

**Summary of Technical Expert Panel (TEP) Meetings  
Severe Obstetric Complications Electronic Clinical Quality Measure  
(eCQM)**

January 2022

**Prepared by:**

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(YNHHSC/CORE)

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*The materials within this document do not represent final measure specifications for the Severe Obstetric Complications eCQM.*

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## Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation - Center for Outcomes Research and Evaluation (CORE) to develop quality measures of hospital performance. Under this contract, CORE is supporting The Joint Commission (TJC) in the development of an electronic health record (EHR)-based outcome measure of maternal morbidity. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 2. The contract number is HHSM-75FCMC18D0042, Task Order Number HHSM-75FCMC19F0001.

CORE is obtaining expert and stakeholder input on the proposed measure. The CORE measure development team is comprised of experts in quality outcomes measurement and measure development. As is standard with all measure development processes, CORE has convened a technical expert panel (TEP) of clinicians, patient advocates, and other stakeholders. Collectively, the TEP members brought expertise in performance measurement, quality improvement, electronic capture of medical records, health care disparities, and obstetrics and gynecology.

This report summarizes the feedback and recommendations received from the TEP during the first meeting, which focused on the importance of the measure, the proposed measure development approach, and preliminary measure specifications, and the second meeting, which focused on the measure specifications, some results of the measure testing, and next steps for completion of testing and implementing the measure.

## Measure Development Teams

Dr. Valery Danilack, MPH, PhD leads the CORE measure development team. Dr. Danilack is an Associate Research Scientist at CORE with experience in perinatal epidemiology, study design, and research using electronic medical record and hospital administrative data. Ms. Grace Glennon, MS, RD co-leads the CORE measure development team. Ms. Glennon is a Project Lead at CORE with experience in the development of several eQMs and hybrid measures. The remainder of the CORE internal measure development team provide a range of expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology. See [Appendix A \(Table A1\)](#) for the full list of members of the CORE measure development team.

Ms. Susan Yendro, MSN, RN, leads TJC's measure development team. Ms. Yendro is an Associate Director at TJC. The remainder of TJC's internal measure development team provide a range of expertise in measure development, including electronic clinical quality measure development, and statistics. See [Appendix A \(Table A2\)](#) for the full list of members of TJC's measure development team.

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## The TEP

In alignment with the CMS Measures Management System (MMS), CORE held a 30-day public call for nominations and convened a TEP for the development of the Severe Obstetric Complication Electronical Clinical Quality Measure (eCQM). CORE solicited potential TEP members via emails to individuals and organizations recommended by the measure development team and stakeholder groups, as well as email blasts sent to CMS physician and hospital email listservs, and through a posting on CMS’s website. An invitation to join the TEP was extended to members of the Technical Advisory Group for The Joint Commission’s perinatal care measures. The TEP is composed of 16 members, listed in [Table 1](#).

The role of the TEP is to provide feedback and recommendations on key methodological and clinical decisions. The TEP was convened February 5, 2020, through March 23, 2020 under the Base Period contract, March 24, 2020 through March 23, 2021 under the Option Period 1 contract, and March 24, 2021 through March 23, 2022 under the Option Period 2 contract.

## Specific Responsibilities of the TEP Members

- Complete and submit all nomination materials, including the TEP Nomination Form, statement of interest, and curriculum vitae
- Review background materials provided by CORE prior to each TEP meeting
- Participate in TEP conference calls
- Provide input on key clinical and methodological decisions
- Provide feedback to CORE and TJC on key policy or other non-technical issues
- Review the TEP summary report prior to public release
- Be available to discuss recommendations following submission of the measures to CMS

## TEP Members

**Table 1. TEP Member Name, Affiliation, and Location**

Name	Title, Organization	Location
Suzanne McMurtry Baird, DNP, RN	Co-Owner and Nursing Director, Clinical Concepts in Obstetrics, LLC	Brentwood, TN
Debra Bingham, DrPH, RN, FAAN	Executive Director, Institute for Perinatal Quality Improvement	Quincy, MA
James Christmas, MD	National Medical Director, Women’s and Obstetrics, HCA Healthcare	Nashville, TN
Blair Dudley, MPH	Senior Manager, Transform Maternity Care, Pacific Business Group on Health	Oakland, CA

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Name	Title, Organization	Location
Tomeka Isaac, MBA	Patient Representative	Denver, NC
Deborah Kilday, MSN, RN	Principle – Women and Infants, Advisory Services, Premier, Inc.	Woodstock, GA
Ajshay James	Patient Representative	Houston, TX
Joseph Kunisch, PhD, RN-BC Informatics, CPHQ	Vice President Quality Programs, Harris Health	Houston, TX
David Lagrew Jr., MD	Professor, Department of Obstetrics and Gynecology, University of California, Irvine; Executive Medical Director Providence St. Joseph Health	Irvine, CA
Elizabeth O’Neil-Greiner, RN, MHA	Business Process Consultant, BJC Healthcare	St. Louis, MO
Sarosh Rana, MD, MPH	Professor, Department of Obstetrics and Gynecology; Section Chief, Maternal Fetal Medicine, University of Chicago	Chicago, IL
Elizabeth Rochin, PhD, RN, NE-BC	President, National Perinatal Information Center	Providence, RI
Michael Ross, MD, MPH	Professor of Obstetrics and Gynecology and Public Health, David Geffen School of Medicine; Fielding School of Public Health at UCLA; Investigator, The Lundquist Institute	Los Angeles, CA
Karey M. Sutton, PhD	Director, Health Equity Research Workforce, Association of American Medical Colleges	Washington, DC
Aswita Tan-McGrory, MBA, MSPH	Director, The Disparities Solutions Center, Massachusetts General Hospital; Adjunct Faculty, Northeastern University	Boston, MA
Brooke Villarreal, DNP, MSRN, RN-BC	Director, Public Reporting and Outcomes Measurement, HCA Healthcare	Nashville, TN

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Name	Title, Organization	Location
<b>Prior TEP members</b>		
LaToshia Rouse, MS  <i>Dates of TEP service: 2019-2020</i>	Patient Expert	Knightdale, NC
Barton C. Staat, MD, FACOG, Colonel, MC  <i>Dates of TEP service: 2019-2020</i>	Chair, Department of Obstetrics and Gynecology, Uniformed Services University of the Health Sciences; Staff, Maternal-Fetal Medicine, Walter Reed National Military Medical Center	Bethesda, MD

**TEP Meetings**

CORE held its first TEP meeting in February 2020. A second meeting was conducted July 20, 2021. A third meeting was conducted November 3, 2021. This summary report contains a summary of the February 2020 TEP meeting, which was an all-day, in-person meeting held in Baltimore, MD, and of the July 2021 and November 2021 TEP meetings, which were both conducted via a Zoom conference call.

TEP meetings follow a structured format consisting of the presentation of key issues identified during measure development, as well as CORE and TJC’s proposed approaches to addressing the issues, followed by an open discussion of these issues by the TEP members.

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## **First TEP Meeting Overview**

[Please Note: As of 2021, the name of this measure is: **Severe Obstetric Complications eCQM**. The Overview and Detailed Summary of the first TEP meeting refer to the measure by its initial name: Maternal Morbidity eCQM.]

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the measure background, measure development process, and proposed measure specifications.

During the first TEP meeting, CORE solicited feedback from the TEP on the measure concept, the proposed cohort and outcome specifications, and the approach to risk-adjustment.

The following bullets represent a high-level summary of what was discussed during the first TEP meeting. For further details, please see [Appendix C](#).

### ***Measure Background and Development Approach***

- **CORE Presentation to the TEP on Measure Development**
  - The Joint Commission (TJC) team is the measure steward for the Maternal Morbidity eCQM. CMS and CORE are collaborating with TJC to provide support for measure development and testing.
  - Dr. Elliott Main provided an overview of the national trends, disparities, and variation in severe maternal morbidity (SMM) and mortality.
  - CORE presented the maternal morbidity eCQM development process, highlighting the goal to develop an all-payer measure derived from EHR data applied at the hospital level to address maternal complications during delivery hospitalizations. CORE highlighted the current gap in national maternal morbidity outcome measures and the measure testing approach.
- **TEP Feedback**
  - One TEP member expressed concern with ways in which race and ethnicity data are collected and how disparities in performance may be difficult to assess. Two other TEP members shared that disparities in maternal morbidity exist across income and education levels. Two additional TEP members encouraged developers to capture information on social determinants of health (SDOH) and different care settings using Z codes, while noting that the feasibility of doing so may pose a challenge.
  - One TEP member inquired about how the measure will capture different care settings, commenting that some cities have different capacity for patients with acuity.
  - One TEP member highlighted the issue of mental health challenges that women face when they experience SMM and the associated financial costs.
  - One TEP member sought information on how the measure developers plan to support hospitals to improve documentation and data extraction from EHRs.

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- TJC stated that they offer user education for data entry into EHR systems when implementing their measures in addition to sharing measure logic. TJC additionally offers webinars for successful reporting.
  - Three TEP members commented on challenges surrounding accurate clinician documentation of maternal morbidity and data collection that hinder data integrity.
- Summary
  - TEP members generally supported the measure development approach while providing critical points for developers to consider regarding data collection and extraction, particularly when examining social risk factors and disparities.

### ***Measure Specifications: Cohort***

- TJC Presentation to the TEP on Proposed Measure Cohort Specifications
  - TJC described the proposed data elements and initial measure cohort criteria for the maternal morbidity eCQM. The initial cohort will include inpatient hospitalizations for patients aged  $\geq 8$  years and  $< 65$  years that are admitted for a delivery procedure. TJC recommends the inclusion of both live births and stillbirths, while excluding patients with less than 20 weeks gestation. TJC recommended the measure include high risk cases and consider risk adjustment for patients' comorbidities.
- TEP Feedback
  - One TEP member suggested renaming the measure from SMM to "Obstetric Morbidity Measure" to be inclusive of the Lesbian Gay Bisexual Transsexual Queer (LGBTQ) community.
  - Three TEP members raised questions about how the measure will capture births for patients in different settings, like the emergency department, as well as for patients transferred from a lower to higher-level facility for delivery.
  - One TEP member noted that developers should take terminations into consideration during measure development.
  - One TEP member inquired if the conditions to be measured would be bundled together and how patient comorbidities would be addressed in the measure.
  - Several TEP members commented on measure utility with two members specifically recommending that the measure be utilized for both quality improvement and accountability purposes.
  - All TEP members agreed with the inclusion of all hospital deliveries with live births and stillbirths.
    - One TEP member specifically suggested accounting for differences in risk during risk-adjustment and stratification due to varied hospital populations.
    - One TEP member recommending including non-hospital births.

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- One TEP member suggested stratifying the cohort by severity similarly to TJC’s PC-06 [Unexpected Complications in Term Newborns] measure.
    - Two TEP members suggested capturing data on midwifery services and home births. One TEP member noted that home births and use of midwives are used frequently among black mothers and the ability to capture these data may impact the measure cohort and assessing disparities.
  - Four TEP members suggested future consideration of including pregnancies at fewer than 20 weeks gestation. One TEP member noted that antepartum admissions may be signals of a complication.
  - Four TEP members expressed support for the recommendation of excluding hospitalizations prior to 20 weeks gestation. One member suggested developers consider the standardized obstetric definition of birth versus miscarriage or abortion for patients at 20 weeks gestation.
  - One TEP member noted that smaller hospitals may be less engaged in quality improvement activities and may need a financial incentive to take improvements in maternal complications seriously.
  - One TEP member suggested comparing hospitals to “like-type peers” to avoid unintended consequences, such as hospitals transferring their patients to avoid penalties for adverse outcomes.
  - One TEP member emphasized importance of including patients transferred to higher-level facilities in the denominator.
  - One TEP member expressed concerns surrounding unconscious bias and racism that influences patient diagnosis and treatment.
  - Two TEP members shared via email support for the proposed measure cohort specifications. One TEP member noted that it would be interesting to understand the proportion of high and low risk births but recognized that definitions around those groups may be undetermined.
- **Summary**
    - All the TEP members agreed with the proposed measure cohort specifications to include both live and stillbirths, with a few recommending inclusions of non-hospital births and/or future considerations in lowering the threshold for weeks of gestation.

***Measure Specifications: Outcome***

- **TJC Presentation to the TEP on Proposed Measure Outcome Specifications**
  - TJC presented the proposed approach for defining the outcome of SMM, which would include women experiencing SMM during a delivery hospitalization with a recommendation to include patients who expire during the delivery episode.
  - TJC also proposed using the Centers for Disease Control (CDC) clinical indicators to capture the measure outcome through International Classification of Diseases,

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- Tenth Revision (ICD-10) codes as well as additional coding such as SNOMED, Logical Observation Identifiers Names and Codes (LOINC), and RxNORM.
- TJC additionally recommended naming the measure ‘Maternal Complications’ to represent both morbidity and mortality captured in the measure outcome.
  - TEP Feedback
    - One TEP member inquired how the overall measure result would be reported and whether the measure score would be inclusive of morbidity and mortality.
      - TJC team and CORE team responded that they are open to feedback on reporting strategies to understand what is most useful from the patient, provider, and public perspective.
    - One TEP member inquired about the weighting of complications since some are far more likely to lead to fatality (e.g., cardiac arrest) compared to others (e.g., hysterectomy). The TEP member asked about the assignment of positive or negative values to some outcomes like transfusion. The TEP member recommended a composite score that would consider the weight of each outcome indicator. Two other TEP members supported the concept of a composite measure and further recommended consideration of reporting the top five complications per hospital, noting that potential challenges may arise for hospitals where the number of outcomes is relatively small.
    - One TEP member noted that developers will need to consider how to handle complications versus risk adjustment, for example how a hospital handles a patient with sickle cell disorder. The member noted that completeness of documentation of some complications is a concern, noting that aneurism may not be well documented.
    - Five TEP members commented on the challenges of including mortality in the measure. It was noted that mortality would be a rare outcome, difficult to tease out from all other complications that result in death if presented in conjunction with morbidity, and that it may lose its importance if bundled with morbidity results.
    - Three TEP members supported including mortality in the measure, one of whom suggested grouping the complication outcomes by level of severity.
    - One TEP member suggested consideration of using related indicators such as oxygen saturation and blood pressure to assess morbidity outcomes such as severe hypertension, heart failure, cerebral hemorrhage, liver hematoma, and stroke. They further suggested consideration for other indicators such as access to prenatal care, number of prior caesarian sections (C-sections), health literacy, stress and racism, and use of extracorporeal membrane oxygenation (ECMO).
    - Two TEP members mentioned a few challenges surrounding eCQMs, noting that eCQMs have not typically captured morbidity and mortality, including some coded events.

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- One TEP member suggested pulling data from nursing documentation, including Nurse Sensitive Indicators such as hemorrhage risk assessment that impact morbidity. Another TEP member added that the TERCAP (Taxonomy of Error, Root Cause Analysis and Practice Responsibility) paper and maternity database for nursing data may serve as resources.
- One TEP member suggested incorporating management of issues rather than conditions, such as deep vein thrombosis (DVT) prophylaxis rather than pulmonary embolism or an assessment of the number of patients that receive heparin rather than venous thromboembolism (VTE) and pulse oxygen results.
- One TEP member recommended leveraging strategies from existing measures to look for timely initiation of treatment and timely labs.
- One TEP member emphasized that morbidity refers to lifelong complications, whereas some complications may be short-term and thus recommended developers investigate ways to separate the individual impacts of short-term complications from the overall measure outcome.
- One TEP member noted that EHR documentation around the coded morbidity events may be hard to capture.
- Three TEP members highlighted importance of portraying disparities by race/ethnicity while being cognizant that women with diverse backgrounds are often categorized together as one race or ethnicity.
- One TEP member sought clarification on inclusion of hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome in the list of complications and another TEP member recommended examining hypertension related complications in greater detail.
- One TEP member asked about complications considered under the ‘ventilation’ category, and if they are included in the measure.
- Two TEP members suggested alternative names for the measure, such as incorporating the words ‘obstetric’ for ‘maternal’ or using the term ‘childbirth’ mortality or morbidity to increase specificity of the outcome being measured.
- Two TEP members shared via email support for the proposed outcome definition, including the importance of including mortality in the outcome.
- **Summary**
  - Some TEP members were in favor of including mortality alongside morbidity in the measure outcome, while others disagreed due to the rarity of maternal death.

### ***Measure Specifications: Risk Adjustment***

- **CORE Presentation to the TEP on Risk Adjustment**
  - CORE presented information on the significance of risk adjustment and the goal for risk adjusting hospital quality measures, which is to account for clinically relevant patient-level factors associated with the outcome.

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- Dr. Main described a list of variables that may be considered for risk adjustment for the SMM measure.
- TEP Feedback
  - One TEP member contemplated consideration of food insecurity as a possible risk variable.
  - One TEP member emphasized importance of considering racial/ethnic differences in risk of maternal morbidity and mortality among women of color overall, despite their socioeconomic status and level of education.
  - One TEP member suggested considering factors like language barriers, homelessness, or substance use disorders.
  - Three TEP members recommended considering cancer as a risk factor.
  - Four TEP members agreed on considering incarceration as a risk factor.
  - One TEP member noted ambulatory mobility as a possible risk factor.
  - One TEP member mentioned emergency contact as a proxy for social support as a potential risk factor to consider.
  - Two TEP members suggested capturing suicides, particularly in relation to pregnancy and mental health status.
  - A few TEP members mentioned various patient-level risk factors to consider including twin/multiple pregnancies, pregnancy spacing, history of thromboembolism, smoking, vaping, lupus, transfer status, previous miscarriages, in vitro fertilization (IVF) status, uterine rupture, and prenatal care (including the quality of prenatal care).
  - Two TEP members highlighted hospital-level risk factors such as hospital role in improving community health, type of hospital, presence of specialists, number of deliveries per year, and availability of trauma care.
  - A TEP member suggested examining other eCQM methods for categorizing risk adjustment to high, medium, and low risk.
  - A TEP member noted the importance of complications that arise during the hospitalization versus comorbidities present at the start of care and noted that the timing of the coding of risk variables is important.
- Summary
  - TEP members cited several additional elements for developers to consider for risk adjustment at the patient level (e.g., comorbid conditions; prior pregnancy history and status; smoking) as well as at the hospital and/or population level (e.g., hospital initiatives for improving community health; type of hospital; access to care).

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## **Second TEP Meeting Overview**

Prior to the second TEP meeting, TEP members received detailed meeting materials outlining the results of measure testing results and proposed updates to the measure specifications. These topics were discussed during the second TEP meeting and TEP members were invited to provide feedback.

Following the meeting, TEP members unable to join the TEP meeting provided additional feedback via email. For further details, please see [Appendix D](#).

The following bullets represent a high-level summary of what was discussed during the second TEP meeting. For further details, please see [Appendix E](#).

### ***Measure Background***

- **CORE Presentation on Measure Background**
  - CORE noted that the alpha testing has been completed, and that beta testing is ongoing; results presented are those conducted to date. CORE explained that the analysts are working on risk model development for the measure, and that the beta testing results presented are unadjusted.

### ***Measure Specifications***

- **TJC Presentation on Measure Specifications**
  - TJC presented the measure specifications. She noted that the numerator definition evaluated in measure testing includes the 21 severe maternal morbidity (SMM) indicators identified by the Centers for Disease Control and Prevention (CDC), mortality as measured with discharge disposition, intensive care unit (ICU) length of stay > 12 hours, serum creatinine  $\geq 2$  mg/dL, partial pressure of oxygen (PaO<sub>2</sub>) > 60 mmHg, and platelet count  $< 100 \times 10^3/uL$ . The initial patient population (IPP) is the same population that is used for other TJC perinatal care measures.
  - The hospital-level outcome is the risk-adjusted rate of patients experiencing severe obstetric complications during the delivery hospitalization. Two additional outcomes will also be assessed:
    - SMM excluding cases where transfusion was the only SMM
    - SMM with transfusion only

### ***Measure Testing***

- **TJC Presentation on Measure Testing and Specification Updates**
  - TJC presented the results of alpha testing and beta testing, for 9 pilot sites, totaling 25 hospitals and 3 EHR systems (Epic, Cerner, Meditech).
  - For alpha testing, a virtual EHR walkthrough session was conducted with pilot sites, who shared their screen while navigating through their EHR system so as to

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review the measure data element specifications in the clinical workflows being discussed. Data element specifications for two data elements, timestamp for the delivery procedure, and laboratory results for the PaO<sub>2</sub>/FiO<sub>2</sub> ratio, were adjusted following feasibility issues revealed during testing. Feasibility scores of 98% for the revised measurement suggest that the measure can be operationalized.

- During beta testing, TJC conducted reliability visits with 6 sites for adjudication of a statistically representative sample of hospital records. Re-abstracted data elements and findings were compared with the original electronically submitted data and discrepancies were adjudicated. Overall measure outcome agreement is 91.2%, kappa score of 0.881.
- CORE is conducting additional beta testing with 5 hospitals; this is ongoing.
- TJC reviewed measure specification changes following the beta testing.
  - SNOMED diagnoses and procedures have been removed from numerator and risk variable definitions, except for blood transfusion, since pilot sites did not map to SNOMED codes and data could not be tested. future incorporation of these codes in the measure will be considered following testing;
  - Platelet count <100 10<sup>3</sup>/uL was removed since this criterion alone does not identify severe SMM;
  - ICD stay >12 hours was removed since generally these are identified with other qualifying codes;
  - Creatinine ≥2 mg/dL was removed since generally these are identified with other qualifying codes; and,
  - PaO<sub>2</sub>/FiO<sub>2</sub> ratio was removed since the test volume is low and it is burdensome for providers to map in the EHR.
- Additional respiratory failure codes were seen that were not initially included in the value sets. The CDC will be releasing an updated SMM ICD-10 code list, including additional respiratory failure codes, and value sets impacted by the CDC update will be revised as part of our measure maintenance process.
- CORE noted the next phase of the beta testing process will expand on these findings.

### ***TEP Discussion***

- CORE presented two discussion questions for TEP consideration: 1) Do you have questions or comments about alpha testing or beta testing results? And 2) Do you have questions or comments about the measure specification?
  - A TEP member noted that with SMM cases it is not unusual to see 10-20% of cases with miscoding and suggested keeping creatinine ≥2 in the measure since it did not appear to give false positives.

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- A TEP member asked whether reliability testing was conducted on a range of patients with multiple morbidities to those with none and noted that more complicated cases might have less reliable data. If these complicated cases are miscoded, it will skew the results. They also noted that different coders capture things differently, which could result in over-coding of events such as postpartum hemorrhage.
  - TJC responded that they did not see more complicated cases with less reliable data but noted the need for improved transfusion data.
- A TEP member noted workflow differences across EHRs, and differences in processes for and recording of blood transfusions. They noted that this is an important lesson for this work to feed back to the EHR companies.
- Several TEP members commented on the candidate risk variables. A TEP member asked how this list of variables was selected, and if they are being tested in the model yet, and another TEP member asked about the risk adjustment process.
  - CORE explained the rationale for risk adjustment, and approach to risk variable selection and for risk model development.
- A TEP member noted housing insecurity to be difficult to collect consistently and asked about social risk factors such as race and ethnicity.
- Another TEP member asked about uterine fibroids, seizures, and ovarian cysts as contributing factors.
  - TJC explained the intention to stratify the outcome by race and ethnicity.
  - TJC also noted the challenges of identifying fibroids and related conditions and noted that seizures are captured under neuromuscular disease.
- A TEP member suggested utilization of B-type natriuretic peptide (BNP) would be an alternative to creatinine, particularly for those for severe preeclampsia, severe breeches, or potential heart failure.
- Several TEP members commented on hospital transfers. One TEP member asked about patients who are admitted then transferred during the continuum of care and the quality of the data for these transferred patients. Another TEP member agreed that transfers are a critical piece of information, since smaller hospitals may transfer the sickest patients to larger institutions. A third TEP member asked about transfers from birth centers.
  - TJC acknowledged the issue of hospital transfers and noted the challenge of identifying them with current EHR data.
- A TEP member asked about the impact of volume on beta testing.
  - TJC noted the range of volume across testing hospitals.
- A TEP member asked about the removal of the ICU stays from the numerator specification, since ICU is a pretty significant morbidity criteria.

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- TJC noted that not all pilot sites had an ICU, the burden of data collection, and limited findings in testing, but noted future reconsideration.
- A TEP member asked if two outcomes could be measured, one with only inpatient admissions in the denominator and another that includes births outside the hospital setting, since some regions of the country see a lot of SMM occurring outside the hospital setting; there could be value in taking more of a public health approach in capturing these data. They suggested making it clear in the technical notes what is and is not included.
  - TJC acknowledged the importance of SMM outside the hospital, but that it would be a different measure.

### ***Summary***

- TEP members noted the strength of the testing results and generally expressed support for the proposed methodology changes. CORE and TJC will continue to share information with TEP members as additional beta testing is completed and the risk model is developed.



## **Third TEP Meeting Overview**

Prior to the third TEP meeting, TEP members received detailed meeting materials outlining measure testing results and proposed updates to the measure specifications. These topics were discussed during the third TEP meeting and TEP members were invited to provide feedback.

The following bullets represent a high-level summary of what was discussed during the third TEP meeting. For further details, please see [Appendix F](#).

### ***Risk Model***

- **CORE Presentation on Risk Model**
  - CORE explained the approach to development of the risk model. CORE noted that a risk model was developed for both severe obstetric complications and severe obstetric complications excluding blood transfusion-only encounters. Both models used the same variables with data from 25 hospitals across 8 different healthcare systems.
  - Exclusion of variables from the final model was based on the amount of missing data or other clinical reasons, not on statistical significance of individual variables, due to expected clinical importance of the variables identified and future opportunity for assessment with more data.
  - The majority of the risk model variables are captured with ICD-10 codes and accompanied by an indicator that the code was present on admission (POA). Additional clinical variables include heart rate, systolic BP, hematocrit, and white blood cell (WBC) count, and these are all the first recorded value within 24 hours before admission up until delivery.
  - The risk model indicated good model discrimination, good calibration of the model, and a reasonable range between the lowest decile and highest decile of predicted ability, given the low prevalence of the outcome.
- **TEP Feedback**
  - A TEP member noted that the “Economic Housing Instability” variable had a noticeably low percentage (0.1%) and suggested that this may not be an accurate representation.
    - Dr. Main confirmed that it is well understood that this is often underreported, and that there is a large effort by many federal agencies to have this coded more frequently.
  - A second TEP member added that codes which generate revenue tend to be more heavily used than the ones that do not. There was a discussion about how including a variable in the measure may result in hospitals collecting and reporting it more often.
  - A TEP member asked if a small sample would dramatically overstate the value of a particular risk factor, and if there is a way to correct for that.

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- CORE acknowledged that this is possible and will be assessed with larger data samples in the reevaluation of the measure.
- A TEP member asked why patients less than 20 years old were displayed as the referent group in the model and expressed that they felt as though this population would be at greater risk for severe maternal morbidity (SMM).
  - CORE explained that odds ratios are not presented, and for inclusion in the predictive model, the selection of a referent group has no mathematical impact on the risk model or measure score results.

### ***Measure Score Results***

- CORE Presentation on Measure Score Results
  - CORE presented risk-standardized rates per 10,000 delivery hospitalizations for the two outcomes: patients experiencing any severe obstetric complication(s) and patients experiencing severe obstetric complication(s) excluding blood-transfusion only encounters. CORE also presented observed frequencies of individual numerator definitions.
- TEP Feedback
  - A TEP member asked about potential bias, noting that the complications rate was high in test site 1, which had 18,070 encounters, or about a third of all the data. It would be expected that the risk-standardized rate would be closer to the observed rate.
    - CORE explained that both a development sample and a validation sample were used, and the results helped to justify that there is not much over-fitting due to specific details of the hospitals that went into the model.

### ***Measure Score Reliability and Validity***

- CORE Presentation on Measure Score Reliability and Validity
  - CORE presented the measure score reliability results and noted that the signal-to-noise reliability results show high reliability for both outcomes. CORE presented results of validity, noting that strong measure validity was indicated.

### ***TEP Discussion***

- A TEP member asked about the classification of most hospitals in the sample as community hospitals.
  - TJC confirmed that some of the hospitals were affiliated with teaching organizations, and that the classifications were obtained from the American Hospital Association (AHA) DataQuery database.
  - TJC stated that a community hospital is any hospital open to the public and includes all hospitals except for a prison or a college infirmary. TJC agreed that the word “community” can be misleading and will remedy this in future descriptions of the measure.

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- A TEP member asked if more data on outcomes to strengthen the validity of the risk model would be considered.
  - CORE confirmed that there is work currently being done to test the measure in 5 additional hospitals.
- A TEP member asked if the risk variables are all weighted the same, and if so, why.
  - CORE confirmed that variables were not weighted differently upon entry into the model.
- A TEP member asked if a variable was kept in the model if it had no impact on the model.
  - CORE explained that variables were removed if they had a significant amount of missing data, and that labs and vital signs were removed if the values across patients lacked variability. Otherwise, variables were included due to expected clinical importance and expected impact with a larger sample size.
- A TEP member commented on the approach to risk model development, noting that usually a univariate analysis of each variable would be done first and significant univariate variables would then be included in a multi-variate analysis with a stepwise process that could be in order of the univariate strength.
  - CORE stated that univariate analysis was conducted and given the evidence of the importance of these risk variables by other investigators, they were included in the model. There will be opportunities for reevaluation of the model in a larger set of hospitals, and inclusion of these variables makes them available for reevaluation. The intent is to create a measure that eventually is appropriate for broad implementation.
- A TEP member suggested that there should be an explanation of how the model will be constantly reevaluated in less technical terms, as would possibly cause less skepticism.
- A TEP member asked if there was a reason why uterine rupture was not listed as one of the risk variables.
  - Dr. Main answered that usually this is not present on admission and usually occurs during the active phase of labor.
  - CORE added that there is not an easy way to get a history as there is not an ICD-10 code for it.
- A TEP member asked about the transfer status of patients.
  - CORE explained that persons contribute to the population at risk in the hospital where they deliver, regardless of whether a transfer occurred before or after delivery.

### **Face Validity Vote**

- CORE presented the TEP the following statement and requested that each member rate it on a scale of 1-6 (1=Strongly Agree to 6=Strongly Disagree): “The risk standardized rate of severe obstetric complication and mortality events obtained from the Severe

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Obstetric Complications eCQM as specified can be used to distinguish between better and worse quality care at hospitals.”

- Several TEP members expressed concern about the wording of the face validity question, specifically about the use of the word “quality” in the question.
- CORE facilitated a discussion of the quality measurement of hospitals and indicated that they would create several face validity questions that could individually assess aspects of the measure validity and use and reach out to TEP members via survey for feedback.
- CORE thanked the TEP members for their input and their time.

### ***Summary***

- TEP members asked thoughtful questions and gave valuable input on the risk model and measure results. TEP members noted that there needs to be more clarity on the definition of community hospital, and that the statement assessing face validity of the measure needs modification. CORE and TJC will work on further clarification and will provide an updated survey for the face validity vote.

## **Next Steps**

### **Ongoing Measure Development**

CORE will continue to encourage further feedback and questions from TEP members, including a Qualtrics survey with face validity questions. CORE will continue to engage stakeholders in a Patient Working Group and will hold a public comment from November 19 through December 18, 2021 to solicit feedback on measure specifications. Additionally, this measure will be submitted to NQF in Spring 2022.

## **Conclusion**

TEP feedback on the use of language was helpful to further refine the presentation of hospital characteristics and to distinguish measuring quality care versus outcomes. CORE will continue to engage with the TEP as the measure moves through measure endorsement and implementation planning.

## Appendix A. CORE and TJC Measure Development Teams

**Table A1. Center for Outcomes Research and Evaluation (CORE) Team Members**

Name	Role
Kathleen Balestracci, PhD, MSW	Division Lead, Hospital Research and Development
Kerry McDowell, MPhilEd, MSEd	Project Manager
Grace Glennon, MS	Project Lead
Valery Danilack, PhD, MPH	Project Lead
Andrea Barthel, MS	Lead Analyst
Tahmidul Islam, PhD	Analyst
Sarah Attanasio, MS	Project Coordinator
Nicole Walton, BS	Research Support
Emma Turchick, MPH	Research Support
Zhenqiu Lin, PhD	Director, Data Management and Analytics
Lisa Suter, MD, PhD	Contract Director, Quality Measurement Program
Harlan Krumholz, MD, MS	Director, CORE

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**Table A2. The Joint Commission Measure Development Team**

Name	Role
JohnMarc Alban, MS, RN, CPHMS	Associate Director
Susan Yendro, MSN, RN	Associate Director
Marilyn Parenzan, MBA, RHIA, CPHQ	Associate Project Director, eClinical
Chris Walas, MSN, RN	Associate Project Director, Clinical
Stephan Schmaltz, MPH, PhD	Associate Director and Senior Biostatistician
Sheila Aguilar, MBA	Senior Research Associate
Jennifer Hurlburt, DNP, MSN, BSN	Associate Director, Department of Standards and Survey Methods

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## **Appendix B. TEP Call Schedule**

### **TEP Meeting #1**

Friday, February 28, 2020 – 8:30am – 3:00pm EST (Location: BWI Airport Marriot, Baltimore, MD)

### **TEP Meeting #2**

Tuesday, July 20, 2021 – 4:00pm – 5:30pm EST (Zoom Conference Call)

### **TEP Meeting #3**

Wednesday, November 3, 2021 – 4:00pm-5:30pm EST (Zoom Conference Call)



## Appendix C: Detailed Summary of First TEP Meeting

[Please Note: As of 2021, the name of this measure is: **Severe Obstetric Complications eCQM**. The Detailed Summary of the first TEP meeting refers to the measure by its initial name: Maternal Morbidity eCQM.]

### Participants:

- Technical Expert Panel (TEP): Suzanne Baird, Debra Bingham, James Christmas, Blair Dudley, Tomeka Isaac, Deborah Kilday, Joseph Kunisch, David Lagrew Jr., Elizabeth O’Neil-Greiner, Sarosh Rana, Elizabeth Rochin, LaToshia Rouse, Barton Staat, Karey Sutton, Aswita Tan-McGrory, Brooke Villarreal
- The Joint Commission (TJC): Tricia Elliott, Mia Nievera, Susan Yendro, Jennifer Hurlburt, Becky Cooper, Stephen Schmaltz
- Yale New Haven Health Services Corporation- Centers for Outcomes Research and Evaluation (CORE): Kathleen Balestracci, Darinka Djordjevic, Shani Legore, Lisa Suter, Rachelle Zribi, Rajvi Shah
- Expert Clinical Consultant: Elliott Main
- The Centers for Medicare & Medicaid Services (CMS): Annese Abdullah-McLaughlin, Cindy Tourison, Renee Fox

### Welcome

- Dr. Katie Balestracci welcomed the group on behalf of CORE and introduced Deb Chromik, who was facilitating the meeting.
- Ms. Rachelle Zribi reviewed the meeting agenda and reminded the group that the content of TEP discussions must remain confidential until made public by CMS and that all personal opinions and experiences, including any personal health information, shared during the TEP meeting are to remain confidential. She stated that TEP members are representing themselves and not the organizations with which they are affiliated. Dr. Balestracci provided a brief overview of the organizations working collaboratively on the hospital-level maternal morbidity eCQM. TJC is developing an outcome-based eCQM to address maternal morbidity in the inpatient hospital setting and will be the measure steward. CMS is committed to addressing maternal morbidity and improving maternal health. CORE, under contract with CMS, will support TJC on measure development and testing.

### Introductions

- Members of The Joint Commission introduced themselves.
- Members of the CORE team introduced themselves.
- Dr. Elliott Main introduced himself.
- Dr. Balestracci introduced Cindy Tourison (CMS), Dr. Renee Fox (Center for Medicaid and CHIP Services (CMCS)/CMS), and Annese Abdullah-McLaughlin (CMS).

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- TEP members briefly introduced themselves and described their key interests related to the measure. Members also disclosed any potential conflict of interest (COI).

### **Review and Approval of the TEP Charter**

- Ms. Zribi facilitated review and approval of the TEP Charter. Members approved the charter unanimously.

### **Measure Background: Severe Maternal Morbidity (SMM)**

- Dr. Elliot Main provided an overview of severe maternal morbidity and mortality, including definitions, rates, racial disparities, and variation by urban and rural locations. He reviewed data from the Centers for Disease Control and Prevention (CDC) and presented the CDC's 21 indicators of severe maternal morbidity. He noted that there is broad national interest in severe maternal morbidity. He presented data on variation in SMM across hospitals using California Maternal Quality Care Collaborative (CMQCC) Maternal Health Center data and presented the rationale for developing a maternal morbidity measure.

### **Measure Development - Maternal Morbidity eCQM**

- Dr. Balestracci presented the process for developing an eCQM for maternal morbidity. She highlighted that the goal of this work is to develop a measure derived from EHR data that can be applied at the hospital level and apply to all payers, addressing maternal complications during delivery hospitalizations. An environmental scan identified no current maternal morbidity outcome measures used in national reporting programs. She noted there are existing state-level agencies and collaboratives addressing maternal health with some use of hemorrhage- and transfusion-related outcome measures.
- Dr. Balestracci highlighted the development and testing process and highlighted challenges throughout these processes. She noted the importance of stakeholder engagement throughout measure development and testing.
- TEP members made the following comments and suggestions:
  - A TEP member shared that challenges exist in data collection of race/ethnicity. Most hospitals don't collect this well and there is variation in how it is collected. This makes it difficult to assess disparities in performance.
  - A TEP member said that disparities exist across income and education levels. We need to be mindful of them and use performance assessment to close the gap.
  - A TEP member asked about using Z codes to look at social determinants of health (SDOH) for data collection.
    - Ms. Yendro from TJC stated that the developers likely will be using Z codes and other coded data available in EHRs such as SNOMED codes.
  - A TEP member said that according to CDC, maternal mortality occurs approximately one third antepartum, one third in the first week, and one third

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after the first week to the first year after delivery. The member asked if this pattern holds for SMM. The member also commented that some cities have different levels of hospitals treating patients with different acuity, and some facilities only have emergency departments. The member asked how these different care settings can be captured in the measure.

- Dr. Main replied that some SMM occurs after hospital discharge or during readmissions. He noted that these would be missed with a focus only on delivery hospitalizations, and suggested the measure be specified for multiple care settings.
- A TEP member asked how the team would look at false negatives in alpha testing.
  - Dr. Balestracci explained false negatives can be identified during the testing process through clinical adjudication. Adjudication identifies a sample of patients who are identified as having SMM and those not; the medical record is used to determine if there was an SMM event or not and whether the measure is appropriately identifying both.
- A TEP member said there may be challenges with how morbidities are captured in the International Classification of Diseases, Tenth Revision (ICD-10) coding with the CDC definition. The actual rates of morbidities may be much higher due to shifts in some of the attributions of harm which may present a challenge when looking at different definitions.
- A TEP member commented on the feasibility of using Z codes to capture SDOH. The member noted that CDC recently had a study on coding of SDOH showing that the rate of capture is increasing but low. Electronic systems still have trouble capturing the data. This may be a factor of administrative processes in facilities: coding departments in hospitals only allow physician data to be entered in certain sections of the record when the case managers have done the documentation. The coders can't use the data entered by case managers.
  - Dr. Main commented that most codes are based on physician charting but potentially Z codes can be entered by others such as case managers and registered nurses. Facilities need education and then more consistency in providing robust coding of SDOH.
- A TEP member noted that the issue of mental health challenges that women face when they have had [SMM] events and also the associated cost. It costs more for some hospitals to address the disparities.
- A TEP member asked if there will be an opportunity to share tools for supporting hospitals to improve documentation, identify, and extract data from the EHR for this measure.
  - Ms. Nievera shared that when TJC rolls out measures, they offer user education on where to input the data in the EHR and share the measure logic.
  - Ms. Elliott said that TJC has webinars on measurement and how to implement with algorithms and flowcharts to make reporting successful.

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- A TEP member commented that getting obstetricians to document is one of the biggest challenges, and it is very important to share expectations about documentation. Organized data will be critical for mining information.
  - Dr. Main commented that the eCQM methodology allows users to look deeper than just physician notes, such as pulling information from nursing notes and labs. There is a lot of documentation that happens around delivery captured in nursing notes.
- Another TEP member commented on the need to collect data correctly. The member said some hospitals in other countries have staff dedicated to entering data in the EHR. The member recommends that hospital expectations be that the data is entered with some rigor to ensure consistency and integrity of data, perhaps by hiring a nurse or paying somebody.

### **Measure Specifications: Cohort**

- Ms. Tricia Elliott provided a brief overview of TJC's proposed maternal morbidity eCQM. She presented a list of proposed data elements for the development of the SMM measure. Many data elements have been used in other TJC measure sets and have been validated for logic and feasibility. Other elements are unique to SMM and are more complex to capture. Elements such as complications, pre-existing conditions, and other risk adjustment variables have yet to be defined.
- Ms. Mia Nievera described the initial proposed cohort for the measure. The cohort will include inpatient hospitalizations for patients admitted for a delivery procedure and will include patients aged  $\geq 8$  years and  $< 65$  years. TJC recommended that the cohort not exclude high risk cases and consider risk/case mix adjustment to account for the complexity of patient conditions that may affect their ability to achieve outcomes of interest. TJC also recommended including both live and stillbirths based on Alliance For Innovation On Maternal Health Program (AIM) and California Maternal Quality Care Collaborative (CMQCC) recommendations. TJC recommended excluding patients with less than 20 weeks gestation with the rationale to focus quality improvement efforts on the population likely to be in the labor and delivery unit.
- Dr. Main commented on the 20 weeks of pregnancy inclusion criteria for the denominator population. He noted that other quality of care issues occur before this milestone, such as ectopic pregnancies and miscarriages. However, there is no count of the total pregnant population (e.g., no denominator) for the pre-20 weeks gestation population.
- TEP members agreed with the proposed approach to the cohort and shared the following comments and recommendations:
  - A TEP member recommended consideration for naming the measure Obstetric Morbidity Measure instead of Severe Maternal Morbidity to be more inclusive of the Lesbian Gay Bisexual Transsexual Queer (LGBTQ) community. A TEP member asked how the measure would capture out-of-hospital births (in the emergency

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department, an ambulance, or transferred from another hospital). Will they be excluded from the cohort?

- Ms. Yendro replied that inclusion of these births would depend on how the event was coded. If the placenta is delivered in the hospital, it could be captured in the delivery coding, but otherwise the birth may not be captured. It depends on how the hospital is coding these events. She noted that the team will determine if the frequency of the events impacts reported performance.
- A TEP member asked if patients transferred from a lower- to higher-level facility for delivery may lead to missed quality issues at the lower-level facility. Complications may occur after transfer and get attributed to the higher-level facility. Also, the transferred patient may not be captured in the initial facility's denominator since they didn't deliver there. And therefore, how do we perform measurement on these smaller hospitals?
- A TEP member agreed and shared that sometimes patients are taken care of at lower-level hospitals but then go to a tertiary hospital for delivery. The measure should capture quality along the continuum. The member also asked how terminations would be captured in the data, noting that some eclamptic patients have to terminate for medical necessity.
  - Ms. Yendro stated that this is a consideration during development. Using the proposed definition, these patients would be included in the denominator if the termination occurs after 20 weeks.
- A TEP member asked for clarification on the purpose of the measure, specifically if it will be used for quality improvement purposes or pay for performance. The member noted that there will be a learning curve and that hospitals should be aware if the measure will be used in a payment program.
  - Ms. Elliott said that under TJC requirements hospitals are required to submit data and use it for quality improvement purposes. TJC is not a payer so does not apply financial incentives or penalties.
  - Dr. Balestracci and Dr. Suter commented that use of the measure is to be determined by CMS. Dr. Suter invited TEP members to note concerns related to either use of the measure, particularly where aspects of the measure could raise concerns about validity for certain uses. She noted that we want to have a measure that is as broadly applicable to as many settings as possible. At this point the intent of the discussion is not to define uses but to identify pressure points that impact various uses.
- A TEP member asked if the conditions to be measured will be bundled together into one measure. The member asked if there will there be guidance on how these co-morbidities are addressed.
  - Ms. Elliott replied that patients with multiple comorbidities are expected to be included in the measure, and that there would be different

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approaches to quality improvement depending on the comorbid conditions that exist with the patient. TJC does not expect the measure will be stratified for reporting, but it will be risk adjusted.

- Ms. Yendro noted that TJC does have accountability criteria that they apply to measures when they build them, and as sufficient data are provided to be considered an accurate representative of performance on the measure, TJC can decide to report rates on their public facing website.
- A TEP member said TJC's PC-06 measure addresses unexpected newborn complications and is built as an accountability measure; they said the SMM measure should not just be for quality measurement but should also be used for accountability for consistency across measures. Otherwise, there could be potential challenges.
- Another TEP member agreed with need for accountability. That member would like to see public SMM score released to patients and used for decision making. The member wants SMM to be more than a quality improvement measure.
- Ms. Nievera invited comments on the proposed measure cohort specifications.
- TEP members made the following comments and suggestions in response:
  - A TEP member recommended including all hospital deliveries for high/low risk mothers, live births and stillbirths. The member noted that more hospitals are moving to classifying deliveries at 16 weeks rather than 20 weeks. Some hospitals have obstetric emergency departments that manage pregnancy at any gestational length. Excluding pregnancies of less than 20 weeks may lead to gaps. Other measurement gaps could occur if there are antepartum admissions, especially to the intensive care unit (ICU), resulting in stabilization without delivery, in instances of venous thromboembolism (VTE) or pneumonia, which may be signals of complication.
  - A TEP member said it would be challenging to define a measure for low risk women only. They agreed that the measure should include deliveries for all women. They suggested examining the impact of specifying the denominator to exclude patients with less than 20 weeks gestation. It would be helpful to find out if there are data for this population. They suggested that over time we could move to reporting on less than 20 weeks, perhaps through stratified reporting.
  - A TEP member strongly agreed on including all deliveries in the denominator. The member pointed out that most pregnancies with catastrophic outcomes were at some point considered low risk until their catastrophe. Regarding exclusion of patients under 20 weeks, the team should consider the standardized obstetric definition of birth versus miscarriage or abortion is 20 weeks. With obstetric emergency departments, the measure will miss those patients that are admitted with the pregnancy complication at 18 weeks' gestation. They

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commented that 20 weeks gestation is the right place for inclusion and will drive quality improvement for patients 20 weeks and less. Regarding measure use, if insurance companies and other payers see a cost differential, it will be used in pay for performance programs.

- A TEP member agreed on inclusion of all deliveries. The member said at 20-21 weeks we see terminations to save the mother's life; there is deeper question on whether to include them. Ultimately, we may have to look at including patients at fewer weeks' gestation over time as data improves. The member said the TJC's PC-06 measure has a moderate/severe category for complications that might be a model for this measure.
- A TEP member agreed with the proposed measure cohort inclusion criteria. The member is interested in use of the measure for quality improvement, though the member noted that smaller hospitals might be less engaged in quality improvement. These hospitals may need financial incentives to take improvement seriously.
- A TEP member supported the proposed measure cohort inclusion criteria. The member shared that stillbirths are a metric of SMM. They agreed with the exclusion of patients less than 20 weeks because there is no good denominator. They noted that nobody is really tracking where some of these patients are getting terminations (Planned Parenthood, or via medications from doctors) which makes it hard to identify the denominator. The member recommended finding a way to measure hospitals that admit and transfer patients, as they are delivering low-risk patients but transferring high-risk patients. The member also recommended considering other options for the measure name and recommended that there is a need to raise the profile of the issue and the measure.
- A TEP member supported including all hospital deliveries but suggested that differences in risk be addressed in risk adjustment and stratification since there are differences in hospital populations. They suggested that there may be problems determining the cohort in some scenarios; from the provider organization perspective, we may need to measure aspects of care for which providers can make a difference. The measure should focus on what can be impacted. Claims-based measures are very coding-dependent and are different from quality measures – sometimes they conflict. Claims-based measurement does not always give a clear picture of what is happening in the organization. For example, the Patient Safety Indicator (PSI) measures are claims based. That member's facility does a case review of the PSIs to understand the clinical and quality implications more fully. For SMM we will need to figure out where to read the chart to get the full clinical and quality picture.
- A TEP member agreed on the proposed measure cohort inclusion criteria. The member recommended future consideration of measuring quality at fewer

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weeks gestation. The member pointed out that there are different ways to capture information across different levels of hospitals for patients transferred. The member recommended comparing hospitals to 'like type peers.' This could prevent the unintended consequence of encouraging hospitals to transfer out their patients to avoid penalties for bad outcomes.

- A TEP member agreed on inclusion of all births with live and stillbirths. The member commented that black women are increasing use of midwives and home births. This may impact the measure cohort and the ability to identify disparities. The developers should consider how community partners of hospitals could be assessed and apply a health equity lens.
- A TEP member agreed on inclusion of all births but did not have a recommendation regarding inclusion of live and stillbirths. Regarding transfer of patients to a higher level of care, the TEP member noted we would not want to lose them from the population attributed to a facility. The TEP member's hospital experienced issues with capturing newborn complications within their facility when these newborns were transferred from their hospital to the connecting children's hospital. The TEP member reiterated the importance of considering impacts of transfers on the maternal morbidity eCQM.
- A TEP member agreed on inclusion of all births with live and stillbirths. The member recommended that we capture non-hospital births. The member said that other TEP members made excellent points about applying an inclusion threshold of 20 weeks and agreed with any approach determined by the TEP. The member would want to capture deliveries that don't happen in the hospital.
- A TEP member agreed on inclusion of all births, both live and stillbirths. The member suggested breaking reporting into groups as is done with PC-06 and considering mortality. The member suggested considering coding issues and admission types to capture midwife services and home births. The member commented that data from the EHR 'problem list' and SNOMED codes may not be consistent across hospitals.
- A TEP member agreed on inclusion of all births with live and stillbirths and to consider how to address inclusion of pregnancies less than 20 weeks as data evolves. Regarding use of the measures, the TEP member noted that payers want providers to pay attention to quality improvement and are likely to create financial incentives to improve SMM. The member agreed with capturing midwife services and home births because choice is important for women; these providers should also be held accountable. There should be incentives for accountability, but not to decrease access or choice.
- A TEP member agreed on inclusion of all births with live and stillbirths. The member expressed concern that unconscious bias and racism influences diagnosis and treatment decisions. This cannot be captured in an EHR. We will need to consider how to address these biases when we consider adjustments.

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- Dr. Main shared the following comments related to preventability, noting the underlying causes of complications for SMM are typically in two categories: hemorrhage and hypertension. These account for 75% of SMM. Regarding race and ethnicity coding, this has been widely addressed by organizations, but coding is not yet consistent. The current gold standard is taking maternal race data from the infant’s birth certificate.

### **Measure Specifications – Outcome**

- Ms. Yendro presented the proposed approach for defining the outcome of SMM in the measure. Women experiencing SMM during a delivery hospitalization would be the measure outcome. The outcome would be captured in the eCQM through ICD-10 codes as well as additional coding such as SNOMED, Logical Observation Identifiers Names and Codes (LOINC) and RxNORM.
  - TJC proposed using the CDC’s 21 clinical indicators of SMM to capture the measure outcome. In addition, the measure outcome will include patients who expire during the delivery episode. Including both morbidity and mortality is more inclusive of all complications. Death is an unexpected complication of pregnancy that should be captured.
  - The name of the measure should be ‘Maternal Complications,’ which is inclusive of both morbidity and mortality and more understandable to the public. Ms. Yendro commented that although TJC recommends the name Maternal Complications, other options include Severe Maternal Morbidity, Severe Obstetric Mortality, or Obstetric Complications.
- Ms. Yendro invited TEP comments on proposed measure outcome specifications.
  - A TEP member recommended clarifying the language regarding disparities, that it is not “women with racial and ethnic disparities” but that there are disparities in outcomes for women with diverse backgrounds.
  - A TEP member asked how the measure would be reported and whether it would be a single rate that includes both morbidity and mortality.
    - Ms. Yendro shared that TJC is open to input on reporting strategies. Reporting could be a roll up for a public facing dashboard, and then parsing out by condition in quality improvement notes. The stratification approach, by race and ethnicity, should provide organizations with information about where they are lagging amongst their peers.
    - Dr. Suter commented that the developers would like to hear ‘What is the most useful information from the perspective of patient and provider organizations?’ She noted that by way of context, CMS has a range of approaches to sharing measure information, such as sharing hospital-specific reports with patient level information. These reports will identify the complication that brought a patient into the numerator for a complications measure, or the hospital to which the patient was

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readmitted for a readmissions measure; it will provide state and national benchmarks. CMS also has public facing information, a 'point estimate', which is a single rate or indicator that represents quality and includes information on statistical differences of one hospital to another. The net result is a range of information that has less public granularity with detail for the entity being measured.

- A TEP member asked if the complications could be weighted or ordered since some are more serious and more likely to lead to fatality (e.g., cardiac arrest and pulmonary embolism) while others are less likely to precede death (e.g., transfusion and hysterectomy). The composite score would weight each indicator. The member also noted that transfusing blood should be a positive thing if the mother survives, rather than a negative thing. So, you could assign negative or positive value to it as an intervention and include this in the weighting.
  - Another TEP member shared via email that coding of blood transfusions is often inconsistent and unreliable which may lead to an underestimation of this outcome. The TEP member raised a question on what expectations there will be for organizations to adequately code blood transfusions in the context of this measure. The TEP member also raised concern on a potential unintended consequence of hospitals not providing timely blood transfusions to patients to avoid the transfusion being captured in this measure outcome and reporting.
- A TEP member expressed support for using more than a single number for hospital performance. The member would like to see something like the 'Top 5' common complications per hospital. This would help patients to understand what is the most common outcomes that occur in the maternity episode and how a hospital performed. Such information helps the patient decide where to get care.
- A TEP member commented that the specifications are reasonable. Developers need to consider how to handle complications versus risk adjustment. For example, we'd like to know specifically how well the hospital treats the patient with the sickle cell disorder complication, not just adjust for it. This might be different for other complications. The member wondered how well aneurism and a couple of other conditions on the list are documented. They noted that you might never get a complications list that is all-inclusive, but it's not an unreasonable list to start with and be open to adding a condition in the future if data suggests you should.
  - Ms. Yendro responded that the PC-01 measure, Early Elective Deliveries, has a list of conditions possibly justifying elective deliveries. Over time, TJC has periodically added conditions to that list as they have revealed themselves.

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- A TEP member supported the concept of having a composite measure that rolls up the morbidity outcomes. The member supported the concept of showing ‘Top 5’ outcomes. The member noted that a statistical challenge is that the number of outcomes per hospital may be small in many hospitals. The member wondered how to handle the small number of events at a lot of facilities and noted that the measure may need to consider a regional approach. The developers would need to determine how to elucidate the detail of the underlying complications. The member also asked how the SMM measure would interact with other measures such as Early Elective Deliveries.
  - Ms. Yendro responded that it may be possible to look at hospitals to see what measures trend together to identify appropriate adjustments.
  - Dr. Main commented that we would not want to adjust for quality issues. For example, people with C- sections have more complications; we would not want to adjust C-section data that might make preventable complications hard to decipher.
- A TEP member commented that it is challenging to include mortality in the numerator. The member asked how we could consider complications such as severe hypertension, heart failure, cerebral hemorrhage, liver hematoma, and stroke. They asked about considering related indicators such as oxygen saturation, blood pressure, access to prenatal care, number of prior C-sections, health literacy, stress and racism. The member raised the specific case of extracorporeal membrane oxygenation (ECMO), asking if it is considered outcome or intervention. The member noted that ECMO is an indicator of very severe distress but is also accompanied by respirator which is already captured in the complications list.
- A TEP member supported including mortality in the measure. The member also supported ‘bucketing the complications’ since some are extremely severe and others less so. Mortality may be its own bucket since we really want to be able to call it out. The member referenced an American College of Obstetricians and Gynecologists (ACOG) article that validated maternal mortality rates from death certificates in Texas with chart review and found high number of false positives and stated we need to be able to accurately identify the pregnancy and mortality.
  - Dr. Main replied that the data reported in the ACOG article was a unique case, resulting from a pregnancy check box on the Texas death certificate that was frequently checked inaccurately. A hospital claim for pregnancy is unlikely to have that same error rate. Maternal mortality is typically 1 in 10,000. Because it is so rare, mortality is often treated more like a sentinel event. Because of the low volume of deaths, inclusion in the measure is unlikely to impact the performance number.

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- A TEP member expressed support for stratified reporting and asked how the data would be reported to patients. The member noted that eCQMs are not currently publicly reported and only four are widely used. There is not currently enough data for comparisons. eCQMs typically have not captured morbidity and mortality, which may cause concern among physicians.
- A TEP member said that ‘by definition’ SMM would not include mortality in the numerator and notes that mortality is a very small number. The member recommended that other outcomes might be included such as diabetic ketoacidosis, trauma, and homicide. They suggested stratifying for in vitro fertilization (IVF).
- A TEP member did not support adding mortality, noting that it would be hard to tease it out versus all the other complications that lead up to death. The member suggested considering pulling data from nursing documentation not just physician documentation. For example, the measure could look at Nurse Sensitive Indicators such as hemorrhage risk assessment and other outcomes impacting morbidity.
  - Dr. Suter asked for clarification on the comment above, specifically whether the TEP member was suggesting that causes of morbidity and mortality are different or if the TEP member did not want mortality included in the measure outcome due to the naming of SMM. Dr. Suter commented that since mortality is so rare it likely can’t be reported by itself in a statistically valid way at the individual hospital level.
  - The member stated mortality loses its importance and impact if it is rolled up as a complication in the SMM measure. The member supports having some way to report mortality, just not rolled up in the SMM measure. Nursing organizations could likely produce lists of information that might be found standard in nursing notes that could be abstracted into the measure.
  - Dr. Suter clarified that the speaker was suggesting that mortality be included in the measure but that transparency about mortality-that is separate from morbidity-also be provided.
  - The TEP member agreed.
  - Dr. Suter also asked if the TEP member could expand upon what information may be available in nursing documentation in addition to hemorrhage assessments.
  - Dr. Main asked where to look for nursing documentation in the EHR.
  - The member stated that the obstetrical nursing association, the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) would be able to identify the risks and the location of documentation hemorrhage, VTE risk, etc.

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- Another member shared that the AWHONN and the Association of Maternal and Child Health Programs (AMCHP) convened a panel and published papers on maternal and child health and recommended looking at vital signs as clinical indicators. There is also a Taxonomy of Error, Root Cause Analysis and Practice Responsibility (TERCAP) paper and a maternity database that may be a resource on nursing data. The member suggested that this is an avenue to explore.
- A TEP member suggested that we could consider incorporating management of issues, such as of deep vein thrombosis (DVT) prophylaxis, rather than the number of people who had pulmonary embolism. Perhaps we should document how many people get heparin rather than VTE and pulse oxygen results.
- A TEP member said that the measure could potentially leverage strategies from existing measures such as timing of VTE treatment and looking for timely initiation and timely labs.
- A TEP member stated that complications are different from morbidity (which is lifelong), and death. Death is one of the more reliable hospital indicators and is already in use. It is possible that death may confound the morbidity results to users if it was included in the measure outcome. Complications that are conceptualized as short term and morbidity which is conceptualized as long term should be differentiated. Some of the complications on the list would come in clusters and recommends investigations on how to separate out their individual impacts on the measure outcome.
- A TEP member said that EHR documentation around some coded events would be hard to capture.
- A TEP member stated support for including mortality in the numerator. That member's hospital looked at C-sections and found two-fold differences in outcomes in black and white patients. The member said that including mortality in the measure helps to identify disparities. The member also recommended having a disparities dashboard, looking at patient experience by race, as well as providing training on race-ethnicity data collection and unconscious bias.
- A TEP member shared interest in knowing what is encompassed in terminology for each complication and asked if hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome is included in the list of complications. The member wants to be sure these complications get captured since some people may have a condition that is not necessarily subsumed under a larger complication name.
  - Dr. Main replied that Disseminated Intravascular Coagulation reflects a problem reflective of HELLP. He noted by way of example that liver failure is missing from the complications list but many of the complications related to liver failure are listed separately.

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- Another TEP member recommended that other hypertension-related complications be called out in more detail.
- A TEP member stated no strong opinion on mortality inclusion if the end measure has a way to identify and look at mortality by race/ethnicity. The member also noted that race and ethnicity are a construct; people have multiple identities and intersectionality. For example, “Black” can mean Afro-Caribbean or Afro-Latina and the term includes many different identities.
- A TEP member did not support including mortality in the measure because of the need to highlight it rather than bury it with other complications. The TEP member shared that from their experience, Black women have a high awareness of maternal mortality and look for hospitals based on their mortality rates and that this population needs to also be aware of a hospital’s complication rates. This member stated that the outcome should be something that happened as a result, not a complication that leads to an outcome.
- A member said it seems strange not to include mortality in a measure because it is a big factor in hospital outcomes. If it is not included in the measure, then the measure name has to be very clear that it’s only morbidity not mortality. The name should include mortality if in fact mortality is included in the measure. Mortality is hard to report at a hospital level and it should not be missed. The member also suggested consideration of not tweaking the outcome too much so that there is the ability to compare nationally to what the CDC has put out, but also noted that things may need to be improved. The member also recommends looking at what’s rolled up under the ‘ventilation’ complication, asking if these complications are counted independently or in the roll up. The member recommended that process measures are critical as complements to measures like this one – hospitals need to be encouraged to investigate the details of what they find in the eCQM to find out why it’s happening.
- A TEP member said using the words obstetric or maternal in the name would be fine. Another member recommended using the term ‘childbirth’ mortality or childbirth morbidity since we want to be very specific about the event we are measuring. That member supported the TEP suggestion to focus on the outcome, not the comorbidity.

### **Measure Specification - Risk Adjustment**

- Dr. Balestracci provided information on the rationale for risk adjusting measures. She noted that the goal of risk adjustment for hospital quality measures is to account for patient-level factors that are clinically relevant and associated with the outcome without hiding important quality differences.
- Dr. Balestracci said that this would be a preliminary discussion of risk adjustment. Because it is complex and depends on the final specifications in the measure, the TEP

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will need to have future discussions of risk adjustment as specifications for the measure are defined.

- Dr. Main addressed some of the variables that could be considered in a risk adjustment approach to SMM, citing information from studies by Bateman.
- Dr. Main invited input from the TEP on the approach to risk adjustment and possible variables to consider.
- TEP members made the following comments and suggestions:
  - A TEP member asked for additional reference information for the Bateman study. The member agreed that we will need more specific discussion once the measure is specified.
    - Dr. Suter noted the frequency of discussion on social risk and race thus far during the meeting. She noted that social risk impacts many things: the patient's condition on arrival at the hospital, access to care, access to medications. Clinical comorbidity is often correlated with social risk factors and is usually well captured in clinical records and used for adjustment. In other measures, CORE has used the approach of examining clinical risk factors first and once a clinical risk model seems appropriate, examine the incremental impact or disparities of social risk. She asked if this seemed like a reasonable approach.
  - A TEP member noted that economic and housing instability was included [in the list Dr. Main presented] as opposed to food insecurity.
    - Dr. Main noted that we need to consider what is "capturable."
  - The member pointed out the need to be mindful that maternal mortality and morbidity is not just a poor black person, or a poor woman of color's problem. People of color with high socioeconomic status and educational attainment have added risk of maternal morbidity and mortality.
  - A TEP member noted that the hospital is the hub of the community; the hospital needs to also respond to the community and act to improve community resources. We would not want to adjust away the hospital role in improving the health of the community.
    - Dr. Suter noted that several considerations have been suggested by the TEP that we may not be able to capture in this measure. However, there are other measures that can capture other elements of population health (a measure of hospital influence in the community and other aspects of access). This measure may not address all of the hospital role factors but there are other levers for addressing these issues, as well.
  - A TEP member reflected on a study examining 'who waits' in the ED and who gets a bed. That member's facility found that patients with limited English proficiency, homelessness, or substance use disorders are less likely to get a bed. The member said these factors may have triggered unconscious bias about how

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much to 'listen to the patient.' The TEP member said these findings make it apparent that we do not want to adjust away factors such as language that enable providers to take patients less seriously.

- A TEP member suggested that the team consider cancer, incarceration and ambulatory mobility as possible risk factors. The member asked if twin/multiple pregnancies are a factor that should be considered as an adjustment. The member said that availability of an emergency contact is often considered a proxy for social support.
- A TEP member suggested considering incarceration (present or former), cancer, suicide attempt as an adjustment variable.
- A TEP member noted major mental health disorder on the risk variable list and wondered if the measure is capturing maternal mortality would it capture suicide as it related to pregnancy and postpartum depression. This member agreed that cancer should be considered. They also supported considering currently incarcerated women since delivery while incarcerated adds risk. That member also suggested looking at the impact of pregnancy spacing.
- A TEP member agreed that currently incarcerated women are something to consider.
- A TEP member wondered if some of the risk factors were not additive but coexist and are instead synergistic. For example, perhaps a person with five complications is worse risk than five people with one complication. So, if some of these variables drop out of the multivariable analysis it could remove the synergistic impact. This member noted the importance of prenatal care as a metric. Other risks to consider are history of thromboembolism, smoking, vaping, lupus, transfer status, hospital factors: presence of specialist, number of deliveries and availability of trauma care.
  - Dr. Main commented that the team will investigate these factors, as some of them may already be included in broader risk adjustment categories (for example, lupus is captured in the connective tissue disease category).
- A TEP member recommended considering adequacy of prenatal care as a risk factor. Current metrics rely on point in time documentation or fixed lookback, which may not capture some care. It is possible to set up a query to identify care provided across all patient encounters but that slows down a reporting system. The TEP member also asked if previous miscarriages are a risk factor.
  - Dr. Main commented that miscarriages are captured in gravidity and parity data, but there may be variations in documentation that should be investigated, such as differentiating ectopics and miscarriages.
- A TEP member suggested capturing IVF status as a risk factor.

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- A TEP member agreed with comments on the challenges with data collection, including with problem lists and defining timestamp requirements, lookback period and criteria for documentation of subjective information such as smoking.
- A TEP member suggested looking at other eCQM methods for categorizing adjustments into high, medium, and low risk. The member asked if there should be some threshold at which the person has so much risk, they should be excluded from the measure cohort.
  - Dr. Suter replied that the focus is on adjusting for factors that the hospital has some control over. Hypertension matters because it can be checked and managed, as does hemorrhage. We will need to differentiate that from the comorbid condition versus the SMM outcome. There will be imperfections in the measure, but we don't want to mislabel categories that result in worse care.
  - Dr. Main commented that this is an example of when we need to consider exclusions versus adjustments. For example, if a hospital that fails to transfer patients it can't handle, we wouldn't want that hospital to get a pass by excluding them.
- A TEP member said there is a difference in the patient that comes in with a problem versus those patients that develop the issue while in the hospital (which is more of a quality problem). They noted consideration of the quality of prenatal care. The member asked if we want to collect data for risk adjustment when the patient is admitted or after the fact and noted that the timing of coded risk factors may be relevant.
  - Dr. Balestracci said that the 'present on admission' factors are the ones we are adjusting for; the risk adjustment will likely consider conditions coded for a patient within 12 months of the delivery.
  - Dr. Main commented that the present on admission code is gaining use in obstetrics.
- A TEP member recommended adding uterine rupture as a risk variable. The member said we need to be data driven and use data to determine risk, not just make assumptions. For example, women with hypertension have higher risk at any age regardless of race. Some factors become population health issues, such as the health of the woman coming into the system, which can impact the rate of SMM. The location, type of hospital and hospital volume all need to be considered.

### **Next Steps**

- Dr. Balestracci provided information on next steps for measure development. The development team will engage with an EHR and/or information technology expert for input about feasibility of required data elements. The team will conduct alpha testing.

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This will encompass data analysis to confirm initial assumptions about measure specifications and adjustments and will help refine specifications.

- TEP members will be asked to fill out a survey regarding code concepts and data elements in the Spring-Summer 2020.
- The next TEP meeting will be held by webinar, likely sometime between September and December. The team hopes to have some data to show alpha testing results and some insights on the mechanics of creating the eCQM.
- The team will circulate the summary report of this meeting for review by members. The names of individuals will not be included in the meeting summary report. The TEP summary report will be publicly posted after CMS approval; after public posting it will be okay for TEP members to share that information. Information not publicly posted will be confidential.
- Dr. Balestracci said that the team will convene a patient working group for input on measure development. Engagement of patients is a critical priority, as is making sure that the measure can be understood by patients.
- Dr. Balestracci invited TEP members to submit additional comments on any aspect of measure development to [cmsmaternalmeasures@yale.edu](mailto:cmsmaternalmeasures@yale.edu). Ms. Elliott suggested that the developers may survey TEP members for additional feedback as needed.
- The development team thanked TEP members on behalf of TJC and CORE and expressed appreciation for feedback that will help to clarify the measure.

## **Appendix D: Summary of Email Correspondence Before and After the Second TEP Meeting**

### **Email Correspondence After the Second TEP Meeting**

#### **TEP Member Email**

Thank you Kerry + Severe Obstetric Complication eCQM team,

A few questions/comments;

For transfusions, has there been consideration in gaining the hospitals “charged” or billing data on blood use? You could then target for example those who have received certain products and or more than 4 units. Charge coding is very reliable.

Coding errors are a natural progression until accountability and consistent coding by hospitals becomes an expectation. This is a population where documentation and coding has not been at the level of expectation as other populations.

Support avoiding undue burden on hospitals collecting and aggregating this data manually or processes for this kind of this measure.

Can the risk adjustment methodology/calculation/weighting eventually be shared with the committee? This would help in understanding the impact of risk adjustment (understand this is in development).

What is the goal of risk adjustment for this measure? Consideration that risk adjusting may diminish the raw SMM rate and potentially undervalue the opportunity to identify and improve impacted outcomes.

Happy to hear stratification will occur. Thank you for clarifying. Should [there] be more weight on stratification vs. risk adjustment?

POA codes are quite useful; with increased accountability expectations for this measure, POA will be quite reliable.

#### **CORE Email Response**

Thank you again for your feedback and questions. Below are our responses to your questions, please don't hesitate to let us know if you have any follow up questions.

For transfusions, has there been consideration in gaining the hospitals “charged” or billing data on blood use? You could then target for example those who have received certain products and or more than 4 units. Charge coding is very reliable.

CORE response: Because this is an EHR based measure, some hospital systems do not consistently incorporate billing data, so at this time, defining data elements on the accessibility of those data is not feasible.

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Coding errors are a natural progression until accountability and consistent coding by hospitals becomes an expectation. This is a population where documentation and coding has not been at the level of expectation as other populations.

CORE response: Thank you, this is one of the reasons EHR data is being incorporated into this measure.

Support avoiding undue burden on hospitals collecting and aggregating this data manually or processes for this kind of this measure.

Can the risk adjustment methodology/calculation/weighting eventually be shared with the committee? This would help in understanding the impact of risk adjustment (understand this is in development).

CORE response: Yes, we plan to have the risk adjustment methodology and results ready to share by the next TEP meeting.

What is the goal of risk adjustment for this measure? Consideration that risk adjusting may diminish the raw SMM rate and potentially undervalue the opportunity to identify and improve impacted outcomes.

CORE response: The goal of risk adjustment is to even the field between hospitals caring for patients with different levels of risk based on preexisting conditions and pregnancy complications occurring before the delivery hospitalization. These risk factors may lead patients to deliver at hospitals with different levels of care.

Happy to hear stratification will occur. Thank you for clarifying. Should [there] be more weight on stratification vs. risk adjustment?

CORE response: Stratification will be for race/ethnicity and risk adjustment will be for other characteristics and conditions.

## **Appendix E: Detailed Summary of Second TEP Meeting**

### **Participants:**

- Technical Expert Panel (TEP): Debra Bingham, James Christmas, Blair Dudley, Tomeka Isaac, Ajshay James, Joseph Kunisch, David Lagrew, Elizabeth O’Neil-Greiner, Elizabeth Rochin, Michael Ross, Karey Sutton
- The Joint Commission (TJC): JohnMarc Alban, Susan Yendro, Chris Walas, Sheila Aguilar, Marilyn Parenzan
- Yale New Haven Health Services Corporation- Centers for Outcomes Research and Evaluation (CORE): Kathleen Balestracci, Valery Danilack, Tahmid Islam, Sarah Attanasio, Nicole Walton, Emma Turchick, Kerry McDowell

### **Welcome**

- Ms. Kerry McDowell welcomed the Technical Expert Panel members (TEP) and reviewed the meeting agenda which included introductions; review and approval of the TEP Charter; review of the measure specifications; review of measure testing results; including alpha testing results and beta testing results; and next steps for testing and implementing the measure.
- Ms. McDowell facilitated introductions of TEP members, requesting updated affiliations and any updated conflict of interest.

### **Review and Approval of TEP Charter**

- Ms. McDowell reviewed the TEP Charter; TEP members noted no concerns and the TEP Charter was unanimously approved.

### **Measure Background**

- Ms. McDowell stated the goal for this meeting is to obtain input on measure testing results, including alpha testing, beta testing, and proposed measure specification updates.
- Dr. Kathleen Balestracci noted the alpha testing has been completed, and that beta testing is ongoing and results presented will be those conducted to date. She noted that the measure specification slides to be presented include the proposed risk variables being explored, but the analysts are working on risk model development, so the beta testing results presented are unadjusted. CORE will continue testing and analyzing score results and will come back to this group once the beta testing is completed.

### **Measure Specifications**

- Ms. Susan Yendro reviewed the Numerator definitions for severe obstetric complications. She stated that, based on those initial TEP discussions, numerator definitions in addition to the 21 severe maternal morbidity (SMM) indicators identified

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by the Centers for Disease Control and Prevention (CDC) were identified for evaluation during measure testing, including mortality measured with discharge disposition, intensive care unit (ICU) length of stay > 12 hours, serum creatinine  $\geq 2$  mg/dL, partial pressure of oxygen (PaO<sub>2</sub>) > 60 mmHg, and platelet count  $< 100 \times 10^3/\mu\text{L}$ .

- Ms. Yendro noted that data were submitted by the hospitals and most of the participating hospitals pulled the EHR data for testing this measure themselves, where in normal day-to-day practice they have vendor support for data. It was interesting and challenging for them, particularly during a pandemic time period when resources were being stretched.
- Ms. Yendro noted the initial patient population (IPP) is the same population that is used for other perinatal care measures in use that were developed by TJC.
- Ms. Yendro described the hospital-level outcome will be the risk-adjusted rate of patients experiencing severe obstetric complications during the delivery hospitalization, and noted that two additional outcomes will be assessed:
  - Severe Maternal Morbidity (SMM) excluding cases where transfusion was the only SMM, and SMM with transfusion only.
  - Ms. Yendro explained that for a variety of reasons, it is important to look at SMM with and without transfusion only, as transfusion makes up a large portion of the SMM. The potential differentiation in outcomes by transfusion is currently being considered in research.
- Ms. Yendro explained that the candidate risk variables for model development are based on work published in the literature, as well as other elements available in the eCQM and hybrid datasets.

## **Measure Testing**

### ***Alpha Testing Results***

- Ms. Marilyn Parenzan presented the results of alpha testing. A virtual EHR walkthrough session was conducted with 9 pilot sites, which represented a total of 25 hospitals, including 3 health systems with multiple hospitals. The pilot sites shared their screen while navigating through their EHR system as we reviewed the measure data element specifications in the clinical workflows being discussed. Then the National Quality Forum's (NQF's) eCQM feasibility scorecard template was used to complete the scorecard for each pilot site during this time.
- Ms. Parenzan stated that following the fourth EHR walkthrough, it was determined that several of the pilot sites were unable to accurately capture:
  - Timestamp for the delivery procedure, and
  - Laboratory results for the PaO<sub>2</sub>/FiO<sub>2</sub> ratio.
  - These feasibility challenges were addressed by revising the alpha testing specifications to better align with clinical intent and decrease the burden for the sites for results not commonly calculated in the EHR.

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- The feasibility scores based on the revised specification increased from 95% for the initial measurement to 98% for the revised measurement. She noted the feasibility rates were very good, suggesting the measure can be operationalized.

### ***Beta Testing Results***

- Ms. Parenzan shared details of the beta testing. These data are from 9 sites, totaling 25 hospitals and 3 EHR systems (Epic, Cerner, Meditech). TJC conducted reliability visits with 6 sites on a statistically representative sample of hospital records. Re-abstracted data elements and findings were compared with the original electronically submitted data and discrepancies were adjudicated. Overall measure outcome agreement is 91.2%, kappa score of 0.881.
- CORE is conducting additional beta testing with 5 hospitals; this is ongoing.

### **Specification Updates**

- Ms. Chris Walas reviewed measure specification updates following beta testing by TJC. She noted that SNOMED diagnoses and procedures have been removed from numerator and risk variable definitions, except for blood transfusion; during pilot testing they learned the hospitals were not mapping to SNOMED except for transfusions. Testing of optimal incorporation of SNOMED codes is ongoing, and future incorporation of these codes in the measure will be considered.
- Ms. Walas noted they recommend removing:
  - Platelet count  $<100 \times 10^3/\mu\text{L}$  since this criterion alone does not identify severe SMM;
  - ICD stay  $>12$  hours since generally these are identified with other qualifying codes;
  - Creatinine  $\geq 2$  mg/dL since generally these are identified with other qualifying codes; and,
  - PaO<sub>2</sub>/FiO<sub>2</sub> ratio since the test volume is low and it is burdensome for providers to map in the EHR.
- Ms. Walas noted during reliability testing, additional respiratory failure codes were seen that were not initially included in the value sets. The CDC will be releasing an updated SMM ICD-10 code list, which includes the additional J96 Respiratory Failure codes. As a result, they will update the value sets based on the CDC update as part of our measure maintenance process.
- Dr. Balestracci noted the next phase of the beta testing process will expand on these findings. For example, CORE will collect both ICD-10 and SNOMED codes and run the measure with and without the SNOMED codes to identify the impact of this specification change. In addition, we will further explore some of these additional numerator definitions. These results will be shared with the TEP.

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## TEP Discussion

- Ms. McDowell presented two discussion questions for TEP consideration, and allowed each TEP participant an opportunity to respond:
  - Do you have questions or comments about alpha testing or beta testing results?
  - Do you have questions or comments about the measure specification?
- A TEP member noted alpha and beta testing results look good. With SMM cases it is not unusual to see 10-20% of cases with miscoding. As far as specification updates, they seem reasonable, but perhaps better to leave in the creatinine  $\geq 2$ . The frequency was low, but it is easy to pick up from coding; and it did not appear to give false positives.
  - Ms. Walas noted 3 cases were identified during reliability testing. Sites noted the serum creatinine test is rarely ordered and suggested it might not be the right test to evaluate.
  - Ms. Parenzan clarified the reliability sample included 180 cases. Feedback from providers suggests submitting lab values is challenging. In the real world, the vendor does a lot of this submission and during testing, the hospitals did not have vendor support, which may explain why they experienced problems.
- A TEP member asked about reliability testing, and whether the cases represented a range from patients with multiple morbidities to patients with no SMM, and if trends were observed showing more complicated cases had less reliable data. The TEP member stated that it seems that more complicated cases might have less reliable data. SMM occurs more frequently than it should, but it is relatively uncommon. If these complicated cases are miscoded, it will skew the results.
  - Ms. Yendro did not see anything to support this concern. With complicated cases, there are more ICD-10 codes; they did not note any significant trends.
  - Ms. Walas noted some codes were very broadly used, noting the codes in charts might not correlate to SMM cases. One thing she noticed with complicated cases was the transfusion protocol was messy. Hospitals use different units. There is a lot of room for improvement in reporting data around transfusion. It is why we are separating out transfusion-only cases as one of the outcomes.
  - Ms. Parenzan observed one reason for the discrepancy in reporting is that some hospitals are not on an EHR for surgery and anesthesia which makes the data difficult to abstract. There is a lot of room for improvement in documenting transfusions.
  - The same TEP member noted concerns about the coding of data; different coders capture things differently. One result of this could be over-coding of postpartum hemorrhage. This TEP member noted preferring direct data points.
  - Another TEP member noted workflow differences across EHRs and the processes around transfusing blood and asked if it was recorded in CC or units. Many hospitals have separate blood bank systems that are disconnected from the EHR. This is an important lesson for this work to feed back to the EHR companies.

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- A TEP member agreed these reflect strong results. They had comments about the candidate risk variables discussed during the initial TEP meeting and asked about how this list of variables was selected and if they are being tested in the model yet.
  - Dr. Balestracci showed slide 19 and noted that there are more candidate risk variables than discussed during the initial TEP. The current list is informed from TEP conversation, feedback from our expert consultant, and additional variables identified in the field. The work that our expert consultant, Dr. Elliott Main, and his colleagues have been doing in California has informed these considerations. In addition, the first resulted values of a number of labs and vitals on the patient have been included based on work indicating that these factors could impact a patient’s trajectory. Candidate variables will be considered using bivariate analyses, and then tested within the risk model to find the best fit while still identifying and measuring hospital quality. There is a strong statistical component, but CORE retains the importance of expert opinion and clinical impact in risk variable selection.
- A TEP member noted it appears to be an aggressive list and it will be interesting to see which ones they will be able to use. Housing insecurity is going to be difficult to collect consistently. They asked about social risk factors such as race and ethnicity since they are not listed.
  - Ms. Yendro noted they intend to stratify the outcome by race and ethnicity. She also noted that we will also be able to pull in present on admission (POA) indicators for risk adjustment, as we were able to get a value set established for POA. Hospitals have access to it, although a couple of providers had challenges mapping it.
- A TEP member asked if creatinine is not an option, would utilization of B-type natriuretic peptide (BNP) be a better option, particularly for those for severe preeclampsia, severe breeches, or potential heart failure. Also, they asked for more information on the risk adjustment process and what they are risk adjusting for?
  - Dr. Balestracci noted they are careful to risk adjust for factors that impact the health outcomes for delivery hospitalizations that are outside the hospital’s control. If not done, it would prevent an even comparison of hospitals because of the different populations served by different hospitals. In risk adjustment, we want to avoid adjusting for factors that we expect hospitals to treat or address during the hospitalization.
- A TEP member noted questions about uterine fibroids, seizures, and ovarian cysts as contributing factors. In addition, they asked about the consideration given to patients who are admitted then transferred during the continuum of care and the quality of the data for these transferred patients.
  - Ms. Walas noted that they discussed fibroids and other conditions with our expert consultant, Dr. Main, and looked at literature. The variability of ICD-10 coding for fibroids creates a challenge. Seizures are captured under neuromuscular disease category. She will provide additional details in response to this following the meeting.

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- Ms. Yendro noted they collected discharge disposition, but it does not capture patients transferred in after delivery. There is not a good way to identify this. The measure identifies a delivery episode and includes only those who deliver during the encounter. The issue of transfers is on our radar, but they are hard to determine with the data available to us. Discharge disposition is only examined to see if a patient expired, but expanding the information obtained from the discharge disposition field could be considered in the future. The measure also does not address post-delivery readmissions. This is of importance to women who experience these complications.
- A TEP member agreed that transfers are a critical piece of information, and that it is particularly important to do risk adjustment. Smaller hospitals may transfer the sickest patients to larger institutions. Another question regarding the beta testing is the impact of volume (low- or high-volume facilities). Volume may have an impact on morbidity and create challenges in EHR collection. Lower volume hospitals may not be as advanced, higher volume hospitals may be overly busy.
  - Ms. Parenzan shared that they had a good provider mix, including community hospitals; the sample was comprised of 8 large, 9 medium, and 10 small facilities, based on the American Hospital Association definition. Two major teaching institutions are represented. Four facilities had less than 500 deliveries during the measurement year, and 4 had greater than 5,000 deliveries.
  - The same TEP member asked about removal of the ICU stays from the numerator specification and noted that three of the cases would not have been picked up by another numerator code. They noted that ICU is a pretty significant morbidity criteria and expressed concern about not picking up these cases if the patient does not have another SMM code.
  - Ms. Walas noted there is a site that does not have an ICU. The data collection seemed burdensome; they can reconsider this once they look at the full dataset. Vendor assistance will make it less burdensome to pull the information together.
  - Ms. Walas noted in at least one case that was excluded, the reason for the ICU stay was unrelated to the pregnancy.
- A TEP member asked if a patient who delivered in a birth center and transferred to the hospital, or a patient who labored in a birth center and then transferred to a hospital would be included in the measure.
  - Ms. Yendro verified that only inpatient deliveries are counted; birth center deliveries are not considered inpatient deliveries.
  - The same TEP member commented about how the hospital workflow impacts how the data were entered and asked if using a vendor will be part of the next portion of testing. They also asked if CORE and TJC will connect with EHR vendors about how the workflow impacts the measure.
  - Ms. Parenzan clarified they will not work with vendors at all during the pilot testing phase.
- A TEP member asked if two outcomes could be measured, one with only inpatient admissions in the denominator and another that includes births outside the hospital

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setting. Some regions of the country see a lot of SMM occurring outside the hospital setting; there could be value in taking more of a public health approach in capturing these data.

- Ms. Yendro noted it is certainly something that needs to be considered but it would be a completely different measure.
- The same TEP member suggested making it clear in the technical notes what is and is not included.
- Three TEP members noted they had no questions about the testing or measure specifications at this time.

### **Next Steps**

- On behalf of CORE, Dr. Balestracci thanked the group for their time and valuable feedback. She noted that continued feedback was welcome and encouraged TEP members to email with additional input. She noted results from additional testing will be brought to the TEP. Regarding next steps, Public Comment will occur in Fall 2021, and NQF measure submission will occur in the spring 2022 cycle. Additional stakeholder engagement with the Patient Working Group is scheduled to occur on July 28.
- Ms. McDowell thanked the participants and closed the meeting.

## Appendix F: Detailed Summary of Third TEP Meeting

### Participants:

- Technical Expert Panel (TEP): Suzanne Baird, Debra Bingham, James Christmas, Blair Dudley, Tomeka Isaac, Ajshay James, David Lagrew, Sarosh Rana, Elizabeth Rochin, Michael Ross, Aswita Tan-McGrory, Brooke Villareal
- The Joint Commission (TJC): JohnMarc Alban, Susan Yendro, Chris Walas, Sheila Aguilar, Marilyn Parenzan
- Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE): Sarah Attanasio, Kathleen Balestracci, Andrea Barthel Valery Danilack, Tahmid Islam, Lisa Suter, Emma Turchick, Nicole Walton
- Expert Clinical Consultant: Dr. Elliot K. Main

### Welcome

- Ms. Sarah Attanasio welcomed the Technical Expert Panel members (TEP) and reviewed the meeting agenda which included introductions; review and approval of the TEP Charter; review of the measure specifications; review of measure testing results; including alpha testing results and beta testing results; and next steps for testing and implementing the measure.
- Ms. Attanasio facilitated introductions of TEP members, requesting updated affiliations and any updated conflict of interests.

### Risk Model

- Dr. Valery Danilack stated that the risk model was developed by identifying candidate risk variables of severe obstetric complications by searching relevant literature and soliciting input from clinicians, patients, and other experts. Using the same variables, a risk model was developed for both severe obstetric complications and severe obstetric complications excluding blood transfusion-only encounters. She noted that this risk model was developed with data from 25 hospitals across 8 different healthcare systems.
- Dr. Danilack shared the risk model results with the team. The inclusion of variables in the final model was based on the amount of missing data or other clinical reasons. No decisions were made based on the statistical results of multivariable modeling in terms of what variables stay in the model due to expected clinical importance of the variables identified and future opportunity for assessment with more data.
- A TEP member noted that the “Economic Housing Instability” variable had a noticeably low percentage (0.1%) and suggested that this may not be an accurate representation.
  - Dr. Elliot Main confirmed that it is well understood that this is often underreported, and that there is a large effort by many federal agencies to have this coded more frequently.
  - A second TEP member added that codes which generate revenue tend to be more heavily used than the ones that do not. There was a discussion about how

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including a variable in the measure may result in hospitals collecting and reporting it more often.

- A TEP member asked if a small sample would dramatically overstate the value of that particular risk, and if there is a way to correct for that.
  - Dr. Danilack acknowledged that this is possible and will be assessed with larger data samples in the reevaluation of the measure. She added that in risk adjustment, all the variables are adjusted together, and individual effect estimates are not reported individually.
- A TEP member asked why patients less than 20 years old were displayed as the referent group in the model and expressed that they felt as though this population would be at greater risk for severe maternal morbidity (SMM).
  - Dr. Danilack explained that if these odds ratios were presented, it would be likely that another category would be chosen to be the referent; however, for its inclusion in the predictive model, the selection of a referent group has no mathematical impact on the risk model or measure score results.
- Dr. Danilack stated that the majority of the variables are captured with ICD-10 codes and were all assessed for present on admission (POA) codes. The additional variables include heart rate, systolic blood pressure (BP), hematocrit, and white blood cell (WBC) count, and these are all the first recorded value within 24 hours before admission up until delivery. Platelets are included in the logic for the purpose of ensuring their availability for future testing and consideration of inclusion in the model.
- Dr. Danilack noted that temperature and respiratory rate were not included due to a lack of variation across encounters. Also, risk variables were removed from consideration if there were greater than 20% missing values. Although hematocrit was included, hemoglobin was removed as it is highly correlated with hematocrit. She also noted that due to low prevalence, Human Immunodeficiency Virus (HIV) was grouped with autoimmune disease, and obstetric venous thromboembolism (VTE) was grouped with long-term anticoagulant medication use in the risk model of severe obstetric complication excluding transfusion-only encounters. The model would not converge with the four separate variables.
- Dr. Danilack presented the risk model performance statistics, indicating good model discrimination, good calibration of the model, and a reasonable range between the lowest decile and highest decile of predicted ability, given the low prevalence of the outcome.

### **Measure Score Results**

- Dr. Danilack presented the measure score results. The total number of delivery encounters across sites were 60,184. The risk-standardized rate of severe obstetric complications across the 8 test sites was 252 per 10,000 delivery encounters, and the

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risk-standardized rate for severe obstetric complications excluding blood transfusion-only cases was 50 per 10,000 delivery hospitalizations.

- A TEP member asked if there is a potential bias in the results. The higher value (in test site 1, which had 18,070 encounters) is about a third of all the data. It would be expected that the risk-standardized rate would be closer to the observed rate.
- Dr. Danilack explained that both a development sample and a validation sample were used, and the results helped to justify that there is not much over-fitting due to specific details of the hospitals that went into the model.

### **Measure Score Reliability and Validity**

- Dr. Danilack presented the measure score reliability results and noted that the signal-to-noise reliability results show high reliability for both outcomes.
- Dr. Danilack presented the measure score validity results, indicating strong measure validity.

### **TEP Discussion**

- A TEP member asked about the classification of most hospitals in the sample as community hospitals.
  - Ms. Marilyn Parenzan confirmed that some of the hospitals were affiliated with teaching organizations, and that the data were obtained from the American Hospital Association (AHA) DataQuery database. She agreed that it was surprising that these were all considered community hospitals, as there were larger university hospitals included.
  - Ms. Susan Yendro commented that the definition includes all hospitals except for a prison or a college infirmary. She agreed that the word “community” can be misleading. She stated that a community hospital is any hospital open to the public.
- A TEP member asked if there is a specific valid metric for designating community hospitals.
  - Ms. Parenzan stated that TJC will go back to the AHA report from which the data were pulled to determine how community hospitals were defined.
  - Ms. Yendro added that TJC can look up the designation of the teaching status as well.
- A TEP member asked if more data on outcomes to strengthen the validity of the risk model would be considered.
  - Dr. Danilack confirmed that there is work currently being done to test the measure in 5 additional hospitals.
- A TEP member asked if the risk variables are all weighted the same, and if so, why.

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- Dr. Danilack confirmed that variables were not weighted differently within the model. She explained that the risk variables were chosen a priori because of their clinical interest. They were then tested in a logistic regression risk model to determine how predictive they are of the outcome. They were then used in the development of the model in risk adjusting for the outcome rates.
- A TEP member asked if a variable was kept in the model if it had no impact on the model.
  - Dr. Danilack explained that the variables were removed if they had a significant amount of missing data, and that labs and vital signs were removed if the values across patients lacked variability. However, if the model was able to converge, it was decided to not exclude variables based on the results, due to expected clinical importance and the small sample size.
- A TEP member commented that usually a univariate analysis of each variable would be done first to see if it is individually associated with the outcome. The significant univariate variables would then be included in a multi-variate analysis with a stepwise process that could be in order of the univariate strength, or a temporal process.
  - Dr. Katie Balestracci stated that univariate analysis was done and noted that these variables have been known to contribute to severe obstetric complication by other investigators and researchers, including Dr. Main. Given the evidence of the importance of these risk variables, these were included in the model knowing that the model is being tested on a relatively small dataset and a small universe of hospitals, and that there will be opportunities for a reevaluation of the model. She added that inclusion of these variables for this electronic clinical quality measure (eCQM) communicates to hospitals which variables need to be mapped, and it is important to keep those in at this point for reevaluation.
  - Dr. Lisa Suter added that if we were trying to create a risk model for this sample only, then this would be approached differently. The intent is to create a measure that eventually is appropriate for broad implementation. Currently, work is being done to define the risk variables that are appropriate to be in the model, and then each time the measure is calculated on a group of hospitals, the same variable and measure methodology would be used, but a recalculation of the coefficients based on updated data would be done. This allows us to continue to adapt the risk adjustment over time.
- A TEP member suggested that there should be an explanation of how the model will be constantly reevaluated in less technical terms, as would possibly cause less skepticism.
- A TEP member asked if there was a reason why uterine rupture was not listed as one of the risk variables.
  - Dr. Main answered that usually this is not present on admission, and usually occurs during the active phase of labor.

- Dr. Danilack added that there is not an easy way to get a history as there is not an ICD-10 code for it.
- A TEP member asked about the transfer status of patients.
  - Dr. Danilack explained that if a person is transferred in before they deliver, they would be counted at the hospital where they delivered.

### **Face Validity Vote**

- CORE presented the TEP the following statement and requested that each member rate it on a scale of 1-6 (1=Strongly Agree to 6=Strongly Disagree): “The risk standardized rate of severe obstetric complication and mortality events obtained from the Severe Obstetric Complications eCQM as specified can be used to distinguish between better and worse quality care at hospitals.”
  - A conversation ensued between the TEP members about the wording of the face validity question. Members expressed concern with the use of the word “quality” in the question.
  - Dr. Suter facilitated a discussion of the quality measurement of hospitals. She suggested that Yale CORE create several face validity questions that could individually assess aspects of the measure validity and use. She thanked the TEP members for their input and their time.
- CORE will create Face Validity questions and send out to the TEP members.

### **Next Steps**

- Dr. Balestracci stated that a Qualtrics survey with Face Validity questions will be sent out to the TEP members.
- Dr. Danilack informed the members that this measure will be in Public Comment from November 19 through December 18, 2021 and submitted to NQF in Spring 2022. She added that stakeholder engagement will continue with a Patient Working Group conducted in the next two weeks.
- Dr. Danilack thanked everyone for their participation.