPTION

This measure assesses the percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year.

- Angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB): At least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year.
- Digoxin: At least one serum potassium, one serum creatinine and a serum digoxin therapeutic monitoring test in the measurement year.

- Diuretics: At least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year.
- Total rate (the sum of the three numerators divided by the sum of the three denominators)

TYPE

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Laboratory, Electronic Clinical Data: Pharmacy This measure is based on administrative claims collected in the course of providing care to health plan members. NCQA collects the Healthcare Effectiveness Data and Information Set (HEDIS) data for this measure directly from Health Management Organizations and Preferred Provider Organizations via NCQA's online data submission system.

No data collection instrument provided Attachment 2371_MPM_Value_Sets.xlsx

LEVEL

Health Plan, Integrated Delivery System

SETTING

Ambulatory Care: Clinician Office/Clinic

TIME WINDOW

The measurement year (e.g., 12 months).

NUMERATOR STATEMENT

This measure is reported as three rates and a total rate.

For annual monitoring for patients on ACE inhibitors or ARBs: the number of patients with at least one serum potassium and serum creatinine therapeutic monitoring test in the measurement year.

For annual monitoring for patients on digoxin: the number of patients with at least one serum potassium, one serum creatinine, and a serum digoxin therapeutic monitoring test in the measurement year.

For annual monitoring for patients on diuretics: the number of patients with at least one serum potassium and serum creatinine therapeutic monitoring test in the measurement year.

For the total rate: sum of the 3 numerators.

NUMERATOR DETAILS

ACE Inhibitors/ARBs: Any of the following during the measurement year meet numerator criteria:

- A lab panel test (Lab Panel Value Set)

OR

- A serum potassium test (Serum Potassium Value Set) and a serum creatinine test (Serum Creatinine Value Set).

Note: The tests do not need to occur on the same service date, only within the measurement year.

Digoxin: Any of the following during the measurement year meet criteria:

- A lab panel test (Lab Panel Value Set) and serum digoxin test (Digoxin Level Value Set).

OR

- A serum potassium test (Serum Potassium Value Set), a serum creatinine test (Serum Creatinine Value Set) and a serum digoxin test (Digoxin Level Value Set).

Diuretics: Any of the following during the measurement year meet criteria:

- A lab panel test (Lab Panel Value Set).

OR

- A serum potassium test (Serum Potassium Value Set) and a serum creatinine test (Serum Creatinine Value Set).

Total: Sum the numerators for the three rates described above.

See attachment for all value sets.

DENOMINATOR STATEMENT

Patients age 18 and older as of the end of the measurement year (e.g., December 31) who are on selected persistent medications (ACE Inhibitors/ARB, Digoxin or Diuretics.)

DENOMINATOR DETAILS

Eligible population:

Patients on who received at least 180 treatment days of ambulatory medication in the measurement year. Treatment days are the actual number of calendar days covered with prescriptions within the measurement year (i.e., a prescription of 90 days supply dispensed on December 1 of the measurement year counts as 30 treatment days). Sum the days supply for all medications and subtract any days supply that extends beyond December 31 of the measurement year. Medications dispensed in the year prior to the measurement year must be counted toward the 180 treatment days.

ACE Inhibitor/ARB: 180 days supply of a medication in table CDC-L.

Digoxin: 180 day supply of Digoxin (no table)

Diuretics: 180 days supply of medication in table MPM-C

Total: Sum of three denominators Table CDC-L: ACE Inhibitors/ARBs

Angiotensin converting enzyme inhibitors: Benazepril; Captopril; Enalapril; Fosinopril; Lisinopril; Moexipril; Perindopril; Quinapril; Ramipril; Trandolapril

Angiotensin II inhibitors: Azilsartan; Candesartan; Eprosartan; Irbesartan; Losartan; Olmesartan; Telmisartan; Valsartan

Antihypertensive combinations: Aliskiren-valsartan; Amlodipine-benazepril; Amlodipine-hydrochlorothiazide-valsartan; Amlodipine-hydrochlorothiazide-olmesartan; Amlodipine-olmesartan; Amlodipine-telmisartan; Amlodipine-valsartan; Benazepril-hydrochlorothiazide; Candesartan-hydrochlorothiazide; Captopril-hydrochlorothiazide; Enalapril-hydrochlorothiazide; Eprosartan-hydrochlorothiazide; Fosinopril-hydrochlorothiazide; Hydrochlorothiazide-irbesartan; Hydrochlorothiazide-lisinopril; Hydrochlorothiazide-losartan; Hydrochlorothiazide-olmesartan; Hydrochlorothiazide-quinapril; Hydrochlorothiazide-telmisartan; Hydrochlorothiazide-valsartan; Trandolapril-verapamil

Note: Patients may switch therapy with any medication listed in above during the measurement year and have the days supply for those medications count toward the total 180 treatment days (i.e., a patient who received 90 days of ACE inhibitors and 90 days of ARBs meets the denominator definition).

Table MPM-C: Drugs to Identify Members on Diuretics

Antihypertensive combinations: Aliskiren-hydrochlorothiazide; Aliskiren-hydrochlorothiazide-amlodipine; Amiloride-hydrochlorothiazide; Amlodipine-hydrochlorothiazide-olmesartan; Amlodipine-hydrochlorothiazide-valsartan; Atenolol-chlorthalidone; Benazepril-hydrochlorothiazide; Bendroflumethiazide-nadolol; Bisoprolol-hydrochlorothiazide; Candesartan-hydrochlorothiazide; Captopril-hydrochlorothiazide; Chlorthalidone-clonidine; Enalapril-hydrochlorothiazide; Eprosartan-hydrochlorothiazide; Fosinopril-hydrochlorothiazide; Hydrochlorothiazide-irbesartan; Hydrochlorothiazide-lisinopril; Hydrochlorothiazide-losartan; Hydrochlorothiazide-metoprolol; Hydrochlorothiazide-moexipril; Hydrochlorothiazide-olmesartan; Hydrochlorothiazide-propranolol; Hydrochlorothiazide-quinapril; Hydrochlorothiazide-spironolactone; Hydrochlorothiazide-telmisartan; Hydrochlorothiazide-triamterene; Hydrochlorothiazide-valsartan

Loop diuretics: Bumetanide; Ethacrynic acid; Furosemide; Torsemide

Potassium-sparing diuretics: Amiloride; Eplerenone; Spironolactone; Triamterene

Thiazide diuretics: Chlorothiazide; Chlorthalidone; Hydrochlorothiazide; Indapamide;

Methyclothiazide; Metolazone

EXCLUSIONS

Exclude patients who had an inpatient (acute or nonacute) claim or encounter during the measurement year.

EXCLUSION DETAILS

The method of identifying inpatient encounters is not defined in the measure specification. Health plans use unique methods for identifying inpatient encounters.

RISK ADJUSTMENT

N/A

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Step 1 – Determine eligible population. To do so, identify all patients in the specified age range who were on persistent medication for at least 180 days (as defined in S.9) during the measurement year:

- Determine number of patients who had persistent use of ACE Inhibitors or ARBs.
- Determine number of patients who had persistent use of Digoxin.
- Determine number of patients who had persistent use of diuretics.

Step 2 – Identify Denominator. Exclude patients from the eligible population who had an inpatient (acute or nonacute) claim or encounter during the measurement year.

Step 3 – Identify Numerators. Determine the number of patients in the denominator who had a monitoring event (as defined in S.6) during the measurement year:

- Determine the number of patients on ACE Inhibitors or ARBs who had a monitoring event during the measurement year.
- Determine the number of patients on Digoxin who had a monitoring event during the measurement year.
- Determine the number of patients on diuretics who had a monitoring event during the measurement year.

Step 4 – Calculate the rate for each medication by dividing the numerator (step 3)/denominator (step 2).

Step 5 – Calculate the total rate by taking the sum of the three numerators (step 3) and dividing by the sum of the three denominators (step 2). No diagram provided

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5.1 Identified measures: 0586: Warfarin_PT/ INR Test

0612: Warfarin - INR Monitoring

0555: INR Monitoring for Individuals on Warfarin

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The specifications of this measure are not harmonized with NQF-endorsed measures 0586, 0612, and 0555 because this measure has a different target population. NQF-endorsed measures 0586, 0612, and 0555 are concerned only with INR monitoring for individuals on warfarin. Therefore the specifications for this measure and the warfarin measures are necessarily different.

5b.1 If competing, why superior or rationale for additive value: This measure does not conceptually address both the same measure focus and target population as any other NQF-endorsed measure.

2426 Elder Maltreatment Screening and Follow-Up Plan

STATUS

Submitted

STEWARD

Centers for Medicare & Medicaid

DESCRIPTION

Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen

TYPE

Process

DATA SOURCE

Administrative claims, Paper Medical Records Medicare Part B claims data

No data collection instrument provided Attachment Data_Dictionary-Code_Descriptions635254597070481973.xlsx

LEVEL

Clinician: Group/Practice, Clinician: Individual

SETTING

Ambulatory Care: Clinician Office/Clinic, Behavioral Health/Psychiatric: Outpatient

TIME WINDOW

This measure is to be reported once during the reporting period for patients seen during the reporting period. The reporting period is 12 months from January 1st to December 31st

NUMERATOR STATEMENT

Patients with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of the encounter and follow-up plan documented on the date of the positive screen

NUMERATOR DETAILS

Definitions:

Screen for Elder Maltreatment – An elder maltreatment screen should include assessment and documentation of all of the following components: (1) physical abuse, (2) emotional or psychological abuse, (3) neglect (active or passive), (4) sexual abuse, (5) abandonment, (6) financial or material exploitation and (7) unwarranted control.

Physical Abuse – Infliction of physical injury by punching, beating, kicking, biting, burning, shaking, or other actions that result in harm.

Emotional or Psychological Abuse – Involves psychological abuse, verbal abuse, or mental injury and includes acts or omissions by loved ones or caregivers that have caused or could cause serious behavioral, cognitive, emotional, or mental disorders.

Neglect – Involves attitudes of others or actions caused by others-such as family members, friends, or institutional caregivers-that have an extremely detrimental effect upon well-being.

Active – Behavior that is willful or when the caregiver intentionally withholds care or necessities. The neglect may be motivated by financial gain or reflect interpersonal conflicts.

Passive – Situations where the caregiver is unable to fulfill his or her care giving responsibilities as a result of illness, disability, stress, ignorance, lack of maturity, or lack of resources.

Sexual Abuse – The forcing of undesired sexual behavior by one person upon another against their will who are either competent or unable to fully comprehend and/or give consent. This may also be called molestation.

Elder Abandonment – Desertion of an elderly person by an individual who has assumed responsibility for providing care for an elder, or by a person with physical custody of an elder.

Financial or Material Exploitation – Taking advantage of a person for monetary gain or profit.

Unwarranted Control – Controlling a person's ability to make choices about living situations, household finances, and medical care.

Follow-Up Plan – Must include a documented report to state or local Adult Protective Services (APS) agency. Note: APS does not have jurisdiction in all states to investigate maltreatment of patients in long-term care facilities. In those states where APS does not have jurisdiction, APS may refer the provider to another state agency — such as the state facility licensure agency — for appropriate reporting. Federal reporting: In addition to state requirements, some types of providers are required by federal law to report suspected maltreatment. For example, nursing facilities certified by Medicare and/or Medicaid are required to report suspected maltreatment to the applicable State Survey and Certification Agency.

For state-specific information to report suspected elder maltreatment, including self neglect, the following resources are available:

- 1. National Adult Protective Services Association- http://www.napsa-now.org/get-help/help-in-your-area/
- 2. Eldercare Locater: 1-800-677-1116 www.eldercare.gov
- 3. National Center on Elder Abuse

http://www.ncea.aoa.gov/NCEAroot/Main_Site/Find_Help/State_Resources.aspx

Not Eligible – A patient is not eligible if one or more of the following reasons is documented:

- 1. Patient refuses to participate
- 2. Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status

NUMERATOR NOTE: Documentation of an elder maltreatment screening must include identification of the tool used. Examples of screening tools for elder maltreatment include, but are not limited to: Elder Abuse Suspicion Index (EASI), Vulnerability to Abuse Screening Scale (VASS) and Hwalek-Sengstock Elder Abuse Screening Test (H-S/EAST).

G-codes are a defined as Quality Data Codes (QDCs), which are subset of HCPCs II codes. QDCs are non billable codes that providers will use to delineate their clinical quality actions, which are submitted with Medicare Part B Claims. There are 6 G-code options for this measure

Elder Maltreatment Screen Documented as Positive AND Follow-Up Plan Documented

G8733: Elder maltreatment screen documented as positive AND a follow-up is plan is documented

OR

Elder Maltreatment Screen Documented as Negative, Follow-Up Plan not Required G8734: Elder maltreatment screen documented as negative, follow-up is not required OR

Elder Maltreatment Screen not Documented, Patient not Eligible

G8535: Elder maltreatment screen not documented; documentation patient is not eligible for the elder maltreatment screen

OR

Elder Maltreatment Screen Documented as Positive, Follow-Up Plan not Documented, Patient not Eligible for Follow-Up Plan

G8941: Elder Maltreatment Screen Documented as positive, follow-up plan is not documented. Documentation that the patient is not eligible for follow-up plan

OR

Elder Maltreatment Screen not Documented, Reason not Given

G8536: No documentation of an elder maltreatment screen, reason not given

OR

Elder Maltreatment Screen Documented as Positive, Follow-Up Plan not Documented, Reason not Given

G8735: Elder maltreatment screen documented as positive, follow-up plan not documented, reason not given

DENOMINATOR STATEMENT

All patients aged 65 years and older

DENOMINATOR DETAILS

Patients aged = 65 years on date of encounter. Patient encounter during the reporting period (CPT or HCPCS): 90791, 90792,90832, 90834, 90837, 96116, 96150, 96151, 97003, 97802, 97803, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99318, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0101, G0270, G0402, G0438, G0439

EXCLUSIONS

A patient is not eligible if one or more of the following reasons is documented: Patient refuses to participate; Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status

EXCLUSION DETAILS

G8535: Elder maltreatment screen not documented; documentation the patient is not eligible for the elder maltreatment screen

RISK ADJUSTMENT

No risk adjustment or risk stratification

No risk model

STRATIFICATION

Not stratified

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Performance Calculation: For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Performance Denominator and Denominator Exclusions.

Numerator (A) Includes: Number of patients meeting numerator criteria

Performance Denominator (PD) Includes: Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (B) Include: Number of patients with valid denominator exclusions

The method of performance calculation is determined by the following: 1) identify the patients who meet the eligibility criteria for the denominator (PD) which includes patients who are 65 years and older with an appropriate encounter, 2) identify which of those patients meet the numerator criteria (A); and 3) for those patients who do not meet the numerator criteria, determine whether an appropriate exclusion applies (B) and subtract those patients from the denominator.

Numerator (A) / (Performance Denominator (PD) - Denominator Exclusions (B))

Exclusion Calculation – The percentage of Denominator Valid (PD) patients with Denominator Exclusions (B).

Denominator Exclusions (B)/ Performance Denominator (PD) No diagram provided

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact:
- 5b.1 If competing, why superior or rationale for additive value:

2564 Documenting the Radiation Dose of Computed Tomography in the Patient Medical Record

STATUS

Submitted

STEWARD

University of California San Francisco

DESCRIPTION

The measure is a process measure. The measure records the proportion of consecutive CT examinations conducted at an institution (facility, health plan, etc.) where one or more measures of CT radiation dose are included in the radiology report, other imaging report or electronic medical record.

TYPE

Process

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry Part B: Electronic Health/Medical Record

LEVEL

Facility, Health Plan, Integrated Delivery System

SETTING

Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care: Outpatient Rehabilitation, Ambulatory Care: Urgent Care

TIME WINDOW

The length of time to accrue a sufficient number of CT scans will be short, as there are no separate strata, and facilities will perform anywhere from 50 – to many hundreds of CT scans per day. The measure should be assessed from 1 months to 12 months.

NUMERATOR STATEMENT

The proportion of CT scans of one of the included anatomic areas with a measure of radiation dose reported in the final approved report. (The reported measure can be DLP, CTDIvol, Effective Dose, SSDE, or any combination of these).

NUMERATOR DETAILS

The proportion of CT examinations with at least one measure of radiation dose included in final approved report. The measures that can be reported are DLP, CTDIvol, SSDE, and Effective Dose. It would be optimum if all four were reported. California law requires the reporting of several of these measures in all diagnostic CT examinations conducted in California and thus all practices in California currently comply with this measure as part of State Law.

DENOMINATOR STATEMENT

Consecutive sample of CTs

DENOMINATOR DETAILS

Consecutive sample of diagnostic CTs

EXCLUSIONS

None

EXCLUSION DETAILS

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

The measure was initially written for diagnostic CT scans. If scans conducted as part of therapy (such as radiation therapy or as part of interventional procedures) these would each count as separate strata.

Thus 1) diagnostic CT 2) CT done for guidance of radiation therapy and 3) CT used for guidance of procedures.

TYPE SCORE

ALGORITHM

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- 5.1 Identified measures:
- 5a.1 Are specs completely harmonized?
- 5a.2 If not completely harmonized, identify difference, rationale, impact:
- 5b.1 If competing, why superior or rationale for additive value:

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