Memorandum

October 20, 2023

To: Patient Safety Standing Committee, Spring 2023

From: Battelle Staff

Re: Post-comment web meeting to discuss public comments received

Background

For the Spring 2023 cycle, Battelle, a consensus-based entity (CBE), convened the Patient Safety standing committee to evaluate four newly submitted measures and one measure undergoing maintenance review against standard measure evaluation criteria.[1] The standing committee recommended to endorse all five measures.

The standing committee recommended the following measures for endorsement:

- CBE #3636 Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel (Surveillance Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention [CDC])
- CBE #3687e ePC-07 Severe Obstetric Complications (The Joint Commission)
- CBE #3728 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization (Centers for Medicare & Medicaid Services [CMS]/Acumen LLC)
- CBE #3746 Avoid Hospitalization After Release with a Misdiagnosis—ED Stroke/Dizziness (Johns Hopkins Armstrong Institute for Patient Safety and Quality)
- CBE #3749e Diagnostic Delay of Venous Thromboembolism (DOVE) in Primary Care (Brigham and Women's Hospital)

Standing Committee Actions in Advance of the Meeting

1. Review this briefing memo and meeting summary.
2. Review and consider the full text of all comments received, the developer/steward responses, and the proposed committee responses to the post-evaluation comments.
3. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Comments Received

Following the standing committee's measure evaluation meeting on August 1, 2023, and August 11, 2023, the committee endorsement recommendations were posted on the Partnership for Quality Measurement (PQM) website for public comment. The commenting period opened on August 25, 2023, and closed on September 13, 2023. The Patient Safety standing committee received 17 comments from organizations and individuals pertaining to three measures under review (CBE #3636, CBE #3746, and CBE #3749e) and the committee endorsement

[1] National Quality Forum. Measure Evaluation Criteria and Guidance. 2021.

recommendations. This memo focuses on comments received after the standing committee's evaluation. All comments are posted on the respective committee post-comment webpage.

Measure stewards/developers were asked to respond to comments where appropriate, which have also been included in the Post-comment Response Excel file. Please review this memo, agenda, and the Post-comment Response Excel file in advance of the meeting and consider whether you have any concerns with the public comments received and the responses for each comment.

To facilitate the discussion, the post-evaluation comments have been categorized into major topic areas or themes for each measure that received comments. Although all comments are subject to discussion, the intent is not to discuss each individual comment during the post-comment call. Instead, Battelle staff will spend most of the time considering the themes discussed below and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit the standing committee's discussion, and the committee can pull any comment for discussion.

Comments and Their Disposition

CBE #3636 Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel (Surveillance Branch, Division of Healthcare Quality Promotion, CDC)

One major theme was identified in the post-evaluation comments for this measure, as follows:

Concerns Regarding Measure Specifications and Burden

Two commenters expressed concerns regarding the measure's term "up-to-date," stating that this term is outdated and unclear. As a result, the lack of clarity in the definition could negatively impact the reliability and validity of CBE #3636. Additionally, both commenters expressed concern with the burden of quarterly reporting of coronavirus disease 2019 (COVID-19) vaccination status of health care workers, arguing the frequency is impractical especially in the context of changing circumstances and the end of the Public Health Emergency.

> **Measure Steward/Developer Response:**
> Even with the expiration of the Public Health Emergency, efforts to counter COVID-19 continue, as do meaningful surveillance metrics to track vaccination coverage - such as the respecified healthcare personnel (HCP) up to date COVID-19 vaccination coverage measure. Surveillance of HCP COVID-19 vaccination coverage remains relevant with or without vaccination mandates.
>
> Vaccines have recently been approved to counter more recently circulating COVID-19 strains, and the "Up to Date" vaccination concept remains especially relevant to providing the public with a meaningful indicator of HCP vaccination coverage over time.
>
> Measure specifications are important to provide a meaningful indicator of HCP vaccination. For the public to interpret a constantly respecified measure may be challenging. The current specifications clearly delineate who is included, in the same fashion as CBE #0431 (HCP Influenza Vaccination) does providing the public a well-defined cohort targeted by the "up to date" measure. Quarterly reporting to NHSN is based upon the definition of up to date as of the first day of the quarter. This can pose a

challenge in communication to facilities, but NHSN/CDC regularly communicates changes to facilities when definitions have been made to ensure they understand which definition to use.

At the same time, the change from primary vaccination to up to date vaccination allows for flexibility over time, as CDC refines recommendations for COVID-19 vaccination.

Proposed Standing Committee Response:
Thank you for the comments. The Patient Safety standing committee does not have any major concerns with the developer's response and recognizes the positive impact of COVID-19 vaccination, HCP vaccination, and booster COVID-19 vaccine doses.

Action Item:
Discuss and finalize standing committee response.

CBE #3746 Avoid Hospitalization After Release with a Misdiagnosis—ED Stroke/Dizziness (Johns Hopkins Armstrong Institute for Patient Safety and Quality)

Two major themes were identified in the post-evaluation comments for this measure, as follows:

1. Support for the Measure
2. Narrow Measure Observations and Lack of Broader Evidence Demonstrating the Measure's Clinical Utility

1. Support for the Measure

Twelve of the 14 public comments received for this measure expressed support, stating the measure is important to patients and purchasers. Amongst these 12 supportive comments were personal stories from patients, caregivers, and patient advocates that have experienced harm due to diagnostic error, including misdiagnosis of dizziness. Several of the 12 supportive comments also underscored the importance of improving diagnostic error in the U.S., and until there is a better understanding of current diagnostic performance in this area, it will be difficult for the U.S. health care system to prioritize interventions for improvement.

Measure Steward/Developer Response:
We appreciate the supportive comments. We know the patient/family voice is crucial as we continue our work to reduce harm caused by diagnostic error.

Proposed Standing Committee Response:
Thank you for your comments. The Standing Committee recognizes diagnostic errors can have severe consequences for patients and their families, as highlighted by the cases mentioned in the comments. We share in the commitment to improving timely diagnosis and enhancing the safety of care provided in emergency departments.

Action Item:
Discuss and finalize standing committee response.

2. Narrow Measure Observations and Lack of Broader Evidence Demonstrating the Measure's Clinical Utility

Two non-supportive comments were received about this measure. The commenters acknowledged the importance of timely diagnosis of conditions with high morbidity and mortality; however, the commenters questioned whether the measure's required steps and testing procedures will lead to improved patient outcomes and care. They emphasized the need for measures to have modifiable processes linked to meaningful clinical outcomes. For instance, the specific processes mentioned - the eye exam, or even MRI - are not clearly shown to improve the 30-day risk of stroke (outcome) or functioning (the real outcome). The commenters also raised concern with the absence of broader data demonstrating the measure's clinical utility and cautioned against creating new practice guidelines based on limited data, particularly from a select setting. Lastly, one of the commenters posited that the largest issue impacting patient safety in the emergency department (ED) is ED overcrowding caused by hospital overcrowding. Focusing on the system issues driving this problem will have a broader, more wide-ranging impact on patient safety in the ED setting.

Measure Steward/Developer Response:
We would like to address some of the concerns raised in these comments:

(1) There are accurate, reliable, feasible, and trainable bedside eye movement examinations to discern posterior stroke from benign causes of dizziness. These facts are supported by two recent systematic reviews of more than a dozen studies conducted in ED settings (PMID: 36453134, 37038843) as well as the recently published Society for Academic Emergency Medicine (SAEM)'s GRACE-3 clinical practice guideline (PMID: 37166022). Studies in 1781 patients have shown that the HINTS/HINTS+ eye movement approach is more accurate than other bedside examinations and MRI (PMID: 36453134), leading to a "high certainty of evidence" recommendation for ED clinicians using this approach --- this was recommended by a panel of 19 experts, including 14 EM physicians, 3 patients, 1 ENT, and 1 neurologist (PMID: 37166022). Importantly, the effectiveness of this approach in the hands of emergency physicians trained with just two 6-hour sessions has been demonstrated and performing these tests at the bedside takes just 5 minutes in the hands of trained ED clinicians (PMID: 34245635).

(2) The appropriate and judicious use of MRI in cases of suspected stroke among dizzy patients has been shown to improve the 30-day risk of stroke. The data prepared for this application clearly show that, nationally in the US, use of MRI (known to be effective in diagnosing posterior circulation stroke [PMID: 35876220]) has a direct positive impact on improving outcome measure #3746. By contrast, our submitted results also clearly show that use of CT (known to be ineffective in diagnosing posterior circulation stroke [PMID: 35876220]) has no positive impact on improving outcome measure #3746.

(3) Any costs for additional appropriate MRIs in evaluating patients with suspected stroke are more than offset by savings from proper bedside evaluation of patients with self-limited forms of dizziness (e.g., that caused by benign paroxysmal positional vertigo). The commenter suggests 500 MRIs per ED dizziness/vertigo stroke case, but this number assumes every dizziness/vertigo patient gets an MRI and there are only 0.2% strokes, when there are, in fact, roughly 4-5% strokes (0.2% is the percentage harmed after their stroke was initially missed, not the number of

dizziness cases due to stroke). If every dizzy patient underwent an MRI, there would be 20-25 MRIs per ED dizziness/vertigo stroke case. However, proper application of eye movement-based diagnosis of dizziness and vertigo would lead to fewer than 2 MRIs per stroke/central case, given the high specificity of the eye movement approach (HINTS) for stroke diagnosis. The subset of patients with dizziness or vertigo who are eligible for the HINTS exam has an overall 25% pre-test probability for stroke and the associated post-test probability for stroke when HINTS suggests a central lesion is 73.8% (PMID: 37038843), meaning the number of MRIs needed to diagnose 1 stroke in acute dizziness is ~1.36. Moreover, effective application of bedside eye exams will lead to cost SAVINGS through reductions in current inappropriate CT neuroimaging and hospitalization --- these potential cost savings are estimated to be approximately $1 billion per year in US EDs alone (PMID: 24048914). To ensure this, measure #3746 would be implemented in conjunction with appropriate balancing measures to assess the impact on rates of neuroimaging or hospitalization.

(4) These specific eye exams (i.e., HINTS), as well as the judicious use of MRI as neuroimaging (as opposed to CT) are, in fact, part of an Emergency Medicine clinical practice guideline for the diagnosis of acute dizziness and vertigo in the ED. The GRACE-3 guidelines were developed and recently published by the Society for Academic Emergency Medicine (SAEM), which endorses a standardized approach to the bedside diagnosis of dizziness in the ED (PMID: 37166022). Measure #3746 will help provider organizations implement an approved Emergency Medicine-endorsed clinical guideline by providing a marker of improved care quality specifically related to the outcomes of interest.

(5) The measure was developed and refined with input over two years from the American College of Emergency Physicians (ACEP), including both leaders and members, as part of a technical expert panel. Furthermore, the measure was endorsed by ED clinicians (n=31) and medical directors (n=36) surveyed by ACEP as part of their E-QUAL network. Over 83% said that receiving hospital/ED-level feedback on missed stroke in dizziness/vertigo presentations would improve their practice and the quality of care for patients with dizziness/vertigo, and over 90% of both groups said they would welcome such feedback.

(6) Overcrowding in the ED is also an important issue which poses a threat to patient safety, but the potential patient harms attributable to overcrowding and diagnostic errors may not be mutually exclusive. For example, the stress of overcrowding on the system can lead to cognitive error through increased distractions and task interruptions for clinical staff, as well as decreased time to focus on individual patients. Even absent cognitive errors, a natural consequence of overcrowding is diagnostic delays (e.g., patients with lower-severity dangerous disease presentations who might be [appropriately] triaged to the ED waiting area for hours with pre-septic infections or evolving strokes). In short, overcrowding in the ED reinforces the need for us to be measuring harms from diagnostic error. Given that missed stroke is the #1 cause of serious misdiagnosis-related harms across care settings (PMID: 37460118) as well as in the ED specifically (PMID: 36574484), measure #3746 is timely, important, and necessary to draw attention to and monitor progress in addressing this critical public health problem.

Proposed Standing Committee Response:
Thank you for the comments. During the initial evaluation meeting, the Patient Safety committee considered the business case and supporting evidence for this measure. The committee agreed there is a gap in care that warrants a measure and by closing this gap, there would be a net benefit in patient care. The developer also satisfied the validity testing requirements for this measure, which included validating the accuracy of the data elements. However, the committee recommends to the developer to consider further testing at the measure score/accountable-entity-level to address some or the commenters concerns. The committee also recommends Battelle generate more guidance and resources about how diagnostic excellence measures should be reviewed. Specifically, these measures should tailor their evidence submissions to show how these diagnostic excellences measures impact outcomes.

Action Item:
Discuss and finalize standing committee response.

CBE #3749e Diagnostic Delay of Venous Thromboembolism (DOVE) in Primary Care (Brigham and Women's Hospital)

Only one comment was submitted for CBE #3749e, which expressed the measure is flawed and requested information about the natural language processing (NLP) algorithm and its training.

Measure Steward/Developer Response:
We do not see the comments from Dr. Sood that are referenced so our response is focused on the NLP algorithm and associated training question posed by Dr. Jodi Segal. The DOVE eCQM uses symptoms documented in primary care when present along with the structured codes (e.g., ICD, CPT and RxNorm) that are associated with the presence of a VTE. This design allows us to link symptoms with well-defined VTE events. In testing the NLP algorithm, we found that the presence of one or more symptoms in the primary care note along with the ICD, CPT, and RxNorm codes was highly predictive for future VTE diagnosis (PPV=1, NPV=.85, Sensitivity=1, Specificity=.9). The DOVE NLP algorithm is a rule-based algorithm that identifies VTE symptoms in primary care notes. We developed and tested the NLP algorithm at Mass General Brigham (MGB). We also tested the NLP algorithm and DOVE eCQM at two external systems University of Kentucky (rural system) and Penn State Health (mix of urban, metro, rural) where we performed beta testing of the DOVE eCQM. On a random sample of 30 notes in each of these external healthcare systems, we found that the NLP algorithm was accurate in identifying VTE symptoms in notes across systems. MGB, University of Kentucky, and Penn State Health have 3 different EHR vendor systems. MGB issued a free license to each of these sites to use the DOVE NLP algorithm. Training involved providing information about setting up the software and providing a set of de-identified notes that the sites could use for "practice" to validate that it was accurately identifying VTE symptoms.

Proposed Standing Committee Response:
Thank you for your comment. The Patient Safety committee considered various aspects of this measure, including the developer's NLP algorithm, in its review and found the measure sufficiently meets the endorsement standards.[1] The committee does not have any major concerns with developer's response.

Action Item:
Discuss and finalize standing committee response.