

# Patient Safety Spring 2023 Cycle: Pre-evaluation Comments

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## **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)**

### **Pre-evaluation Public Comments**

**Public comments received for committee consideration of this measure can be found here:** [Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel \(3636\) | Partnership for Quality Measurement \(p4qm.org\)](https://www.p4qm.org/quarterly-reporting-of-covid-19-vaccination-coverage-among-healthcare-personnel-3636)

### **Pre-evaluation Standing Committee Comments**

#### **1a. Evidence**

- There is no objective evidence that the quality of care in a facility is better when HCP COVID vaccination rates are higher. Now that CMS has revoked the requirement for HCPs to be vaccinated against COVID-19, I am concerned that the reporting will change significantly, and we will see reduced numbers of HCPs who are up to date. This should not be taken as an indication of poor facility quality.
- Level of evidence with prelim rating of insufficient with exception. Should be discussed by committee in greater detail.
- No empirical evidence to hold providers accountable for this measure. No clear evidence it will affect patient outcomes. The epidemiology of the COVID-19 coronavirus has changed since this measure was developed. There is no clear evidence that this will make any difference in patient quality of care at this point.
- Yes, evidence seems to be lacking, is this still needed? - rated insufficient
- This is a process measure submitted for re-endorsement. While there has been no published data on up-to-date COVID-19 coverage reporting among healthcare workers, the real-world data shows strong evidence that vaccination help increase protection from COVID-19 infection, reduce morbidity and mortality. And work place vaccination decreases COVID-19 infection transmission in facilities and thus provides better protection to patients, residents, and co-workers, which can reduce workplace disruption. However, the evidence is rated as insufficient based on the algorithm.

#### **1b. Gap in Care/Opportunity for Improvement and Disparities**

- With the revocation of CMS' requirement for HCPs to receive the COVID-19 vaccine, my concern is we will see wide variations emerge in the data by geography and other factors. This is not a signal that there is a gap in care. HCPs are a reflection of the population in the communities where they live.
- No concerns
- COVID-booster update reporting is at this point not reliable.
- lack of evaluation per developer
- No latest performance gap was evaluated by the developer due to limited data from the

updated NHSN reporting, although SNFs and dialysis facilities had the largest number of reporting. Studies on disparities during the pandemic showed that the update rates of vaccine booster were lower for non-white race, lower socioeconomic status, lower education, and those without health insurance. The opportunity for improvement is rated as moderate.

## 2a. Reliability

- The specifications as stated are not a concern, but the overall measure is a concern to me since I do not believe it is associated with facility quality of care.
- No concerns
- The definition of "up to date" is still unclear and changing.
- No concerns
- Specifications were updated to include boosters in addition to primary COVID vaccination. No concerns.
- New reliability test was conducted and the average from those analyzed was around or greater than 0.90, which high. So no concerns.

## 2b. Validity

- No concerns, but my overarching comments stand.
- No concerns
- not risk adjusted, ?outdated already
- No concerns
- New validity testing was conducted. No concerns.

## 2b2-2b6. Potential Threats to Validity

- Exclusions
  - Religious exemptions should be an additional exclusion.
  - No concerns
  - The difficulty with this data is q3 month reporting makes it difficult to capture part-time or per-diem employees accurately
  - No concerns
  - No concerns.
- Risk Adjustment
  - No concerns.
  - No concerns
  - Not risk adjusted.
  - Not risk adjusted but evidence points to disparities.
  - No risk adjustment or stratification is applied. No concerns.
- Meaningful Difference
  - I do not believe this measure identifies differences about quality of care in facilities.
  - No concerns
  - going forward, i do not think this data will be reliable due to changing recommendations about need for vaccination for HCP and definition of "up to date"

- No concerns
- The differences between the 10th and 90th percentiles for SNFs and HPS are 71.81% and 75.65%. The numbers show considerable differences in reporting..
- Comparability of Data Sources
  - No concerns
  - No concerns
  - uses only one set
  - No concerns
  - No concerns.
- Missing Data
  - No concerns
  - No concerns
  - yes
  - No concerns
  - 99% of SNFs and 90% of HPS facilities reported data for all months in reporting period. So it seems missing data is minimum. Validity is rated as moderate.

### 3. Feasibility

- No concerns
- No concerns
- would be onerous and difficult to obtain this data accurately for all staff
- No concerns
- No concerns.

#### 4a. Use

- I am concerned that this measure will be misinterpreted to mean a facility is a poor quality facility if its HCPs have a low level of COVID-19 vaccination.
- No concerns
- Is this measure still needed?
- The developer indicates that this measure is currently in use in public reporting, public health/disease surveillance, and regulatory and accreditation programs. These include the use by the NHSN to provide a LTCFs COVID-19 module and states' assessment for CMS-certified nursing homes and outpatient dialysis centers.
- Feedback from stakeholders, particularly the providers affected, has not resulted in any changes to the measure. Yet, CMS revoked the mandate for COVID-19 vaccination for HCPs
- Feedback was obtained through a public comment period on proposed rulemaking by CMS to include this updated measure in quality reporting programs. Many concerns were raised by those being measured. The developer responded to each concern and no modifications were made. I have no concerns.

#### 4a. Usability

- I don't believe this measure contributes to enhancing quality of care because the reasons HCPs don't accept vaccines are complex and changing as the mandate changes.

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- No concerns
- this is not clear and an underlying problem with this measure.
- Is this still needed?
- No concerns.
- I believe there could be harm to the facilities by the use of this measure because of misinterpretation.
- No concerns
- staff dissatisfaction; patient demand for only vaccinated staff to care for them, etc.

## CBE #3687e - ePC-07 Severe Obstetric Complications (The Joint Commission)

### Pre-evaluation Public Comments

Public comments received for committee consideration of this measure can be found here: [ePC-07 Severe Obstetric Complications \(3687e\) | Partnership for Quality Measurement \(p4qm.org\)](#)

### Pre-evaluation Standing Committee Comments

#### 1a. Evidence

- No concerns
- No concerns
- no concerns
- No concerns
- This is a new outcome measure and will be analyzed at facility level. Maternal morbidity and mortality rates has been increasing the United State, affecting so many women's lives resulted from obstetric complications. This is an important outcome measure that is needed to improve maternal care quality and safety. The evidence is strong, and no concerns.

#### 1b. Gap in Care/Opportunity for Improvement and Disparities

- No concerns
- No concerns
- no concerns
- No concerns
- There is a moderate opportunity for improvement and risk disparities are significant among different race and ethnic groups. No concerns.

#### 2a. Reliability

- No concerns
- No concerns
- testing not submitted due to submission for trial use measure
- No concerns
- Measure specifications are clear and precise. No concerns.
- No testing submitted for a trial measure
- No concerns
- testing not submitted
- No concerns
- No reliability testing was submitted because the measure was submitted as for trial use.

#### 2b. Validity

- No testing submitted for a trial measure
- No concerns

- not tested
- Not been tested
- No validity testing was submitted.

### **2b2-2b6. Potential Threats to Validity**

- Exclusions
  - With all we understand better about COVID-19 now, is it still necessary or advisable to exclude patients with a COVID-19 diagnosis?
- Risk Adjustment
  - N/A
- Meaningful Difference
  - I would be interested in others' comments on sample size since this was raised in the document.
- Comparability of Data Sources
  - N/A
- Missing Data
  - N/A

### **3. Feasibility**

- No concerns
- No concerns
- no concerns
- No concerns
- Across the 9 pilot test sites, feasibility rate on average is 98%, which is high.

### **4a. Use**

- No concerns
- No concerns
- new measure, credible plan for implementation provided
- No concerns
- The measure is currently publicly reported and used in accountability programs, such hospital accreditation programs by the Joint Commission and CMS quality reporting programs.
- currently publicly reported
- Feedbacks were sought during a public comment period and a patient working group. Support from stakeholder groups for such an important healthcare outcome measure was strong. No concerns.

### **4a. Usability**

- No concerns
- No concerns
- no concerns
- MAP recommended conditional use in 2021 successful pending completion of testing - application indicates still pending?
- It is a new measure, so no performance improvement data were provided. But, I wonder

if the developer could still provide some evaluation on performance improvement, since the measure has been publicly reported and used in accountability programs.

- The comment about clinicians focusing on just the conditions listed in the measure and not being as attentive to other possible conditions is interesting.
- resources needed for electronic reporting
- No implementation findings were provided and one of the unintended consequences is that hospitals may potentially shift their focus away from other kinds of complications. But, I think this may happen to any other measures. Also, this measure had been reviewed by one of the MAP programs in 2021 with conditional support. There was a concern about the sample size used for testing in the measure.



## **CBE #3728 - Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization (SNF HAI) (Acumen, LLC/Centers for Medicare & Medicaid Services)**

### **Pre-evaluation Public Comments**

**Public comments received for committee consideration of this measure can be found here:** [Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization \(SNF HAI\) \(3728\) | Partnership for Quality Measurement \(p4gm.org\)](#)

### **Pre-evaluation Standing Committee Comments**

#### **1a. Evidence**

- No concerns
- No concerns
- no concerns
- No concerns
- HAI can have many devastating impacts on patients and nursing home residents in particular vulnerable resident populations living in SNF, and yet, many HAIs are avoidable. There is an increasing need to protect our vulnerable elderly through measures like this to prevent and reduce the HAI rate at nursing facilities. The evidence is strong, and I have no concerns.

#### **1b. Gap in Care/Opportunity for Improvement and Disparities**

- No concerns
- No concerns
- no concerns
- No concerns
- Data collected from 2019 to 2021 demonstrate considerable performance gap among SNFs. No concerns.

#### **2a. Reliability**

- No concerns
- No concerns
- no concerns
- No concerns
- No concerns on the measure specifications.
- The reliability testing shows the intra-class correlation coefficient is 0.49 [0.48-0.51] on average. The preliminary rating is moderate. But, I am a little concerned that the ICC is right at the boundary between poor and moderate reliability.

#### **2b. Validity**

- No concerns
- No concerns

- no concerns
- No concerns
- Validity is rated as moderate. No concerns.

## 2b2-2b6. Potential Threats to Validity

- Exclusions
  - I'm not sure if the data for Medicare Advantage enrollees is available, but with more than 45% of all Medicare beneficiaries now enrolled in an MA plan nationally, I am concerned that we are missing an opportunity to look at the care experience of a significant portion of the Medicare population. Further, it would also be helpful to compare the care experience between those enrolled in traditional Medicare vs. MA plans.
  - No concerns
  - no concerns
  - No concerns
  - No concerns on exclusion.
- Risk Adjustment
  - No concerns
  - No concerns
  - no concerns
  - No concerns
  - The developer aligned SNF HAI risk adjustment categories with those used for other claims-based quality measures (i.e., SNF 30-Day All Cause Readmission Measure, Potentially Preventable 30-Day Post Discharge Readmission Measure, and Discharge to Community). I agree that the social risk should be excluded from the risk adjustment; I think a person's social risk should not be a factor to increase the person's risk of infection. However, I am concerned that a resident's age, disability, comorbidities, length of prior hospital stay, and prior ICU use are included in the risk adjustment model. It is true that these residents may be more susceptible to infections than the younger, healthy population. But, that does not mean they are associated with higher rates of HAIs as "expected" (or unavoidable) in risk adjustment. In fact, these are the residents who require more protection from infections, and with extra care, such as proper screening, surveillance and decolonization, etc., their infections can be prevented. A better way to handle this may be using resident stratifications.
- Meaningful Difference
  - Some states have mandated (since 2020) much more stringent provisions related to the presence and role/responsibility of an infection preventionist and/or infectious disease physician in a SNF. NJ is one example. Is it important to control for whether certain facilities have stricter IPC requirements than others?
  - No concerns
  - no concerns
  - No concerns
  - No concerns.
- Comparability of Data Sources
  - No concerns

- No concerns
- no concerns
- No concerns
- Missing Data
  - No concerns
  - No concerns
  - no concerns
  - No concerns
  - The developer shows that the missing data are rare, so no concerns.

### 3. Feasibility

- No concerns
- No concerns
- no concerns
- No concerns
- Feasibility is rated high. No concerns.

#### 4a. Use

- No concerns
- No concerns
- no concerns
- No concerns
- It is currently publicly reported, used in accountability programs, and will be implemented in the skilled nursing facility value-based purchasing program in 2026. The measure is also currently used for quality improvement and benchmarking. No concerns.
- Public comments and feedback were sought in a number of opportunities including MAP rulemaking process. No concerns.

#### 4a. Usability

- No concerns
- No concerns
- Only concern is measure does not include Medicare advantage patients, who comprise a higher percentage of patients in many parts of the country.
- No concerns
- Usability is rated as moderate. No concerns.
- Appreciate the attention paid to the issue of potential "cherry picking" of patients from acute care into the SNF.
- developer addressed concern regarding NH avoidance of higher risk patients.
- The developer noted that the measure may result in facilities selectively enrolling residents by either encouraging or avoiding admission of certain types of residents. But, the developer states that the resident-risk adjustment may help mitigate facilities' incentive to selectively enroll residents or transfer residents to hospitals early.

## **CBE #3746 - Avoid Hospitalization After Release with a Misdiagnosis—ED Stroke/Dizziness (Avoid H.A.R.M.—ED Stroke/Dizziness) (Johns Hopkins Armstrong Institute for Patient Safety and Quality)**

### **Pre-evaluation Public Comments**

Public comments received for committee consideration of this measure can be found here: [Avoid Hospitalization After Release with a Misdiagnosis—ED Stroke/Dizziness \(Avoid H.A.R.M.—ED Stroke/Dizziness\) \(3746\) | Partnership for Quality Measurement \(p4qm.org\)](#)

### **Pre-evaluation Standing Committee Comments**

#### **1a. Evidence**

- No concerns
- No concerns
- The evidence to support this measure is strong. I have no concerns
- No concerns
- No concerns

#### **1b. Gap in Care/Opportunity for Improvement and Disparities**

- The performance gap seems to be well-documented. I appreciate the explanation of the approach to getting at differences in the population., even though the measure is not risk-adjusted.
- No concerns
- Both performance scores and disparity data suggest high performance gap and opportunity for improvement.
- No concerns
- No concerns

#### **2a. Reliability**

- No concerns
- No concerns
- No concerns. The reliability is rated high.
- No concerns
- No concerns

#### **2b. Validity**

- No concerns
- No concerns
- No concerns.
- No concerns
- No concerns

## 2b2-2b6. Potential Threats to Validity

- Exclusions
  - No concerns
  - No concerns
  - No concerns. I agree that this measure should not have exclusions.
  - No concerns
  - No concerns
- Risk Adjustment
  - No concerns
  - No concerns
  - No concerns about no risk adjustment. Every patient should have an equal opportunity to be correctly diagnosed.
  - No concerns
  - No concerns
- Meaningful Difference
  - No concerns
  - No concerns
  - No concerns.
  - No concerns
  - No concerns
- Comparability of Data Sources
  - No concerns
  - No concerns
  - Not apply for this measure.
  - No concerns
  - No concerns
- Missing Data
  - No concerns
  - No concerns
  - It does not seem to be significant. No concerns.
  - No concerns
  - No concerns

## 3. Feasibility

- No concerns
- No concerns
- Feasibility is rated high. No concerns.
- No concerns
- No concerns

## 4a. Use

- No concerns
- No concerns
- It is a new measure, so no public reporting and not used in any accountability programs. But, it is in the future plan. No concerns.

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- No concerns
- No concerns
- The developer sought feedbacks from ED physicians and ED quality and safety experts.  
No concerns.

### 4a. Usability

- No concerns
- No concerns
- Usability is high and no concerns.
- No concerns
- No concerns
- Overdiagnosis of stroke in patients presenting with dizziness, overprescription of MRIs.
- I do not see unintended harm but the measure could help save more patients' lives.

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

### **Pre-evaluation Public Comments**

Public comments received for committee consideration of this measure can be found here: [Diagnostic Delay of Venous Thromboembolism \(DOVE\) in Primary Care \(3749e\) | Partnership for Quality Measurement \(p4qm.org\)](#)

### **Pre-evaluation Standing Committee Comments**

#### **1a. Evidence**

- No concerns
- No concerns
- No concerns
- VTE is a commonly misdiagnosed medical condition and can have serious, devastating impacts on a patient's quality of life and outcome. There are very few patient safety measures involved with misdiagnosis. I think this is an important patient safety measure that can help improve diagnosis of VTE and improve patient outcomes. The evidence is strong for this measure and I have no concerns.

#### **1b. Gap in Care/Opportunity for Improvement and Disparities**

- No concerns
- No concerns
- No concerns
- The performance gap was evaluated at two sites. Data from first site showed considerable opportunity for improvement. No significant differences were found in delayed VTE diagnosis rates by patients' race, age, sex, ethnicity, and insurance. However, the analysis showed African Americans are associated with higher rates of VTE complications when compared to the white race. No concerns.

#### **2a. Reliability**

- No concerns
- No concerns
- No concerns
- No concerns
- Reliability was tested at both the patient encounter level and the accountable-entity level. The sensitivity and specificity tested at the patient encounter level were 100% and 96.6%. Reliability was rated as moderate.

#### **2b. Validity**

- Other than the noted questions for discussion, I have no concerns.
- No concerns
- No concerns

- No concerns

### **2b2-2b6. Potential Threats to Validity**

- Exclusions
  - No concerns
  - No concerns
  - No concerns
  - No concerns
- Risk Adjustment
  - No concerns
  - No concerns
  - No concerns
  - I agree that there should be no risk adjustment.
- Meaningful Difference
  - No concerns
  - No concerns
  - No concerns
  - To assess meaningful differences, clinician groups were stratified into five cohorts and assessed overall DOVE rate and range. The rates ranged from 65.78% to 77.14%, although not sure about the statistical significance
- Comparability of Data Sources
  - No concerns
  - No concerns
  - No concerns
  - There is an issue on whether this measure is at the clinician-group practice level only, or if integrated delivery systems should also be considered.
- Missing Data
  - No concerns
  - No concerns
  - No concerns
  - The developer believes that all data elements required for encounter inclusion in the measure and measure calculation are commonly available within the EHR.

### **3. Feasibility**

- No concerns
- No concerns
- No concerns
- Rated as high. No concerns.

### **4a. Use**

- This remains to be seen based on what was submitted.
- No concerns
- No concerns
- This new eCQM is currently not in use for public reporting. But the developer states that the measure will be submitted in May 2023 for potential inclusion as a MIPS measure for



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CMS.

- It seems adequate. No concerns

### **4a. Usability**

- Remains to be seen, but no concerns generally
- No concerns
- No concerns
- No concerns
- Since the measure is not currently in use, no benefits vs. harms are identified.