NATIONAL QUALITY FORUM

Memo

September 11, 2019

To: Patient Safety Standing Committee

From: NQF staff

Re: Post-comment web meeting to discuss public comments received and NQF member expression of support

Purpose of the Call

The Patient Safety Standing Committee will meet via web meeting on September 18, 2019 from 1:00 pmto 3:00 pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period for the spring 2019 review cycle;
- Provide input on proposed responses to the post-evaluation comments;
- Revote on the validity criterion and overall suitability for endorsement for measure 0138 for which consensus was not reached; and
- Determine whether reconsideration of any measures or other courses of action are warranted.

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).
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:

- Standing Committee members, public participants, and NQF staff dial **800-768-2983** to access the audio platform.
- Access code: **2770682**
- Weblink: https://core.callinfo.com/callme/?ap=8007682983&ac=2770682&role=p&mode=ad

Background

Measures in the Patient Safety portfolio target various patient safety events and practices across healthcare settings. In this review cycle, measures span several types of healthcare settings and are connected to important areas in patient safety, including hospital-acquired infections, mortality following hospitalization, nurses' practice environment, antibiotic use, and electronic clinical quality measures (eCQMs) that measure harmful events within hospitals.

The 23-person Patient Safety Standing Committee reviewed 11 measures. Nine were recommended for endorsement; one was not recommended for endorsement; and the Committee did not reach consensus on one measure.

Recommended:

- 0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (Centers for Disease Control and Prevention)
- 0204 Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract) (American Nurses Association)
- 0205 Nursing Hours per Patient Day (American Nurses Association)
- 2720 National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (Centers for Disease Control and Prevention)
- 2726 Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections (American Society of Anesthesiologists)
- 3498e Hospital Harm – Pressure Injury (CMS/IMPAQ International)
- 3502 Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (CMS/Yale-CORE)
- 3503e Hospital Harm – Severe Hypoglycemia (CMS/IMPAQ International)
- 3504 Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (CMS/Yale-CORE)

Not Recommended:

- 3501e Hospital Harm – Opioid-Related Adverse Events (CMS/IMPAQ International)

Consensus Not Reached:

- 0138 National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (Centers for Disease Control and Prevention)

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 during a 16-week comment period via an online tool on the project webpage.

Pre-evaluation Comments

NQF solicits comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period opened on April 24, 2019 for the measures under review. The majority of the comments received (31 comments) requested that the Committee carefully examine the risks and benefits related to measure 0138, particularly for persons with spinal cord injury. Two commenters for measure 3498e had concerns related to the 24-hour timeframe from admission to declare a hospital-acquired pressure injury, the reliability and validity, and a lack of clear guidance as to where pressure injury documentation will be extracted from in the electronic medical record. One commenter

was supportive of measure 3498e over the existing PSI 03 measure. All pre-evaluation comments were provided to the Committee prior to the measure evaluation meeting.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on July 26, 2019 for 30 calendar days. During this commenting period, NQF received 19 comments from 4 member organizations:

Member Council	# of Member Organizations Who Commented
Health Professional	1
Provider Organization	3

We have included all comments that we received in the comment table (excel spreadsheet) posted to the Committee SharePoint site. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and draft responses (including measure steward/developer responses) for the Committee's consideration. Please review this table in advance of the meeting and consider the individual comments received and the proposed responses to each.

In order to facilitate discussion, post-evaluation comments have been categorized measure by measure. Although all comments are subject to discussion, the intent is not to discuss each individual comment on September 18 post-comment call. Instead, we will spend the majority of the time considering the key points emphasized by commenters and, specifically, examining comments for the measure on which consensus was not reached (0138). Please note that the organization of the comments into major topic areas is not an attempt to limit Committee discussion.

Comments and their Disposition

Measure-Specific Comments

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

Eight comments were received regarding this measure from three commenters. One commenter was not supportive of the measure as currently specified, explaining in detail the measure's unintended adverse consequences for patients with spinal cord injury (with references included for various points) and suggesting specific key topics that should be re-examined and resolved. Another commenter shared that individual clinicians may attempt to reduce urinary catheter use in patients who require continuous bladder drainage, but noted that this represents a small patient subpopulation and should not warrant removal of endorsement. Another comment expressed concern that the validity testing is aggregated at the state level rather than for each facility and that results are not presented for each data element.

Measure Steward/Developer Response:

NHSN's surveillance protocol and reporting guidance for the system's users and NHSN's clinical quality measures do not recommend or call for preferential use of specific clinical practices or procedures. The protocol, guidance, and measures are designed for

purposes of tracking, summarizing, and responding to adverse events that are associated with use of specific practices or procedures or exposures to other healthcare risks. Because spinal cord injured patients are at high risk for catheter-associated urinary tract infections (CAUTIs), these patients are included in NHSN's CAUTI surveillance protocol, reporting guidance and clinical quality measure. To exclude this patient population without compelling evidence of unintended adverse consequences attributable to including them would preclude the availability of surveillance and measure data for prevention and quality improvement purposes. NHSN readily acknowledges that clinical quality measures can have unintended consequences and is prepared to respond accordingly, including excluding affected patient populations, if there are compelling reasons to do so. Anecdotal reports of unintended consequences of the CAUTI measure on bladder management of spinal cord injured patients fall short of actionable data. A systematic study confirming the purported unintended adverse consequence of the CAUTI measure has yet to be reported—perhaps not yet initiated despite NHSN's recommendations to design and complete such a study. NHSN remains committed to surveillance and measurement of adverse events in healthcare and providing comprehensive, high caliber data for measurement purposes and to guide prevention and quality improvement.

Reliability testing of critical data elements is performed by many of the state health departments that have implemented mandatory reporting of CAUTI data to the state using NHSN as the data entry system and the source of case definitions and surveillance methodology. NHSN provides a guidance toolkit that suggests the selection methodology of a sample of facilities and medical charts to determine the accuracy of data elements. The recommended sample sizes are developed with a priori assumptions of expected accuracy and prevalence of CAUTI events. The state health departments using the NHSN guidance methodology conduct external validations. Data validations are conducted at each facility and facility specific data accuracy estimates are provided to each facility by the respective state health departments. These data are shared with NHSN on an aggregate level for estimation of state specific accuracy of reporting.

NHSN has confidence that the sampling methodology as described is adequate for purposes of rendering estimates of accuracy and meets the NQF criteria for data element validity. Testing for this measure has satisfactorily been through the rigor of NQF Methods Panel and was passed. If the commenter continues to have concerns about validity testing for this measure, we would be willing to talk further with the commenter about this concern.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

Action Item:

After discussion, the Committee must revote on the validity criterion. If the measure passes validity, the Committee will vote on overall suitability for endorsement.

0139 National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure

One commenter expressed the same concern about the validity testing for this measure as explained above for measure 0138. The commenter is concerned that the validity testing is aggregated at the state level rather than for each facility and that results are not presented for each data element. Accordingly, the developer's response is essentially the same.

Measure Steward/Developer Response:

Reliability testing of critical data elements is performed by many of the state health departments that have implemented mandatory reporting of CLABSI data to the state using NHSN as the data entry system and the source of case definitions and surveillance methodology. NHSN provides a guidance toolkit that suggests the selection methodology of a sample of facilities and medical charts to determine the accuracy of data elements. The recommended sample sizes are developed with a priori assumptions of expected accuracy and prevalence of CLABSI events. The state health departments using the NHSN guidance methodology conduct external validations. Data validations are conducted at each facility and facility specific data accuracy estimates are provided to each facility by the respective state health departments. These data are shared with NHSN on an aggregate level for estimation of state specific accuracy of reporting.

NHSN has confidence that the sampling methodology as described is adequate for purposes of rendering estimates of accuracy and meets the NQF criteria for data element validity. Testing for this measure has satisfactorily gone through the rigor of NQF Methods Panel and was passed. If the commenter continues to have concerns about validity testing for this measure, we would be willing to talk further with the commenter about this concern.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

2720 National Healthcare Safety Network (NHSN) Antimicrobial Use Measure

Two commenters highlight areas of concern regarding the measure. One commenter suggested that risk adjustment or stratification of institutions by additional attributes may help improve measure utility and noted persistent low levels of reporting and the complexity of reporting to the NHSN AU module. The commenter also highlighted that it is problematic that small hospitals, least likely to have an antibiotic stewardship program, are inadequately represented in the measure as they lack infrastructure to report. Another commenter stated that since the measure is not appropriate for accountability purposes at this time, they do not feel the measure should maintain endorsement.

Measure Steward/Developer Response:

The standardized antimicrobial administration ratio (SAAR) is the statistical centerpiece of the NHSN Antimicrobial Use measure that was endorsed by NQF in December 2015 and that is under review for re-endorsement. In the time period since the measure was initially endorsed, the number of hospitals participating in NHSN's antimicrobial use (AU) surveillance has increased seven-fold, to over 1400 hospitals. These hospitals

submit AU data to NHSN and use NHSN's analytic features to benchmark their AU performance. The SAAR is the statistical measure by which hospitals can benchmark their performance to all hospitals participating in NHSN's AU surveillance. While the commenter reports that there is "still controversy about how to conduct inter-institutional comparisons" with the SAAR metric, CDC is pleased to report that hundreds of hospitals are using SAAR data to make valid comparisons, enabling those hospitals to identify opportunities to improve antimicrobial prescribing. Further, NHSN has worked to improve the SAAR predictive models in the AU measure proposal submitted for re-endorsement consideration, and these improvements include taking additional predictive factors into account such as average length of stay and percentage of beds that are in an ICU. The commenter expresses concerns about "persistent low levels of reporting" of AU data to NHSN, a concern that is corrected and mitigated by substantial and steady increases in hospital participation in NHSN's AU surveillance. To address the commenter's concern about poor representation in the NHSN AU data for hospitals less than 200 beds, the median (and interquartile range) among hospitals reporting AU data from adult patient care locations in 2017 was 176 (86, 307). The commenter also expresses concerns about the complexity and costs of that participation, which again overlooks the fact that participation is rapidly increasing and is all voluntary. No state or federal mandates have required hospitals to submit AU data to NHSN. If complexity and costs are prohibitive, why do hospitals continue to join? The commenter observes that "automated platforms" may eventually augment AU reporting to NHSN, an observation that overlooks the fact that all AU reporting to NHSN is automated. There is no manual data entry. Despite the commenter's concerns, we are pleased that the commenter supports the NHSN AU module "as written." NHSN also agrees that the AU measure submitted to NQF for re-endorsement consideration should not be used for public reporting and reimbursement purposes. That said, NHSN supports use of the measure for non-publicly reported comparisons of antibiotic use between facilities, and NHSN looks forward to further work with hospitals throughout the U.S. that are using the measure for precisely that purpose.

NHSN serves as a national data aggregating system for AU and engages with multiple antimicrobial stewardship programs that use of AU data for stewardship purposes on a voluntary basis. The continuing growth in AU reporting to NHSN —a greater than five-fold increase in hospital participation since NQF initially endorsed the NHSN AU measure —is indicative of the measure's value even without an external accountability application. As a result of this increased participation in AU reporting, much more AU data was available for NHSN to develop AU predictive models used in this measure proposal than were used in the initial proposal. Additional data, e.g., extent of infectious disease burden and indications for antimicrobial prophylaxis, are candidates for additions to NHSN's AU predictive models. NHSN is working to identify or develop sources for these additional data, and will apply this work and work products in the next iteration of its AU predictive models.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

3498e Hospital Harm – Pressure Injury

Two commenters supported the measure's intent, but suggested additional work is needed before endorsement. One commenter referenced the Measure Application Partnership's (MAP) discussions around the need to consider additional exclusions. The commenter also expressed concern regarding the ability to capture pressure injury staging in the electronic health record (EHR) and was not convinced there are meaningful differences in performance scores. Another commenter also was concerned about the lack of standardization around pressure injury documentation. Also referenced was the need for consistency around who determines staging and the length of time for considering an injury hospital-acquired.

Measure Steward/Developer Responses:

Thank you for your comment. We understand that the MAP has expressed broad support for the measure and agreed that the measure can reduce patient harm caused by pressure injury. As the commenter pointed out, the MAP has also suggested that the measure may need to exclude certain types of patients. MAP's suggestion was taken into account during measure testing. Based on the evidence gathered during testing and from expert input, the measure does not exclude patients with certain conditions from the denominator. Evidence suggests most newly acquired pressure injuries can be prevented through best practices that are customized to the patient's risk. The most common causes of pressure injuries (limited mobility during acute illness, friction against skin) put all hospitalized patients at similar risk [1][2]. Overall, this measure aims to be as inclusive as possible to ensure the most impact on the safety of all patients.

The information required for this eCQM is collected during routine patient assessment in accordance with national clinical guidelines. During measure development and testing, we noted that the eCQM requirement for documentation in discrete fields resulted in a need to adjust clinical workflow in some hospitals, but this was offset by the benefit of capturing accurate information from which to drive quality improvement efforts. Documentation is an important component of the quality signal as hospitals cannot measure what is not documented.

We note that measure testing was done in compliance with NQF requirements for eCQM development, including NQF's recommendation to conduct eCQM testing in more than one EHR system. The empirical results demonstrated that the measure exhibited high reliability and data element validity.

Lastly, we understand the commenter's concern about the measure's performance rates. We, however, note that the wide variation of rates across hospitals indicates that there is ample room for improvement with this serious harm event.

[1] Gunningberg, L., Donaldson, N., Aydin, C., Idvall, E. (2011). Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action. 18. 10.1111/j.1365-2753.2011.01702.x. Journal of evaluation in clinical practice, 904-910.

[2] Berlowitz, D., VanDeusen Lukas, C., Parker, V., Niederhauser, A., Silver, J., Logan, C., Ayello, E., Zulkowski, K. (2012). Preventing Pressure Ulcers in Hospitals-A Toolkit for Improving Quality of Care.

Thank you for your comment. We understand that clinician variability in documenting stages of pressure injuries can present challenges. We clarify that the measure numerator includes all new hospital-acquired pressure injuries stage 2-4, unstageable pressure injuries, and deep tissue pressure injuries. The measure, as specified, does not discriminate by stage and does not penalize hospitals based on variability in clinician staging of pressure injuries.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

3501e Hospital Harm – Opioid-Related Adverse Events

Two comments were received for this measure. One commenter agreed with the Committee's decision not to recommend this measure for endorsement citing the lack of score variation to support a performance gap and the potential for the measure to misrepresent hospital performance. Another commenter offered recommendations: clarify the measure rate is not expected to be zero, exclude patients with cancer or palliative care, and also exclude patients for which naloxone is administered for suspected overdose but later found to be unrelated to opioid harm.

Measure Steward/Developer Responses:

Thank you for your comment. The measure steward will consider what changes, if any, should be incorporated into this important measure for future use. We, however, note that testing results showed statistically significant variation in performance rates across the hospitals tested. The wide variation suggests there exists ample room for improvement on this harm event.

Thank you for your comment. The intent of this measure is not to reduce clinically appropriate use of naloxone nor to bring the measure rate to zero, but to identify if hospitals have particularly high rates of naloxone use as an indicator of high rates of over-administration of opioids in the inpatient setting, thereby incentivizing improved clinical practices. Proper dosing of opioids and monitoring of patients on opioids can reduce the need for naloxone use in patient care. We thank the commenter's suggestion for the potential refinement specific to the exclusion criteria. We will take this suggestion under consideration as we review consider what changes, if any, should be incorporated into this important measure for future use.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

3502 Hybrid Hospital-wide (All-Condition, All-Procedure) Risk-standardized Mortality Measure and 3504: Claims-only Hospital-wide (All-Condition, All-Procedure) Risk-standardized Mortality Measure

Two similar comments pertaining to both measure 3502 and measure 3504 were received from one commenter. The commenter expressed detailed concerns regarding various aspects of these measures. The commenter stated there is a lack of evidence to support the measure's focus, a lack of convincing validity testing, inadequate support for the risk-adjustment approach, and limited usefulness of results for quality improvement and accountability purposes.

Measure Steward/Developer Response:

We appreciate your comments and have addressed each of your concerns below, separately.

Death within 30 days as a hospital quality measure

The claims-only and hybrid Hospital-Wide Mortality (HWM) measures include deaths that occur within 30-days of hospital admission. This is consistent with CMS's condition- and procedure-specific mortality measures currently reported on Hospital Compare. The 30-day time frame is also supported by the input we have received from clinical experts, empirical analyses performed during the development of this measure, and the published literature.

From a clinical perspective, adverse events that occur within the immediate post-discharge timeframe are often attributable to the hospital stay. For example, a patient released from the hospital may experience dizziness while driving, from medication or anesthesia administered during the hospital stay, and experience a fatal car accident. Also, adverse events that occur 30 days post-discharge can be attributed to the hospital. For example, a patient given a diuretic at discharge may become dehydrated, leading to kidney failure and death. However, input we received from clinical experts suggested deaths beyond 30 days are seldom attributed to care received during the hospitalization and are more commonly attributed to underlying health or care received in other settings.

From an empirical data analysis perspective, during measure development we reviewed survival curves (for Medicare beneficiaries 65 years and older) up to 90 days following admission to evaluate the appropriateness of the 30-day time frame across the HWM cohort. We found that 30 days post-admission included the largest declines in mortality and therefore, was the most appropriate time frame to capture most post-hospitalization deaths.

The published literature indicates that existing condition- specific, 30-day mortality measures support targeted quality improvement work, and may have contributed to national declines in hospital mortality rates for measures conditions and/or procedures. Studies have shown that, for selected conditions and diagnoses, mortality within 30 days of hospital admission is related to quality of care and variable mortality rates across hospitals indicate opportunities for improvement.

Finally, we examined the published literature and found that older adults are more vulnerable to adverse health outcomes within 30 days of a hospital admission and that mortality can be influenced by hospital care and the early transition to the outpatient setting during this time. Based on the evidence discussed above, a 30-day measurement period is the most appropriate period to measure mortality in a hospital setting.

Validity testing

The measures' NQF submissions meet NQF's criteria for validity testing. In terms of face validity, five of six Technical Expert Panel (TEP) member respondents somewhat, moderately, or strongly agreed with the statement that the HWM measures as specified can be used to distinguish good from poor quality. NQF does not specify the number of experts that are required to assess the measures' validity.

New measures are only required to submit evidence for face validity, however we also provided empiric validity with this initial endorsement submission. We chose three quality measures (nurse to bed ratio, Overall Hospital Quality Star Ratings mortality measure group score, and Overall Hospital Quality Star Ratings), as comparator measures, and demonstrated a relationship with the HWM measure scores in the expected direction for each comparator measure. We did not evaluate CMS's Hospital-Wide Readmission (HWR) measure score as a comparator because such testing is not a requirement of NQF's consensus development process. We agree that once implemented, it is important to examine trends in complementary measures and expect to do so as part of endorsement maintenance, should this measure be endorsed. Examination of correlation in measures scores after implementation are an important feature of surveillance for unintended consequences and should be part of rigorous measure maintenance.

Identification and testing of social risk factors as supplementary to clinical risk factors

We agree that, in the risk-adjusted outcome measures, CMS first considers adjustment for clinical conditions and then examines additional risk imparted by social risk factors after the potential for greater disease burden is included in the risk model. We believe that this is consistent with NQF current guidance and is appropriate given the evidence cited in our submission that people who experience greater social risk are more likely to have more disease burden compared with those who do not; and that this is clearly not a signal of hospital quality. In addition, according to NQF guidance, developers should assess social risk factors for their contribution of unique variation in the outcome – that they are not redundant. Therefore, if clinical risk factors explain all or most of the patient variation in the outcome, then NQF guidance does not support adding social risk factors that do not account for variation.

An extensive set of analyses of the impact of including social risk variables in the risk adjustment model was included as part of the NQF application submitted for these measures' endorsements. For example, one analysis examined the strength and significance of the SES variables in the context of a bivariate model compared with a

multivariable model. When these variables were included in a multivariate model that includes all the claims-based clinical variables, the odds ratios for both the dual eligible and AHRQ SES variables in the multivariate model are almost always lower than the odds ratio for the bivariate association. This indicates that the comorbid risk variables that are already in the model (in the multivariate view) are capturing the risk associated with the outcome seen in the bivariate analysis (with the social risk factor alone), and the dual eligible variable in a multivariate model would not play a significant role in the model (the coefficients/odds ratios are not different from 1). Additional analyses provided in the application also showed that correlation coefficients of measure scores comparing models with and without the social risk variables are near 1.0 and that C-statistics with the social risk variables in vs. out of the model, are unchanged.

Usefulness of the measures; variation in the measure score

Mortality is an important health outcome that is meaningful to patients and providers, and updated estimates suggest that more than 400,000 patients die each year from preventable harm in hospitals. The existing condition- and procedure-specific mortality measures have a narrow focus, only capturing specific patient populations, while the HWM measures capture most Medicare FFS beneficiaries.

The hospital-level variation in performance on the measure score for the claims-only HWM measure between the lowest-performing hospitals (risk-standardized mortality rate or RSMR of 3.95%) and the highest performing hospitals (RSMR of 8.7%) shows there is a clear quality gap. In terms of performance compared to the median (6.93%), some hospitals can achieve substantially lower overall risk-standardized mortality rates than the average-performing hospital, while other hospitals are performing substantially worse than an average performer. Specifically, the best performing hospital (RSMR of 3.95%) is performing 43% better than an average performer, while the worst performing hospital (RSMR of 8.70%) is performing 25% worse than an average performer. (Note that the average performer refers to hospital with the same case and service-line mix, performing at the average [median]).

In terms of outliers, in the updated ICD-10 version of the measure (which was submitted to NQF), using 95% confidence interval (uncertainty) estimates to categorize hospital outliers, there were 14 hospitals with performance that was statically significantly worse than the national average, and 103 hospitals with performance that was statistically significantly better than the national average. In total, this measure identified 2.6% of hospitals as outliers, which is consistent with other CMS condition- and procedure-specific measures that display a range of 2.5% - 11.2% of hospitals as outliers. However, using 95% confidence interval (uncertainty) estimates to categorize hospital outliers is conservative by design. The distribution and mortality rates themselves (cited in the paragraph above), however, do convey meaningful variation. This variation provides a quality signal and we believe reporting hospital mortality scores will improve transparency and promote quality improvement.

The HWM measures were also designed to support quality improvement efforts. By providing a hospital-wide quality score, as well as division-level results, the measures

give hospitals an overall evaluation of a hospital's performance on an important outcome and provides actionable information for quality improvement. Should CMS include the HWM measures in public reporting, consistent with other measures, hospitals would receive confidential, patient-level data for quality improvement, allowing for thorough investigation of patient scenarios that resulted in mortality. In addition, similar to CMS's HWR measure, confidential data and mortality results may be provided to all hospitals for each of the service-line divisions, allowing hospitals to identify service lines with greater mortality and target them for improvement.

Hospital-wide measures provide patients and consumers with an overall outcome score (in this case, mortality) for most acute care hospitals in the nation, including smaller, low volume hospitals without enough cases to publicly report scores for the condition- and procedure-specific measures.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

3503e Hospital Harm – Severe Hypoglycemia

Two comments were received for this measure. One commenter did not support the measure because it provides no clear guidance on the medications to be monitored or the types of glucose tests that would apply. Another commenter supported the measure's intent, but suggested additional work is needed before endorsement. The commenter highlighted MAP conversations around the need for a balancing measure to account for unintended consequences, expressed that additional feasibility and validity testing is needed, and stated that differences in scores may be minimal.

Measure Steward/Developer Responses:

Thank you for your comment. This measure assesses the use of specific antihyperglycemic medications documented in the National Library of Medicine (NLM) Value Set Authority Center (VSAC) that can cause severe hypoglycemia. This measure considers both point-of-care test results and laboratory test results, which are also documented in the NLM VSAC.

Thank you for your comment. We recognize the importance of measuring hyperglycemia as a balancing measure in conjunction with hypoglycemia. We have submitted a balancing hyperglycemia measure to the NQF Patient Safety Standing Committee for the fall 2019 cycle, as well as the 2019-2020 Measures Under Consideration (MUC) list. We agree with the importance of continually monitoring for unintended consequences, and we intend to consider these comments when implementing these measures in the future.

We understand the value of sample size in measure testing and note that measure testing was done in compliance with NQF requirements for eCQM development. This measure was tested in two EHR systems that had good representation of hospitals across the country. This aligns with NQF's recommendation to conduct eCQM testing in

more than one EHR system. The empirical results demonstrated that the measure exhibited high reliability and data element validity.

We also note that testing results demonstrated statistically significant variation in performance rates across the hospitals tested. This wide variation indicates that there exists ample room for improvement on this harm event.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on September 18, 2019.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for each measure submitted for endorsement consideration to inform the Committee's recommendations. Three NQF members provided their expressions of support/nonsupport: See Appendix A.

Appendix A: NQF Member Expression of Support Results

Three NQF members provided their expressions of support/nonsupport. One of the eleven measures under consideration received support, while eight measures received an expression of "do not support." Results for each measure are provided below.

0138: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (Centers for Disease Control and Prevention)

Member Council	Support	Do Not Support	Total
Health Professional	1	1	2
Provider Organization	0	1	1

0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (Centers for Disease Control and Prevention)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

2720 National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (Centers for Disease Control and Prevention)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

3498e Hospital Harm – Pressure Injury (CMS/IMPAQ International)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

3501e Hospital Harm – Opioid-Related Adverse Events (CMS/IMPAQ International)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

3502 Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (CMS/Yale-CORE)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

3503e Hospital Harm – Severe Hypoglycemia (CMS/IMPAQ International)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

3504 Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (CMS/Yale-CORE)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1