NATIONAL QUALITY FORUM

Memo

TO: Patient Safety Standing Committee

FR: NQF Staff

RE: Post-Comment Call to Discuss Public and Member Comments NQF Endorsed Measures for Patient Safety

DA: July 11, 2014

Background

Patient Safety related events due to medical errors result in tens of thousands of premature deaths each year. Currently, NQF's portfolio of safety measures spans a variety of topic areas including, but not limited to, safety, health care associated infections, falls, pressure ulcers, surgical complications, and workforce issues. 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 avoidable patient safety measures beyond the hospital setting as well as harmonize safety measures across sites and settings of care.

NQF has a 10 year history of focusing on patient safety. Through various projects, NQF has previously endorsed over 100 consensus standards related to patient safety and are important tools for tracking and improving patient performance.

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 to evaluate 4 new measures and 12 previously endorsed measures undergoing maintenance review against NQF's standard evaluation criteria. Only 8 of the 16 measures were recommended for endorsement by the Committee:

- 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 Committee conducted an ad hoc review of measure 0500 Severe Sepsis and Septic Shock: Management Bundle, recommending removal of element 'F' from the measure,

which involves the requirement for invasive monitoring with a central line in all patients with severe sepsis and septic shock.

Purpose of the Call

The Patient Safety Standing Committee will meet via conference call on Monday, July 14, 2014 from 2-4pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period.
- Provide input on proposed responses to the post-evaluation comments.
- Determine whether reconsideration of any measures or other courses of action is warranted.

Due to time constraints, during this call we will review comments by exception, holding discussion in cases where the Committee disagrees with the proposed responses.

Standing Committee Actions

1. Review this briefing memo and Draft Report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments (see Comment Table and additional documents included with the call materials).
3. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Conference Call Information

Please use the following information to access the conference call line and webinar:

Speaker dial-in #: 1 (855) 223-0818 (*NO CONFERENCE CODE REQUIRED)*
Web Link: http://nqf.commpartners.com/se/Rd/Mt.aspx?488560
Registration Link: http://nqf.commpartners.com/se/Rd/Rg.aspx?48560

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full committee and once a report of the proceedings has been drafted.

Pre-evaluation comments

The pre-evaluation comment period was open from February 21 – March 6 for the measures under review. A total of 24 pre-evaluation comments were received on eight of the measures. All of these pre-evaluation comments were provided to the Committee prior to their initial deliberations held during the workgroups calls and in-person meeting.

Post-evaluation comments

The Draft Report went out for Public and Member comment May 28 – June 26. During this commenting period, NQF received 66 comments from 17 member organizations:

Consumers – 3	Professional – 15
Purchasers – 1	Health Plans – 7
Providers – 18	QMRI – 1
Supplier and Industry – 1	Public & Community Health - 0

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

In order to facilitate discussion, the majority of the post-evaluation comments have been categorized by measure. Where possible, NQF staff has proposed draft responses for the Committee to consider. Although all comments and proposed responses are subject to discussion, we will not necessarily discuss each comment and response on the post-comment call. Instead, we will spend the majority of the time considering the major topics and/or those measures with the most significant issues that arose from the comments.

We have included all of the comments that we received (both pre- and post-evaluation) in the Comment Table. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses for the Committee's consideration. Please refer to this comment table to view and consider the individual comments received and the proposed responses to each.

Comments and their Disposition

Measure Specific Comments

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

Comments about this measure included support of the committee's decision as well as recommendations for improvements. Commenters agreed that the measure data greatly facilitates improvement efforts and provides further direction and benchmarking for infection prevention strategies. Overall, commenters suggested 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 that the measure recognizes the variations in urinary culture frequency. In addition, commenters noted that the use of this measure cannot be applied to certain populations such as in pediatrics where it is not commonly used and in the spinal cord injury populations in which it has been known to lead to complications.

> **Developer Response:** See developer responses to individual comments in the comment table
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> **Proposed Committee Response:** NQF has reviewed your comment and appreciates your input. Your comment has been forwarded to the developer and Standing Committee for consideration.

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

Similar to NQF#0138, this measure received supportive comments as well as recommendations for improvement. Commenters agreed with the importance of this measure in addressing a high needs area and shared the committee's concern about the reliability and addition of the Adjusted Ranking Measure (ARM) given the confusion it causes to the consumer. Additional commenters suggested that this measure be expanded to non ICU settings including outpatient and home health settings where PICC lines are frequently used.

> **Developer Response:** See developer responses to individual comments in the comment table
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> **Proposed 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.

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.

> **Action Item:** After review and discussion of the comments on this measure, does the Committee wish to re-vote on the measure (and therefore potentially change the overall recommendation against endorsement)?
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> **Developer Response:** N/A
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> **Proposed Committee Response:** Pending Committee discussion

0510 Exposure time reported for procedures using fluoroscopy

Comments on this measure were in opposition of the committee's decision to not recommend NQF#0510 for endorsement given that radiation exposure is a major patient safety concern. 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, there was a concern that lack of radiation exposure measures in NQF's Patient Safety Portfolio suggests that this is not an important patient safety issue. Another commenter noted the importance of educating both providers and patients about the potential risks of radiation exposure and recommended that perhaps a composite

measure that includes the specifications of NQF#0739, NQF#2564, and NQF#0510 can be an alternative solution.

Action Item: Was any new information presented to make you reconsider your decision to not recommend the measure for endorsement?

Developer Response: N/A

Proposed 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.

0500 Severe Sepsis and Septic Shock: Management Bundle

Several comments were received about the decision by the committee to recommend that item 'F', the requirement for invasive monitoring in all patients with severe sepsis and septic shock be removed from the measure. The comments that were submitted re-iterated much of the discussion that was considered by the committee. Specifically, commenters that supported the committee's decision to remove the item 'F' cited the results of the ProCESS trial and other randomized trials, specifically the Jones et al. trial that there were are no differences in outcomes for patients receiving early-goal directed therapy with SCVO2 monitoring compared to patients receiving aggressive resuscitation without invasive monitoring.

In addition, commenters noted the patient risks of central line placement, including the risk of infection and pneumothorax. In addition, there were concerns that many hospitals do not have the capacity to safety insert central lines in all patients with severe and sepsis and septic shock, supporting that pushing facilities to do this without the capacity could increase patient harm. There were also several commenters thought that it was premature to eliminate item F. One commenter had a f physiological rationale : that central lines offer the for clinicians to continuously monitor SCVO2 rather than intermittent sampling, which allows clinicians to respond better to the rapidly changing pathophysiology of sepsis.

Other commenters suggested that the ProCESS trial only involved a small fraction (3%) of the total body of evidence of the data on early-goal directed therapy, and that because the trial was conducted in academic sites and does not reflect the experience of community hospitals. 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 trail 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 lead a major journal to give it a level 2 recommendation, despite it being a randomized trial.

There were also concerns that the ProCESS trial had a much lower mortality rate (20%) than previous historial mortality (46%) and that 56% of the non-EGDT patients ultimately received a central venous catheter. The commenters also cited 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.

> **Action Item:** Was any new information presented to make you reconsider your decision to recommend that item F be removed from Measure 0500?
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> **Developer Response:** See letters from Dr. Sean Townsend and Dr. Emmanuel Rivers
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> **Proposed Committee Response:** Pending Committee discussion

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.

> **Action Item:** After review and discussion of the comments on this measure, does the Committee wish to re-vote on the measure (and therefore potentially change the overall recommendation against endorsement)?
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> **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).

Proposed Committee Response: Pending Committee discussion

0532 Pediatric Safety for Selected Indicators (PDI 19)

Comments about this measure were both supportive and in opposition to the committee's decision to not recommend it for NQF endorsement. One comment was received requesting further clarification on NQF's process for reviewing this measure. The commenter found the voting results to be inconclusive (sub-criterion 2d. 39.13% to 60.87%) and requested a continued review of the measure. Another comment supported the committee's decision to not recommend this measure because it's weighting scheme poses threats to validity. However the commenter also stated that revisions to the weighting scheme components in the composite would strengthen this measure and strongly recommend endorsing the measure once this has been resolved.

Developer Response: N/A

NQF Response: It is NQF policy that a measure may be recommended for endorsement by the Standing Committee when the vote margin on all major criteria (Importance, Scientific Acceptability) and overall is 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.

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

A comment received on this measure expressed concern about the use of administrative prescription data for compliance. The comment stated that claims data can be troublesome in that it does not take into consideration factors such as drug samples, generic prescription under the $4 program, or changes to patient's prescriptions due to financial constraints.

Developer Response: Adherence to medications treating chronic disease is essential to maintaining or improving patient health. The measure, Proportion of Days Covered (PDC): 3 rates, uses a standard and commonly used methodology (PDC) to determine patient exposure to chronic medication to determine adherence. This measure uses prescription claims data submitted to a health plan for payment. Clinical studies have demonstrated a link between patient outcomes and adherence to medications as measured by the Proportion of Days Covered metric. Also, we have evidence that plans measured by the PDC metric can improve the adherence of their members.

Medication samples and prescriptions paid with cash and not submitted through the patient's health plan are not captured by the measure. There are several reasons why samples and cash prescriptions have little impact on the measure score, including the following:

- The measure requires that two prescriptions be filled for inclusion in the denominator. Samples are usually provided to the patient prior to filling the first prescription, so this gap would not be included in and would not impact the accuracy of the measure. The

beginning date of the measure does not start until the first prescription is filled by the patient and submitted for payment to the health plan.

- Paying cash for prescriptions through discount (e.g., $4) generic programs is another matter. Health plans have made efforts to decrease the number of cash paid prescriptions by using lower co-payments for generic medications and through value-based insurance designs to lower costs for essential drugs to eliminate the cost barrier to medication adherence to encourage the patient to use the prescription drug plan benefit. This strategy is in part driven by the need to capture prescription claims data for inclusion in the adherence measure as well as for patient safety (Drug Utilization Review, or DUR) programs. None-the-less, we recognize this as a small factor affecting overall compliance measurement. Importantly though, it is not a factor isolated to one particular geography or insurance design, so would not be expected to significantly impact plan measurements differentially.
- The measure is based on days' supply rather than quantity of the prescription. If a physician is asking the patient to split a tablet, the days' supply will account for the time the patient has medication available to them, and so does not impact the adherence measure.
- No measure is perfect; there are always trade offs that have to be made in measure construction. Use of the PDC measure has been effective in raising the awareness of the importance of medication adherence, has demonstrated that plans can improve their performance by increasing adherence of their members to chronic medications, and most importantly is associated with better patient outcomes.

Proposed Committee Response: Thank you for your comment; the Committee was satisfied with the developer's response.

0555 INR Monitoring for Individuals on Warfarin

One comment was received on this measure stating that INR monitoring for individuals on warfarin is linked to the desired outcome of increased time in therapeutic range. Therefore, it was suggested that the interval time for monitoring be extended from 56 to 90 days to allow more flexibility for patients whose testing threshold extends further than two months.

Developer Response: We appreciate your comment. This issue was discussed extensively by both our Technical Expert Panel and the NQF Steering Committee and the decision was made to use a 56-day interval. We provided a briefing document to the steering committee on this topic which provided detailed rationale for selection of the 56 day interval. In essence, the best available 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. Finally, very limited uptake of a 90 day interval in practice was noted by clinical experts. Overall, the 56 day interval provided the best balance of ensuring patient safety and increased flexibility from the prior specification of a 40 day interval.

Proposed Committee Response: Thank you for your comment; the Committee discussed this issue during its deliberations, and was satisfied with the developer's response.

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

Comments about this measure included recommendations for more consistency and clarity when describing measure specifications. One commenter requested that NQF and measure developers be more consistent when describing measures, numerators, denominators, and exclusions since the target ages in this measure are unclear. Another commenter raised concerns about this measure leading to unnecessary testing further burdening the health care system with unavoidable costs.

Developer Response: N/A

Proposed Committee Response: Thank you for your comment.

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

Comments on this measure were generally supportive of the Committee's decision to recommend it for endorsement. Supportive comments agreed that this measure is highly important given the volume of admissions into long term care facilities such as nursing homes and skilled nursing facilities. Another commenter suggested that sufficient evidence to support the measure exists, and that the Committee should not be concerned about this issue.

Action Item: N/A

Developer Response: The Centers for Medicare & Medicaid Services (CMS) appreciates this comment.

As the commenter states, the more recent literature continues to support the evidence presented in the Measure Submission Form. This literature, including those articles cited by the commenter (Genao 2012, CDC 2012) as well as Dwyer et al. (2013), supports the importance of this measure, particularly in terms of disease burden associated with urinary tract infections in long-term care residents. In addition, UTI was identified by a panel of experts as sensitive to nursing services (Estabrooks et al., 2013). Walsh and colleagues (2012) identified UTI as one of five conditions (including pneumonia, congestive heart failure, dehydration and chronic obstructive pulmonary disease/asthma) responsible for 78% of potentially avoidable hospitalizations among dually eligible Medicare and Medicaid beneficiaries from nursing facility and Home- and Community-Based Service waiver programs.

CMS acknowledges that some references cited in the measure submission are older, but notes that the evidence presented in support of UTI measure importance includes the most up-to-date, evidence-based US guidelines available at the time of measure submission to NQF. In addition, various older articles regarding infection in long-term care settings are seminal papers that are still important to the field and are cited in recent papers.

Unfortunately, the 2014 update to the 2008 Infectious Diseases Society of America and Society for Healthcare Epidemiology of America guidelines for prevention of CAUTI was not published in time for inclusion in the current submission of NQF #0684 for endorsement review. At the earliest opportunity, the referenced guidelines will be

updated to reflect the updated CAUTI guidelines and any other new long-term care guidelines that may have become available.

Proposed Committee Response: Thank you for your comments.

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.

Developer Response: N/A

Proposed Committee Response: Thank you for your comments. 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.

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.

Developer Response: N/A

Proposed Committee Response: Thank you for your comments.

2337 Antipsychotic Use in Children Under 5 Years Old

Although comments received on this measure were supportive of NQF's decision to recommend it for endorsement, some concerns about the evidence were raised. One commenter noted that there were limited circumstances in which the use of antipsychotics would be appropriate and suggested that the measure exclusions be further articulated in the specifications. Another commenter agreed that this was an important area of care that deserved attention but questioned the strength of the available evidence. The commenter also agreed that with the committee that the circumstance dictates whether prescribing an antipsychotic to a child five and under might be appropriate and should not be reflected negatively on the clinician. Finally,

a third comment expressed concern about the overuse of antipsychotic medication in children under five particularly for those in Medicaid and foster programs.

Developer Response: N/A

Proposed Committee Response: Thank you for your comments.

2371 Annual Monitoring for Patients on Persistent Medications

One comment was received expressing concerns about the variations in prescribing medications to patients resulting in inconsistent claims data. Another comment stating that monitoring requires testing for therapeutic levels not just documentation of a prescription being filled.

Developer Response: See developer responses to individual comments in the comment tableType equation here..

Proposed Committee Response: Thank you for your comments.

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.

Developer Response: N/A

Proposed Committee Response: Thank you for your comments. 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.

Comments on General Draft Report

On the whole, comments on the general draft report were supportive of the Committee's recommendations. One commenter suggested that there is a need for measures of organizational safety culture.

Developer Response: N/A

Proposed Committee Response: Thank you for your comment. The Committee agrees that safety culture is an important measurement gap, and will include this in its recommendations for future measure development.