Public Comment Summary Report

Project Title: Severe Obstetric Complications Electronic Clinical Quality Measure (eCQM)

Dates:

The Call for Public Comment ran from November 19, 2021, to December 18, 2021.

Project Overview:

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 a hospital-level electronic clinical quality measure (eCQM) for assessing severe obstetric complications. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospitals and Eligible Clinicians, Option Period 2. The contract number is HHSM-75FCMC18D0042, Task Order Number HHSM-75FCMC19F0001. As part of its measure development process, CORE requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project. The goal of this project is to develop an eCQM for assessing the occurrence of specific severe obstetric complications during delivery hospitalizations for use by hospitals for CMS quality programs. This eCQM is expected to inform hospital efforts to improve maternal health outcomes, reduce maternal morbidity and mortality, and thus also reduce the costs associated with adverse health outcomes.

Information About the Comments Received:

The measure developer solicited public comments by email notification to CMS listserv groups, emails to relevant stakeholders and stakeholder organizations, and posting on the CMS Public Comment website.

We received eighteen responses on this topic. Specifically, from:

- One quality-focused organization/measurement expert
- Two medical specialists
- Two individual consumers
- Two maternal health societies
- Three medical associations and societies
- Seven hospitals/health systems
- One purchaser
Stakeholder Comments

General Stakeholder Comments:

CORE received eighteen comments on various aspects of the Severe Obstetric Complications (SOC) electronic clinical quality measure (eCQM). We have provided high-level summaries of comments and responses below, and the verbatim comments can be found in the Public Comment Verbatim Table at the end of this document. Some of the comments received were general comments supportive of the development of a hospital-level eCQM assessing severe obstetric complications. Others related to the nine categories below, which align with the specific questions outlined in the public comment materials for the Severe Obstetric Complications eCQM.

- **Usefulness in Assessing and Improving Quality of Care for Patients:** How useful is this measure in assessing and improving the quality of care for patients?
- **Whether Numerator Specifications Effectively Captured the Outcome:** Do the numerator specifications effectively capture severe obstetric complications?
- **Publicly Reporting Measure Rates:** Input on which measure rates would be most important to publicly report: all identified severe obstetric complications, severe obstetric complications excluding encounters with only transfusion numerator events, or both.
- **Usefulness and Meaningfulness to Patients:** Will the hospital measure result be useful and meaningful to patients?
- **Extent to which Clinical Concepts are Routinely Captured in Clinical Workflow:** Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow?
- **Extent to which Clinical Concepts are Available in Structured, Extractable Fields:** Are all clinical concepts related to this measure available in structured, extractable fields in electronic health record (EHR) systems? Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable?
- **Feasibility of Systematized Nomenclature of Medicine (SNOMED) Codes and Present on Admission (POA) Status:** Input on the feasibility of implementing SNOMED codes and the ability to identify present on admission status for these codes.
- **Capture of Specific Data Elements:** Input and clarification regarding specific data elements.
- **Other:** Information not captured by one of the previous categories.

Measure-Specific Stakeholder Comments:

General

*Seven commenters* provided general comments expressing support for focusing measurement on addressing severe maternal morbidity and improving maternal health outcomes.

- Six commenters noted support for the attention to the United States’ high rates of maternal morbidity and mortality through the development of a quality outcome measure, one commending the collaborative effort among organizations. Another commenter applauded the efforts towards relevant, timely quality obstetrical measures.
• Two commenters noted the high importance of this Severe Obstetric Complications measure, one specifically noting that it will drive improvements in maternal complications and death.
• Two commenters commended the approach to measurement using electronic health records (EHR) data for better quality of care and improved patient outcomes.

Response:
We appreciate the commenters’ support of the development of an obstetric outcome measure focused on maternal morbidity and mortality and improving maternal health outcomes. We agree that this measure addresses an important healthcare issue and a national measurement gap.

One commenter expressed appreciation for CMS’ development of meaningful quality measures.
• One commenter expressed thanks for CMS’ ongoing efforts to develop meaningful metrics to advance healthcare quality.

Response:
We appreciate the commenter’s support for this work.

Usefulness in Assessing and Improving Quality of Care for Patients

Seven commenters expressed support for the usefulness of this measure in assessing and improving the quality of care for patients.
• One commenter noted the value in reviewing severe maternal morbidity (SMM) cases in order to look for process and system issues that can be addressed to improve patient safety and the quality of care.
• Two commenters noted the preventability of many SMM events, noting that other developed countries have shown that deaths from conditions such as preeclampsia and eclampsia can be virtually eliminated, demonstrating the need for this measure.
• One commenter noted that the measure is critical to improve quality of care for patients by identifying SMM in order to prevent injuries that lead to mortality and to highlight opportunities to avoid repeat injuries.
• One commenter stated that the measure has the capacity to improve the quality of care for patients by creating transparent information for patients, hospital administrators, and providers. They indicated appreciation that the measure specifications were built on existing Joint Commission perinatal care measures, which have improved quality for patients, and for the diversity of settings and electronic medical record (EMR) systems in which the measure was tested.
• One commenter noted that this Severe Obstetric Complications eCQM will improve quality of care by clearly communicating that the perinatal patient population is a high priority.
• One commenter noted that the Severe Obstetric Complications measure would help assess care and improve quality. The commenter noted the importance of the additional outcome of severe obstetric complications excluding deliveries where blood transfusion was the only numerator event and supported stratification by race/ethnicity.
Response:

We appreciate the commenters’ support regarding the usefulness of this measure in assessing and improving the quality of care for patients. There are currently only a small number of quality measures focused on maternal health, and those implemented at the national level are mostly process measures and limited in scope. While these existing measures aim to promote coordination of care and standardize health care processes, maternal health outcome measures are sorely needed.

Three commenters provided input on measure specifications.

- One commenter made several comments on measure specifications, including:
  - Coverage of hospitalized patients of at least 8 years to less than 65 years of age is too broad. They recommend narrowing the current age span for the initial population as pregnancies at the extremes of age are uncommon and that these parameters thereby increase the likelihood of inclusion errors in the administrative dataset.
  - Asking for clarification on how “delivery” is defined. They noted that the measure should capture deliveries (vaginal and cesarean) as well as dilation and evacuation given the gestational age range of inclusion.
  - Recommending that the gestational age for inclusion in the measure be lowered to 16 weeks. They believe more meaningful obstetric and pregnancy-related maternal morbidity may be captured in the window of 16-20 weeks’ gestation.
  - Expressing concern about using the first resulted value for heart rate and systolic blood pressure, which they state may not be the most representative value.
  - Expressing concern about including rare events in the outcome, noting that they may be related to a patient’s underlying condition, and out of control of the hospital.

- Another commenter also expressed concern about rare outcome events, noting that measuring relatively rare events may unintentionally skew statistics from the hospital-level data. One commenter recommended individual disease-specific metrics to create a composite measure, incorporating subcategories of complications and specific metrics to allow for clinicians to address the drivers of maternal morbidity and mortality more precisely.

- One commenter recommended reevaluating the risk adjustment model in a greater sample size to help understand the balance between the differences in performance across facilities and broader issues of health inequity in driving high maternal mortality rates.

Response:

We appreciate the commenters' input and recommendations on measure specifications. We appreciate the comment on the age parameters defining the cohort and note that they were specifically chosen to align with other Joint Commission Perinatal Care measures. Regarding delivery definitions, delivery is defined by the value set entitled Delivery Procedures (OID 2.16.840.1.113762.1.4.1045.59) which includes 114 International Classification of Diseases (ICD)-10 and Systematized Nomenclature of Medicine (SNOMED) codes; these include codes for extraction of products of conception.

Gestation earlier than 20 weeks was considered by the measure developers and discussed in-depth with the Technical Expert Panel (TEP) informing the development of this measure. The measure developers...
note that deliveries at fewer than 20 weeks’ gestation are frequently not captured in hospital EHR systems and often occur outside of the delivery hospitalization, the unit for which this measure is capturing complications. We note that patients at gestation fewer than 20 weeks represent a distinct population from the population of perivable and viable deliveries targeted in this measure; the standard obstetric definition of birth versus miscarriage is 20 weeks. While this measure is not specified to include patients at less than 20 weeks’ gestation, it is expected that improvement in maternal health care delivery will have some positive impacts for these patients as well.

Regarding the reevaluation of the risk adjustment model in a greater sample size, we too recommend further testing in reevaluation to assess measure specifications in a larger sample.

Three commenters provided input on how to implement the measure most effectively.

- One commenter recommended that the measure be implemented in a performance evaluation process, which would then allow hospitals a period to implement evidence-based interventions to reduce their complication rates. This commenter also recommended a less technical explanation of how the measure developer arrived at the predicted compared to expected events for the Standardized Risk Ratio (SRR) as it impacts the Risk-Standardized Obstetric Complications Rate (RSOCR). This could help organizations understand how they can impact their scores for future improvement.
- One commenter recommended that facilities be tracked for whether they are in a rural, urban, or suburban location, as well as other categories and regulatory features (e.g., hospital size, number of deliveries per year, American Congress of Obstetricians and Gynecologists [ACOG] levels of maternal care, neonatal levels of care).
- One commenter expressed concern about low sample sizes, and recommended individual maternal complications be measured at facilities with more than 2,000 deliveries per year and incorporated into a composite measure.

Response:

We appreciate the commenters’ input and recommendations for the most effective implementation of the measure. We will share your suggestions with CMS for consideration in potential future implementation planning and reevaluation.

With regard to contemplating the measure with individual instead of composite outcomes, the individual components of the outcome, even the more common ones, would likely be too rare to serve as a reliable outcome.

Whether Numerator Specifications Effectively Captured the Outcome

Six commenters agreed that the numerator specifications effectively capture severe obstetric complications.

- One commenter specifically supported this measure’s alignment with the well-established Centers for Disease Control and Prevention (CDC) SMM ICD-10 codes.
Response:

We appreciate the commenters’ feedback and support for the use of the CDC’s SMM ICD-10 codes.

Two commenters disagreed that the numerator specifications effectively capture severe obstetric complications.

- One commenter expressed concern with this measure’s use of Sepsis-2 codes. By using several ICD-10 codes that identify sepsis without organ failure as morbid conditions, the metric is identifying more morbidity than it should be identifying. The commenter suggested stripping the eCQM of all the sepsis codes that identify simple sepsis without organ failure and use the two codes for “severe sepsis” (R65.20, R65.21) to capture cases of sepsis with organ failure.
- One commenter stated that the severe maternal morbidity codes used by the CDC sometimes miss patients that should be included or add patients with complications that are not actually severe.

Response:

We appreciate the commenters’ feedback on sepsis codes and criteria. There is current controversy regarding the optimal definition of sepsis with two competing national definitions using Sepsis-2 and Sepsis-3 criteria. The controversy involves the requirement of end-organ injury often to the extent of organ failure. The CDC first identified the ICD-9 codes for Severe Maternal Morbidity based on their association with maternal death as well as their degree of morbidity. Following the transition to ICD-10, the general codes for sepsis remain associated with longer hospital stays, intensive care unit (ICU) admissions and maternal deaths. Maternal deaths are rare and are usually (but not always) associated with the additional codes for organ failure. The sepsis cases identified with these codes are of a similar level of morbidity as cases with other morbidity codes in the measure supporting the current approach. Furthermore, the frequency of these codes is quite low, 1-2 per thousand births, so they are not being used indiscriminately nor do they disproportionately drive the measure. We appreciate the commenters’ feedback on the numerator specifications. We chose to align the severe obstetric complications outcome with the 21 diagnoses and procedures widely accepted as severe maternal morbidity as defined by the CDC. Stakeholders supported alignment to ensure comparability of rates with other maternal morbidity identification.

Eleven commenters provided feedback on the numerator specifications, with several commenters making multiple comments.

- Three commenters addressed the need for clearer language regarding measure specifications.
  - Two commenters requested clearer communication regarding the definition of Severe Obstetric Complications and whether it is the same as Severe Maternal Morbidity.
  - One commenter noted that the details in the proposed metric are not easily followed and may skew results depending on coded comorbidities. They recommended a simpler explanation of what comorbidities are included in order to ascertain the ability of the metric to discern quality across systems.
- Four commenters addressed numerator inclusions.
One commenter questioned why postpartum hemorrhage was not on the list.

One commenter recommended that the numerator specifications be expanded to capture preeclampsia with severe features, in the absence of a diagnosis on admission of both preeclampsia. The commenter also recommended consideration of mental health conditions and diabetic ketoacidosis (DKA) as a numerator.

One commenter recommended that overdose should be included as an outcome.

One commenter asked whether hemorrhage was only counted if disseminated intravascular coagulation (DIC) or shock was coded.

Six commenters addressed numerator exclusions.

One commenter stated that several of the severe obstetric complications should be excluded as they are not markers of quality nor indicative of clinician performance (e.g., aortic aneurysm, cardiac arrest, eclampsia, sickle cell anemia with crisis, blood transfusion, ventilation).

One commenter noted that patient diagnoses upon arrival to a health care facility or shortly afterward should not be captured in the measure since they do not reflect the clinical quality of the case, specifically concerning maternal deaths.

Two commenters noted that multiple numerator events have fewer than ten occurrences. One commenter stated that the numerator should exclude events that occur infrequently (i.e., indicators that occur fewer than ten times). The other commenter recommended that rare events be included in an aggregate quality measure since they are not controllable by the institution.

Two commenters stated that transfers should not be included or attributed to the new hospital in which they are moved to. One of the commenters recommended that those transferred to a higher level of care should not be included but noted to be present on admission.

Four commenters discussed blood transfusions as an inclusion in the numerator.

One commenter noted that transfusions of four or more units of blood should not be included as an indicator of severe maternal morbidity as it is typically indicative of a preexisting condition not related to pregnancy. The commenter recommends including a specific numerator exclusion for transfusions of four or more units of blood to ensure that appropriate severe maternal morbidity identification is achieved without penalizing providers for non-pregnancy related disorders.

One commenter noted that they consider blood transfusion a result of good care, so they recommended removing blood transfusion from the numerator or considering blood transfusion alone as an additional measure.

One commenter stated that the CDC criteria includes women who only receive one unit of blood as a blood transfusion. They feel that one unit should not be considered severe maternal morbidity, otherwise the SMM rate would be overcalled.

One commenter expressed concern that transfusions of four or more packed red blood cells (PRBCs) would be included as pregnancies complicated by placenta accreta spectrum or hysterectomies.

One commenter expressed support for including “case mix” to address the influence of patient characteristics and comorbidities on obstetrical quality data.

One commenter stated that the numerator specifications only effectively capture the outcome at the time of delivery and do not capture patients who return with severe obstetric complications.
complications in the initial couple of weeks postpartum. They recommended capturing readmission rates within 7-14 days, or some other agreed-upon timeframe for these patients.

- One commenter expressed support for using a co-morbidity risk adjustment to put hospitals on a more level set playing field.

Response:

We appreciate the commenters’ feedback regarding the measure’s numerator specifications.

With regard to the difference between Severe Obstetric Complications and Severe Maternal Morbidity, it is important to note that a standard and consistent definition for maternal morbidity and mortality is currently lacking; existing definitions vary in scope and in the time frame during which SMM or maternal death is captured. For this measure, measure specifications are modeled after the nationally available and adopted CDC definition for severe maternal morbidity with the addition of maternal mortality. At times, we may refer to the CDC indicators of morbidity as severe maternal morbidity, but the outcome of the measure, which includes morbidity and mortality, is referred to as severe obstetric complications. We will strive for greater clarity around these concepts going forward.

For those comments with recommended changes to the numerator specifications, we chose to align the severe obstetric complications outcome with the 21 diagnoses and procedures widely accepted as SMM, as defined by the CDC. Stakeholders supported alignment to ensure comparability of rates with other maternal morbidity reporting. We will continue to assess the numerator definition during reevaluation of this measure.

Regarding the low occurrence for multiple numerator events, while rates of maternal morbidity and mortality have continued to trend upward in the United States in recent decades, severe maternal morbidity or mortality are relatively rare outcomes, and as defined with 22 numerator definitions (21 SMM indicators as identified by the CDC and mortality), require a substantial sample size for testing. For this reason, eight test sites representing 25 hospitals were included for initial beta testing, and an additional five hospitals were identified for subsequent beta testing. As testing results have revealed low frequencies for some of the numerator definitions, future testing in reevaluation will be important for assessing measure specifications.

With regard to capturing readmission rates, we recognize the importance of post-discharge maternal complications, and support the future development of hospital quality measures that capture these complications. This eCQM has been developed to capture severe obstetric complications during hospital delivery and will provide hospitals with benchmarking and actionable data to inform their quality improvement efforts; the use of EHR data will provide them with the potential to repurpose the data and measure logic for internal quality control using real-time feedback to further mitigate harm to mothers. Moreover, we believe that by improving the quality of care during a delivery hospitalization, the quality of care for the postpartum population will also be improved.

Regarding transfers, this measure identifies a delivery episode and includes only those who deliver during the encounter. If a person is transferred to a new hospital before they deliver, they would be
counted at the hospital where they delivered. Persons contribute to the population at risk in the hospital where they deliver, regardless of whether a transfer occurred before or after delivery.

Regarding blood transfusions, we tested an additional outcome definition: severe obstetric complications as defined above but excluding delivery hospitalizations for which blood transfusion was the only numerator event. Blood transfusions, in response to excessive bleeding around delivery, account for the greatest proportion of patients identified as having an obstetric complication, but patients for whom this is the only identified numerator event may represent a less severe outcome experience. The secondary outcome definition captures severe obstetric complications experienced in delivery hospitalizations without numerator events defined solely by a blood transfusion. In addition, the alpha testing for this measure revealed inconsistent documentation across hospitals and EHRs of blood transfusion, and varying definitions for the volume contained in a “unit” of blood. As such, we recommend using both ICD-10 codes identified by the CDC as well as SNOMED codes translated from ICD-10 codes for capture of this indicator.

Publicly Reporting Measure Rates

One commenter supported publicly reporting an overall rate of severe obstetric complications which includes transfusion-only cases.

- Specifically, the commenter stated that reporting both rates may not be necessary given the minimal difference in the two data sets for most severe maternal morbidity variables. They recommended using the data set that includes all variables, including transfusions, in order to be most transparent. The commenter also noted that patients with pre-existing conditions that increase their risk for transfusion should be identified.

Five commenters supported publicly reporting a rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication.

- One commenter stated that some transfusions are needed due to normal blood loss and anemia, which should not be thought of as a negative outcome; because of this, transfusion-only cases should be excluded.
- One commenter stated that including transfusion-only cases would not be a useful indicator as it might drive actions that would lead to greater morbidity and mortality.
- One commenter noted the lack of distinction of cases with transfusions of four or more units of blood in the measure specifications. Because of this, the commenter feels it is most appropriate to remove transfusion-only cases from public reporting requirements.
- One commenter stated that transfusions would dilute the rate of the other severe obstetric complications.
- One commenter noted that because blood transfusion is a substantial component of SMM and is inconsistently coded, examining SMM rates without transfusion may be a more valid indicator of hospital quality.

Four commenters supported publicly reporting both an overall rate of severe obstetric complications and a rate of severe obstetric complications excluding blood transfusion-only cases.
• One commenter stated that publicly reporting both rates would allow hospitals to track/trend perinatal and perinatal-related blood management outcomes, as well as track/trend how blood products are utilized during the inpatient encounter for delivery.
• One commenter noted that compounded complications increase the overall impact of SMM, so having a full understanding of severe obstetric complication with and without transfusion-only cases would provide a complete picture to the public.
• One commenter stated that tracking both rates would be useful. However, they recommend excluding placenta accreta cases for the transfusion-only rate, as the condition represents one of the major causes of transfusions. The commenter recommended that both rates be organized according to disease-specific or cause-specific cases. They also recommended that the measure developers clarify a specific threshold for blood transfusion that is reflective of severe maternal morbidity cases.
• One commenter supported the public reporting of both rates but noted that all blood product administrations would need to be coded to get a true overall rate of severe obstetric complications which includes transfusion-only cases.

Response:

We appreciate the commenters’ feedback. We will share this with CMS for careful consideration in potential future implementation planning.

With regard to comments about capture of blood transfusion thresholds, pilot testing showed that hospitals do not consistently incorporate billing data into the EHR and determining the specific amount of blood transfused is challenging. Hospitals also use different units when recording the amount of blood that is transfused. We appreciate there is disagreement about the use of and cutoffs for blood transfusion. However, many patients consider any transfusion to be a significant event and thus we will continue to evaluate the impact of transfusions in this measure. Regarding blood product administration, the Blood Transfusion value set (OID 2.16.840.1.113762.1.4.1029.213) contains the following blood products, distinguished by autologous vs. non-autologous: whole blood, frozen plasma, fresh plasma, plasma cryoprecipitate, red blood cells, platelets, and fibrinogen.

Usefulness and Meaningfulness to Patients

Five commenters agreed that the hospital measure results would be useful and meaningful to patients.

• One commenter stated that publicly reporting a standardized severe obstetric complication measure will help communicate and educate the public about risk factors and patient care outcomes, as well as hold clinical care teams accountable for providing the best standards of care.
• One commenter noted the hospital measure results would provide insight into the evidence-based practice activities, as well as strong structures and processes. They noted that patients could use the data to make an informed decision on their delivering facility.
• One commenter stated that this measure could be useful and meaningful to patients, especially in conjunction with the recently instituted Maternal Morbidity Structural Measure in the Inpatient Prospective Payment System (IPPS) final rule.
• Two commenters expressed the need for patient education, including clear explanations on measure specifications and conditions that are captured in the measure.

Response:

We appreciate the commenters’ feedback on the usefulness and meaningfulness to patients. We strive to continue to educate the public about risk factors, develop measures which incentivize the delivery of high-quality care, and help patients to make the best decisions regarding their care.

Five commenters were unsure if the hospital measure results would be useful and meaningful to patients.

• One commenter noted that there are many factors that go into the delivering facility a patient chooses. The commenter also expressed concern that measure results would cause rural patients to seek care further away from home.
• Another commenter also noted that the measure results could cause patients to seek care further away from home, resulting in further obstetric volume loss eventually resulting in programs that are not sustainable, requiring systems to discontinue obstetrical services. The commenter also expressed concern that insurance payors could begin to use the data against hospitals and deny coverage for services at certain facilities.
• One commenter stated that the measure results may give patients a false sense of the quality of care provided at an organization that the delivering facility may not have control over.
• One commenter stated that obstetric patients would not use this measure to help select their delivering hospital because patients oftentimes go to the closest hospital available or are high-risk patients who are referred to regional facilities. The commenter recommended designing a user-friendly, patient-facing tool that allows patients to filter hospital performance metrics by preferred geographic proximity.
• One commenter noted that a hospital composite measure per number of deliveries would be a useful comparator for patients.

Response:

We appreciate the commenters’ feedback on the usefulness and meaningfulness to patients. We understand that patients may have limited choices in hospital selection due to geographical, among other, considerations. However, we believe that patient choice is important when it can be exercised, and that providing patients with quality performance information assists with making informed healthcare choices. We will share this information with CMS for careful consideration in potential implementation planning.

Extent to which Clinical Concepts are Routinely Captured in Clinical Workflow

Nine commenters agreed that the clinical concepts are routinely captured in clinical workflow.

Response:
We appreciate the feedback. Pilot testing and feasibility assessment conducted for this measure indicated the capture, accessibility, and feasibility of data elements supporting the clinical concepts for this measure.

**Four commenters** provided feedback regarding the challenges to capturing clinical concepts in the normal course of clinical workflow.

- One commenter stated that it could be difficult to capture discrete data as providers tend to chart in a narrative form.
- One commenter noted that coding issues, lack of EHR integration, lack of available data streams, absence of data reporting, and irregular separate coding of transfusions could impact the capture of the clinical concepts. Because of this, dedicated resources would be necessary for accurate capture.
- One commenter expressed concern that many of the pre-existing conditions included in the risk variables are not often captured in coding because only the top five issues are coded, causing many relevant diagnoses to be missed.
- One commenter noted that tracking maternal mortality can be challenging since current standards measure maternal mortality on an annual basis instead of more granularly.

**Response:**

We appreciate the commenters’ feedback and understand that there may be challenges in capturing clinical concepts in the normal course of clinical workflow. Although efforts may require hospitals to initially invest resources to support capture of the maternal and obstetrical health data specified for this measure, we anticipate that such investments will help them more fully utilize their EHRs to improve care for pregnant and delivering women, which is a shared goal among stakeholders.

**One commenter** stated that the clinical concepts are not routinely captured in clinical workflow and provided feedback for improvement at the hospital level.

- The commenter recommended that EMR clinical documentation be standardized rather than relying on free text notes to ensure that key clinical information is consistently documented. The commenter also recommended that race/ethnicity perinatal outcomes are transparently shared to ensure that hospitals are confronting their systems-level opportunities for improvement on a continual basis.

**Response:**

We appreciate the commenter’s feedback. Regarding transparency with racial/ethnic perinatal outcomes, this measure intends to stratify measure results by race/ethnicity. Research and prevalence data have indicated racial and ethnic disparities in maternal outcomes, and it was determined that illumination of outcome disparities by race/ethnicity, rather than adjustment of outcomes by race/ethnicity, would best inform stakeholders and patients and be most impactful in incentivizing improvements in quality of maternal care. Approaches to stratification or measure results by race/ethnicity are being considered.
Regarding standardized EMR clinical documentation, we agree that increasing standardized approaches to clinical documentation would improve facility access and capture of data elements and concepts represented in the specifications of this measure.

Extent to which Clinical Concepts are Available in Structured, Extractable Fields

**Seven commenters** agreed that the clinical concepts related to this measure are available in structured, extractable fields in EHR systems.

**Response:**

We appreciate the feedback. Pilot testing and feasibility assessment conducted for this measure indicated that the data elements supporting the clinical concepts captured for this measure were available in structured, extractable fields in the facilities in which this measure was tested.

**Eight commenters** provided feedback regarding the challenges to capturing the clinical concepts in EHR systems.

- One commenter noted the challenge of consistent and up-to-date patient information and clinical documentation for hospital coders to code a patient’s inpatient encounter accurately. The commenter also noted the intensive time needed to initially set up an automated data abstraction workflow to streamline data validation.
- One commenter noted that extractable fields vary in each EHR system. They recommended that CMS query multiple EHR organizations for available fields and opportunities for modifications/updates.
- One commenter stated that the test site results do not provide sufficient detail of the data from the records that were evaluated. The commenter asked for a breakdown from the tested EMR records to ascertain what data elements were missed.
- One commenter recommended that this measure be further tested to assess the feasibility of collecting the required data elements from EHRs and to determine if the measure is reliable and valid across a broader set of EHR vendors and hospitals.
- One commenter noted challenges with EHR reporting capabilities and limited information technology (IT) support to build changes within EHRs.
- One commenter recommended that inconsistent coding definitions be resolved and conflicting results on the utility of SMM be reconciled before the measure is widely adopted.

**Response:**

We appreciate the commenters’ feedback and understand that some facilities may experience challenges in the availability of clinical concepts in structured, extractable fields. We note that this measure was tested in three different EHR systems (Epic, Meditech, and Cerner) to assess data element capture and feasibility across different systems. Feasibility rates were 94%-100% for all sites and the overall data element agreement rate was 90%. Sections 2.2.2 Missing Data and 3.5 Reliability in the Measure Methodology Report and the Feasibility Scorecard provide details of the data elements that were missed. We support efforts at data standardization and interoperability that would support better
and more feasible capture of clinical data in facility EHRs. Although efforts may require hospitals to initially invest resources to support capture of the maternal and obstetrical health data specified for this measure, we anticipate that such investments will help them more fully utilize their EHRs to improve care for pregnant women, which is a shared goal among stakeholders.

Feasibility of Systematized Nomenclature of Medicine (SNOMED) Codes and Present on Admission (POA) Status

Five commenters provided input on the feasibility of implementing SNOMED codes and the ability to identify present on admission (POA) status for these codes.

- One commenter explained that their hospital system, including nurses, stakeholders, nurse informatics, data analysts, and hospitals coders, identified SNOMED and POA codes within the EMR. However, their hospital system had access to a large maternal data center where severe obstetric complication data is tracked.
- One commenter stated that most are unfamiliar with SNOMED codes, but that they could be beneficial if accuracy of coding is improved.
- One commenter expressed that hospital coders should be familiar with coding for POA.
- One commenter explained that they capture POA by diagnosis codes that have a status of chronic in the problem list or have been on the problem list prior to admission.
- One commenter expressed concern over the reliability of the measure results given the challenges organizations may face with coding the POA comorbidities.

Response:

We appreciate the commenters’ feedback. We expect to reassess the inclusion of SNOMED codes and the accurate assessment with POA codes during reevaluation of this measure, with consideration of progress in the use of SNOMED codes and accurate and consistent use of POA codes. Implementation of SNOMED codes in the future will be considered based on reevaluation findings.

Capture of Specific Data Elements

Two commenters provided input and asked for clarification regarding specific data elements.

- One commenter asked how long-term anticoagulant medication use is defined. They stated that they would only be able to capture this element if the patient was on an anticoagulant home medication where the clinic is also part of the network. They are unsure if they could capture the length of time.
- One commenter expressed concern that there are a few fields that are unlikely to be easily extracted (e.g., disseminated intravascular coagulation, hemorrhagic shock, heart failure, long-term anticoagulant use, conversion of cardiac rhythm) as they may not align with how facilities’ EHR systems define them. They recommended these conditions should be revisited for data capture and feasibility purposes.
  - The commenter also asked for clarity on the definition of “conversion of cardiac rhythm.”
Response:

We appreciate the commenters’ feedback and request for clarification regarding long-term anticoagulant medication use, conversion of cardiac rhythm, and coding. Long-term anticoagulant use is defined based on the ICD10PCS codes contained in the OID 2.16.840.1.113762.1.4.1029.364 and the SNOMED codes in the OID 2.16.840.1.113762.1.4.1029.365. Conversion of cardiac rhythm is defined based on the ICD10PCS codes contained in the OID 2.16.840.1.113762.1.4.1029.247 and the SNOMED codes in the OID 2.16.840.1.113762.1.4.1029.248.

Other

Three commenters shared concerns and recommendations regarding hospital level of care.

- One commenter expressed concern that a decrease in rate is considered improvement because a higher level of care facility (e.g., level three or four) may show an increase or no change in rate if they are receiving patients from lower-level facilities. They recommended investigating a significant increase in rate to signify improvement.
- One commenter stated that comparisons of SMM must account for regionalization of care for maternity services with higher level of care facilities serving as referral centers for lower-level facilities in the management of high-risk cases.
- One commenter recommended that it be clearly identified how the list of POA indicators will be determined for patients transferred to a higher level of care.

Response:

We appreciate the commenters’ feedback. POA indicators are used in the measure specifications of this eCQM to determine that identified risk factors are present on admission, and that numerator events were not present on admission. It is expected that patients who transfer from a lower level of care facility to a higher level of care facility prior to delivery will have present on admission codes as such in the delivery encounter record. We will share considerations provided about reporting of rates to CMS for consideration in potential future implementation planning.

One commenter expressed interest in other SMM outcomes.

- Specifically, the commenter expressed interest in determining whether cases of SMM are reviewed and evaluated as preventable or needs improvement in care.

Response:

We appreciate the commenter’s thoughts. The current eCQM will provide hospitals with benchmarking and actionable data to inform their quality improvement efforts; the use of EHR data will provide them with the potential to repurpose the data and measure logic for internal quality control using real-time feedback to further mitigate harm to mothers. Additionally, the eCQM can provide information that allows patients to compare hospitals’ performance to aid in their decision making when choosing care.
Five commenters expressed concerns and provided recommendations regarding risk adjustment variables.

- One commenter recommended the inclusion of recurrent pregnancy loss and infant loss to the list of risk adjustment variables, as this medical history can impact obstetric complications in subsequent pregnancies.
- One commenter expressed concern of whether the inclusion of some risk factors, specifically severe and other preeclampsia and obstetric venous thromboembolism (VTE), could potentially mask avoidable severe maternal morbidity.
- One commenter questioned whether rural factors had been considered in social determinants for risk adjustment.
- One commenter recommended adding both surgical (e.g., dense adhesive disease) and medical (e.g., cystic fibrosis) complexities to the pre-existing conditions lists. The commenter also recommended adding additional specificity and updating the existing language from placenta accreta spectrum to placenta accreta, placenta increta, and placenta percreta.
- One commenter expressed concern that the first resulted value may not be the most representative value and questioned whether the approach had been validated by the measure developer. The commenter also noted that some variables excluded from risk adjustment may be due to their prevalence at the selected test sites while other conditions, such as sickle cell disease and creatinine levels, were not assessed at all.

Response:

We appreciate the commenters’ feedback regarding variables used in the risk adjustment model. We identified candidate risk variables of SMM for consideration in the measure risk adjustment model by utilizing literature and research findings, including An Expanded Obstetric Comorbidity Scoring System for Predicting Severe Maternal Morbidity by Dr. Stephanie Leonard, the NQF Maternal Morbidity and Mortality Environmental Scan, and our initial environmental scan/literature review findings on specific drivers of severe obstetric complications and maternal mortality. We also solicited input from clinicians, patients, and other experts in the TEP who identified for consideration numerous risk adjustment variables at the patient and hospital levels. These included, but were not limited to, prior pregnancy history, housing instability, and availability of specialists and trauma care in hospitals. We acknowledged and carefully considered recommendations from the TEP and Patient Working Group for selection of candidate risk adjustment variables and will continue to reassess the model in additional samples as feasible.

The intent is to create a measure that is appropriate for broad implementation. As the risk model is applied for measure calculation during subsequent measure periods for measure calculation of hospital scores, 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 appropriately adapt the risk adjustment over time.

One commenter provided recommendations regarding public reporting.
Specifically, the commenter recommended the program be piloted for six months before publicly reporting the outcome data. In addition, they recommended stratifying hospitals into levels by hospital type or patient complexity for comparison and reporting. The commenter also recommended the inclusion of a hospital and/or Gynecology and Obstetrics service profile for each participating hospital for any future public reporting.

Response:

We appreciate the commenter’s feedback regarding public reporting. We will share this with CMS for consideration in potential future implementation planning for the measure outcomes to be publicly reported effectively.

One commenter had a request regarding access to electronic data sets.

• Specifically, the commenter asked for the electronic data sets to be published with the call for measure comments in the future for data element transparency with stakeholders and the public.

Response:

We appreciate the commenter’s feedback on the most useful information for review of this eCQM. While the full clinical quality language (CQL) specifications were not available for review at the time of public comment, the Measure Authoring Tool (MAT) Header and Measure Methodology Report included OIDs for value sets referenced in the measure specifications. The full CQL language will be available for stakeholder review and feedback prior to any future potential use of this measure by CMS.

Three commenters had comments and recommendations regarding COVID-19.

• Two commenters expressed support for the exclusion of patients diagnosed with COVID-19.
• One commenter recommended including COVID-19 as a comorbidity.

Response:

We appreciate the commenters’ feedback regarding COVID-19. A denominator exclusion for COVID-19 plus respiratory conditions was added following conclusion of pilot testing due to the growing evidence of perinatal complications in women who have COVID-19 infection with respiratory conditions. Patients with confirmed diagnosis of COVID-19 with COVID-related respiratory conditions or patients with confirmed diagnosis of COVID-19 with COVID-related respiratory procedures are excluded.

Preliminary Recommendations

We plan to incorporate the recommendations received during the public comment period into the development and future implementation of our measure. Specifically:

• We will continue to assess the most appropriate approach to race/ethnicity stratification.
• We will continue to evaluate the most effective measure score rate to publicly report.
• We will ensure CMS is aware of the public input received for any future implementation planning, including the availability of clinical concepts in structures, extractable fields, using more patient-friendly language, and the performance evaluation process.
• We will continue to evaluate the risk adjustment model and numerator specifications during future measure reevaluation.

Overall Analysis of the Comments and Recommendations

The feedback on the measure and the measure’s proposed use as a hospital-level electronic clinical measure to assess severe obstetric complications was positive. Commenters identified several technical issues and concerns related to measure specifications and implementation that we will address through future measure implementation planning and reevaluation.
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<td>11/19/21</td>
<td>Sean R. Townsend, MD, Vice President of Quality and Safety, California Pacific Medical Center</td>
<td>Quality-Focused Organizations or Measurement Experts</td>
<td>Severe Obstetric Complications eCQM</td>
<td>By way of introduction, I am one of two of the CMS measure stewards for SEP-1. I built and designed the SEP-1 measure. The Severe Obstetric Complications eCQM has a major flaw as regards it’s treatment of sepsis morbidity. The flaw reflects a major definitional problem in the field. CMS has avoided the problem you now have by NOT adopting sepsis-3 definitions of sepsis, which are highly controversial. The Severe Obstetric Complications eCQM metric is designed to capture maternal morbidity. Sepsis with organ failure is considered a morbid condition. Sepsis without organ failure is not. For example, a laboring mother has developed sepsis with renal dysfunction or coagulopathy as comorbidities. However, the developers of this metric have included a number of ICD-10 codes that identify sepsis without organ failure (so-called simple sepsis) as morbid conditions. This means the metric as configured is identifying more morbidity than it should be identifying. Add to this picture the change in sepsis definitions from sepsis-2 to sepsis-3. Sepsis-2 in effect since 1991 called sepsis with organ failure “severe sepsis” and sepsis without organ failure “sepsis.” Sepsis-3 definitions published in 2016 called sepsis with organ failure “sepsis” and without organ failure “infection.” This means all of the ICD-10 codes that identify the term “sepsis” that were created and last updated in 2015 prior to sepsis-3 publication were identifying sepsis without organ failure – no morbidity. In fact, to emphasize that there was no morbidity sepsis-3 no longer even classified those cases as a sepsis syndrome</td>
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| 11/19/21             | Continued from the previous page                | Continued from the previous page | Continued from the previous page | and instead called them simply “infection.” ICD-10 was not updated to reflect this change. The error comes from lifting the ICD-10 codes that were not updated and using them in the Severe Obstetric Complications eCQM. Thinking they were staying current, CDC and Joint Commission adopted the sepsis-3 definitions. This means without updating ICD-10, CDC and Joint Commission just transferred the codes which were not updated to the new metric calling “sepsis” (which was meant to be without organ failure) to mean with organ failure. The mistake you are making is that those cases are not sepsis cases at all under sepsis-3. They are just infections.

CMS has avoided this problem by staying with sepsis-2 definitions. The introduction of the Severe Obstetric Complications eCQM that inadvertently is mixing codes designed for sepsis-2 (without organ failure) as having the same meaning under sepsis-3 (with organ failure) is a major error in the development of this metric.

The problem is especially problematic when it comes to benchmarking – the ostensible purpose of such a measure. Hospital systems show wide variation in coding of sepsis based on the problematic introduction of the sepsis-3 definition and CMS’ refusal to adopt it. If this measure continues to use codes meant for one definition of sepsis while some hospitals use the other definition, you are not comparing apples to apples.

The basic solution to this problem is to strip the Severe Obstetric Complications eCQM of all the sepsis codes that under sepsis-2 identified simple sepsis without organ failure. If this were done, you could just use the 2 codes for “severe sepsis” (R65.20, R65.21) and properly capture cases of sepsis with organ failure. You may wish to include |
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<td>the “O” codes, although it’s not clear these identify organ failure, since they are specific to obstetrics. However, all of the “A” codes do not imply organ failure, and under sepsis-3 would not be, for example, “sepsis due to streptococcus, group A” but more properly called, “infection due to streptococcus group A.” Since the authorities that develop ICD-10 include CMS and CMS opposes sepsis-3, these will not be updated.</td>
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|                         |                                                  |                      |                      | O85 Puerperal sepsis |
|                         |                                                  |                      |                      | O86.04 Sepsis following an obstetrical procedure |
|                         |                                                  |                      |                      | T81.44XA Sepsis following a procedure, initial encounter |
|                         |                                                  |                      |                      | R65.20 Severe sepsis without septic shock |
|                         |                                                  |                      |                      | R65.21 Severe sepsis with septic shock |
|                         |                                                  |                      |                      | A40.0 Sepsis due to streptococcus, group A |
|                         |                                                  |                      |                      | A40.1 Sepsis due to streptococcus, group B |
|                         |                                                  |                      |                      | A40.3 Sepsis due to Streptococcus pneumoniae |
|                         |                                                  |                      |                      | A40.8 Other streptococcal sepsis |
|                         |                                                  |                      |                      | A40.9 Streptococcal sepsis, unspecified |
|                         |                                                  |                      |                      | A41.01 Sepsis due to Methicillin susceptible Staphylococcus aureus |
|                         |                                                  |                      |                      | A41.02 Sepsis due to Methicillin resistant Staphylococcus aureus |
|                         |                                                  |                      |                      | A41.1 Sepsis due to other specified staphylococcus |
|                         |                                                  |                      |                      | A41.2 Sepsis due to unspecified staphylococcus |
|                         |                                                  |                      |                      | A41.3 Sepsis due to Hemophilus influenzae |
|                         |                                                  |                      |                      | A41.4 Sepsis due to anaerobes |
|                         |                                                  |                      |                      | A41.50 Gram-negative sepsis, unspecified |
|                         |                                                  |                      |                      | A41.51 Sepsis due to Escherichia coli [E. coli] |
|                         |                                                  |                      |                      | A41.52 Sepsis due to Pseudomonas |
|                         |                                                  |                      |                      | A41.53 Sepsis due to Serratia |
|                         |                                                  |                      |                      | A41.59 Other Gram-negative sepsis |
|                         |                                                  |                      |                      | A41.81 Sepsis due to Enterococcus |
|                         |                                                  |                      |                      | A41.89 Other specified sepsis |
|                         |                                                  |                      |                      | A41.9 Sepsis, unspecified organism |
|                         |                                                  |                      |                      | A32.7 Listerial sepsis |

I’m hopeful you take this to heart. You have a real
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| 11/19/21             | Continued from the previous page                 | Continued from the previous page | Continued from the previous page | problem on your hands here.  
I am available to you at any time to answer questions. |
| 11/22/21             | Sarah J. Kilpatrick, MD, PhD  
Professor, Endowed Chair,  
The Helping Hand of Los Angeles;  
Chair, Department of Obstetrics and Gynecology,  
Associate Dean for Faculty Development and Diversity,  
Cedars-Sinai Medical Center | Medical Specialist | Severe Obstetric Complications eCQM | Dear Reader:  
As a maternal fetal medicine specialist and an expert in severe maternal morbidity I have some questions and comments:  
1. I see that “improvement notation” = decrease in rate.  
This is tricky because a level 3 or 4 type hospital may actually be showing increase or no change in rate if they are getting the appropriate transfers or transports from level 1 or 2. So no decrease in rate should not be considered a negative. Perhaps a significant increase in rate (over an acceptable baseline) should be investigated. The usual rates generally reported now are about 1-2%.  
2. SMM Diagnoses:  
It seems that you only counting hemorrhage if DIC or shock coded??? You would be missing a lot of major hemorrhages  
If using the CDC criteria that include blood transfusion that includes even if only 1 unit so many women with only 1 unit are not really SMM so the SMM rate is overcalled  
3. Under population criteria  
And numerator: you do not define severe obstetric complication??? Is that the same as SMM diagnoses?  
4. I really wish there was a way to pick up whether cases of SMM are reviewed and evaluated as preventable or needs improvement in care which is really the event to measure and reduce (preventable or needs improvement SMM). |
| 12/3/21              | Laura Clime-Coates, Towson University Graduate Student,  
Women’s and Gender Studies | Individual consumer | Severe Obstetric Complications eCQM | This comment is regarding the Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 2, contract |
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<td>The Severe Obstetric Complications Electronic Clinical Quality Measure (eCQM), while important in so many ways, does not currently include history of recurrent pregnancy loss or previous infant loss in the stated list of &quot;Risk Adjustment Variables.&quot; Recurrent pregnancy loss can indicate underlying health problems or conditions which may impact maternal outcomes and future pregnancies, in addition to having impacts on women's mental health (Tavoli, Mohammadi et al. 2018). According to the American College of Obstetricians and Gynecologists, some of the conditions that can cause recurrent pregnancy loss include problems with reproductive organs, autoimmune disorders, clotting disorders, problems with maternal circulation, and various infections and diseases (2021). Early detection of conditions that have led to miscarriages and/or infant loss should be included in any discussion of health care quality as many of these problems constitute high-risk designation and can cause severe obstetric complications. Social determinants, geography and access to care are important interconnected variables, and there is undisputed evidence that minorities have higher rates of maternal morbidity and mortality in the U.S., as well as higher rates of infant and pregnancy loss (Howell, 2019; Shi &amp; Singh, 2019). Improving maternal care is incredibly important and should include improvements not only in the quality of the care received before, during and after delivery, and improvements in maternal and fetal/infant safety, but should also include early detection of maternal conditions and frequent fetal monitoring for high-risk pregnancies. Improving prenatal care and patient education have been shown to improve outcomes (Howell,</td>
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<td>Improvements are also needed in postpartum care, including postpartum mental health, depression and grief care following pregnancy loss, but starting by improving quality measures across obstetric practitioners is certainly a step in the right direction. I would recommend adding recurrent pregnancy loss and infant loss to the list of risk adjustment variables, as this medical history can impact obstetric complications in subsequent pregnancies.</td>
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<td>12/5/21</td>
<td>Kisha Semenuk, MSN, RN, CPHQ, Certified Professional in Healthcare Quality</td>
<td>Individual Consumer</td>
<td>Severe Obstetric Complications eCQM</td>
<td><strong>I am submitting Public Comments as an Individual, but I was a Pilot site Team Lead for Phase 1. Questions CMS encourages you to submit general comments or specific feedback on measure specifications. In particular, please provide feedback on the following questions and prompts: 1. How useful is this measure in assessing and improving the quality of care for patients? Please explain your answer with input as to how to design...</strong></td>
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| 12/5/21             | Continued from the previous page                | Continued from the previous page | Continued from the previous page | and implement this measure most effectively. In the current state, hospital-based Perinatal Quality Improvement (QI)/Performance Improvement (PI) is often a lower priority and is in constant competition for resources with other high priority CMS driven Inpatient Adult QI/PI initiatives (i.e. Falls, HAI, Readmissions) because of their financial implications (lack of reimbursement). Another pressing challenge is that the focus on SOC is retrospective and not near real-time. In my role as a hospital-based Perinatal Quality Nurse, I worked with my Stakeholders to integrate data-driven perinatal QI/PI and patient safety workflows on a continuous basis. The SOC eCQM measure will improve the quality of care for patients by clearly communicating that CMS regards the perinatal patient population as a high priority! In regards to implementation, hospitals will need to assess what existing workflows can be adapted to ensure that this measure is integrated and not just another 'add-on' measure to track. Another key aspect to implementation is to optimize technology systems to ensure clinically meaningful data can be consistently abstracted to provide timely data reports to the frontline clinical care team! Timely case reviews of SOC cases will also provide ongoing opportunities for improvement and systems-learnings. **I would recommend that there be a concerted effort in clearly communicating to Stakeholders and the Public that Severe Obstetric Complications (SOC) is the same as Severe Maternal Morbidity (SMM). SMM is the commonly used term. 2. Do the numerator specifications effectively capture severe obstetric complications? Yes, the most important aspect is to align with the
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12/5/21 | Continued from the previous page | Continued from the previous page | Continued from the previous page | well-established CDC SMM ICD-10 codes! The CDC SMM ICD-10 codes are being used extensively across the nation by state-based Perinatal Quality Collaborative (PQCs), Federally funded perinatal QI/PI initiatives (i.e. AIM Program (MCHB/ACOG), OWH/Premier) and hospitals.

3. For public reporting, which of the following measure rates would be most important to report? Please explain your answer.
   a. An overall rate of severe obstetric complications which includes transfusion-only cases? Yes, because this rate will help hospitals track/trend both perinatal and perinatal related blood management outcomes
   b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication? Yes, it is clinically meaningful to track/trend how blood products are utilized during the Inpatient encounter for delivery
   c. Both rates identified in a & b? Yes, providing data segmentation will allow hospitals to track/trend both on an continuous basis and inform their decision-making when planning their annual organizational/unit quality and safety workplan goals

4. Will the hospital measure result be useful and meaningful to patients?
   Yes, there is still a pervasive lack of understanding about SOC/SMM by the public. While pregnancy is not a disease, nor always high risk, the public is not aware of the common and prevalent patient risk factors that contribute to hospital-based SOC/SMM. Having a standardized SOC/SMM measure that is publicly reportable will help clearly communicate and educate the public about risk factors and patient care outcomes, as well as hold the frontline clinical care team accountable for providing standards of care/best practices.
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| 12/5/21             | Continued from the previous page                | Continued from the previous page | Continued from the previous page | 5. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured? No, they are not. (2) opportunities for improvement currently exist at the hospital level:
1. Standardize EMR clinical documentation: Instead of relying on free text notes, create standardized Flowsheets or pre-set SOC Templates (i.e. Smartphrases, SmarText) so that key clinical information is consistently documented by the frontline clinical care team. This will streamline the clinical documentation workflow for both the frontline clinical care team and organizational data analysts, while improving the quality of clinical documentation
2. Race/Ethnicity Perinatal Outcomes must be transparent and shared to ensure that hospitals are tackling their systems-level opportunities for improvement on a continual basis. This will also reinforce the importance of tackling structural racism within healthcare and systems-learning. Hospitals need to own that they are stewards of public trust!

6. Are all clinical concepts related to this measure available in structured, extractable fields in EHR systems? Yes, but the challenge is making sure that the patient information and clinical documentation is consistently entered and up-to-date so that the Hospital Coders can code the patients’ Inpatient Encounter accurately.
If not please identify which are not and provide suggestions on alternatives that are available in structured, extractable fields in the EHR systems.
N/A
Is the level of burden associated with capturing and documenting the data elements required to
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<td>The following comments are submitted on behalf of the members of the Association of Women’s Health, Obstetrics and Neonatal Nurses (AWHONN).</td>
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<td>calculate the eCQM reasonable? Please consider workflow issues when answering. Yes, it is reasonable, but it is initially time intensive to set-up an automated data abstraction workflow to streamline data validation. 7. While measure specifications for the cohort, numerator, and risk adjustment variables are defined using International Classification of Diseases, Tenth Revision (ICD-10) codes, the value sets for these specifications also include Systematized Nomenclature of Medicine (SNOMED) codes for future implementation consideration. We are looking for input on the feasibility of implementing SNOMED codes and the ability to identify present on admission (POA) status for these codes. Please describe any approach you have used, with codes (e.g., LOINC, SNOMED), structured fields, or onset dates, to identify POA with SNOMED Codes. In my role as a Perinatal Quality Nurse, I worked with my Stakeholders, Nurse Informatics, Data Analyst, and Hospital Coder colleagues to identify these codes within the EMR. I also had access to the external California Maternal Quality Care Collaborative (CMQCC) Maternal Data Center where SOC/SMM data is actively being track/trended.</td>
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<td>12/14/21</td>
<td>Karen Crowley, DNP, APRN-BC, WHNP Vice President of Nursing, Education, Research and Practice, Association of Women’s Health, Obstetrics and Neonatal Nurses (AWHONN)</td>
<td>Maternal Health Societies</td>
<td>Severe Obstetric Complications eCQM</td>
<td>The following comments are submitted on behalf of the members of the Association of Women’s Health, Obstetrics and Neonatal Nurses (AWHONN). Contact information: Karen Crowley, DNP, APRN-BC, WHNP Vice President of Nursing, Education, Research and Practice 1. How useful is this measure in assessing and improving the quality of care for patients?</td>
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<td>Providing a list of measures will be especially useful in determining a national SMM rate. It is appreciated that the measure specifications are built on existing specification developed by the JC [PC-01; PC-03]. Which have improved the quality of the patients served, including other contributors of SMM in addition to HTN disorders and Hemorrhage.</td>
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In addition, addressing SMMs and providing goals to improve outcomes within the accreditation process is essential to enhance the quality of care for patients. It is appreciated that the diversity of settings including location nationally, type (e.g., community, profit, non-profit, Government) and a variety of EMR systems was incorporated. Please explain your answer with input as to how to design and implement this measure most effectively.

One of the biggest challenges in combating maternal mortality and morbidity is the inability to identify needed actions at the facility level for process improvements. Providing SMM specific quality metrics as well as conditions present on admission that predispose patients toward SMM incidents, would help all clinicians as well as facilities prioritize work (guidelines, policy, processes) as well as dedicated resources (data, data alerts). The measures would be useful for hospitals, patients, payers, for assessment and improvement of quality. Each hospital could be ranked according to set benchmarks. The hospital can use to assess their own care using a dashboard and comparing to others in region/state/nation. The potential for more real-time measure results would be in service of supporting hospital QI. Recognizing this is intended to be used alongside existing perinatal QI work is a win. The goal of
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| 12/14/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | building a system that does not require changes in clinical workflow and electronic specifications, are simple to understand and implement. Ensuring cost considerations related to interoperability should be considered, as well as developing training resources and implementation toolkits. If information is reported publicly, patients could view data and make decisions regarding where they seek care. This transparency would result in the hospitals to improve on each metric. In addition, payers can use benchmarks as part of VBP and state Perinatal Quality Collaboratives could use the data to inform strategic decisions. 2. Do the numerator specifications effectively capture severe obstetric complications? The numerator specifications could be expanded to capture preeclampsia with severe features, in the absence of a diagnosis on admission of both preeclampsia. The acute and chronic impact of preeclampsia is significant and, in the format, the absence of diagnosis on admission or inpatient transition to eclampsia, this data may not be captured. Consideration of mental health conditions and DKA as a numerator is recommended and that the numerator specifications are updated over time as MMM data is revised nationally. 3. For public reporting, which of the following measure rates would be most important to report? Please explain your answer. a. An overall rate of severe obstetric complications which includes transfusion-only cases? b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication? c. Both rates identified in a & b? Compounded complications increase the overall
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<td>impact of SMM and having a full understanding of severe obstetric complication with and without transfusion only cases would provide a complete picture to the public.</td>
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4. Will the hospital measure result be useful and meaningful to patients? The hospital measure would be meaningful to clinicians and patients. It would provide insight into the evidenced-based practice activities as well as strong structures and processes. Patients can use this data to select their delivering facility. Patient education will be needed to assist the patient in understanding the hospitals measures and SMM; however once educated patients will be able to make an informed decision on delivering facility, considering their own pre-existing conditions.

5. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured? Yes, the clinical concepts are captured in the normal course of clinical workflow. While clinical incidents are documented, coding issues, lack of HER integration, lack of available data streams, and absence of data reporting will impact the capture. Dedicated resources are needed at each facility / system to accurately capture. While this is a large lift, it is necessary. The recommendation / requirement from CMS for eCQM related to SMM will prompt healthcare leadership to provide needed elements to capture which will subsequently improve patient outcomes and decrease SMM. In addition, separate coding of transfusions may not be regularly captured at all facilities.

6. Are all clinical concepts related to this measure...
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<td>available in structured, extractable fields in HER systems? Not please identify which are not and provide suggestions on alternatives that are available in structured, extractable fields in the HER systems. Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable? Please consider workflow issues when answering. To adequately assess available HER fields, CMS would have to query multiple HER organizations (Cerner, EPIC, Meditech) for available fields and opportunities to modify / update ongoing, as extractable fields vary in each HER system. Regardless, there is always ongoing updating occurring, so while a burden, this should fall within a necessary one to combat this crisis. 7. While measure specifications for the cohort, numerator, and risk adjustment variables are defined using International Classification of Diseases, Tenth Revision (ICD-10) codes, the value sets for these specifications also include Systematized Nomenclature of Medicine (SNOMED) codes for future implementation consideration. We are looking for input on the feasibility of implementing SNOMED codes and the ability to identify present on admission (POA) status for these codes. Please describe any approach you have used with codes (e.g., LOINC, SNOMED), structured fields, or onset dates, to identify POA with SNOMED codes. Most are unfamiliar with SNOMED codes, however if it assists with improved accuracy of coding, which would be beneficial.</td>
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<td>12/15/21</td>
<td>Edward Chien, MD, MBA, Cleveland Clinic, Department Chair of Obstetrics and Hospital/Health System</td>
<td>Severe Obstetric Complications eCQM</td>
<td>Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. With a footprint in</td>
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12/15/21 | Gynecology, Maternal Fetal Medicine | Continued from the previous page | Continued from the previous page | Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 19 hospitals with approximately 6,000 staffed beds, 21 outpatient Family Health Centers, 11 ambulatory surgery centers, and numerous physician offices. Cleveland Clinic employs over 4,600 salaried physicians and scientists. Last year, our system cared for 2.4 million unique patients, including nine million outpatient visits and 273,000 hospital admissions and observations.

Cleveland Clinic appreciates the opportunity to respond to the call for public comment regarding the development of a hospital-level electronic clinical quality measure (eCQM) for assessing severe obstetric complications. We provide our recommendations regarding this proposed eCQM in response to the specified questions below.

How useful is this measure in assessing and improving the quality of care for patients?

We agree that the severe obstetric complications eCQM is an important measure and are pleased about its development. While the underlying intent has value, we believe some of the current specifications of this eCQM ought to be refined or clarified to advance its usefulness in measuring and improving the quality of hospital care for obstetric patients. Our recommendations are as follows:
• We believe the coverage of hospitalized patients of at least 8 years to less than 65 years of age to be too broad. We recommend that the measure developer consider narrowing the current age span for the initial population as pregnancies at the extremes of age are uncommon and thereby increase the likelihood of inclusion errors in the administrative dataset.
• We understand this eCQM aims to capture “delivery” hospitalizations. However, it is unclear...
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| 12/15/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | from the supporting documents how delivery is defined. The measure should capture deliveries (vaginal and cesarean) as well as dilation and evacuation given the gestational age range of inclusion.  
• We recommend that the measure developer lower the gestational age for inclusion in the measure to 16 weeks. We believe more meaningful obstetric and pregnancy-related maternal morbidity may be captured in the window of 16-20 weeks gestation.  
• Regarding risk adjustment variables, according to page 2 of the measure authoring tool header document, the “first resulted value 24 hours prior to start of encounter and before time of delivery” will be used for heart rate and systolic blood pressure. Our concern is that the first value may not be the most representative value, and we query whether this approach is being validated by the team developing the model. This is not readily apparent in the documentation and would need further clarification. In addition, some variables excluded from risk adjustment may be due to their prevalence at the selected test sites while other conditions, such as sickle cell disease and creatinine levels, were not assessed at all.  
• We note that multiple numerator events have less than 10 occurrences. These rare events often relate to the patient’s underlying disease rather than the care that is being provided. The measure developer should reconsider including rare events in an aggregate quality measure if they are not controllable by the institution.  
2. Do the numerator specifications effectively capture severe obstetric complications?  
If the goal is to impact quality of care and encourage practice improvements, then the numerator needs to exclude events that occur |
infrequently. Generally, the indicators outlined in Table 7 of the eCQM Methodology Report that occur 10 or more times could be considered relevant to achieve the objectives of this measure. The following would be deemed important events: disseminated intravascular coagulation, shock, acute renal failure, acute respiratory distress syndrome, pulmonary edema, sepsis, eclampsia, and hysterectomy, given that the quality of care delivered might actually increase or decrease the rates of these events occurring.

3. For public reporting, which of the following measure rates would be most important to report?
   a. An overall rate of severe obstetric complications which includes transfusion-only cases?

   We do not agree that including transfusion-only cases would be a useful indicator. Transfusion can be life-saving, and using a measure that segregates out those who received transfusions from those who do not might obscure issues in care delivery.

   b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication?

   Excluding transfusion-only cases from the rate of severe obstetric complications would be reasonable. Including transfusion-only cases in the measure might drive actions that would lead to greater morbidity and mortality.

4. Will the hospital measure result be useful and meaningful to patients?

   A hospital composite measure per number of deliveries would be a useful comparator.

5. Are all clinical concepts related to this measure
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| 12/15/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured?  
Table 3 in the Methodology Report lists risk variables that include many pre-existing conditions. Many of these conditions are often not captured in coding. Consequently, this may create additional variance because many individuals who have pre-existing conditions often have multiple conditions. Because only the top five issues may be coded, many relevant diagnoses end up being missed.  
6. Are all clinical concepts related to this measure available in structured, extractable fields in HER systems? If not please identify which are not and provide suggestions on alternatives that are available in structured, extractable fields in the HER systems. Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable? Please consider workflow issues when answering.  
Many of the fields within electronic health record systems are likely to be extractable as demonstrated by the results in Table 8 of the Methodology Report. However, the test site results displayed in the tables do not provide sufficient detail of the data from the records being evaluated. It would be useful to get a breakdown from the tested electronic medical records to ascertain what elements were missed.  
Thank you for conducting a thoughtful process that allows us to provide input on such important issues. Should you need any further information, please don’t hesitate to contact me. |
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<td>12/15/21</td>
<td>Koryn Rubin, American Medical Association (AMA)</td>
<td>Medical Associations and Societies</td>
<td>Severe Obstetric Complications eCQM</td>
<td>The American Medical Association (AMA) remains committed to addressing inequity and decreasing maternal morbidity and mortality and we believe that this measure in addition to initiatives such as the Centers for Disease Control and Prevention (CDC) Alliance for Innovation on Maternal Health (AIM) bundles will drive improvements in maternal complications and death. Based on the materials released for public comment by the Centers for Medicare and Medicaid Services (CMS) on November 19, 2021, an exclusion for patients diagnosed with Covid-19 is under consideration and the AMA strongly encourages its addition to CMS. We also ask the developer to re-consider whether inclusion of some of the risk factors, specifically severe and other preeclampsia and obstetric VTE, are appropriate since their inclusion could mask potentially avoidable severe maternal morbidity.</td>
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| 12/15/21             | Sarah Shaw, RN, Maternal Program Manager, Texas Vista Medical Center | Hospital/Health System | Severe Obstetric Complications eCQM | CMS encourages you to submit general comments or specific feedback on measure specifications. In particular, please provide feedback on the following questions and prompts:  
1. How useful is this measure in assessing and improving the quality of care for patients? Please explain your answer with input as to how to design and implement this measure most effectively. The reason there is a the saying “History repeats itself” is because it is true. Although some SMM are not preventable many are. We NEED to find out if there is a way to prevent the ones that we can. We have to start by knowing where the issue lies.  
2. Do the numerator specifications effectively capture severe obstetric complications? Yes, except where is Postpartum hemorrhage. There needs to be a version of PPH on the list  
3. For public reporting, which of the following measure rates would be most important to report? |
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| 12/15/21            | Continued from the previous page               | Continued from the previous page | Continued from the previous page | Please explain your answer.  
a. An overall rate of severe obstetric complications which includes transfusion-only cases? NO, some transfusions will be needed due to normal blood loss and anemia combination, especially in certain areas of the country. That should not be thought of as a negative outcome.  
b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication? Yes  
c. Both rates identified in a & b?  
4. Will the hospital measure result be useful and meaningful to patients? YES! More and more people are becoming informed before selecting hospital care, especially in regards to OB as they have time to plan for the event.  
5. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured? Yes  
6. Are all clinical concepts related to this measure available in structured, extractable fields in HER systems? If not please identify which are not and provide suggestions on alternatives that are available in structured, extractable fields in the HER systems. Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable? Please consider workflow issues when answering. Yes  
7. While measure specifications for the cohort, numerator, and risk adjustment variables are defined using International Classification of Diseases, Tenth Revision (ICD-10) codes, the value sets for these specifications also include Systematized Nomenclature of Medicine (SNOMED) codes for future implementation consideration. We are looking for input on the feasibility of implementing SNOMED codes and the ability to identify present on admission (POA)
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<td>status for these codes. Please describe any approach you have used with codes (e.g., LOINC, SNOMED), structured fields, or onset dates, to identify POA with SNOMED codes.</td>
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<td>12/16/21</td>
<td>Randall M. Clark, MD, FASA, President, American Society of Anesthesiologists</td>
<td>Medical Associations and Societies</td>
<td>Severe Obstetric Complications eCQM</td>
<td>Dear Yale-CORE: On behalf of the 54,000 members of the American Society of Anesthesiologists® (ASA), I am pleased to offer feedback and comments on the Severe Obstetric Complications Electronic Clinical Quality Measure (eCQM) developed by the Centers on Medicare &amp; Medicaid Services (CMS), Yale New Haven Health Services Corporation - Center for Outcomes Research and Evaluation (CORE), and The Joint Commission (TJC). ASA commends this collaborative effort to address the United States’ high rates of maternal mortality and build a system that will track and assess maternal morbidity and mortality trends. A successful eCQM will allow clinicians and health care facilities the ability to assess the care they provide, refine existing best practices, and better navigate social determinants of health in providing the best possible care to obstetric patients. ASA believes that tapping into the vast wealth of information offered by electronic health records (EHR) is a crucial element of working toward better quality of care and improved patient outcomes. Obstetric patients have benefited from the safe, effective, and patient-centered care that anesthesiologists offer each day. We have identified several considerations that we hope will re-shape the measure to better meet this project’s objectives. As examples, small sample sizes for outcomes like mortality, although very important, can easily mask a hospital’s overall performance. In addition, we believe several listed complications will need to be better defined before they can be</td>
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1. How useful is this measure in assessing and improving the quality of care for patients? Please explain your answer with input as to how to design and implement this measure most effectively.

If properly constructed, an eCQM on severe obstetric complications could be of great use to hospitals, physician anesthesiologists, other clinicians, and their patients in assessing and improving quality of care. But as currently constituted, the measure will not provide a fully accurate or actionable representation of the care a patient receives. We believe the eCQM will require some structural changes, along with several minor refinements, to play a role in advancing obstetric quality of care.

Based on the sample data sets and methodology provided, we are concerned that measuring relatively rare events may unintentionally skew statistics from the hospital-level data. As an example, the mortality rate in the provided data is approximately one in 5,000 obstetric patients. This means that one additional patient death could significantly alter the performance rate for a given institution, especially considering that this could feasibly occur even at facilities delivering the highest quality of care. For patients, this might erode their sense of safety when assessing hospitals, especially since there are often multiple contingencies that may affect a patient’s care and risk of death. We believe the measure should prevent statistical outliers and small sample sizes from creating inaccurate interpretations of the data. We recommend the measure be contemplated more as a composite measure,
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| 12/16/21            | Continued from the previous page                 | Continued from the previous page | Continued from the previous page | based upon several individual measures, incorporating subcategories of complications and specific metrics to allow for physicians and other clinicians to more precisely address the drivers of maternal morbidity and mortality. To prevent low sample sizes, TJC and Yale-CORE could explore new individual measures focused on facilities with more than 2,000 deliveries a year. Severe obstetric complications, as defined in this measure, are rare. For the measure to effectively improve patient outcomes at scale and address national maternal mortality rates, we believe TJC and Yale-CORE should also create disease-specific metrics within the eCQM (or eCQMs). Research in recent years has shown that national emphasis on best practices for managing hemorrhages and preeclampsia for obstetric patients has driven down maternal mortality rates. Similar progress can be made on other conditions with outsized effects on U.S. maternal mortality, such as sepsis and VTE prophylaxis. There are many comorbidities, whether preexisting or developed over the course of pregnancy/labor, that contribute to severe obstetric complications without any proven preventative strategies or interventions. These conditions include peripartum cardiomyopathy, amniotic fluid embolism, and disseminated intravascular coagulopathy. While data on these conditions could be useful to clinicians over time as effective treatments are developed, disease-specific data on the treatable conditions most closely correlated with maternal mortality and morbidity will be the most pertinent information to improve near-term care quality. ASA encourages TJC and Yale-CORE to further scrutinize the risk-adjusted model provided in the materials for the proposed eCQM. In this model,
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<td>the differences between facilities were dramatically lower than in the other datasets. This could point to a significant impact of underlying conditions and social determinants of health on severe obstetric complications that outweighs the difference in quality and performance between hospitals. Seeing whether adjusting for risk keeps the differences in obstetric case outcomes low with a greater sample size would be helpful to understand the balance between the differences in performance across facilities and broader issues of health inequity in driving high maternal mortality rates. Adding to that effort, TJC and Yale-CORE could consider tracking whether facilities are in a rural, urban, or suburban location. We recommend additional categories and regulatory features that would enhance our understanding of maternal mortality and provide a more complete interpretation of the data: • Size of hospital • Number of deliveries per year • ACOG levels of maternal care: This model divides obstetric care into basic care (level I), specialty care (level II), subspecialty care (level III), and regional perinatal health care centers (level IV). • Neonatal levels of care: Such a model divides neonatal care into well newborn nursery (level I), special care nursery (level II), neonatal intensive care unit (level III), and regional neonatal intensive care unit (level IV). 2. Do the numerator specifications effectively capture severe obstetric complications? The numerator specifications are effective in that they include a significant list of complications. Several of the complications, currently labeled as “severe morbidities,” should be excluded from the measure, as they are not markers of quality nor</td>
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| Continued from the previous page | Continued from the previous page | Continued from the previous page | | indicative of clinician performance. Further, the measure should account for the transfer of patients. If a patient moves to a new hospital while already experiencing a severe complication, we recommend that their condition not be attributed to the new hospital. Similarly, patient diagnoses upon arrival to a health care facility or shortly afterward should not be captured in the measure since they do not reflect the clinical quality of the case. This issue of attribution will be particularly important in measuring deaths. Recent data has indicated that most maternal deaths occur outside of facilities before a patient arrives. These cases should not count for a given facility’s maternal mortality numbers.

We have identified a few additional conditions categorized as “severe morbidities” that should be excluded from the measure or excluded in certain circumstances:

- Aortic aneurysm: This outcome is unrelated to obstetric care and should be excluded from the measure.
- Cardiac arrest: During obstetric care, one possible cause of cardiac arrest is an amniotic fluid embolism, which is not a preventable condition. We recommend cardiac arrest cases be excluded from the measure.
- Eclampsia: Patients are often diagnosed with eclampsia upon arrival to the hospital or soon afterward. Patients diagnosed with eclampsia should be excluded from the measure.
- Sickle cell anemia with crisis: Although physicians and other clinicians use monitoring and prevention strategies for obstetric patients with sickle cell anemia, sickle cell anemia is not necessarily an obstetric complication.
- Blood transfusion: Physicians, other clinicians, and their facilities should not be penalized or discouraged from using blood transfusion when

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• Ventilation: We are unclear how ventilation is defined in the measure. We suggest this feature of the measure could be covered under a broader complication label of “respiratory failure.”  
ASA believes that “overdose” as one end result of substance use disorder should be included as a measure outcome. Substance use disorder is correctly labeled in the measure as a risk adjustment, but overdoses have become an unfortunate major cause of maternal mortality and should be re-categorized as an outcome. Additionally, we believe that COVID-19 infections should be added as a comorbidity, especially as some patients may defer receiving their COVID-19 vaccine while pregnant. Extracorporeal membrane oxygenation is another comorbidity worth tracking in the eCQM.  
We thank Yale-CORE for providing us with the data value set for “several anesthesia complications.” However, we ask that Yale-CORE and CMS publish those electronic data sets with the call for measure comments in the future so that commenters can have every opportunity to provide meaningful feedback. As currently structured, a login and password are needed, along with other registration requirements, to retrieve that data set. ASA is excited about the opportunities that eCQMs and digital quality measures will play in the future but transparency in data elements for stakeholders and the public to view is important. Otherwise, we will only partially understand how this and other measures will impact the workflows our members use and the care patients receive.  
3. For public reporting, which of the following measure rates would be most important to report? Please explain your answer. |
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| 12/16/21            | Continued from the previous page                 | Continued from the previous page | Continued from the previous page | a. An overall rate of severe obstetric complications which includes transfusion-only cases?  
b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication?  
c. Both rates identified in a & b?  
ASA recommends that TJC and Yale-CORE use option “c.” ASA maintains that transfusion should not be labeled as a “severe morbidity” or a marker of clinical performance (see our answer to Question 2 above). However, it would be useful to track transfusion-only cases alongside a rate that excludes those cases, as transfusion rates have been correlated with severe maternal morbidity rates. We recommend excluding placenta accreta cases for the transfusion-only rate, as this condition represents one of the major causes of transfusions at many facilities, despite not classifying as a severe morbidity. We also note that these rates would be particularly helpful to physicians if they were organized according to disease-specific or cause-specific cases, as discussed in our response to the first question.  
Regarding blood transfusions, we are unclear on a specific threshold for blood transfusion (e.g. >= 4 units) that would generally be reflective of severe maternal morbidity cases. We encourage TJC and Yale-CORE to consider adding the threshold to provide some clarity on how transfusions are incorporated into the eCQM.  
4. Will the hospital measure result be useful and meaningful to patients?  
ASA recognizes the importance of providing transparent data to patients so the patient can make an appropriate decision on where they will receive their care. Most obstetric patients would not use this measure in selecting a hospital for
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<td>their care, as patients oftentimes must go to one of the closest hospitals available to receive care urgently when in labor or experiencing obstetric complications. Meanwhile, high-risk obstetric patients are generally referred to regional facilities. One way to bridge the gap between these contingencies might be for TJC and Yale-CORE to consider designing a user-friendly, patient-facing tool to the measure that allows patients to filter hospital performance metrics by preferred geographic proximity.</td>
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5. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured?

Anesthesiologists, other physicians, and clinicians would be able to capture the comorbidities, demographics, and other patient-level features within this measure. We recognize that maternal mortality may be challenging to track since current standards measure maternal mortality on an annual basis instead of more granularly. We requested additional consideration and scrutiny of anesthesia-related complications, as they cover a wide range of severity. Further clarity on how these complications are defined in the measure may be required to know the availability of this data in routine workflows.

6. Are all clinical concepts related to this measure available in structured, extractable fields in EHR systems? If not please identify which are not and provide suggestions on alternatives that are available in structured, extractable fields in the EHR systems. Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable? Please
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<td>consider workflow issues when answering. Most clinical concepts in this measure are available within EHR systems and can likely be extracted without undue burden. Our physicians have identified a few fields that are unlikely to be easily extracted as they may not align with how the conditions or factors are defined by facilities’ EHR systems. TJC and Yale-CORE should consider revisiting disseminated intravascular coagulation, hemorrhagic shock, heart failure, long-term anticoagulation use, and conversion of cardiac rhythm for data capture and feasibility purposes. We request additional clarity on the definition of the term “conversion of cardiac rhythm.” 7. While measure specifications for the cohort, numerator, and risk adjustment variables are defined using International Classification of Diseases, Tenth Revision (ICD-10) codes, the value sets for these specifications also include Systematized Nomenclature of Medicine (SNOMED) codes for future implementation consideration. We are looking for input on the feasibility of implementing SNOMED codes and the ability to identify present on admission (POA) status for these codes. Please describe any approach you have used, with codes (e.g., LOINC, SNOMED), structured fields, or onset dates, to identify POA with SNOMED Codes. We do not have any comments for Question 7.</td>
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<td>Deb Fischer-Clemens, Senior Vice President of Public Policy, Avera Health</td>
<td>Hospital/Health System</td>
<td>Severe Obstetric Complications eCQM</td>
<td>Avera is pleased to submit these comments on the referenced Centers for Medicare &amp; Medicaid Services’ (CMS’) and The Joint Commission (TJC) draft measure for Severe Obstetric Complications eCQM. Avera Health has six facilities that submit eCQMs</td>
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| 12/16/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | for Inpatient Quality Reporting and The Joint Commission for maternal and infant quality measures. We pride ourselves with the care we give to our maternal and infant population, with the largest of our facilities with over 2400 births per year and a level three NICU.

As we reviewed the measures we would like you to keep in mind our rural population in the upper Midwest. We are glad you are considering social determinants as a risk adjustment but are unsure if you are including rural factors into your calculations. Some questions to consider as your build this measure:
- What social determinant tool are you using?
- What is considered rural? We often times will have maternal transfers from a rural hospital. Would you consider the patient’s resident as rural or the hospital as rural?

Within the measure you have blood transfusion listed as an inclusion in the numerator. We consider a blood transfusion as a result of good care not a severe maternal morbidity (SMM). Please consider removing blood transfusion from the numerator inclusion unless you are going to consider blood transfusion alone as an additional measure.

Please see answers to your requested questions:
1. We do feel the severe obstetric complication measure helps assess care and will help in the quality improvement efforts. We think it is important to also have the additional measure of severe obstetric complications excluding deliveries where blood transfusion is the only numerator event. We do believe the stratification by race/ethnicity is important.
2. Yes, the numerator captures the most severe complications.
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<td>3. For public reporting, the rate of severe complications excluding cases where transfusion is the only severe complication should be used. 4. We are unsure if this measure will be helpful to patients. There are many factors for choosing a facility and this would only be one. We worry that this will cause our rural patients to seek care further away from home. 5. Yes, the clinical concepts are captured routinely. 6. Most of the clinical concepts are capture in a structured, extractable field. How do you define long-term anticoagulant medication use? We would be able to capture if the patient was on an anticoagulant home medications where their clinic is also part of our network, but unsure we have the ability to capture the length of time. 7. We have been capturing eCQM data for close to 10 years. We capture POA by diagnosis code that has a status of chronic in the problem list or has been on the problem list prior to the admission.</td>
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<td>12/16/21</td>
<td>Diana Patterson, MPH, CSSGB, Emanate Health</td>
<td>Hospital/Health System</td>
<td>Severe Obstetric Complications eCQM</td>
<td>This is in response to the public comment period for measure Severe Obstetric Complications eCQM. Our concern is related to the reliability of the measure results given the challenge organizations may face with coding some of the present on admission comorbidities included in the measure. Are other organizations confident in their ability to capture this criteria as present on admission vs not present on admission?</td>
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<td>12/16/21</td>
<td>Tilithia McBride, Vice President, Quality, Federation of American Hospitals (FAH)</td>
<td>Medical Associations and Societies</td>
<td>Severe Obstetric Complications eCQM</td>
<td>The Federation of American Hospitals (FAH) strongly supports efforts to address pregnancy-related morbidity and mortality and we appreciate the Centers for Medicare and Medicaid Services (CMS) developing an outcome measure that specifically addresses this issue. The FAH strongly encourages CMS to add the exclusion for patients diagnoses with Covid-19 in light of the public health emergency and to submit the measure to</td>
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In addition, while we encourage CMS to further test this electronic clinical quality measure (eCQM) to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) and determine if the measure is reliable and valid across a broader set of EHRs vendors and hospitals, we were encouraged to see the number of hospitals and vendor systems used in testing.

Thank you for the opportunity for comment.

12/16/21

David B. Nelson, MD, Chief of Obstetrics and Maternal Medical Director, Parkland Hospital; Associate Professor, Division of Maternal-Fetal Medicine Division, Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center at Dallas

Catherine Y. Spong, MD, Professor and Chair, Department of Obstetrics and Gynecology, Paul C. MacDonald Distinguished Chair in Obstetrics and Gynecology, University of Texas Southwestern Medical Center at Dallas

This comment is written in response to the Severe Obstetric Complications Electronic Clinical Quality Measure (eCQM) recently proposed to provide timely and accurate data to inform hospital improvement efforts and patient decision making from the perspective of a large, publicly funded birthing facility responsible for the care of the medically underserved of Dallas County in Texas. Parkland Hospital serves approximately 12,000 delivering women each year. For context, this single maternity service represents a total delivery volume more than 10 individual states in the country. In addition, Parkland Hospital is a level IV (highest) designated facility for the Maternal Levels of Care Designation in Texas. As part of this designation, Parkland Hospital prides itself on tracking patient outcomes to improve patient care through robust tracking of quality measure recommended by leading organizations, including National Quality Forum.

To the members of the Centers for Medicare & Medicaid Services and Yale New Haven Health Services Corporation-Center for Outcomes Research and Evaluation,
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| 12/16/21             | Continued from the previous page                 | Continued from the previous page | Continued from the previous page | As such, we applaud the efforts working towards relevant, timely quality obstetrical measures. We have twice provided invited testimony in the past two years to the United States Congress on improving maternal care in this country.1,2 Both highlighted the importance of identifying and measuring relevant quality metrics within obstetrical care. Indeed, we have explicitly stated that there must be recognition that case mix influences a given facility’s severe maternal morbidity (SMM) or mortality rate. Thus, we agree that including “case mix” to address the influence of patient characteristics and co-morbidities on obstetrical quality data is key. For example, placenta accreta spectrum (PAS) often requires hysterectomy as a life-saving, definitive treatment, and after excluding transfusion, hysterectomy is one of the most common SMM indicators.3 Thus, a patient with PAS present on admission is likely to result in a coded SMM event. That said, the details in the PC-07 proposed metric are not easily followed, and may skew results depending upon coded co-morbidities. A more simple explanation of what comorbidities are included is needed to ascertain the ability of this metric to discern quality across systems. Second, comparisons of SMM must account for regionalization of care for maternity services with higher level of care facilities serving as referral centers for lower-level facilities in the management of high-risk cases, such as PAS with its attendant risks for SMM, given that some states (e.g. Texas) have passed legislation to mandate designated care of these cases.4 Although the current effort of severe obstetric complications using available administrative billing codes is well-intentioned, we caution that adoption without further study is premature. Two key issues that demand further study before widespread adoption are: (1) resolve inconsistent coding.
Second, there is conflicting published data on the utility using SMM (including transfusion) as a relevant quality measure. A recent publication in The Joint Commission Journal on Quality and Patient Safety by Fridman and colleagues report data from a population-based retrospective cohort study using severe maternal morbidity (SMM) as a facility-specific quality measure among various California hospital settings.7 Because of the substantial contribution of blood transfusion to the composite metric and recognized variation in transfusion coding, SMM rates including and excluding blood transfusion were examined amongst four hospital types. Sophisticated models for SMM from 2016–2017 were developed with testing for observed-to-expected ratios for each hospital and identification of over- and under-performing hospitals using data from 2018 for these facilities. The authors concluded that there

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**Text of Comments**: definitions, and (2) reconcile conflicting results on utility of SMM. First, consistent definitions and data quality must be ensured when utilizing administrative codes. As an example, acute renal failure—an SMM indicator—is poorly defined in the gravid patient given the normal physiologic changes of pregnancy.5 For SMM, there are six ICD-10 codes proposed for acute renal failure with specifications including tubular, cortical, and medullary necrosis, “other” and “unspecified,”, and “postpartum.”3 The heterogeneity of documentation and potential presence on admission (e.g., preeclampsia) challenges interpretation of associated morbidity and may misclassify the presence or absence of renal disease.6 It is problematic to use SMM measures to hold hospitals accountable for a “complication” that is not consistently defined, is present on admission, or is unrelated to the obstetric management.6
was significant variation in SMM rates among each of the four hospital types, and thus, posited that SMM can be used as a quality indicator—especially when excluding transfusion. Because blood transfusion is a substantial component of SMM and is inconsistently coded, examining SMM rates without transfusion may be a more valid indicator of hospital quality. This finding has immediate relevance given that blood transfusion has been identified to be the major contributor—up to 80%—to the national SMM rate.3

Regardless of the chosen obstetric quality metric, more data are needed.6 Put simply, we must fully understand the metric before attempting to mandate as a measure or compare individual hospitals’ performance. The immediate need for a better understanding of obstetric quality metrics is paramount. We advocate that more data are needed before we recommend adopting any of these measures as definitive obstetric quality metrics because the threat of misuse may inadvertently lead to inappropriate conclusions and unintended consequences. To objectively assess performance, guide health policy, and importantly, improve the care of women and their unborn children who we serve, we must have reliable, relevant obstetric quality metrics.6

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<td>12/17/21</td>
<td>Erin Lambie Alston, MS, MPH, American College of Obstetricians and Gynecologists (ACOG)</td>
<td>Maternal Health Societies</td>
<td>Severe Obstetric Complications eCQM</td>
<td>The American College of Obstetricians and Gynecologists (ACOG) represents more than 60,000 obstetrician-gynecologists and partners in women's health, providing decision support guidance and resources for women's health care. We are engaged on a number of topics regarding Medicaid, Medicare, and private payer issues, including quality measure maintenance and development. ACOG appreciates the opportunity to provide feedback on the new Centers for Medicare and Medicaid Services (CMS) and Yale</td>
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| 12/17/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) project titled Severe Obstetric Complications Electronic Clinical Quality Measure (eCQM). Please see our detailed feedback below.  
1. How useful is this measure in assessing and improving the quality of care for patients? Please explain your answer with input as to how to design and implement this measure most effectively.  
ACOG appreciates the emphasis CMS and CORE are placing on improving maternal health outcomes and preventing adverse health outcomes. The U.S. is experiencing a maternal mortality crisis and is the only developed country with a rising maternal death rate. Equally, severe maternal morbidity (SMM) is rising in the U.S. Identifying SMM is important for preventing injuries that lead to mortality and for highlighting opportunities to avoid repeat injuries. Therefore, the creation of measures around SMM, including the Severe Obstetric Complications eCQM, is critical to improving quality of care of patients.  
This new measure tackles the issue of SMM by utilizing an outcome based on the Centers for Disease Control and Prevention (CDC) definition of SMM, which includes 21 indicators of SMM. Many of these indicators are commonly utilized and recognized components to identifying SMM and are reflected in the 2021 Alliance for Innovation on Maternal Health’s (AIM) SMM Codes List. The current measure documentation references the 2019 AIM SMM Codes List and it is recommended to update the reference to the most current version of the AIM SMM Codes List.  
2. Do the numerator specifications effectively capture severe obstetric complications? |
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<td>ACOG has not officially endorsed or created a single, comprehensive definition of SMM. This is relevant as ACOG’s 2016 Obstetric Care Consensus on Severe Maternal Morbidity: Screening and Review (reaffirmed in 2021) specifically indicates that transfusions of four or more units of blood should not be included as indicator of SMM as it is typically indicative of a preexisting condition not related to pregnancy. Blood transfusions are included as an indicator of SMM as part of the numerator of this measure. While the risk adjustment component of the measure includes bleeding disorders, there should be consideration of including a specific numerator exclusion for transfusions of four or more units of blood to ensure that appropriate SMM identification is achieved without penalizing providers for non-pregnancy related disorders. 3. For public reporting, which of the following measure rates would be most important to report? Please explain your answer. a. An overall rate of severe obstetric complications which includes transfusion-only cases? b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication? c. Both rates identified in a &amp; b? Given the lack of distinction of cases with transfusions of four or more units of blood in the current measure specifications, it is most appropriate to remove transfusion-only cases from public reporting requirements and report on the overall rate for cases without transfusion. 4. Will the hospital measure result be useful and meaningful to patients? This measure has the potential to useful and</td>
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| 12/17/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | meaningful to patients, especially in conjunction with the recently instituted Maternal Morbidity Structural Measure in the Inpatient Prospective Payment System (IPPS) final rule focused on the implementation of quality improvement patient safety bundles through perinatal quality collaboratives. Institutions should be striving to develop and implement measures that focus on tackling issues surrounding maternal morbidity and mortality, similar to these current efforts. The measure specifications should be available to patients in clear language and appropriately include explanations for conditions that are captured in the measure.  

5. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured?  

ACOG promotes the review of SMM cases and believes physicians should be able to capture important SMM-related information without undue administrative burden.  

6. Are all clinical concepts related to this measure available in structured, extractable fields in EHR systems? If not please identify which are not and provide suggestions on alternatives that are available in structured, extractable fields in the EHR systems. Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable? Please consider workflow issues when answering.  

No comment.  

7. While measure specifications for the cohort,
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<td>numerator, and risk adjustment variables are defined using International Classification of Diseases, Tenth Revision (ICD-10) codes, the value sets for these specifications also include Systematized Nomenclature of Medicine (SNOMED) codes for future implementation consideration. We are looking for input on the feasibility of implementing SNOMED codes and the ability to identify present on admission (POA) status for these codes. Please describe any approach you have used with codes (e.g., LOINC, SNOMED), structured fields, or onset dates, to identify POA with SNOMED codes. No comment.</td>
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<td>12/17/21</td>
<td>Sarah Duggan Goldstein, DrPHc, MPH, The Blue Cross and Blue Shield Association (BCBSA)</td>
<td>Purchaser</td>
<td>Severe Obstetric Complications eCQM</td>
<td>To whom it may concern, We are pleased to submit comments on the development of PC-07. The Blue Cross and Blue Shield Association (BCBSA) considers this measure is of high importance. The gap in the US outcomes compared to other wealthy countries is well documented in the development review. Other developed countries, and some US work, have shown that deaths from conditions such as pre-eclampsia and eclampsia can be virtually eliminated – demonstrating that these measures are actionable. BCBSA has committed to reducing SMM and particularly disparities in SMM between racial group over the next 4+ years, and therefore these measures are strongly aligned with Blue Plans focus, these are the measures we have chosen to define our work by. For public reporting, we support a rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication. We at the Association have chosen this metric as well. While we will track and monitor</td>
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<td>an overall rate with transfusion as well, we felt transfusion would dilute the rate of the other severe complications. We recognize that transfusion may also be amenable to improvement and so have chosen to track that as well. In reference to the other specific questions requested by CMS: • We believe the hospital measure result be of great importance to patients. • We agree the clinical concepts related to this measure are captured routinely in the normal course of clinical workflow. • We concur that the numerator specifications effectively capture severe obstetric complications. • To our knowledge all clinical concepts related to this measure are available in structured, extractable fields in EHR systems, and the burden is reasonable. Some of these definitions may have to captured by hospital coders, but this is similar to any other complication. Public reporting may actually drive better coding and capture. • Our experience is that Hospital coders should be familiar with coding for POA.</td>
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| 12/17/21            | Lisa Lokken, CNS, Ascension Wisconsin Health System  
Leah Hanson, MSN, RN, C-EMF, Ascension Wisconsin Health System | Hospital/Health System | Severe Obstetric Complications eCQM | 1. How useful is this measure in assessing and improving the quality of care for patients? Please explain your answer with input as to how to design and implement this measure most effectively. We have found value in reviewing SMM cases as a group to look for process and system issues that can be addressed to improve patient safety and the quality of care. 2. Do the numerator specifications effectively capture severe obstetric complications? We have found that the codes used by the CDC to determine a severe maternal morbidity sometimes miss patients that should be included or add patients with complications that aren’t actually severe. Some of this may be a mapping issue when... |
moving from ICD-9 to ICD-10.

For example, any documentation of thrombocytopenia in the chart codes out as DIC, but those aren’t actually equivalent issues. Additionally, clinicians often use AKI as shorthand when they see a short-term elevation in creatinine for preeclamptic patients. This code maps to the acute renal failure morbidity.

We have also found that the procedural code for blood product administration is not a mandatory code, but is instead only used for patients with certain insurance types. Therefore we have seen wide variation in reporting of transfusions, with many cases missed.

3. For public reporting, which of the following measure rates would be most important to report? Please explain your answer.
   a. An overall rate of severe obstetric complications which includes transfusion-only cases?
   b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication?
   c. Both rates identified in a & b?
   We would recommend using both rates identified with the caution that all blood product administrations would need to be coded to get a true rate for a. If that is not possible, then we would recommend that only non-transfusion cases be measured.

4. Will the hospital measure result be useful and meaningful to patients?
   This measure will be very useful for hospitals to monitor, but may give patients a false sense of the quality of care provided at an organization (e.g. level of maternal care available at a site and other variables in patient population that the delivering facility may not have control over).

5. Are all clinical concepts related to this measure?
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<td>captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured? Coding is captured in the normal course of workflow, however providers often chart in a narrative form, which makes it difficult to capture discrete data.</td>
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<td>12/17/21</td>
<td>Bruce Hall, MD, PhD, MBA, Vice President and System Chief Medical Officer, BJC Healthcare</td>
<td>Hospital/Health System</td>
<td>Severe Obstetric Complications eCQM</td>
<td>BJC HealthCare, as one of the largest nonprofit healthcare integrated delivery organizations in the country, is committed to improving the health and well-being of the people and communities we serve through leadership, education, innovation, and excellence in medicine. As such, we strive to deliver care to our patients that is safe, efficient, effective, patient-centered, accessible, and equitable. BJC supports The Centers for Medicare &amp; Medicaid Services (CMS), Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (CORE) and The Joint Commissions efforts in development of an EHR-based risk-adjusted outcome measure of maternal morbidity and mortality and appreciate the opportunity to comment.</td>
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<td>1. How useful is this measure in assessing and improving the quality of care for patients? Please explain your answer with input as to how to design and implement this measure most effectively. The Severe Obstetric Complications eCQM measure has the capacity to improve the quality of care for patients by creating transparent information for patients, hospital administrators, and providers. It is important that when these measures are implemented that it is done in a performance evaluation process to then allow hospitals a period to implement evidence-based interventions to reduce their complication rates. This process, given its high reliability in capturing realistic and relevant data, will certainly create the need for hospitals to adapt with increasing focus on quality and safety across the hospital. In addition, other goals must be set to reduce the increased burden of complications for women of color with a focus on these specific interventions for hospitals with evidence of disparity in care. The design of the measure suits the needs of the data request to assess quality of care and understanding of women who experience severe maternal morbidity. It would be helpful to have an improved explanation in less technical terms how the group arrived at the predicted compared to expected events for the Standardized Risk Ratio (SRR) as this impacts the Risk-Standardized Obstetric Complications Rate (RSOCR). This may help organizations understand how they can impact their scores for future improvement. The numerator and denominator inclusion criteria are legitimate for this quality measure. Correlation with risk factors is valuable data as well.</td>
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<td>2. Do the numerator specifications effectively capture severe obstetric complications?</td>
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| 12/17/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | Yes, but only for patients at the time of delivery. This process will not capture patients who return with severe obstetric complications such as readmission for complications secondary to severe preeclampsia or other maternal cardiac diseases that may worsen acutely in the initial couple of weeks postpartum. Finding a way to also capture readmission rates within 7-14 days, or some other agreed-upon timeframe for these patients, would be helpful. There is concern that some patients who have preexisting medical conditions may not be identified until admission for delivery and be inaccurately labeled as having severe maternal morbidity. We know patients with high-risk conditions are at higher risk for having SMM. Institutions that take care of a higher percentage of these patients could be disadvantaged and labeled as having higher rates of SMM when compared to institutions that take care of a lower risk and healthier populations. There have been co-morbidity risk adjustments that have been developed by perinatal quality collaboratives like the California Maternal Quality Care Collaborative, and when used seem to put these institutions on a more level set playing field. • We agree in using a co-morbidity risk adjustment so that systems are not disadvantaged by taking care of a higher risk populations. We say this with some hesitancy realizing that the risk adjustment made for one region may not function similarly in other regions or locations. • We agree with others that planned ICU transfers should not be included and categorized as SMM. Patients with SMM are often transferred to a higher level of care and we support any decision to ensure these are not included and noted to be present on admission. • We are concerned that transfusions of 4 or more PRBC will be included as pregnancies complicated
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| 12/17/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | by Placenta Accreta Spectrum that require more extensive surgeries and hysterectomies often require significant units of PRBC.  
3. For public reporting, which of the following measure rates would be most important to report? Please explain your answer.  
a. An overall rate of severe obstetric complications which includes transfusion-only cases?  
b. A rate of severe obstetric complications excluding cases where transfusion is the only severe obstetric complication?  
c. Both rates identified in a & b?  
Public reporting that includes both rates of severe obstetric complications (including transfusion-only cases and then excluding transfusion only cases) may not be necessary given the minimal difference in the two data sets for most severe maternal morbidity variables. For the most transparent data, the data set should at minimum include all variables, including the transfusions. It is also important to note that patients with pre-existing conditions that increase their risk for transfusion, such as anemia, placental implantation or adherence abnormalities, and bleeding disorders, are identified.  
4. Will the hospital measure result be useful and meaningful to patients?  
The meaningful use of this data for patients will be realized if patients understand what the Risk-Standardized Obstetric Complications Rate means and how to interpret Odds Ratios (OR) and Confidence Intervals (CI). If this data is transparent to patients, it will provide them with the ability to make informed decisions about where they would like to receive care and may also hinder them if payors begin to use this information against
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<td>hospitals and denying coverage for services at certain facilities. This could result in barriers to care if the information is used incorrectly. Also, system community providers expressed concern they see a fair volume of patients coming from miles to hours away, many of them include the worried who drive past one, or more, perfectly acceptable facilities for their needed level of care because they have a perception, they need care in the city or at a higher-level suburban facility due to lack of confidence in their local facility. The benefits of local access to care are often not valued until the care is no longer available. Concern is that public availability of this information by facility, if not provided in the correct context, could drive patients away from their communities at an even greater pace resulting in further obstetric volume loss from these critical access hospitals eventually resulting in programs that are not sustainable requiring systems to discontinue obstetrical services. In a state like Missouri, where care deserts are already of concern, we worry this type of shift could have devastating consequences for maternal morbidity and mortality, as well as neonatal and child outcomes.</td>
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<td>5. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? If not, please identify which are not, and do you have suggestions on alternatives that are more routinely captured?</td>
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<td>Considering there was a 99% feasibility in workflow and this organization uses EPIC, one of the studied EHR platforms, it is not anticipated that workflow will be a concern for capturing this measure.</td>
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<td>6. Are all clinical concepts related to this measure available in structured, extractable fields in EHR systems? If not please identify which are not and</td>
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January 2022
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<td>12/17/21</td>
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<td>provide suggestions on alternatives that are available in structured, extractable fields in the EHR systems. Is the level of burden associated with capturing and documenting the data elements required to calculate the eCQM reasonable? Please consider workflow issues when answering. There is not concern on available data elements in extractable fields within the EHR system. There are several new data elements that require mapping and validation. As your team is likely aware, Perinatal Care measure timestamps for various data elements can be complicated to capture accurately.</td>
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<td>12/18/21</td>
<td>April M. Taylor, MS, MHA, CPPS, CPHQ, Vice President, Quality, The Johns Hopkins Hospital; Recommendations from the Gynecology and Obstetrics leadership team</td>
<td>Medical Specialties</td>
<td>Severe Obstetric Complications eCQM</td>
<td>Dear Measure Developers, Thank you for your ongoing efforts to develop meaningful metrics to advance healthcare quality through measurement. This is a goal we also share here at the Johns Hopkins Hospital! Below please find a few recommendations that our Gynecology and Obstetrics leadership team have developed in response to the request for comment on the proposed Severe Obstetric Complication eCQM. We appreciate your review and response. Recommendation #1- Pilot the program for six months before publicly reporting outcome data. Rationale - Piloting the program for six months would allow for additional testing of the risk adjustment score methodology with a more diverse set of hospitals and allow reporting hospitals the opportunity to identify potential process improvements. This is especially helpful as the process has currently been tested only at community hospital sites and not large academic centers with different referral patterns and/or acuity levels.</td>
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| 12/18/21            | Continued from the previous page                | Continued from the previous page | Continued from the previous page | Recommendation #2- Expand the pre-existing conditions list to include both surgical and medical complexities. Surgical complexities like dense Adhesive Disease, obesity, and prior uterine and non-uterine surgery increase the risk of hemorrhage requiring blood transfusion. These and other surgical complexities should be included in the pre-existing conditions list. Medical complications specific to respiratory failure like COVID-19, Cystic Fibrosis, and other chronic lung disease processes should also be added to the pre-existing conditions list. These patients are at increased risk of intubation and mechanical ventilation in pregnancy. Further, we recommended to add additional specificity and update the existing language from placenta accrete spectrum to placenta accrete, placenta increta, and placenta percreta using their respective ICD-10 codes.  
Rationale - The beta testing sites for the eCQM were all community hospitals. In higher- acuity academic medical centers, the list of pre-existing conditions may be much larger.  
Recommendation #3- Clearly identify how the list of Present on Admission indicators will be determined for patients transferred in for a higher level of care.  
Rationale - The goal of risk adjustment is to account for patient-level factors that are clinically relevant, have strong relationships with the outcome, and are outside of the control of the reporting entity without obscuring important quality differences. As such, it is important to ensure that appropriate adjustment is applied for hospitals that have a large number of patients transferred in for specialized care.  
Recommendation #4- Stratify hospitals into levels |
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| 12/18/21            | Continued from the previous page                 | Continued from the previous page | Continued from the previous page | by hospital type or patient complexity for comparison and reporting.  
**Rationale**: Stratification would better enable the identification of opportunities for improvement by hospitals with analogous populations while also promoting collaboration and sharing of best practices.

**Recommendation #5**: For any future public reporting, include a hospital and/or Gynecology and Obstetrics service profile (e.g. services offered, patient volume, etc...) for each participating hospital.

**Rationale**: Publicly reported metrics may be misinterpreted by the end user without additional information on the site of care. We’d like to see additional information provided to lay public to help them better understand the differences in hospitals across the nation and relationship to reported measures.