NATIONAL QUALITY FORUM
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Meeting Summary

Patient Safety Standing Committee – Spring 2021 Post-Comment Web Meeting

The National Quality Forum (NQF) held a web meeting for the Patient Safety Standing Committee on October 13, 2021, from 2:00-5:00 PM ET.

Welcome, Review of Meeting Objectives and Attendance

Tamara Funk, NQF director, opened the meeting and welcomed the Standing Committee to the web meeting. Standing Committee Co-Chairs Dr. Ed Septimus and Dr. Iona Thraen also provided welcome messages. Erin Buchanan, NQF manager, conducted the Standing Committee roll call. Ms. Funk then provided an overview of the objectives:

- Re-vote on the Consensus Not Reached (CNR) measure
- Review and discuss comments received during the post-evaluation public and member commenting period
- Provide input on proposed responses to the post-evaluation comments
- Review and discuss NQF members' expression of support of the measures under consideration
- Determine whether the reconsideration of any measures or other courses of action are warranted

Ms. Buchanan noted that during this review cycle, the Patient Safety Standing Committee reviewed six measures during the measure evaluation meeting on February 10, 2021. The Standing Committee recommended five measures for endorsement but did not reach consensus on the remaining measure. Eighteen Standing Committee members were present for the discussion, allowing the Standing Committee to re-vote on the CNR measure.

Re-vote on Consensus Not Reached Measures and Discussion of Public Comments

Ms. Funk provided an overview of the process for discussing and re-voting on the CNR measure. NQF staff clarified for the Standing Committee that during the post-comment measure review, more than 60 percent of the Standing Committee's votes must be passing; otherwise, the measure does not pass. During the meeting, the Patient Safety Standing Committee voted on the CNR measure from the spring 2021 measure evaluation meeting.

Rating Scale: H – High; M – Medium; L – Low; I – Insufficient; NA – Not Applicable

NQF #3501e Hospital Harm - Opioid-Related Adverse Events (IMPAQ International, LLC)

Measure Steward/Developer Representatives at the Meeting

Kendall Hall, MD, IMPAQ International; Anna Michie, IMPAQ International; Bo Feng, IMPAQ International

Standing Committee Votes

- **Performance Gap**: H-3; M-13; L-1; I-1 (Pass – 16/18)

Standing Committee Recommendation for Endorsement: Yes-15; No-3 (Yes - 15/18)

Ms. Funk began the discussion by introducing the first measure: NQF #3501e, *Hospital Harm – Opioid-Related Adverse Events*. During the spring 2021 meeting, the Standing Committee did not reach consensus on the performance gap criterion. NQF #3501e assesses the proportion of inpatient hospital encounters in which patients 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (i.e., naloxone) within 12 hours. The measure excludes opioid antagonist (naloxone) administration that occurs in the operating room setting.

Ms. Funk reminded the Standing Committee that during the original measure discussion, the Standing Committee had noted that this measure was tested at six hospitals with a range in performance of 0.11 to 0.45 percent. The Standing Committee had voiced concerns regarding the very small number of times this event occurred as a proportion of hospital encounters, and a low absolute number of events. Ms. Buchanan then described the public comments that were received for the measure. These comments expressed concerns about the unintended consequences of the measure as well as the performance gap. The developer then clarified that among the public comments, several agreed that the measure did meet NQF's performance gap criteria. The developer proceeded to emphasize two points: First, testing data showed a four-fold difference, which does represent a large gap in performance; second, since the spring 2021 discussion, data had been gathered from 13 additional hospitals. Data from these hospitals demonstrated an even larger performance gap, varying from 0.11 to 0.61 percent, which is a six-fold difference. Lastly, in terms of the total number of harms, these numbers are actually not low. An extrapolation exercise was performed, and it estimated that greater than 60,000 patients per year in the United States (U.S.) likely experience such an event. The Standing Committee did not have any further discussion following the discussion of this comment.

Ms. Funk reminded the Standing Committee about the criteria for performance gap, and they re-voted. The Standing Committee passed the measure on performance gap with the above vote totals. Next, the Standing Committee was asked to give further opinions on the measure's overall suitability for endorsement. The Standing Committee did not provide any further comments or discussion and voted to recommend the measure for endorsement with the vote totals noted above.

Related and Competing Measures Discussion

The Standing Committee discussed two related measures to NQF #3501e discussed by the Standing Committee: NQF #3316 *Safe Use of Current Opioids – Concurrent Prescribing*, and NQF #3389 *Concurrent Use of Opioids and Benzodiazepines*. NQF #3316 measures the proportion of patients age 18 and older who were prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (i.e., inpatient or emergency department [ED], including observation stays). NQF #3389 focuses on the percentage of individuals greater than or equal to 18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year. Both of these measures were deemed to be related but not directly competing with NQF #3501e; the Standing Committee accepted the developer's rationale regarding the differences among the three measures, and how they had been harmonized. The Standing Committee did not have any further discussion.

Discussion of Public Comments for Additional Measures

NQF #3621 Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single (American College of Radiology)

Next the Standing Committee moved to NQF #3621 Composite weighted average for 3 CT Exam Types: Overall Percent of CT Exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single Phase Scan and CT Head/Brain Without Contrast/Single Phase Scan.

Ms. Buchanan summarized one comment that raised concerns about a physician's choice of protocol and its inclusion of only single-phase scans, not double phase scans. Concerns were also raised regarding the population denominator, as well as the lack of evidence to support that a higher-phase protocol provides better diagnostic utility. In response, the developer explained that single phase scans represent approximately 75 percent of overall scans. In addition, the developer described additional work that is in process to examine the indication for the exam; however, this information is limited due to the variation in how indications are reported, which sometimes occurs in non-standardized ways. A Standing Committee member asked whether examining multiple-phase scans would be considered in the future. In response, the developer stated that additional work needs to be done to examine the variation in the dose length product with those computed tomography scans (CTs). The Standing Committee did not provide any additional questions or comments.

NQF #0500 Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)

The Standing Committee then turned their attention to NQF #0500 *Severe Sepsis and Septic Shock: Management Bundle* (SEP-1). NQF #0500 focuses on adults 18 years of age and older with a diagnosis of severe sepsis or septic shock. It specifically assesses the processes of measuring lactate; obtaining blood cultures; administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, and reassessment of volume status and tissue perfusion; and repeating lactate measurement.

The Standing Committee was reminded ahead of the discussion that three of its members were recused from the discussion due to previously disclosed conflicts of interest. Several public comments were received from groups that expressed concerns about the measure, including the Infectious Diseases Society of America, American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and the Society of Infectious Disease Pharmacists. They raised issues regarding the burden of chart abstraction, considering that a considerable effort is involved in the reporting of this measure. Concerns were also raised regarding the potential for the unintended consequences of including both sepsis and septic shock in the measure due to differing evidence that supports the clinical actions required in NQF #0500. Additional concerns were raised regarding the quality of the evidence for including serial lactate measurements as part of sepsis care. Conversely, several groups provided supportive comments, including the Sepsis Alliance, the Alliance for Aging Research, Americare CSS and Americare Inc., Home Care Association of New York State, The Leapfrog Group, MoMMA's Voices Coalition, NTM Info & Research, Peggy Lillis Foundation, and the Society to Improve Diagnosis in Medicine. Dr. Thraen clarified that the concerns the specialty societies raised actually supported a sepsis measure and were focused on needed improvements to the measure, in contrast to being non-supportive. A Standing Committee member disagreed, stating that several of the comments were actually non supportive. The developer explained that the concerns of the specialty societies had been rebutted in their written responses, which were provided to the Standing Committee.

Another Standing Committee member commented that many of the organizations that care for septic patients have major concerns about the measure. In particular, this Standing Committee member stated that the degree of scientific rigor included in the measure is insufficient to warrant support from these clinician organizations, specifically that certain components of the measure meet NQF's criteria for evidence. It was also noted that during the Surviving Sepsis campaign's recent review of the evidence the evidence supporting many of these components was reported to be low-quality.[1]

In addition, concerns were raised about unintended harm to patients. A Standing Committee member brought forth another study that examined these unintended consequences and found that the onset of SEP-1 was associated with increased broad spectrum antibiotic use across 111 hospitals.[2] It was also mentioned that the measure may be out of step with current recommendations for a wait-and-see approach in some septic patients without giving antibiotics to patients who are not in septic shock in the current Surviving Sepsis guideline. The developer clarified that this matter was fully addressed in the comments provided to the Standing Committee; in addition, the measure is consistent with current sepsis care guidelines and has evolved along with the science. The developer further stated that NQF permits a moderate level of evidence in support of a measure, which includes evidence of three to four observational studies that control for confounding factors, which the developer sufficiently provided as part of the evidence within their submission.

Two additional concerns noted in comments addressed the burden of chart abstraction and the insufficiency of the evidence to support inclusion of serial lactates. The developer clarified that serial lactate measurement is the single most important predictor of outcomes in sepsis care. A Standing Committee member then asked what time zero is for sepsis, considering that patients can develop sepsis while in the hospital, and it may not be present on arrival. The developer clarified that the definition of time zero is currently provided in the measure specifications; in addition, if a more reliable time zero is identified, the developer clarified that it would be used in future versions of the measure.

A Standing Committee member stated that the developer and the specialty societies were interpreting the evidence in some fundamentally different ways. The developer clarified that differences are present in mortality between compliant (21 percent) and non-compliant SEP-1 (NQF #0500) (27 percent) patients. A Standing Committee member stated that this is not necessarily a causal relationship. Prolonged discourse took place between the Standing Committee and the measure developer in an attempt to determine whether the developer had adequately addressed the new evidence being discussed. Additionally, the Standing Committee was requested to more specifically address which new evidence and guidelines they determined the developer was failing to account for. A Standing Committee member then suggested that further discussion could continue in a different setting regarding this measure.

NQF staff reminded the Standing Committee that the measure was recommended for endorsement during the June measure evaluation meeting; however, the Standing Committee does have the option to reconsider a measure they have already passed. If the Standing Committee wanted to pursue this option, they would have to provide a clear rationale that new information is available that was previously unavailable at the time of the submission. If they presented this clear rationale, the Standing

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[1] Evans L, Rhodes A, Alhazzani W, et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021. Crit Care Med. 2021 Nov 1;49(11):e1063-e1143. doi: 10.1097/CCM.0000000000005337. PMID: 34605781.

[2] Pakyz AL, Orndahl CM, Johns A, Harless DW, Morgan DJ, Bearman G, Hohmann SF, Stevens MP. Impact of the Centers for Medicare and Medicaid Services Sepsis Core Measure on Antibiotic Use. Clin Infect Dis. 2021 Feb 16;72(4):556-565. doi: 10.1093/cid/ciaa456. PMID: 32827032.

Committee could then call for a vote to reconsider the measure. Another option available to the Standing Committee would be to use new information to propose an ad hoc review outside of a typical measure review cycle, especially if the unintended consequences related to a measure in current use can be shown. A Standing Committee member stated that new evidence was available, particularly the new Surviving Sepsis guidelines and other literature that had not been discussed during the spring 2021 meeting. The Standing Committee Co-Chair confirmed with the Standing Committee member that new information was made available since the time of the Standing Committee's review, including new guidelines as well as other evidence. The Standing Committee member requested that the Standing Committee vote to reconsider the measure in light of this new information.

Reconsideration Request

Following the discussion detailed above, a reconsideration vote was conducted for NQF #0500 based upon the rationale that new guidelines and evidence had been brought to the Standing Committee's attention that were previously unavailable at the time of the original discussion. The Standing Committee voted not to reconsider the measure, with six Standing Committee members voting "yes" to reconsideration (38 percent) and 10 voting "no" to reconsideration (62 percent).

NQF #3389 Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance)

The Standing Committee then discussed NQF #3389 *Concurrent Use of Opioids and Benzodiazepines*. This measure focuses on the percentage of individuals greater than or equal to 18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year. Five comments expressed support for the measure due to feasibility, evidence, and performance gap. The Standing Committee was not required to take any further action because all the comments expressed support for the Standing Committee's decisions.

NQF #0674 Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Next, the Standing Committee discussed NQF #0674 *Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay)*. NQF #0674 reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury reported in the look-back period no more than 275 days prior to the target assessment. No public comments were received; therefore, the Standing Committee was not required to take any further action.

NQF #0679: Percent of High-Risk Residents with Pressure Ulcers (Long Stay)

Lastly, the Standing Committee discussed NQF #0679 *Percent of High-Risk Residents With Pressure Ulcers (Long Stay)*, which assesses the percentage of long-stay, high-risk residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. No public comments were received; therefore, the Standing Committee was not required to take any further action.

Public Comment

NQF staff opened the meeting for public comment. No public comments were provided during this time.

Activities and Timelines

Ms. Buchanan reviewed the next steps. The Consensus Standards Approval Committee (CSAC) will consider the Standing Committee's endorsement recommendations during its meetings on November 30-December 1, 2021. Following the CSAC meeting, the 30-day Appeals period will be held from

December 7, 2021 to January 5, 2022.