TO: Consensus Standards Approval Committee (CSAC)

FR: Andrew Lyzenga, MPP, Kathryn Streeter, MS, Laura Ibragimova, MPH

RE: Patient Safety Member Voting Results

DA: October 6, 2014

The CSAC will review recommendations from the Patient Safety project at its October 14, 2014 web meeting. This memo includes a summary of the project, recommended measures, and responses to the public and member comments.

Member voting on the recommended measures ended on September 26, 2014.

Accompanying this memo are the following documents:

1. **Patient Safety Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table**. Staff has identified themes within the comments received. This table lists comments received during the pre-evaluation, post evaluation, and supplemental comment periods. The pre-evaluation comment period was open from February 21-March 6, 2014 for the measures under review. A total of 24 comments were received on eight of the measures. All of the pre-evaluation comments were provided to the Committee prior to their initial deliberations held during workgroup call and in person meeting. The post-evaluation comment period was open from May 28-June 26, 2014. A total of 66 comments were received. Additional comments not included in the comment table were submitted by:
    - Agency for Healthcare Research and Quality
    - Sean Townsend, MD, California Pacific Medical Center
    - Emanuel P. Rivers, MD, MPH, Henry Ford Hospital

    A supplemental comment period was also held for measure 0531 from July 25-August 7, 2014. A total of 30 comments were received. Because this measure has been deferred to the Safety Committee's next evaluation cycle, these comments will be provided to the Committee at that time.

CSAC ACTION REQUIRED

Pursuant to the CDP, the Consensus Standards Approval Committee (CSAC) may consider approval of 16 candidate consensus standards.

Patient Safety Measures Recommended for Endorsement:

- 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

Patient Safety Measures Not Recommended for Endorsement:

- 0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI – Central Venous Catheter (CVC)
  0510 Exposure Time Reported for Procedures Using Fluoroscopy
- 0532 Pediatric Patient Safety for Selected Indicators (PDI 19)
- 0739 Radiation Dose of Computed Tomography (CT)
- 0740 Participation in a Systemic National Dose Index Registry
- 2426 Elder Maltreatment Screening and Follow-Up Plan
- 2564 Documenting the Radiation Dose of Computed Tomography in the Patient Medical Record

Patient Safety Measure Deferred:

- 0531 Patient Safety for Selected Indicators (PSI 90)

Ad-hoc Measure

- 0500 Severe Sepsis and Septic Shock: Management Bundle

BACKGROUND

This project seeks to identify and endorse performance measures for accountability and quality improvement that address patient safety-specific conditions. The patient safety topic area includes measures for safety, health care associated infections, falls, pressure ulcers, surgical complications, and workforce issues.

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 serving on any ad hoc or expedited projects in its designated topic areas. On April 17-18, 2014, the Patient Safety Standing Committee convened, in person, to evaluate 4 new measures and 12 previously endorsed measures undergoing maintenance review against NQF's standard evaluation criteria. In addition, the Committee conducted an ad hoc review of measure 0500 Severe Sepsis and Septic Shock: Management Bundle.

DRAFT REPORT

The Patient Safety Draft Report presents the results of the evaluation of 16 measures considered under the CDP and one ad hoc measure. Eight measures were recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement and eight were not recommended. In addition, the Committee approved a compromise agreement on element 'F' in

measure 0500, which was under ad hoc review as part of this project. The measures were evaluated against the 2013 version of the measure evaluation criteria.

	MAINTENANCE	NEW	TOTAL
Measures considered	12	4	16
Withdrawn from consideration	2	0	2
Recommended	6	2	8
Not recommended	6	2	8
Reasons not Recommended	Importance- 3 Scientific Acceptability- 1 Overall- 2 Competing Measure- 0	Importance- 2	

COMMENTS AND THEIR DISPOSITION

NQF received 66 comments from 46 organizations, including 17 member organizations, and individuals pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Patient Safety project page under the Materials section.

MEASURE SPECIFIC COMMENTS

The measure specific comments include one of the not-recommended measures, three radiation measures, one ad hoc measure and one deferred measure that warrant CSAC discussion.

Measures Not Recommended

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

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:** 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). 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.

Radiation Measures

0739 Radiation Dose of Computed Tomography (CT)

Comments on this measure were both supportive and in opposition of NQF's decision to not recommend it for NQF endorsement. One opposing comment emphasized the importance of acknowledging the use of process measures in order to capture the necessary data and benchmarking for radiation exposure. Measuring CT's radiation exposure is new and CT metrics are evolving as are the methods of linking these measures in selected settings. In addition, the need to optimize radiation exposure for patient safety prompted the development of both quality and safety improvement programs for CT. In addition, one supportive comment recommended that a composite radiation measure be developed to capture the data and address the patient safety concern.

> **Committee Response:** The Committee agreed 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.

0740 Participation in a Systematic National Dose Index Registry

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 directly improves outcomes.

> **Committee Response:** 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.

2564 Documenting the Radiation Dose of Computed Tomography (CT)

One comment on this measure was received indicating that for all associated radiology measures, continuous education for providers and patients on the potential risks of over exposure are essential. Therefore, a composite measure is required to ensure that the data collected leads to desired outcomes.

Committee Response: The Committee agreed that optimizing radiation exposure is an important safety goal, and supported continuous 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.

Measure Deferred

0531 Patient Safety for Selected Indicators (PSI 90)

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 (iatrogenic 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).

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.

Ad-hoc Measure Specific Comments

Reason for this Request
NQF initiated an ad hoc review of element 'F' of measure 0500 to address concerns raised by stakeholders in light of the Protocolized Care for Early Septic Shock (ProCESS) trial, the results of which suggested that the use of central venous catheters for central venous pressure and oxygenation measurement in patients with severe sepsis or septic shock did not improve mortality rates when compared to usual care.

Ad-hoc Review Process
According to NQF policy for ad-hoc reviews, the Standing Committee evaluated the issue under review and made a recommendation to the CSAC.

0500 Severe Sepsis and Septic Shock: Management Bundle
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 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.

Developer Response: See letters from Dr. Sean Townsend and Dr. Emmanuel Rivers

Committee Response: 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 voted to recommend removal of item 'F' from Measure 0500. The final vote was 11-7 in favor of removing item F, which relates to invasive monitoring of central venous pressure and oxygen levels in patients with severe sepsis or septic shock. 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.

The Committee was surveyed and voted to approve the compromise proposed by the developers. NQF staff will work with the measure developers to submit detailed specifications that will be shared with the Committee when available.

NQF MEMBER VOTING RESULTS

A total of 15 votes were cast by NQF members on eight of the 15 measures recommended for endorsement by the Patient Safety Standing Committee; the remaining seven measures recommended by the Committee did not receive votes from the membership. Seven of the measures receiving votes received approval from greater than 60 percent of member councils. The eighth measure receiving votes (#0556: INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications) received approval from only 50 percent of eligible member councils, meaning that consensus was not reached on this measure. Representatives of seven member organizations voted; no votes were received from the Public and Community Health Agency Council.

REMOVE ENDORSEMENT OF MEASURES

Ten measures previously endorsed by NQF have not been re-submitted, withdrawn from maintenance of endorsement, or not recommended for continued endorsement. One new additional measure was withdrawn after initial submission.

Measure	Description	Reason for removal of endorsement
0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI – Central Venous Catheter (CVC)	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.	Due to the lack of reliability testing, the measure did not pass the Scientific Acceptability criterion.
0510 Exposure Time Reported for Procedures Using Fluoroscopy	Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time.	The measure did not pass the Evidence criterion.
0532 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 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 measure failed on the composite subcriterion due to expressed concerns about the weighting methodology.
0612: Warfarin - INR	The percentage of patients taking warfarin who had PT/INR monitoring	The developer did not resubmit this measure for maintenance review.
0586: Warfarin PT/INR Test	The percentage of patients taking warfarin who had PT/INR monitoring	The developer did not resubmit this measure for maintenance review.
0542: Adherence to Chronic Medications	The measure addresses adherence to three types of chronic medications: statins,	The specifications of this measure were harmonized with measure 0541 to the extent possible, and

Measure	Description	Reason for removal of endorsement
	levothyroxine, and angiotensin converting enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs). The measure is divided into three submeasures: Measure A: The percentage of eligible individuals who had at least two prescriptions for statins and who have a Proportion of Days Covered (PDC) of at least 0.8 during the measurement period (12 consecutive months). Measure B: The percentage of eligible individuals who had at least two prescriptions for levothyroxine and who have a PDC of at least 0.8 during the measurement period (12 consecutive months). Measure C: The percentage of eligible individuals who had at least two prescriptions for ACEIs/ARBs and who have a PDC of at least 0.8 during the measurement period (12 consecutive months).	0542 was withdrawn from consideration.
0739 Radiation Dose of Computed Tomography (CT)	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 did not pass the Evidence criterion.
0740 Participation in a Systemic 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	The measure did not pass the Evidence criterion.

Measure	Description	Reason for removal of endorsement
	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.	
2410: Bleeding Outcomes Related to Oral Anticoagulants	This measure estimates the Accountable Care Organization (ACO)-level, risk-standardized rate of bleeding outcomes related to the use of oral anticoagulants. The rate of bleeding outcomes is defined as the number of initial bleeding events that lead to a hospitalization or emergency department visit per 1000 patient-days for individuals 18 years of age or older who are on oral anticoagulant therapy.	Withdrawn at request of developer in response to testing results.

APPENDIX

Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

0464 Prevention of Catheter-Related Bloodstream Infections (CRBSI) – Central Venous Catheter (CVC)
Submission
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 Measure Steward: American Society of Anesthesiologists

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

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").

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

2. Scientific Acceptability of Measure Properties: **Consensus was not reached on the Scientific 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:

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

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **NA**

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.

0531 Patient Safety for Selected Indicators (PSI 90)
Submission
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

0531 Patient Safety for Selected Indicators (PSI 90)

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.

0531 Patient Safety for Selected Indicators (PSI 90)

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria (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.

0531 Patient Safety for Selected Indicators (PSI 90)

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 (iatrogenic 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).

0531 Patient Safety for Selected Indicators (PSI 90)
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.

0739 Radiation Dose of Computed Tomography (CT)
Submission

0739 Radiation Dose of Computed Tomography (CT)

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:

0739 Radiation Dose of Computed Tomography (CT)

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: The measure did not meet the Scientific Acceptability criteria

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

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

Rationale:

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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:

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4. Use and Usability: NA

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

Rationale:

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0739 Radiation Dose of Computed Tomography (CT)
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.

0740 Participation in a Systematic National Dose Index Registry
Submission

0740 Participation in a Systematic National Dose Index Registry

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.

0740 Participation in a Systematic National Dose Index Registry
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.

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

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

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

1. Importance to Measure and Report: <u>Consensus was not reached on the Importance criterion</u>

(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**

<u>Rationale</u>:

- 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 Acceptability criteria</u>

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

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

<u>Rationale</u>:

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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)

<u>Rationale</u>:

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4. Use and Usability: NA

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

<u>Rationale</u>:

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **NA**

2564 Documenting the Radiation Dose of Computed Tomography in the Patient Medical Record
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 sub-criterion. The Committee expressed an interest in re-evaluating the measure once more data was available.