

Patient Safety Fall 2022 Post-Comment Web Meeting

Battelle convened the Patient Safety committee for the Fall 2022 [post-comment web meeting](#) on Tuesday, June 13, 2023, from 10:00 AM – 1:00 PM ET.

Welcome, Review of Meeting Objectives, and Attendance

Dr. Matthew Pickering, endorsement and maintenance technical lead, welcomed the standing committee and provided an overview of the meeting's objectives:

- Review the [post-comment memo](#) and the [meeting summary](#) from the Fall 2022 measure evaluation meeting.
- Provide feedback and input on the full text of comments received and the proposed responses to the post-evaluation comments.
- Discuss and revote on one measure that did not achieve consensus, referred to as a “consensus not reached” (CNR) measure.

Some standing committee members were unable to attend the entire meeting due to early departures and late arrivals. Quorum (14 of 20 active members) was not maintained for the entirety of the meeting. Therefore, the committee discussed the public comments, the developer responses to those comments, the proposed committee response, and the CNR measure (CBE #3025). However, due to loss of quorum, the committee voted on the CNR measure offline. Voting results for the CNR measure are provided below.

Dr. Pickering reminded the committee that during the Fall 2022 cycle, the Patient Safety standing committee reviewed five measures during the measure evaluation meeting on February 9, 2023:

- CBE #3025 Ambulatory Breast Procedure Surgical Site Infection Outcome Measure (Centers for Disease Control and Prevention [CDC])
- CBE #3498e Hospital Harm-Pressure Injury (Centers for Medicare & Medicaid Services/American Institutes for Research [CMS/AIR])
- CBE #3686 CDC, National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure (CDC)
- CBE #3688 CDC, NHSN Healthcare Facility-Onset, Antibiotic-Treated Clostridiodes Difficile Infection Outcome Measure (CDC)
- CBE #3713e Hospital Harm-Acute Kidney Injury (CMS/AIR)

The standing committee recommended four out of the five measures for endorsement (CBE #3498e, CBE #3686, CBE #3688, and CBE #3713e). The committee did not reach consensus on performance gap, a must-pass criterion, for one measure (CBE #3025). The February 9 [meeting summary](#) was posted on the Partnership for Quality Measurement (PQM)TM website for public comment from March 28, 2023, to May 5, 2023. During this commenting period, the committee received six comments, of which three comments raised concern and/or disagreement with the measures and/or the committee's recommendations. The remaining three comments were in support of the measures and/or committee recommendations. The committee did not discuss these remaining three comments because they agreed with the committee's decision. The committee thanks all the commenters for their comments.

Consideration of the Consensus Not Reached Measure

Dr. Pickering reminded the standing committee that consensus was not reached on performance gap for CBE #3025, as the standing committee raised concerns regarding (1) the lack of updated data on performance gap, (2) the low unadjusted surgical site infection (SSI) rate, (3) variability among facilities with a standardized infection ratio (SIR), and (4) how facilities with low procedure volumes are handled, where the SIR calculation is limited. During the February 2023 measure evaluation meeting, the developer provided a verbal update from the past four years, which showed a consistent 0.26 percent unadjusted SSI rate. Additionally, those data showed variability among facilities with a standardized infection ratio (SIR) ranging from zero to 6.9. The developer also explained that the SIR is not calculated when the predicted number of infections is less than one and conceded that this is a limitation for facilities with small procedure numbers.

Dr. Pickering noted that two comments were received in support of the measure. One of the comments was from the developer, noting that Ambulatory Surgical Centers (ASCs) play an important role in the current health care delivery system and that outcome measures in the ASC space are lacking. CBE #3025 tracks patients to 90-days, which is important when considering that patients who undergo surgery at an ASC do not return to the ASC post-discharge for follow-up care. The developer further stated that in response to the coronavirus disease 2019 (COVID-19) pandemic, CMS recommended that non-essential (e.g., elective surgeries) procedures performed at these facilities, including breast procedures, be postponed to ensure patient and staff safety. Due to these recommendations, many ASCs limited the number of procedures they performed or temporarily closed their doors. Once ASCs were able to perform surgeries again, they were not able to take on abstraction of this measure because they focused on the backlog of elective surgery cases that were delayed due to COVID-19. As a result, the developer was unable to demonstrate a performance gap or an opportunity for improvement for this current measure endorsement cycle. The developer further cited evidence that breast surgeries are classified as clean procedures, however the SSI risk in breast surgery is higher than other clean surgical procedures with rates between 2-38%.

The second comment was from the ASC Quality Collaboration and the Colorado Department of Public Health. Both organizations collaborated with CDC in the testing of the measure in an ASC setting. The comment stated that the measure fills an important gap in the reporting of health care-associated infections occurring in the ASC setting, and that the volume of reporting has been low and has limited the accessibility of data for improving patient care.

Opening the discussion to the committee, some members questioned whether the COVID-19 public health emergency justified the lack of data demonstrating a performance gap. The developer responded, noting that ASCs faced limitations in redirecting their focus and allocating resources away from the public health emergency. The developer further noted its ongoing discussions with ASCs to expand the uptake of this measure and address its regulatory implications.

The committee noted that the measure is affected by the volume and frequency of certain surgeries, which are not indicative of a facility's performance. The committee also recognized that these surgeries are performed in outpatient settings where infections may not be adequately measured. A committee member argued that these infection measures are not always a reflection of the overall quality of the facility. Instead, the variation between individuals and the consistent application of infection prevention practices plays a significant role.

Regarding the limited SIR for some facilities, one committee member urged the committee to shift its focus from evaluating whether SIR is an effective way to determine the quality of surgical outcomes and prevent infections to whether this measure is suitable for assessing and providing actionable information for patients and health care facilities. In response, the developer assured the committee that when sufficient data are available, the measure can distinguish and identify facilities with higher infection rates.

During the meeting, the quorum required for voting was lost. Therefore, the standing committee voted after the meeting using an online voting tool. The committee voted to pass the measure on performance gap and overall suitability for endorsement.

- **Performance Gap:** Total Votes: 15; H-3; M-11; L-0; I-1 (14/15 – 93.3 percent, Pass)
- **Overall Suitability for Endorsement:** Total Votes: 15; Yes-15; No-0 (15/15 – 100 percent, Pass)

Review and Discuss Post-Evaluation Comments Received

Dr. Pickering presented the one post-evaluation public comment received for CBE #3713e. The commenter praised the measure for being a good outpatient measure since pain control is shifting to high dose use of nonsteroidal anti-inflammatory agents. However, the commenter questioned whether the measure should include some longitudinal criteria and suggested stratification by age, race, and ethnicity. The commenter also suggested a possible tie-in with dose and longevity of use with certain drugs. Dr. Pickering summarized the developer's response to the comment, which stated that (1) the proposed measure logic is based on longitudinal assessment of a patient's kidney function through their entire hospital stay for up to 30 days, (2) the measure has been developed as an inpatient measure for use in the Hospital Inpatient Quality Reporting program, and (3) the measure also incorporates race-neutral equations for estimating glomerular filtration rate, which allows users to stratify the measure by race or ethnicity, if desired.

Dr. Pickering summarized the proposed committee response, which thanked the commenter for submitting their comment. During the measure evaluation meeting on February 9, 2023, the Patient Safety standing committee considered the developer's risk-adjustment of patients with comorbidities, which it acknowledged is necessary to account for differences in the way hospitals and providers respond to each medical situation. The committee ultimately passed the measure on the validity criterion, which includes an assessment of risk-adjustment.

The committee did not have any concerns with the developer's response and did not have any disagreement with the proposed committee response.

Related and Competing Measures

Dr. Pickering briefly reviewed the related measures for CBE #3688 and shared that the developers noted that the measures had been harmonized to the extent possible. No competing measures were identified for this measure. The standing committee agreed that the measures were harmonized to the extent possible.

Opportunity for Public Comment

Dr. Pickering opened the web meeting to allow for public comment. No public comments were provided during this time.

Next Steps

Dr. Pickering informed attendees that the Consensus Standards Approval Committee (CSAC) will consider the standing committee's recommendations during its meetings on July 24, 2023. Following the CSAC meeting, the 30-day appeals period will be held from August 1-30, 2023. Dr. Pickering then thanked the committee, the co-chairs, the developers, and others on the call and adjourned the meeting.