Partnership for Quality Measurement
Powered by Battelle

Fall 2022 Cycle

Patient Safety Final Technical Report

October 2023

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Executive Summary

Patient safety is a broad and important aspect of health care that is fundamental for ensuring the highest quality of care. It emerged alongside increased complexity of the health care system, with the goal of preventing and reducing risk, errors, and harm.[1]Millions of people each year suffer from some form of patient harm. Reducing avoidable errors is of the utmost importance to improve patient outcomes.

Quality measures are necessary tools for assessing improvements in patient safety, as well as the extent to which health care stakeholders are using evidence-based strategies to advance the quality of care. To support this effort, Battelle endorses and maintains performance measures related to patient safety through a standardized, consensus-based process.

For this project's measure review cycle, six measures were submitted for endorsement consideration (Table 1). One measure submitted for initial endorsement (CBE #3732) was withdrawn from consideration by the developer. Of the remaining five measures reviewed by the Patient Safety standing committee, all were recommended for endorsement. The Consensus Standards Approval Committee (CSAC) upheld the committee's endorsement recommendations.

Effective March 27, 2023, the National Quality Forum (NQF) is no longer the consensus-based entity (CBE) funded through the Centers for Medicare & Medicaid Services (CMS) National Consensus Development and Strategic Planning for Health Care Quality Measurement Contract. Battelle has been selected to oversee the endorsement & maintenance (E&M) of clinical quality and cost/resource use measures. Since the Fall 2022 cycle launched at NQF, measures submitted for Fall 2022 E&M cycle continued along the prior E&M protocols that were in place at time of the Fall 2022 "Intent to Submit." In addition, the Scientific Methods Panel review and the committee's measure evaluation meeting for the Fall 2022 cycle were conducted under NQF. Battelle took over the E&M work beginning with the public comment period to close out the Fall 2022 cycle. This included launching the Fall 2022 post-comment period, convening the E&M committees for the post-comment meeting, convening the CSAC to render a final endorsement decision, and executing the Appeals period.

Table 1. Measures Submitted for Endorsement Consideration

Measure Number	Measure Title	New/ Maintenance	Developer/Steward	Final Endorsement Decision
3025	Ambulatory Breast Procedure Surgical Site Infection Outcome Measure	Maintenance	Centers for Disease Control and Prevention (CDC)	Endorsed

Measure Number	Measure Title	New/ Maintenance	Developer/Steward	Final Endorsement Decision
3686	CDC, National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure	New	CDC	Endorsed
3688	CDC, NHSN Healthcare Facility-Onset, Antibiotic-Treated Clostridiodes Difficile Infection Outcome Measure	New	CDC	Endorsed
3713e	Hospital Harm-Acute Kidney Injury	New	Centers for Medicare & Medicaid Services (CMS)	Endorsed
3732	Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting (IP/OP 90-Day THA/TKA Complication Measure)	New	Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)/ CMS	Withdrawn from endorsement consideration by developer
3498e	Hospital Harm-Pressure Injury	New	American Institutes for Research/ CMS	Endorsed

Summaries of the measure evaluation meetings are linked within the body of the report. Detailed summaries of the committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Patient safety continues to be one of the most important topic areas for health improvement, with the World Health Organization estimating patient harm as the 14th leading cause for morbidity worldwide. An estimated 15% of hospital spending and activity is associated with patient harm events.[2] Improving outcomes is possible, as can be seen in the significant improvement to patient safety outcomes in the U.S. seen in the decade prior to the coronavirus disease 2019 (COVID-19) pandemic.[3] The infrastructure of health care should be designed to protect, measure, and subsequently improve patient safety.[4] Continued effort toward ensuring least harm to patients will lead to improved health of the public, reduced spending, and improved efficiency.

Quality measures are tools to measure or quantify health care processes, outcomes, patient perceptions, and organizational structures and/or systems that are associated with the ability to provide high-quality health care. Furthermore, quality measures can be powerful tools in helping identify performance gaps in patient safety, affecting patient outcomes and overall cost.

Battelle, a CBE, convenes volunteer committees to evaluate and build consensus around quality measures for endorsement based on a standardized set of criteria. For the Fall 2022 cycle, the Patient Safety standing committee reviewed measures focused on health care-associated infections and hospital-acquired injuries.

Health Care-Associated Infections

Infections acquired in the health care setting are an ongoing concern, fueled further by increasing antibiotic resistance. An estimated 1 in 31 patients has at least one hospital-acquired infection at any given time, resulting in worse patient outcomes and increased spending.[5] Simple solutions like proper hand hygiene practices can contribute to a reduction in rates, but more coordination and focused effort toward mitigating these preventable events are needed.

Hospital Injuries

Hospital injuries, including acute kidney injury and pressure injury, increase resource use by hospitals and overall lead to worse outcomes in patients. Millions of people in the US every year suffer from a pressure injury, impacting their recovery process and increasing their risk of infection.[6] Acute kidney injury has been shown to be associated with higher rates of hospital readmission.[7]

Patient Safety Measure Evaluation

For this measure review cycle, the Patient Safety standing committee (Appendix B) evaluated four new measures and one measure undergoing maintenance review against standard measure evaluation criteria.

Table 2a. Number of Fall 2022 Patient Safety Measures Submitted and Reviewed

	Maintenance	New	Total
Number of measures submitted for endorsement review	1	5	6
Number of measures withdrawn from consideration*	0	1	1
Number of measures reviewed by the committee	1	4	5
Number of measures endorsed	1	4	5
Number of measures not endorsed	0	0	0

**Measure developers/stewards can withdraw a measure from measure endorsement review at any point before the CSAC meeting. Table 2b provides a summary of withdrawn measures.*

Table 2b. Measures Withdrawn from Consideration

Measure Number	Measure Title	Developer/Steward	New/Maintenance	Reason for Withdrawal
3732	Hospital-Level 90-Day Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for a Combined Inpatient (IP) and Outpatient (OP) Setting (IP/OP 90-Day THA/TKA Complication Measure)	Yale CORE / CMS	New	Withdrawn by developer without rationale

Scientific Methods Panel Measure Evaluation

For the Fall 2022 cycle, the Scientific Methods Panel did not review any of the Patient Safety measures as the measures and/or testing methods were deemed to be non-complex by NQF .

Comments Received Prior to Standing Committee Evaluation

For this evaluation cycle, no pre-evaluation comments were submitted prior to the measure evaluation meeting on February 9, 2023.

Comments Received Post Standing Committee Evaluation

Following the standing committee's measure evaluation meeting, the committee endorsement recommendations were posted on the PQM website for public comment. The commenting period opened on March 28, 2023, and closed on May 5, 2023. The committee received six comments pertaining to the measures under review and the committee endorsement recommendations. Two supportive comments received for CBE #3025 expressed disagreement with the committee's vote of consensus not reached on performance gap and usability and emphasized the measure's significance in filling gaps in the reporting of health care-associated infections in the ambulatory surgical center setting. One supportive comment submitted for CBE #3686 highlighted the measure's benefit in infection prevention, promoting evidence-based practices and enhancing patient care and outcomes. For CBE #3498e, one comment was received, which expressed support for the measure as it can increase awareness and attention to hospital harm-pressure injuries. Lastly, CBE #3713e received two supportive comments, commending the measure and suggested including longitudinal criteria and stratification by age, race, and ethnicity.

Battelle convened the committee for the Fall 2022 post-comment web meeting on June 13, 2023, to review and provide feedback on the full text of comments received and to discuss and revote on reliability for one measure (CBE #3025), which did not achieve consensus on this must-pass criterion during the measure evaluation meeting, referred to as a "consensus not reached" (CNR) measure. A summary of comments for each measure reviewed is provided in Appendix A.

Summary of Potential High-Priority Gaps

During the standing committee's evaluation of the measures, no potential high-priority measurement gap areas emerged.

Summary of Major Concerns or Methodological Issues

During the standing committee's evaluation of the measures, no major concerns or methodological issues emerged. Details of the standing committee's discussion and ratings of the criteria for each measure are included in Appendix A.

References

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Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Under the NQF process, quorum is 66% of active standing committee members minus any recused standing committee members. Due to the exclusion of recused standing committee members from the quorum calculation, the required quorum for live voting may vary among measures. Quorum (14 out of 20 standing committee members) was met and maintained throughout the review of CBE #3025, CBE #3686, and CBE #3498e. Quorum was lost during the discussion of CBE #3688 and CBE #3713e. Therefore, the committee discussed all remaining criteria for CBE #3688 and CBE #3713e and voted after the meeting using an online voting tool. The standing committee received a recording of the meeting and a link to submit online votes. Voting closed after 48 hours with at least the number of votes required for quorum. Voting results are provided below.

A measure is recommended for endorsement by the standing committee when greater than 60% of voting members select a passing vote option (i.e., Pass, High and Moderate, or Yes) on all must-pass criteria and overall suitability for endorsement. A measure is not recommended for endorsement when less than 40% of voting members select a passing vote option on any must-pass criterion or overall suitability for endorsement.

A.1 Measures Endorsed

CBE #3025 Ambulatory Breast Procedure Surgical Site Infection Outcome Measure (Centers for Disease Control and Prevention [CDC])

Staff Assessment | Specifications

Numerator Statement: Surgical site infections (SSIs) during the 30-day (superficial SSI) and 90-day (deep and organ/space SSI) postoperative periods following breast procedures in Ambulatory Surgery Centers.

Denominator Statement: Breast procedures, as specified by the operative procedure codes that comprise the breast procedure category of the NHSN Outpatient Procedure Component Protocol, are performed at ambulatory surgery centers.

Exclusions: Hospital inpatients and hospital outpatient department patients, patients under age 18 or age 109 or over, and brain-dead patients whose organs are being removed for donor purposes

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Ambulatory Care, Outpatient Services

Type of Measure: Outcome

Data Source: Electronic Health Records, Electronic Health Data, Data collection for SSIs following outpatient operative procedures is via NHSN Outpatient Procedure Component

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE EVALUATION

Table A.1-1.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-14; Pass-14; No Pass-0 (14/14 – 100%, Pass)	• The committee recognized that this maintenance measure has a logic model depicting a reduction in breast surgical site infections (SSIs) as a direct outcome of combined best practices within successful ambulatory surgery centers and attributable to reductions in opportunities for microbial infection with said facilities. • The developer cited a Centers for Disease Control and Prevention guideline focused on steps that can be taken to prevent SSI based on a targeted systematic review of the available evidence on SSI prevention from 1998 through April 2014. • The developer also provided updated citations supporting the same underlying evidence from the initial measure review in 2017, which suggests that actions can be taken to prevent infections. • During the discussion of evidence, a committee member expressed concerns about the measure's potential to encourage overuse of prophylactic antibiotics. Other committee members did not share that concern because there are facility protocols for the prevention of antibiotic overuse. • A committee member raised a concern about the differences between outpatient and inpatient settings. However, they acknowledged that infection control practices effectively reduce infections and should apply universally. • The committee did not raise any additional concerns and passed the measure on evidence.

Criterion	Total Votes	Rationale
1b. Performance Gap	• Total Votes-15; H-0; M-6; L-8; I-1 (6/15 – 40%, Consensus Not Reached) • Post-comment Evidence Revote: Total Votes-15; H-2, M-13, L-0, I-0	• The developer provided an exploratory analysis of NHSN data showing that out of 67,150 ASC procedures reported to NHSN from 2010 to 2013, 30,787 (45.9%) were breast procedures. Out of the 142 SSIs reported from ASCs during the same time period, 78 (54.9%) were related to breast procedures, indicating a risk of SSI of 0.25%. • The committee noted that the developer did not provide updated data for performance gap; however, the developer provided a verbal update from the past four years, which showed a consistent 0.26% unadjusted SSI rate. • The data provided by the developer showed variability among facilities with a standardized infection ratio (SIR) ranging from 0 to 6.9. • The committee also noted the low unadjusted surgical site infection (SSI) rate, variability among facilities with a standardized infection ratio (SIR), and lastly, how facilities with low procedure volumes are handled, where the SIR calculation is limited. • The committee inquired about the developer's approach to low-volume facilities. The developer clarified that SIR is not calculated when the predicted number of infections is less than 1, acknowledging this as a limitation for facilities with small procedure numbers. • The committee did not reach consensus on performance gap during the measure evaluation meeting. • During the post-comment meeting, the committee re-voted and passed the measure on performance gap after review and discussion of the comments received, which were largely supportive of the measure.

Table A.1-1.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale
2a. Reliability	• Total Votes-15; H-1; M-13; L-0; I-1 (14/15 – 93.3%, Pass)	• The committee noted that that reliability testing was conducted at the accountable entity level: • The developer conducted a signal-to-noise analysis using data from January 1 to December 31, 2021, from 16 facilities from seven different US states. ▪ The developer found that 94% (15 out of 16) of facilities have reliability scores above 0.7 mean reliability and one facility had a reliability score below 0.7 of 0.687. • A committee member raised a concern regarding capturing all patient infections due to variability in clinical judgment and practice. • In response, the developer noted the use of standardized case definitions and NHSN surveillance guidelines for reproducible results across facilities. • The committee did not express any additional concerns and passed the measure on reliability.

Criterion	Total Votes	Rationale

2b. Validity	• Total Votes-15; H-0; M-10; L-4; I-1 (10/15 – 66.7%, Pass)	• The committee noted that new validity testing was not conducted; however, the previous iteration of the measure's validity was tested at the Accountable Entity Level:
		  • The developer conducted face validity testing for the measure's initial endorsement in 2015.
		  • The Ambulatory Surgery Center Quality Collaboration (ASC QC) administered a questionnaire that included questions related to the four measure attributes to 11 professionals.
		▪ The questionnaire rated the respondent's level of agreement with statements related to each measure attribute based on a 5-point Likert Scale.
		▪ The developer reported a high level of agreement among the ASC professionals in response to the question of whether the measure appears to measure what it is intended to (nine of 11 agreed).

Table A.1-1.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-15; H-0; M-11; L-4; I-0 (11/15 – 73.3%, Pass)	• The committee acknowledged that data elements for this measure were found in the medical record and can be submitted electronically but requires some manual review. • The committee acknowledged that manual chart review is challenging yet feasible. • The committee did not raise any concerns and passed the measure on feasibility.

Table A.1-1.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-14; Pass-14; No Pass-0 (14/14 – 100%, Pass)	• The committee acknowledged that the measure is used for public reporting, public health/disease surveillance, quality improvement with benchmarking, and internal quality improvement within NHSN, with 284 ASCs reporting. • The committee did not have any concerns and passed the measure on use.
4b. Usability	• Total Votes-14; H-0; M-7; L-6; I-1 (7/14 – 50%, Consensus Not Reached)	• The committee noted the lack of data to show improvement trends and expressed concern about being able to determine whether the measure is making a difference given its use in only five states. • Moving to a vote, the committee did not reach consensus on usability, which is not a must-pass criterion based on the NQF measure evaluation criteria guidance.

Table A.1-1.5. Related and Competing Measures

Criterion	Related Measures	Rationale
5. Related and Competing	• CBE #3357 Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers • CBE #2687 Hospital Visits after Hospital Outpatient Surgery • CBE #0527 Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision • CBE #0528 Prophylactic Antibiotic Selection for Surgical Patients • CBE #0529 Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time • CBE #0269 Timing of Prophylactic Antibiotics - Administering Physician	• The developer noted that the related measures focus on the same target population (ASC patients), while this measure specifically evaluates occurrence of breast SSIs.

Table A.1-1.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Votes: 15; Yes-15; No-0 (15/15–100%, Pass)	• The committee passed the measure on its overall suitability for endorsement.

Table A.1-1.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• Two	Pre-evaluation comments: • None Post-evaluation comments: • A commenter supported the measure and expressed that they do not agree with the committee's vote of 'consensus not reached' on the performance gap and usability criteria. • Another comment in support of the measure emphasized the important gap this measure fills in the reporting of healthcare-associated infections occurring in the ASC setting.
Non-supportive comments	• N/A	N/A

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-1.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-1.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3686 Center for Disease Control and Prevention (CDC), National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Staff Assessment | Specifications

Numerator Statement: Observed bacteremia and fungemia among patients previously admitted to acute care hospitals.

Denominator Statement: The HOB measure denominator is the predicted number of HOB events in an acute care hospital based on predictive models using facility-level and patient-level factors.

Exclusions: N/A

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Outcome

Data Source: Electronic Health Records, Claims

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE EVALUATION

Table A.1-2.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-14; Pass-11; No Pass-3 (11/14 – 78.6%, Pass)	• The committee recognized that this new measure has a logic model depicting successful hospital infection prevention practices, such as proper insertion and care of indwelling devices; following of best practices for prevention of surgical site infections; environmental cleaning, transmission-based precautions, and hand hygiene; and surveillance, audit, and feedback, can lead to reduction in transmission of pathogens and development of infections among hospitalized patients, which can ultimately lead to reduction in hospital-onset bacteremia and fungemia events. • The developer cited a three-year study of 2,109 Hospital-Onset Bacteremia & Fungemia (HOB) events across 12 hospitals, which found that 66% of patients with HOB events had central lines, and 28% had undergone surgery in the previous 30 days. • The committee noted missing evidence that established a relationship between specific processes, interventions, structures, or staffing and how they could increase or decrease the rate of HOB. • The committee questioned the added value of this measure considering that existing measures capture more specific outcomes and whether this measure is meant to replace the more specific measures. • The developer noted that this measure includes bloodstream infections from midline catheters, peripheral IVs, and other sources not routinely reported to NHSN. • The developer also noted the measure aims to capture bloodstream infections, such as bacteremia and fungemia, not subject to current NHSH surveillance. • The standing committee did not raise any questions or concerns and passed the measure on evidence.

Criterion	Total Votes	Rationale

1b. Performance Gap	• Total Votes-15; H-0; M-13; L-2; I-0 (13/15 – 86.7%, Pass)	• The committee acknowledged the lack of performance data due to the measure being new.
		• In the absence of performance data, the developer presented a summary of data from a five-year study to demonstrate an opportunity for improvement.
		• The committee noted the low rate of infection and substantial variability between hospitals.
		• In its analysis of disparities, the developer delved into patient demographics related to HOB events using the Premier Healthcare Database, which included 10,092,282 hospitalizations in 260 hospitals from January 1, 2012, to December 31, 2017.
		  • Patients with HOB were found to be slightly younger and more likely to be Black compared to patients with negative blood cultures and those with bacteremia or fungemia upon admission.
		  • In comparison to all hospitalizations from the same time period, patients with HOB events tended to be older with a higher proportion of HOB events occurring among males and Black patients but less among Hispanic patients.
		  • An additional comparison to 2020 US Census Data revealed that HOB incidents were more prevalent among males and individuals identifying as Black or African American.
		  • The developer also noted that the proportion of HOB events among Hispanic patients was lower in comparison to 2020 U.S. Census data.
		• The committee passed the measure on performance gap.

Table A.1-2.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	• Total Votes-15; M-14; L-1; I-0 (14/15 – 93.3%, Pass)	• The committee noted that reliability testing was conducted at the patient/encounter level:
		  • Chart review inter-rater reliability for HOB was conducted for critical data elements by evaluating agreement among four expert chart reviewers in the field of infectious disease and hospital epidemiology.
		  • The developer used % agreement and Cohen's kappa statistic to adjust for chance agreement for categorical data assessed pairwise between reviewers (10 charts) as well as against an adjudicated reference standard.
		▪ Reviewers 1 and 2: 90.9% agreement and 0.79 kappa
		▪ Reviewers 2 and 3: 81.8% agreement and 0.54 kappa
		▪ Reviewers 1 and 4: 81.8% agreement and 0.65 kappa
		▪ Reviewers 4 and 3: 100% agreement and 1 kappa
		▪ The developer noted that healthcare associated infections such as central line-associated bloodstream infections had especially high agreement among infection preventionists (kappa = 0.562 +/- 0.080).
		  • The committee asked for clarification on the gold standard for inter-rater variability, and the developer clarified that variability is largely due to how infections are documented.
		• The committee did not express any additional concerns and passed the measure on reliability.

2b. Validity	• Total Votes-15; M-15; L-0; I-0 (15/15 – 100%, Pass)	• The committee noted that validity testing was conducted at the patient/encounter level:
		  • To demonstrate patient/encounter-level validity, the developer assessed the sensitivity and specificity of HOB events.
		  ○ Sensitivity: 95.8% (95% Confidence Interval [CI] of 88.3% to 99.1%)
		  ○ Specificity: 82.6% (95% CI of 71.6% to 90.7%)
		• Face validity was conducted through a web-based cross-sectional survey of hospital epidemiologists and infection preventionist members of the Society for Healthcare Epidemiology of America (SHEA) Research Network in 133 hospitals and 89 individuals.
		• The developer noted that there were no statistically significant differences in the results when the data were stratified by academic affiliation, hospital size, or US versus non-US hospitals.
		• The committee noted the developer's risk adjustment model, which highlighted limited data on hospital events in both small and large hospitals.
		• Furthermore, the committee indicated there were no indications of plans to update the risk adjustment with characteristics that would lower infection rates.
		• The committee acknowledged the developer's plan of capturing HAIs in hospital settings moving forward.
		• Expressing no additional concerns, the committee passed the measure on validity.

Table A.1-2.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-15; H-7; M-8; L-0; I-0 (15/15 – 100%, Pass)	• The committee noted that the electronic nature of the measure is meant to streamline the data collection process, as all data elements can be found in structured fields within an electronic health record (EHR). • The committee asked the developer for details about the burden on hospitals to generate electronic fields for this measure. • The developer noted minimal burden with data collection and stated that the data can be submitted via the Fast Interoperability Healthcare Resources (FHIR) Application Programming Interface (API), which is now standard in many hospitals. • The committee did not raise any concerns and passed the measure on feasibility.

Table A.1-2.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-15; Pass-15; No Pass-0 (15/15 – 100%, Pass)	• The committee acknowledged that the measure is not currently in use but is planned for use in the HOB NHSN module later in 2023. • The committee did not have any questions or concerns and passed the measure on use.
4b. Usability	• Total Votes-14; H-5; M-9; L-0; I-0 (14/14 – 100%, Pass)	• The committee acknowledged the value of the measure and noted the limited results for performance improvement considering that this is a new measure. • The committee highlighted the challenges to improvements posed by a low rate of events. • Lastly, the committee agreed that larger facilities have more opportunity for improvements. • The committee did not have any additional concerns and passed the measure on usability.

Table A.1-2.5. Related and Competing Measures

Criterion	Related Measures	Rationale
5. Related and Competing	• CBE #0139 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure • CBE #1716 National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	• This committee agreed that the measures are harmonized to the extent possible.

Table A.1-2.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-15; Yes-15; No-0 (15/15 –100%, Pass)	• The committee passed the measure on its overall suitability for endorsement.

Table A.1-2.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• One	Pre-evaluation comments: • None Post-evaluation comments: • A commenter expressed that implementing the measure would benefit infection prevention and antimicrobial stewardship efforts, promote evidence-based practices, and potentially enhance patient care and outcomes.
Non-supportive comments	• N/A	• N/A

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-2.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-2.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3688 CDC, NHSN Healthcare Facility-Onset, Antibiotic-Treated Clostridiodes Difficile Infection Outcome Measure (CDC)

Staff Assessment | Specifications

Numerator Statement: Total number of observed incident healthcare facility-onset, antibiotic-treated CDI (HTCDI) events among all inpatients in the facility.

Denominator Statement: Total number of expected incident HT-CDI events based on predictive models using facility-level and patient-level factors.

Exclusions: N/A

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Outcome

Data Source: Electronic Health Records

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE EVALUATION

Table A.1-3.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-15; Pass-15; No Pass-0 (15/15 – 100%, Pass)	• The committee recognized that this new outcome measure has a logic model depicting a link between successful hospital infection prevention practices in combination with optimal patient care to produce a reduction in the development and transmission of pathogens and subsequent infections among hospitalized patients that leads to a decrease in health care facility-onset, antibiotic-Treated Clostridioides difficile Infection (HT-CDI) events. • The developer referenced 2017 clinical guidelines for management of CDI, and notes that an expert review panel from the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) graded existing evidence for control and prevention of CDI. • The developer cited the Centers for Disease Control and Prevention´s Healthcare Infection Control Practices Advisory Committee (HICPAC) graded evidence for the disinfection/sterilization, isolation precautions, and hand hygiene guidelines. • The committee did not express any concerns and passed the measure on evidence.

Criterion	Total Votes	Rationale

1b. Performance Gap	• Total Votes-15; H-1; M-14; L-0; I-0 (15/15 – 100%, Pass)	• The committee noted that neither performance gap nor disparities data were available because this is a new measure.
		• The developer presented a summary of data (2020) from the literature demonstrating an opportunity for improvement.
		  ○ The developer reported that the national SIR was 0.518, with state-level estimates ranging from 0.13 to 0.82.
		• The developer provided a summary of data from the 2018 Annual CDI Report from the Emerging Infections Program, which addresses current disparities in care broken down by age, sex, and ethnicity.
		  ○ CDI incidence increases with age (1 to 17 years: 9.03/100,000; 18 to 44 years: 17.82/100,000; 45 to 64 years: 72.12/100,000; >=65 years: 262.35/100,000).
		  ○ Slightly higher incidence among females as compared to males (66.23/100,000 persons vs. 62.04/100,000).
		  ○ Slight predominance in white populations as compared to non-white populations (69.54/100,000 vs. 53.18/100,000).
		• The committee questioned the validity and accuracy of the social determinants of health (SDOH) data in the database used by the developer.
		• The committee acknowledged the challenges of collecting SDOH data and passed the measure on performance gap.

Table A.1-3.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	• Total Votes-15; H-2; M-13; L-0; I-0 (15/15 – 100%, Pass)	• The committee noted that reliability testing was conducted at the patient/encounter level:
		  • The developer conducted an inter-rater reliability assessment that focused on three electronic extraction data elements: date of admission, presence of a CDI test, and presence of five+ days of antimicrobial therapy.
		  • A Cohen's kappa statistic was calculated to adjust for chance agreement for categorical data assessed between electronic chart extraction and manual chart review.
		  ○ Date of Admission: 84.3% of sampled encounters had an exact match between the electronic health extraction and manual chart review.
		  ○ Positive CD test: 0.9696 (kappa); 0.9567 to 0.9825 (95% CI)
		  ○ 5+QAT if CD test positive: 0.9754; 0.9638 to 0.987
		  ○ HT-CDI event determination: 0.956; 0.9511 to 0.9789
		• In response to the committee's concern regarding medical administration versus medical order, the developer noted that the consistency of electronically extracted data is limited because the CDI only requires documentation of medical orders into the FHIR API but not medical administration.
		• The committee discussed the potential for systematic bias toward that could lead to errors or issues in sizeable data populations.
		• The committee did not raise any additional concerns and passed the measure on reliability.

2b. Validity	• Total Votes-14; H-1; M-13; L-0; I-0 (14/14 – 100%, Pass)	• The committee acknowledged that validity testing was conducted at the patient/encounter level:
		  • The developer compared HT-CDI rates versus reference standard case definitions for sensitivity and specificity.
		  ○ Sensitivity of 0.98 with a 95% CI of 0.97 to 0.99 and a specificity of 0.96 with a 95% CI of 0.94 to 0.97
		  • Comparison of Sensitivity and Specificity of electronic HT-CDI to electronic capture of CDI LabID (final CD test positive) as compared to Reference Standard:
		  ○ Sensitivity of 0.97 with a 95% CI of 0.96 to 0.99 for Electronic LabID and a sensitivity of 0.98 with a 95% CI of 0.97 to 0.99 for HT-CDI.
		• The committee acknowledged the electronic HT-CDI measure's high likelihood of correctly including patients with HT-CDI and correctly excluding patients who do not have HT-CDI.
		• The committee did not express any concerns and passed the measure on validity.

Table A.1-3.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-14; H-5; M-9; L-0; I-0 (14/14 – 100%, Pass)	• The committee noted that all the data elements are electronically available. • The committee did not raise any concerns and passed the measure on feasibility.

Table A.1-3.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-14; Pass-14; No Pass-0 (14/14 – 100%, Pass)	• The committee acknowledged that the measure is new and not in use and acknowledged the developer's planned reporting into the HT-CDI NHSN module in 2023. • The committee did not have any questions or concerns and passed the measure on use.
4b. Usability	• Total Votes-14; H-3; M-10; L-1; I-0 (13/14 – 92.8%, Pass)	• The committee recognized that the measure is not yet implemented in a public reporting program, so improvement cannot be evaluated. • The committee did not have any questions or concerns and passed the measure on usability.

Table A.1-3.5. Related and Competing Measures

Criterion	Competing Measure	Rationale
5. Related and Competing	• CBE #1717 Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network (NHSN), Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	• The developer states that CBE #1717 and CBE #3688 are harmonized across the patient population included in the measures. • CBE #3688 improves upon CBE #1717 in that it will be a fully electronic measure through automated transfer of data from the facility into the NHSN application and will be calculated algorithmically and objectively without the requirement for infection preventionists to directly decide each event. Therefore, it may be better suited for quality reporting programs than some related HAI measures.

Table A.1-3.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-14; Yes-14; No-0 (14/14 –100%, Pass)	• The committee passed the measure on its overall suitability for endorsement.

Table A.1-3.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	N/A

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Non-supportive comments	• N/A	N/A

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-3.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-3.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3498e Hospital Harm-Pressure Injury (Centers for Medicare & Medicaid Services/American Institutes for Research [CMS/AIR])

Staff Assessment | Specifications

Numerator Statement: Inpatient hospitalizations for patients with a new deep tissue pressure injury (DTI) or stage 2, 3, 4, or unstageable pressure injury, as evidenced by any of the following:

• A diagnosis of DTI with the DTI not present on admission;

• A diagnosis of stage 2, 3, 4 or unstageable pressure injury with the pressure injury diagnosis not present on admission;

• A DTI found on exam greater than 72 hours after the start of the encounter; or

• A stage 2, 3, 4 or unstageable pressure injury found on exam greater than 24 hours after the start of the encounter.

Denominator Statement: Inpatient hospitalizations where the patient is 18 years of age or older at the start of the encounter.

Exclusions: • Inpatient hospitalizations for patients with a DTI or stage 2, 3, 4 or unstageable pressure injury diagnosis present on admission.

• Inpatient hospitalizations for patients with a DTI found on exam within 72 hours of the start of the encounter.

• Inpatient hospitalizations for patients with a stage 2, 3, 4, or unstageable pressure injury found on exam within 24 hours of the start of the encounter.

• Inpatient hospitalizations for patients with diagnosis of a COVID-19 infection during the encounter.

Adjustment/Stratification: No risk adjustment or stratification

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Outcome

Data Source: Electronic Health Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE EVALUATION

Table A.1-4.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-14; Pass-14; No Pass-0 (14/14 – 100%, Pass)	• The committee recognized that this new eCQM outcome measure has a logic model depicting an increased monitoring of patients at risk for pressure injury, including risk and skin assessments, frequent repositioning, proper skin care, and specified cushions/beds leading to lower rates of pressure injuries acquired during hospitalization. The logic model then shows lower rates of pressure injuries acquired during hospitalization leading to lower rates of HAPI-associated infections, lower rates of sepsis, reduced pain, and reduced discomfort. • The developer cited three strong positive recommendations from the 2019 Clinical Practice Guideline on the Prevention and Treatment of Pressure Ulcers/Injuries. • The developer also cited one strong recommendation from the 2015 Clinical Practice Guideline on the Risk Assessment and Prevention of Pressure Ulcers. • The committee noted that this measure was first submitted for endorsement during the spring 2019 cycle but was withdrawn due to feedback from stakeholders. The committee recognized that the withdrawal was prompted by the establishment of a 72-hour window for pressure injuries to appear and addressing issues identified by stakeholders regarding the omission of stage II pressure injuries within structured nursing documentation. • The committee did not have any concerns and voted to pass the measure on evidence.

1b. Performance Gap	• Total Votes-14; H-2; M-11; L-1; I-0 (13/14 – 92.9%, Pass)	• The developer analyzed data from 18 diverse hospitals in 2020 to demonstrate performance gap.
		  ○ Pressure injury rates ranged from 0 to 2.02 per 100 qualified inpatient admissions.
		  ○ Weighted average of 1.06 per 100 qualified inpatient admissions, with a standard deviation of 0.56.
		  ○ Interquartile range of 0.63 per 100 qualified inpatient admissions.
		• The developer reports the following trends for the subgroups of age, sex, ethnicity, and primary payer across all test sites and within the measure denominator population:
		  ○ Patients aged 65 or above were more likely to experience HA-PI than those 64 or younger.
		  ○ Male patients had higher chance of experiencing hospital acquired (HA) PI than female patients.
		  ○ Non-Hispanic African Americans had a moderately higher chance of developing HA-PI than other ethnicities.
		  ○ Medicare beneficiaries were more likely than Medicaid beneficiaries or commercially insured patients to experience PI during hospitalization.
		• The committee did not express any concerns and passed the measure on performance gap.

Table A.1-4.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	• Total Votes-14; H-5; M-9; L-0; I-0 (14/14 – 100%, Pass)	• The committee noted that reliability testing was conducted at the accountable entity level:
		  ○ Using health records (January 2020 to December 2020) from 128,323 qualified inpatient encounters at 18 hospitals (25 to 499 beds), the developer conducted a signal-to-noise ratio (SNR) analysis and intra-class correlation coefficient (ICC) via the split-half sample approach.
		  ○ SNR ranged from 0.86 to 1.00, with mean and median values of 0.96 and 0.97 respectively.
		  ○ Estimated ICCs had a median of 0.99, with a mean ranging from 0.79 to 0.97.
		• A committee member asked about COVID-19 patient exclusion and data gathered during the public health emergency.
		• The developer clarified that data from 2020 would not be used in public reporting; focus on 2023 data moving forward.
		• A committee member asked about the 72-hour detection threshold and the developer explained that it is based on circulation stabilization and the evolution of pressure injury.
		• Satisfied with this explanation, the committee passed the measure on reliability.

2b. Validity	• Total Votes-14; H-1; M-13; L-0; I-0 (14/14 – 100%, Pass)	• The committee noted that validity testing was conducted at the patient/encounter level:
		  ○ The developer conducted a comparison of EHR exported data from medical charts for a subsample of the measure population.
		  ○ Empirical validity was calculated using frequency of missingness, % match agreement, positive predicative value (PPV), sensitivity, negative predicative value (NPV), and specificity.
		  ○ PPV results ranged from 0.97 to 1.0, with near perfect sensitivity, NPV, and specificity across measure components and sites.
		• Validity testing was also conducted at the accountable entity level:
		  ○ The developer conducted measure score validity by assessing convergent validity to determine whether multiple measures are correlated.
		  ○ The developer analyzed patient safety outcomes from related infection measures then estimated Spearman's rank correlation coefficients.
		• The committee inquired about the validity of extracted data compared to clinical documentation.
		• In response, the developer noted that structured documentation flows around whether pressure ulcers were utilized, including those completed by nurses or physical therapists.
		• The committee acknowledged the rationale for the measure not being risk-adjusted; the developer followed the precedent for other CMS pressure-injury measures that do not risk-adjust.
		• Having no further concerns, the committee passed the measure on validity.

Table A.1-4.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-14; H-3; M-11; L-0; I-0 (14/14 – 100%, Pass)	• The committee acknowledged that the data elements for this measure are generated or collected by and used by health care personnel during the provision of care. • The committee did not raise any concerns and passed the measure on feasibility.

Table A.1-4.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-14; Pass-13; No Pass-1 (13/14 – 92.9%, Pass)	• The committee acknowledged that the measure is not currently used in an accountability program as the measure is new; however, at the time of this review, the measure was submitted to the 2022 Measures Under Consideration (MUC) list and will be reviewed by the Measure Applications Partnership (MAP) during the 2022-2023 review cycle. • The committee did not have any questions or concerns and passed the measure on use.
4b. Usability	• Total Votes-14; H-3; M-11; L-0; I-0 (14/14 – 100%, Pass)	• The committee noted that trend data were not available due to the measure being new and no unexpected findings or potentials harms were identified. • The committee passed the measure on usability.

Table A.1-4.5. Related and Competing Measures

Criterion	Related Measure(s)	Rationale
5. Related and Competing	• Patient Safety Indicator (PSI) 03: Pressure Ulcer Rate	• The committee considered this non-CBE endorsed measure highlighted by the developer and acknowledged that harmonization between PSI 03 and this measure was not necessary because the measure focus, target population, and the data sources used for each are different. • The committee did not express any concerns.

Table A.1-4.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-14; Yes-14; No-0 (14/14 – 100%, Pass)	• The committee passed the measure on its overall suitability for endorsement.

Table A.1-4.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• One	A commenter acknowledged the significance of the measure and expressed support in increasing awareness and attention to this topic.
Non-supportive comments	• N/A	• N/A

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-4.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-4.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3713e Hospital Harm-Acute Kidney Injury (CMS/AIR)

Staff Assessment | Specifications

Numerator Statement: Inpatient hospitalizations for patients who develop acute kidney injury (AKI) (stage 2 or greater) during the encounter, as evidenced by:

- A subsequent increase in serum creatinine value at least 2 times higher than the lowest serum creatinine value, and the increased value is greater than the highest sex-specific normal value for serum creatinine; or
- Kidney dialysis (continuous renal replacement therapy (CRRT), hemodialysis or peritoneal dialysis) initiated 48 hours or more after the start of the encounter.

Denominator Statement: Inpatient hospitalizations for patients 18 years of age or older at the start if the encounter without a diagnosis of obstetrics, with a length of stay of 48 hours or longer who had at least one serum creatinine value after 48 hours from the start of the encounter.

Exclusions:

- Inpatient hospitalizations for patients with an increase in serum creatinine value of at least 0.3 mg/dL between the index serum creatinine and a subsequent serum creatinine taken within 48 hours of the encounter start (indicating AKI present on admission).
- Inpatient hospitalizations for patients with the index estimated glomerular filtration rate (eGFR) value of <60 mL/min within 48 hours of the encounter start (indicating chronic kidney disease, stage 3a or greater, present on admission).
- Inpatient hospitalizations for patients who have less than two serum creatinine results within 48 hours of the encounter start (indicating that the hospital stay was too short to diagnose AKI).
- Inpatient hospitalizations for patients who have kidney dialysis (CRRT, hemodialysis or peritoneal dialysis) initiated within 48 hours of the encounter start (indicating end stage renal disease, a severe acute metabolic derangement, or AKI present on admission).
- Inpatient hospitalizations for patients with at least one specified diagnosis present on admission that puts them at extremely high risk for AKI:
    - Hemolytic Uremic Syndrome (HUS)
    - Large Body Surface Area (BSA) Burns
    - Traumatic Avulsion of Kidney
    - Rapidly Progressive Nephritic Syndrome
    - Thrombotic Thrombocytopenic Purpura
- Inpatient hospitalizations for patients who have at least one specified procedure during the encounter that puts them at extremely high risk for AKI:
    - Extracorporeal membrane oxygenation (ECMO)
    - Intra-Aortic Balloon Pump
    - Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)
    - Nephrectomy

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Inpatient/ Hospital

Type of Measure: Outcome

Data Source: Electronic Health Records

Measure Steward: Centers for Medicare & Medicaid Services/ American Institutes for Research

STANDING COMMITTEE EVALUATION

Table A.1-5.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale

1a. Evidence	• Total Votes-14; Pass- 13; No Pass- 1 (13/14 – 92.9%, Pass)	• The committee recognized that this new eCQM has a logic model depicting that high-risk individuals should receive a kidney health assessment and depending on the results of the assessment a kidney health response is initiated. The logic model attests that if the kidney health response is implemented, it is expected to lead to primary prevention of AKI, prevention of progression from stage one to stage two, reduction of risk of dialysis initiation, and improved long-term outcomes.
		• The developer cited a 2009 meta-analysis of randomized controlled trials on the effects of perioperative hemodynamic goal-directed therapy for 4,220 adult surgical patients.
		  ○ The developer reported that hemodynamic optimizations reduced the odds of postoperative acute renal injury.
		  ○ Significant reduction compared to the control group.
		• The developer highlighted evidence supporting the effectiveness of the 2012 KDIGO recommendations in preventing AKI.
		• The committee questioned if there were any challenges to the evidence pertaining to surgical patients considering the measure's broader scope.
		• The developer clarified that the reason for this focus was because the literature used to create the baseline for chronic kidney disease focuses on inpatient surgical patients.
		• The committee did not raise any questions or concerns and passed the measure on evidence.

Criterion	Total Votes	Rationale

1b. Performance Gap	• Total Votes-14; H-0; M-14; L-0; I-0 (14/14 – 100%, Pass)	• The developer presented data collected from 20 participating hospitals from the full 2020 calendar year.
		  ○ Observed performance rate in acute kidney injury: Ranged from 0.76 to 4.43 per 100 qualified admissions.
		  ○ Weighted average measure rate: 1.52% per 100 qualified inpatient admissions.
		  ○ Interquartile range: 0.66 unadjusted and 0.84 adjusted.
		• The developer cited an additional study of critically ill patients admitted to the intensive care units at six hospitals in four countries where the KDIGO criteria were applied to estimate variation in the incidence of stage one or greater AKI.
		• The developer presented the rate of AKI per 100 denominator encounters for different subgroups: age, sex, race, ethnicity, and payer type.
		• The committee noted the small gap between the cited benchmarks on performance and passed the measure on performance gap.

Table A.1-5.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	• Total Votes-14; H-3; M-11; L-0; I-0 (14/14 – 100%, Pass)	• The committee noted that that reliability testing was conducted at the Accountable Entity Level:
		  ○ Using health records (January 2020 to December 2020) from 58,936 denominator encounters across 20 hospitals (25-499 beds), the developer conducted a signal-to-noise (SNR) analysis and intra-class correlation coefficient (ICC) via the split-half sample approach.
		  ▪ SNRs ranged from 0.20 to 0.97 with a mean of 0.84 and median of 0.91.
		  ▪ Estimated ICCs (observed measure rates): median 1.0, no simulations below 0.99; mean range 0.25 to 0.91.
		  ▪ Estimated ICCs (adjusted measure rates): median 0.99, almost all simulations above 0.95; median value of mean was 0.62.
		• The committee did not have any questions or concerns and passed the measure on reliability.

Criterion	Total Votes	Rationale

2b. Validity	• Total Votes-14; H-2; M-12; L-0; I-0 (14/14 – 100%, Pass)	• The committee noted that the validity testing was conducted at the patient/encounter level:
		  ○ The developer conducted a comparison of EHR exported data from medical charts for a subsample of the measure population.
		  ○ Validity was calculated using frequency of missingness, % match agreement, positive predictive value (PPV), sensitivity, negative predictive value (NPV), and specificity.
		  ○ The developer then assessed whether excluded cases for EHR data truly met the intent for exclusion.
		• Validity testing was also conducted at the accountable entity level:
		  ○ Known groups (Hospital teaching/academic status, Hospital bed size, Hospital urban/rural location) validity testing was used to assess the measure's ability to differentiate between groups of measured entities known to differ on their underlying latent construct.
		  ○ Risk-adjusted AKI rates were 27% lower in teaching hospitals than at non-teaching hospitals.
		• The committee questioned why dementia was not included in the risk adjustment model.
		• The developer clarified that dementia patients are not excluded from the denominator, but rather the exclusions pertain to the risk model. Additionally, the developer stated that dementia's absence in the risk model is due to it not being detected as a robust feature in the model and not directly relating to AKI.
		• The committee expressed concern about risk-adjusting patients with comorbidities, which the developer clarified is necessary to account for differences in the way hospitals and providers respond to each medical situation.
		• Responding to the committee's inquiry on excluding patients with heart failure, the developer noted that such patients would not be excluded and would garner the same level of care as patients with AKI.
		• The committee did not raise any additional concerns and passed the measure on validity.

Table A.1-5.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-14; H-2; M-11; L-1; I-0 (13/14 – 92.9%, Pass)	• Regarding feasibility, the committee acknowledged that the data elements are generated or collected and used by healthcare personnel during the provision of care. Further, the data elements are coded by someone other than the person obtaining original information. • The committee also recognized that seven of 29 sites that were sampled offered dialysis as an outsourced service, making clinical documentation unavailable as a structured data element. • The committee did not find an issue with the dialysis sampling since the measure can capture the intended dialysis population through ICD-10 codes and passed the measure on feasibility.

Table A.1-5.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-14; Pass-13; No Pass-1 (13/14 – 92.9%, Pass)	• The committee acknowledged that the measure is not currently used in an accountability program as the measure is new; however, at the time of this review, the measure was submitted to the 2022 Measures Under Consideration (MUC) list and will be reviewed by the Measure Applications Partnership (MAP) during the 2022-2023 review cycle. • The committee did not have any questions or concerns and passed the measure on use.
4b. Usability	• Total Votes-14; H-2; M-10; L-1; I-1 (12/14 – 85.7%, Pass)	• The committee noted that trend data were not available due to the measure being new and no unexpected findings or potentials harms were identified. • The committee asked about the percentage of AKI that is preventable. The developer responded that it varies based on the setting and underlying conditions of the patient. • The committee did not have any additional questions and passed the measure on usability.

Table A.1-5.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• Patient Safety Indicator (PSI) 10: Postoperative Acute Kidney Injury Requiring Dialysis Rate	• The committee considered this non-CBE endorsed measure highlighted by the developer and acknowledged that harmonization between PSI 10 and this measure was not necessary because the goal and data sources used for each are different. • The committee did not express any concerns.

Table A.1-5.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-14; Yes-13; No-1	• The committee passed the measure on its overall suitability for endorsement.

Table A.1-5.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• Two	Pre-evaluation comments: • None Post-evaluation comments: • The commenter praised the measure for being a good outpatient measure but 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. • The commenter commended the measure for focusing on detecting potentially avoidable AKI and excluding high-risk individuals.
Non-supportive comments	• N/A	• N/A

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-5.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-5.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

Appendix B: Patient Safety Standing Committee and Battelle Staff

PATIENT SAFETY STANDING COMMITTEE

John James, PhD (Co-Chair)
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Geeta Sood, MD, ScM (Co-Chair)
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