

## National Consensus Development and Strategic Planning for Health Care Quality Measurement

# Spring 2025 Cycle Endorsement and Maintenance (E&M) Comment Summary Guide (Advisory Group Feedback)


## Initial Recognition and Management

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## Overview of Spring 2025 Measures for Review

During this measure review cycle, developers and stewards submitted one measure to the Initial Recognition and Management committee for endorsement consideration ([Table 1](#)).

**Table 1. Overview of Measure Under Endorsement Review**

CBE Number	Measure Title	New/Maintenance	Developer/Steward
<a href="#">4715</a>	CVD Risk Assessment Measure- Proportion of Pregnant/postpartum patients who receive CVD Risk Assessment with a standardized tool	New	University of California (UC), Irvine

### Advisory Group Feedback

The Advisory Group convened on [June 5, 2025](#). Twenty of 27 (74%) active Advisory Group members attended to share feedback and ask questions regarding the measure under endorsement review. The developer/steward of the respective measure also attended and provided responses to the Advisory Group questions. After the meeting, the developer/steward had the opportunity to submit additional written responses to Advisory Group member feedback and questions. The measure evaluation summaries of this comment summary guide contain overviews of the Advisory Group member discussions and developer/steward responses.

To support the review of the public comments and Advisory Group summaries, the number of comments received or number of individuals who shared similar comments, feedback, and/or questions is represented as “a few” (two to three individuals), “several” (four to six individuals), and “many” (more than six individuals).

## Measure Under Endorsement Review

### **CBE 4715 – CVD Risk Assessment Measure- Proportion of Pregnant/postpartum patients who receive CVD Risk Assessment with a standardized tool**

#### Advisory Group Feedback

Feedback/Questions	Summary of Developer Response
<p><b>Supportive Comments:</b> Several committee members, including patient partners, expressed the importance of this measure, especially as it pertains to making patients aware of their risk for cardiovascular disease (CVD) and addressing maternal morbidity and mortality. A patient shared their personal experience with friends who had unexpected cardiac issues after giving birth.</p>	<p>N/A.</p>
<p><b>Patient Burden and Clinician Training:</b> A committee member inquired about the financial, emotional, and psychological burden that might be placed on the patient due to the assessment. They also asked how the measure might affect the interaction between the patient and physician if the patient is not expecting to be evaluated for CVD risk. They noted that this might add to the patient’s emotional burden and asked whether physicians received guidance on managing these conversations.</p>	<p>Clinicians receive thorough training to effectively communicate CVD risks during pregnancy and postpartum to help patients make informed decisions. Findings from a <a href="#">recent study</a> showed that participants had a low awareness of pregnancy-related heart disease risk. They expressed surprise and concern upon learning about their elevated risk and while they appreciated frequent monitoring, they wanted more education. As a result, while some patients improved their lifestyle habits immediately, others waited for clinician guidance. The study underscores that strengthening CVD risk assessment in clinical care is essential and highlights the need for the proposed measure, which calls for universal screening and quality improvement initiatives to enhance care. Patient burden is minimal, as the CVD risk assessment is part of standard care. For those at risk, clinicians are prompted to order follow-up tests (B-type natriuretic peptide [BNP], electrocardiogram [EKG], echocardiogram) and possibly refer to maternal-fetal medicine (MFM) or cardiology specialists. Insurance generally covers these tests, although echocardiograms may require pre-authorization.‡</p>
<p><b>Feasibility and Implementation:</b> Several committee members discussed the feasibility of implementing the tool. One member inquired about whether the tool was embedded in an electronic health record (EHR) system. Another member provided a summary of the</p>	<p>If the tool is integrated into an EHR, some information will be pre-populated for providers to minimize additional questions (e.g., vital signs, demographics, comorbidities) and the tool calculates risk in about 30 seconds using existing medical record data. A menu of</p>

Feedback/Questions	Summary of Developer Response
<p>major components of the tool, noting that it aligns with clinical practice guidelines. Specifically, they indicated that while screening for cardiovascular disease in pregnant patients is a recommended practice from organizations such as the American College of Gynecology (ACOG), clinical guidelines do not specify a particular tool. The California Maternal Quality Care Collaborative (CQMCC) has developed a more structured and comprehensive approach, which includes symptom assessment, vital signs, risk factors, and exam findings, all integrated into a standardized scoring system. This tool guides further diagnostic testing and specialist referral for patients with elevated scores.</p> <p>A committee member noted that most providers have robust EHR systems with similar screenings already integrated. While implementation may require some adjustments and integration, most of the components of the screening are routine.</p> <p>Another committee member raised concerns about the feasibility and burden of the measure, particularly for safety net hospitals where patients may have only one prenatal visit before delivery. They asked how follow-up is ensured (“closing the loop”) and whether the measure should be limited to patients already in high-risk or MFM clinics.</p> <p>A committee member also asked about the current adoption of the tool and what would be required for broader implementation.</p>	<p>follow-up options is displayed at the end.</p> <p>The paper version takes roughly 45 seconds to complete, and clinicians receive a handout with follow-up guidance. Unpublished results from a clinician survey (n=19) showed 84.2% agreed the tool is valuable; 73.7% said it is not time-consuming, and 78.9% felt it did not disrupt or pose a burden to their workflow.</p> <p>The measure supports flexible implementation, with frequency tailored to patient volume for each setting and determined by the accountable entity. High-volume clinics may assess monthly, while low-volume sites may opt for biannual reporting. A key strength of the measure is its adaptability, allowing use of standardized tools beyond just the CMQCC algorithm. ‡</p> <p>The tool’s adoption is growing, with some sites using modified or self-developed versions—though these have not been tested for reliability and validity. Some facilities have committed to sharing data for reliability analysis. In addition to five health networks, the tool (or a modified version) has been implemented across a multitude of institutions nationwide (e.g., University of Pennsylvania, Sutter Health, and Northwell Health). A University of California (UC)-wide maternal health workgroup is also planning deployment to all UC health systems. ‡</p> <p>The widespread implementation and growing interest in standardized CVD risk assessment highlights the urgent need to address rising maternal mortality and morbidity. The lack of Healthcare Effectiveness Data and Information Set (HEDIS) indicators for pregnant and postpartum populations further highlights the importance of validated tools (like this one), which support systematic performance measurement and improved clinical integration of CVD risk detection. ‡</p>
<p><b>Moving from Process to Outcome:</b> Several committee members said the measure should eventually become an outcome measure to ensure that patients receive appropriate care. Currently, the measure is a process measure that focuses on ensuring patients are screened. They asked if the developer has plans to move from a process measure to an outcome measure.</p>	<p>Initially there were two separate measures—one for risk assessment and one for follow-up—but, based on feedback from the Centers for Medicare &amp; Medicaid Services (CMS) to streamline, these were combined into a single measure focused on risk assessment and referral. Tracking whether referred patients receive follow-up is the logical next step and is under consideration for future measure development.</p>
<p><b>Evidence:</b> A few committee members said the measure lacks</p>	<p>Linking the screening process to long-term cardiovascular outcomes is</p>

Feedback/Questions	Summary of Developer Response
<p>evidence linking the screening process to earlier identification, effective treatment, and improved maternal outcomes, including morbidity and mortality.</p> <p>One committee member highlighted that identifying abnormalities through screening is not sufficient because abnormal test results, especially elevated BNP, are often not clinically significant. They added that the developer presents nothing from the right side of the table (“Outcomes” or “Impacts”).</p>	<p>complex due to many intervening factors, so the measure instead focuses on whether screening leads to abnormal test findings and changes in clinical behavior. Small-sample patient interviews found that awareness of risk often leads to positive behavior changes, such as improved diet and exercise. The measure intent is to empower patients and improve clinician awareness, as well as to close gaps in care caused by delayed or missed diagnoses of cardiovascular disease during pregnancy and postpartum. Earlier identification improves adherence to guidelines and treatment options, particularly for conditions such as peripartum cardiomyopathy, which often emerge postpartum.</p> <p>The process measure is grounded in evidence that the consistent use of a standardized CVD risk assessment tool improves clinical outcomes when implemented with fidelity (i.e., achieving 100% assessment of eligible individuals). Clinician feedback and patient input during testing indicate a connection between CVD risk assessment and changes in both clinical practice and patient behavior. While more research is needed, early data from partners and stakeholders provides a strong foundation for continued evaluation. ±</p>
<p><b>Measure Impact:</b> A committee member noted that although ACOG’s guidelines recommend assessing cardiovascular disease in the antepartum and postpartum periods using the California Improving Health Care Response to Cardiovascular Disease in Pregnancy and Postpartum toolkit algorithm, this is it is not a strength-of-evidence-based or graded recommendation:</p> <p>The committee member also noted that the finding described by the developer regarding the sensitivity of the screener in identifying patients with catastrophic outcomes is isolated and does not demonstrate that use of the tool would—or did—impact health outcomes.</p> <p>In clinical practice, screening is often found to be ineffective due to factors such as poor performance characteristics of the tool (e.g., low predictive value), limited ability of providers to interpret or act on results effectively, and a lack of interventions that are more beneficial during the screening interval than after diagnosis via conventional means. For example, the effectiveness of prostate cancer screening remains debated, and pancreatic cancer screening is generally</p>	<p>The CVD risk assessment tool serves as a diagnostic screening instrument for CVD and as a mechanism to identify potential CVD-related complications during pregnancy, which may mimic typical pregnancy symptoms and increase the risk of delays and misdiagnosis. Therefore, the occurrence of a “false positive” result (where an abnormal follow-up test does not confirm disease presence) retains clinical significance as clinicians should continue to monitor the patient closely, maintain a high index of suspicion, and have a low threshold of initiating cardiac workup if these patients present with signs or symptoms suggestive of CVD during pregnancy or after delivery.</p> <p>The role of the CVD risk assessment tool during the perinatal and postpartum periods differs fundamentally from tools such as prostate-specific antigen (PSA) screening for prostate cancer or mammography for breast cancer detection. Currently, the identification of CVD risk largely depends on the clinicians’ expertise and their subjective judgment, highlighting the pressing need for a standardized risk assessment protocol applicable across all health care settings for</p>

Feedback/Questions	Summary of Developer Response
<p>considered ineffective.</p>	<p>pregnant and postpartum patients. Several research initiatives are focused on developing alternative methodologies for assessing CVD risk in this population. The hope is that, in the future, clinicians will have access to a variety of CVD risk assessment tools, akin to the range of instruments available for measuring postpartum depression.</p>
<p><b>Measure Rationale:</b> A committee member noted the measure’s relevance to high-risk groups, particularly rural, obese, and older pregnant women. They suggested that the rationale for the measure could be strengthened by including data on demographic trends, such as the increasing age of mothers, higher rates of obesity, and a significant rise in comorbidities—including mental health issues—among pregnant women.</p>	<p>The measure is important for high-risk populations, especially in rural settings where balancing appropriate follow-up with minimizing patient burden is critical. Tennessee rural hospitals using the standardized tool reported a notable outcome: no on-site deliveries of patients with cardiac conditions. At the St. Thomas Level I hospital, which sees 100-150 pregnant and postpartum patients monthly, six patients were identified as at risk and referred to a Level IV facility for advanced care. This reflects the tool’s intended impact—ensuring high-risk patients receive specialized care—while improving safety, avoiding last-minute referrals, and not adding strain to staff. The tool also raised clinician awareness of conditions such as postpartum preeclampsia.</p>
<p><b>Logic Model:</b> A committee member recommended that the logic model better connect activities and outputs to the measure’s goals, and that outputs such as clinician training and abnormal ECG findings should be explicitly included as part of the measure’s objectives.</p>	<p>The expectation is that increased clinician and patient awareness, informed risk profiles, and promotion of lifestyle changes will reduce CVD-related complications during pregnancy and childbirth. The logic model highlights how standardized risk assessment improves identification of patients needing follow-up, avoids unnecessary procedures, and supports efficient resource use. As a result, clinicians can more proactively monitor pregnant and postpartum patients at elevated CVD risk, potentially decreasing CVD-related complications during pregnancy and childbirth. The measure also emphasizes understanding individual risk profiles and promoting lifestyle changes to prevent future cardiovascular conditions. Despite possible confounding factors, the research demonstrates a strong link between comprehensive CVD risk assessment and the detection of previously unrecognized CVD cases. A manuscript detailing these findings is currently under peer review.<sup>‡</sup></p>
<p><b>Clinician Type:</b> One committee member discussed the need to identify the specific clinician responsible for conducting the risk assessment. They noted that physicians, for example, are more likely than doulas to address complex cardiovascular issues. The different</p>	<p>Training on how to use the tool is currently being done across different types of providers with a plan to conduct reliability analyses to assess provider differences.</p>

Feedback/Questions	Summary of Developer Response
<p>ways different types of clinicians might approach the risk assessment might lead to different responses to questions which poses reliability concerns.</p>	
<p><b>Prenatal and Postpartum Populations:</b> Several committee members discussed concerns with the timing of the assessment and the appropriateness of capturing prenatal and postpartum populations in the same measure.</p> <p>A committee member recommended stratifying the prenatal and postpartum populations or splitting the two populations a priori and addressing them separately. They highlighted that the earlier CVD risk is detected, the more likely an intervention will help. Another committee member recommended also stratifying the measure by age, race, parity, income, and urbanicity to improve recordkeeping and overall utility.</p> <p>Another committee member noted that combining both populations complicates the measure’s operationalization. The specifications allow for flexible timing (monthly or quarterly), which is unusual for quality measures, and this variability makes it unclear whether screening occurred earlier or later in the care cycle. The denominator is based on the number of visits for pregnant and postpartum patients, and the numerator is based on a subset of these patients who have the tool applied. Therefore, the specification does not clearly indicate whether the screening occurred during a previous or future month or reporting period. They recommended focusing the measure on the first prenatal and the postpartum visits, with clear specifications tied to those specific encounters.</p>	<p>Internal analysis considering both populations found that most patients are tested in the prenatal period. However, most deaths occur in the postpartum period, so the postpartum assessment is valuable in addressing the goal of reducing maternal morbidity and mortality. Screening in the postpartum period also increased nursing staff’s awareness of risk. However, postpartum screening could eventually be part of a separate measure to ensure comprehensive care across the continuum.</p> <p>Current guidelines recommend at least one standardized CVD risk assessment during prenatal or postpartum care.</p> <p>Outpatient prenatal and postpartum patients are identified through an active pregnancy episode, established at the first prenatal visit, and kept open for 60-90 days post-delivery. If a patient is determined to be “Not at Risk,” the assessment does not need to be repeated unless the patient reports new symptoms at a later appointment.</p> <p>Risk assessment status is tracked on a rolling basis. For a given period (e.g., 3 months), all pregnant/postpartum patients seen at a clinic are in the denominator; the numerator includes those with a documented risk assessment (At Risk or Not at Risk). For example, if 800 patients are seen in a month and 600 have completed assessments, the clinic’s rate is 75%. Lower-volume clinics may prefer to report quarterly or semi-annually.</p> <p>The measure currently applies to obstetric settings and defines the postpartum period as up to 2 months post-delivery. Further studies will explore extending monitoring into primary and emergency care settings for up to 12-24 months postpartum, with potential updates to the measure based on findings.‡</p>
<p><b>Measure Changes:</b> A committee member noted that this measure was previously submitted but did not receive endorsement. They asked how the measure has changed.</p>	<p><i>The Battelle facilitator clarified that the measure was reviewed during the Spring 2024 cycle. The Recommendation Group wanted to see information on how the measure performed in rural versus urban settings as well as evidence demonstrating the clinical benefit of the measure beyond CVD diagnosis to justify additional follow-up testing burden.</i></p>

Feedback/Questions	Summary of Developer Response
	<p>The measure specification is the same. Since the previous submission, additional data have strengthened the evidence surrounding the impact of the risk assessment. A recent publication now shows that patients identified as at risk through the assessment were more likely to have abnormal test results compared to those evaluated solely by clinical judgment.</p>
<p><b>Use of Retrospective vs Prospective Data:</b> A committee member noted that the recent publication evaluation the risk assessment used retrospective data and asked if prospective cohort data existed to evaluate key outcomes (e.g., unnecessary testing or patient burden).</p>	<p>Although the risk assessment was implemented prospectively, the analysis was retrospective based on a 4-year review of electronic health records (The study is described as retrospective because patients were not consented at the start; instead, researchers requested permission to review existing records). Patients were screened and tracked through follow-up and delivery. The natural comparison group were their partners who did not implement the risk assessment at the same time and thus had patients who did not receive the tool.</p>
<p><b>Exclusions:</b> A few committee members inquired about the use of the measure as it relates to pregnancies that are terminated, with one noting that these patients appear to be excluded. They noted that if the measure is stratified by prenatal and postnatal status, that may result in privacy concerns.</p> <p>Another committee inquired if abortion providers should use the tool.</p>	<p>The intent is not to exclude patients who terminate a pregnancy. Rather, patients who attend a specified clinic or health care facility for other reasons (e.g., management of chronic diseases or sexually transmitted infections) and receive or plan to receive pregnancy care at other sites are excluded. Patients who established prenatal care at the facility should receive risk assessments and be included in the measure regardless of their intention to carry the pregnancy to term. They edited the specification so that it reads, “Patients who have another reason for visiting the clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as an OB provider are excluded.”</p>
<p><b>Codebook Inconsistencies:</b> A committee member noted the codebook logic is not consistent with the measure intent. They said many relevant codes are missing, such as those for type 1 diabetes, as well as numerous heart failure diagnoses. They recommended that the developer revise the codebook based on clinical definitions and standardized coding practices, rather than relying solely on codes present in the dataset used during development.</p>	<p>The measure developers, co-investigators, and technical expert panel (TEP) evaluated International Classification of Diseases 10<sup>th</sup> revision (ICD-10) and CPT codes for inclusion in the codebook. The TEP assessed and validated the relevance of each code.</p> <p>The developer is not opposed to incorporating the codes suggested by the reviewer, even though they fall under O90.3 – Cardiomyopathy during the puerperium, which serves as the primary code for all patients with cardiomyopathy in the pregnancy and postpartum periods. The I codes function as secondary codes, aligning with</p>

Feedback/Questions	Summary of Developer Response
	<p>standard obstetric coding practices.</p> <p>The previous codebook was included in error and an <a href="#">updated codebook</a> is available. This version includes all codes and dates to track obstetrics visits, risk assessments, and follow-ups. Billing—whether global, bundled, or per-visit—depends on insurance and provider. The codebook covers all relevant billing codes for obstetric care.</p>
<p><b>Measure Calculation:</b> A committee member highlighted significant concerns with how the measure is calculated, stating that the measure cannot achieve the intended purpose as specified. They indicated that the central issue lies in the calculation of the measure score.</p> <p>Specifically, the measure instructs users to calculate the numerator before the denominator, which contradicts standard methodology for proportion measures, where the numerator must be a subset of the denominator. This sequencing risks including patients in the numerator who do not meet denominator eligibility within the defined time period (e.g., 1 month or one quarter), thereby distorting the measure results.</p> <p>The member also stated the current grouping of codes are problematic because Group B, described as the “Denominator for Measure 1,” includes all evaluation and management CPT codes. It is not restricted to office visits and includes hospital-based and observation care encounters. Additionally, it is not specific to pregnant or postpartum care. Group A contains delivery-related codes that only apply at the time of delivery and do not appear in prenatal or postpartum visits. Since these groups are not aligned in time or intent, combining them does not reliably capture appropriate episodes of care; Group A codes could occur months apart from relevant Group B visits, leading to inconsistency. The developer seems to intend to identify patients who had a delivery (Group A) and then assess care windows before and after delivery. However, this approach requires longitudinal tracking over the pregnancy episode, which is not possible with the current use of monthly or quarterly data snapshots. Without a fixed reference point like delivery, the measure cannot ensure that those included in the denominator actually received obstetric care.</p>	<p>A description of how to calculate the proposed measure did contain an error and the developer provided steps for calculating the measure (see details in <a href="#">Appendix A</a>).</p>

±The developer’s full written response can be found in [Appendix A](#).

## Appendix A

### **CBE #4715 – CVD Risk Assessment Measure- Proportion of Pregnant/postpartum patients who receive CVD Risk Assessment with a standardized tool – Full Responses Written by Developer**

Feedback/Questions	Full Developer Response
<p><b>Timing Related to Calculating the Proposed Measure</b></p>	<p>Currently, it is recommended that a standardized CVD risk assessment should be performed at least once for prenatal or postpartum patients.</p> <p>A patient’s risk assessment status is accounted for in the measure calculation on a rolling basis. For a specific timeframe (e.g., 3-month period), all pregnant/postpartum patients who presented for a prenatal and/or postpartum care visit at a specified clinic or healthcare facility are counted in the denominator. The numerator includes all pregnant/postpartum patients who presented for a prenatal and/or postpartum care visit at a specified clinic or healthcare facility during the specified time period and have a completed risk assessment documented in their health record (i.e., At Risk or Not at Risk).</p> <p>For instance, a high-volume obstetric clinic may see 800 pregnant and postpartum patients in a given month, and 600 patients have a completed risk assessment documented in their medical record. The clinic’s performance for that month equates to 75%. Clinic sites with a low volume of pregnant/postpartum patients may prefer to calculate the measure on a quarterly or semi-annual basis.</p>
<p><b>Timing Related to Conducting the CVD Risk Assessment</b></p>	<p>Our recommendation for the timing of the CVD risk assessment tool is to administer it at the first visit a patient presents for prenatal or postpartum care at that site, usually in the first trimester of pregnancy. For transfers or patients entering prenatal care this may be in the second or even third trimester. Once the CVD risk assessment is documented in the medical chart, it is not expected to be repeated unless there are any new symptoms that develop during the pregnancy or postpartum period.</p>
<p><b>Clinician Burden</b></p>	<p>Implementation Burden – The EHR embedded CVD risk assessment automatically calculates a patient’s risk by automatically populated elements already documented in the patient’s medical record. The</p>

Feedback/Questions	Full Developer Response
	<p>EHR embedded CVD risk assessment algorithm takes clinicians approximately 30 seconds to administer. A paper version of the CVD risk assessment can also be used and takes clinicians approximately 45 seconds to manually calculate a patient’s risk.</p> <p>Unpublished results from a clinician survey completed by 19 faculty/attending physicians, fellows, residents, and nurses from two hospital networks showed that 84.2% of clinicians either strongly agree or agree that the CVD risk assessment tool is valuable for evaluating pregnant and postpartum patients. Importantly, 73.7%, disagreed or strongly disagreed with the notion that the tool is time-consuming, and 78.9% strongly agreed or agreed that the CVD algorithm poses no burden to their workflow (unpublished data).</p>
<p><b>Patient Burden</b></p>	<p>Financial Burden – There is minimal patient burden related to the proposed measure as the CVD risk assessment is administered as a part of standard care. For patients determined to be ‘At risk’ clinicians are prompted to order follow-up tests and potentially additional consultation with maternal-fetal medicine (MFM) or cardiology specialists. Follow-up tests – BNP (B-type natriuretic peptide), EKG (electrocardiogram), and echocardiography – are usually covered by the health insurance as part of prenatal care, although echocardiograms sometimes require pre-authorization.</p> <p>Emotional Burden – Clinicians receive comprehensive training on effectively communicating the potential risks associated with unknown CVD or the likelihood of developing CVD during pregnancy and postpartum. This training ensures that healthcare professionals can engage with patients meaningfully, fostering awareness and empowering them to make informed health decisions. Our recent study published in the Journal of Patient Experience revealed a lack of awareness among participants regarding the increased risk of heart disease during pregnancy. General reactions were surprise and concern upon discovering their elevated risk. While respondents valued frequent monitoring by their healthcare providers, they were eager for more comprehensive information and education about their condition. Some individuals took immediate action to improve their diet, physical activity, and self-care, whereas others awaited guidance from their clinicians. Strengthening the integration efforts of CVD risk assessment into clinical interactions is crucial, particularly in</p>

Feedback/Questions	Full Developer Response
	<p>enhancing resources dedicated to heart health during pregnancy and postpartum. This underscores the urgent need for our proposed measure which calls for universal CVD risk assessment to be accompanied by robust quality improvement initiatives within the healthcare setting. By doing so, we seek to elevate the overall quality of care provided.</p>
<p><b>Evidence of Widespread Adoption of a Standardized CVD Risk Assessment Tool</b></p>	<p>In addition to the five health networks represented by our co-investigators—University of California, Irvine; University of California, San Diego; Saint Luke’s Health System in Kansas City, Missouri; University of Tennessee; and Montefiore Medical Center in the Bronx, New York—the CMQCC CVD Risk Assessment algorithm, and modified versions, has been implemented across a multitude of institutions nationwide. Some of these include University of Pennsylvania Health System, University of Pittsburgh Medical Center, Northside Hospital in Georgia, Northeast Georgia Health System, Sutter Health in Sacramento, Martin Luther King Jr. Community Hospital, and Northwell Health in New York. Moreover, the University of California Office of the President has convened a UC-wide maternal health workgroup, which is preparing to deploy the CVD risk assessment tool throughout all UC health systems in California.</p> <p>The widespread implementation and growing interest in standardized CVD risk assessment highlights the urgent need for innovative tools and strategies to combat the alarming rates of maternal mortality and morbidity in the United States.</p> <p>It is also essential to emphasize the absence of HEDIS (Healthcare Effectiveness Data and Information Set) indicators specifically designed for pregnant and postpartum populations, which would require the integration of CVD detection and risk assessment protocols utilizing validated assessment tools. The CVD risk assessment measure provides a systematic approach for assessing clinic- and facility-level performance regarding the integration of CVD risk assessments into obstetric clinical practice, thereby improving detection and management of CVD in this population.</p>
<p><b>Outcomes Related to the Proposed Process Measure</b></p>	<p>Rural hospitals in Tennessee that have adopted the standardized CVD risk assessment tool have reported a significant achievement: they have not delivered any patients with cardiac conditions on-site. At the St. Thomas Level I hospital, they see 100-150 pregnant and</p>

Feedback/Questions	Full Developer Response
	<p>postpartum patients per month. Since implementation, six pregnant and postpartum patients were determined to be at risk for CVD and subsequently referred for higher-level care for delivery and postpartum care at the St. Thomas Level IV hospital. This outcome exemplifies the intended impact of the tool, as pregnant patients with cardiac disease should ideally be directed to facilities equipped to provide advanced levels of care and specialized treatments. Such referrals ensure that these patients receive the comprehensive medical attention they need in environments that are better suited to manage complex cardiovascular issues. Additionally, this enhancement in patient safety was achieved without adding any additional strain on the staff, while simultaneously elevating clinicians' awareness of postpartum preeclampsia. Prior to the implementation of the tool, patients often were not referred or referred at the last minute, resulting in disruptions of care and creating a need for emergent transport that could have been avoided.</p> <p>We appreciate Advisory Group Members questions related to outcomes as demonstrated in the Logic Model. We anticipate that increased awareness of CVD during pregnancy among both clinician and patients, understanding each patient's risk profile, coupled with healthy promotion of lifestyle modifications for prevention of cardiovascular conditions in the future, will lead to a decline in CVD-related complications during pregnancy and childbirth. These are important components represented in the measure Logic Model. Concerning identification of previous CVD cases, the manuscript describing the positive predictive value of the tool is still under review (see also response to comment 2).</p>
<p><b>Exclusion of Patients Who Decided to Terminate Their Pregnancy</b></p>	<p>Patients who attend a specified clinic or healthcare facility for other reasons (e.g., management of chronic diseases or sexually transmitted infections) and receive or plan to receive pregnancy care at other sites are excluded. Patients who established prenatal care at the facility should receive risk assessments and be included in the measure regardless of their intention to carry the pregnancy to term. We edited the specification so that it reads,</p> <p>“Patients who have another reason for visiting the clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as an OB provider are excluded.”</p>

Feedback/Questions	Full Developer Response
<p><b>Defining the Postpartum Period</b></p>	<p>The proposed measure is limited to the obstetric care setting and defines the postpartum period until the pregnancy episode is closed, typically 2 months after delivery. We will conduct further feasibility studies in primary care and emergency care settings to monitor CVD risk for longer postpartum periods (up to 12 or 24 months after delivery). We plan to amend the measure once we have completed these assessments.</p>
<p><b>Evidence Base:</b> The evidence base is insufficient to support a process measure when there is no demonstrated linkage with any patient-centered outcome.</p>	<p>The proposed process measure is predicated on evidence indicating that the implementation of a standardized tool for evaluating cardiovascular disease (CVD) risk among pregnant and postpartum individuals, when executed with fidelity (i.e., achieving 100% assessment of eligible individuals), will enhance the likelihood of multiple patient outcomes, as outlined in the measure Logic Model.</p> <p>As described in our submission, clinician feedback and patient interviews that were conducted as part of the testing and implementation of the tool suggest that there is a link between CVD risk assessment and clinician CVD awareness and lifestyle and clinical practice change. While additional studies will shed more insights on the impact of complementary health literacy intervention and factors impacting patient decisions on lifestyle changes, we believe that the data from our partners and patient stakeholders and clinician build a strong foundation to gather additional evidence on this topic.</p>
<p><b>Logic Model:</b> "...standardized CVD risk assessment yielded more abnormal composite test results than clinician judgment alone (6.9% vs. 4.2%; <math>p &lt; 0.0001</math>). Patients assessed for CVD had 1.69 times the odds of having an abnormal test than those tested based on clinician judgment alone (<math>p &lt; 0.0001</math>)..." This is simply an intermediate step in the logic model – the middle column (“Outputs”) in the logic model table – but the developers present nothing from the right side of the table (“Outcomes” or “Impacts”). Abnormal test results are often not clinically significant, especially elevated BNP in the postpartum setting and minor ECG abnormalities.</p>	<p>The findings outlined here are a foundational aspect of the Logic Model, specifically regarding CVD risk assessment, leading to enhanced identification of patients who require follow-up testing for CVD, effectively reducing unnecessary procedures that may impose additional burden on patients and directly influencing resource utilization and allocation. Consequently, clinicians are poised to adopt proactive monitoring strategies for pregnant and postpartum patients exhibiting elevated CVD risk, which we anticipate will lead to a decline in CVD-related complications during pregnancy and childbirth. Understanding each patient’s risk profile, coupled with healthy promotion of lifestyle modifications for prevention of cardiovascular conditions in the future, are important components represented in the measure Logic Model. Notwithstanding the presence of potential confounding factors, our research establishes a compelling link between comprehensive CVD risk assessment and the identification of</p>

Feedback/Questions	Full Developer Response
<p><b>Clinical Practice Guidelines:</b> Although the ACOG guidelines say: “Maternal mortality reviews indicate that most women who die from cardiovascular disease had either undiagnosed cardiovascular disease or new-onset cardiovascular disease of pregnancy, specifically peripartum cardiomyopathy. Therefore, all women should be assessed for cardiovascular disease in the antepartum and postpartum periods using the California Improving Health Care Response to Cardiovascular Disease in Pregnancy and Postpartum toolkit algorithm (Fig. 1). Use of this algorithm could have identified individuals as high risk requiring further cardiac evaluation and referral in 88% of maternal deaths (50).” This is NOT a strength-of-evidence-based or graded recommendation. They “applied the algorithm to 64 CVD deaths from 2002-2006 CA-PAMR, 56 out of 64 (88%) cases of maternal mortality would have been identified... Detection increased to 93% when comparison was restricted to 60 cases that were symptomatic.” (Source: <a href="https://www.cmqcc.org/files/CVDToolkitTeachingSlidesetFinal.ADACompliant6.2018_4.pptx">https://www.cmqcc.org/files/CVDToolkitTeachingSlidesetFinal.ADACompliant6.2018_4.pptx</a>)</p> <p>But this isolated finding on the sensitivity of the screener in identifying patients with a catastrophic outcome does not indicate that use of the tool WOULD or DID have any impact on health outcomes. In clinical practice, we often find that screening is ineffective due to the performance characteristics of the screener (e.g., low predictive value, in this case), inability of healthcare provider to effectively utilize the screener results, lack of clinical interventions that are more effective during the screening interval than after diagnosis through conventional pathways, etc. Screening for prostate cancer has arguable effectiveness, for example, and screening for pancreatic cancer is generally regarded as ineffective.</p>	<p>previously unknown or undiagnosed cases of CVD. This manuscript is currently undergoing peer review.</p> <p>We would like to emphasize that the CVD risk assessment tool serves not only as a diagnostic screening instrument for CVD but also as a mechanism to identify potential CVD-related complications during pregnancy, which may mimic typical pregnancy symptoms and increase the risk of delays and misdiagnosis. Therefore, the occurrence of a “false positive” result (where an abnormal follow-up test does not confirm disease presence) retains clinical significance as clinicians should continue to monitor the patient closely, maintain a high index of suspicion, and have a low threshold of initiating cardiac work up if these patients present with signs or symptoms suggestive of CVD during pregnancy or after delivery. The role of the CVD risk assessment tool during the perinatal and postpartum periods differs fundamentally from tools such as PSA screening for prostate cancer or mammography for breast cancer detection. Currently, the identification of CVD risk largely depends on the clinicians' expertise and their subjective judgment, highlighting the pressing need for a standardized risk assessment protocol applicable across all healthcare settings for pregnant and postpartum patients.</p> <p>We are aware of several research initiatives focused on developing alternative methodologies for assessing CVD risk in this population. Our hope is that, in the future, clinicians will have access to a variety of CVD risk assessment tools, akin to the range of instruments available for measuring postpartum depression.</p>
<p><b>Measure Calculation:</b> First, when ratio/proportion measure scores are calculated, the denominator is always calculated first because the numerator must be a subset of the denominator.</p> <p>If the numerator is calculated first, as suggested in 1.18, then the numerator could include patients who were not in the denominator</p>	<p>Thank you for identifying this error in our description of how to calculate the proposed measure. We corrected section 1.18 and clarified the appropriate steps for calculating the proposed measure as follows:</p> <ol style="list-style-type: none"> <li>1. Compile all patients with an active/open pregnancy episode and receive obstetrical care at a designated clinic or health</li> </ol>

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<p>based on a specific time period (e.g., one month or one quarter).</p>	<p>care facility</p> <ol style="list-style-type: none"> <li>2. Specify the time frame: month, quarter, or year</li> <li>3. The denominator is the total number of pregnant and postpartum individuals who attended an obstetric care visit at a designated clinic or health care facility during the specified time frame.</li> <li>4. Calculate the numerator by identifying the number of pregnant and postpartum individuals with a completed CVD risk assessment using a standardized tool among the total number of pregnant and postpartum individuals who attended an obstetric care visit at a designated clinic or health care facility during the specified time frame.</li> <li>5. Divide the numerator value by the denominator value</li> <li>6. Multiply the result by 100 to determine the percentage of pregnant or postpartum patients at a clinic or health care facility who were assessed for CVD risk with a standardized tool.</li> </ol> <p>CVD Risk Assessment Quality Measure = (Pregnant + Postpartum patients who had a CVD risk assessment)/ (All Pregnant + Postpartum patients seen at a facility without prior history of known cardiac disease)</p> <p>The aim is to perform a CVD risk assessment using a standardized tool on all (100%) eligible pregnant/postpartum patients.</p>
<p><b>Codebook Logic:</b> Second, the codebook logic is not consistent with 1.18. Group B is described as the “Denominator for Measure 1,” but it is simply a list of all CPT codes for evaluation and management (E&amp;M) visits. It is NOT limited to “office visits,” as it also includes hospital and observation care visits. It is NOT limited to pregnant and postpartum care. I presume that the developers intend to combine Group A with Group B to require a delivery-related diagnosis or procedure specified in Group A PLUS an E&amp;M visit code in Group B. But the Group A codes only apply to the delivery episode, so if a visit occurs in the 4th month of pregnancy (for example) there is no Group A code. No postpartum visit will have a Group A code. The Group A code may appear many months before or after the Group B code(s).</p>	<p>Thank you for bringing to our attention the Code Book included in our submission. This Code Book was attached in error. We apologize for any resulting confusion and have included the correct Code Book to accompany our response to Advisory Group comments.</p> <p>The correct Code Book contains all codes and associated dates to accurately see the timeline by which a patient attends an OB visit, is risk assessed, and potentially attends any scheduled follow-up visits. Global, bundled, and per-visit billing codes depend on a patient’s insurance coverage and who is providing obstetric services. The global obstetrical package includes all services (antepartum care, delivery, and postpartum care) provided within routine maternity care. Obstetrical care may also be billed per visit during the recipient’s entire</p>

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<p>I presume what the developers intend is to find everyone who had a Group A delivery code, and then to look backward for 9 months previously to see if there were any antepartum CV risk assessments during Group B E&amp;M visits.</p> <p>The same procedure could be applied to look forward for 42 days (although the interval is not currently specified) after the Group A delivery code to see if there were any postpartum CV risk assessments during Group B E&amp;M visits. Neither of these procedures could be accomplished with only one month or one quarter of data. If you have only one month of data, you won't be able to identify previous or subsequent Group A deliveries, and hence you won't even know whether the patient was receiving obstetric care (based on the Code Book provided).</p> <p>In other words, the current specification of the measure is illogical. Given that there is no requirement to do CV risk assessment at every visit, the measure needs to be specified at a patient level, using the Group A delivery event as the index event to confirm that the patient actually had a delivery. Then an appropriate ascertainment period before the index event can be defined (e.g., 9 months), and each patient can be classified as having had a CV risk assessment or not during their ascertainment period. In this way, the numerator is a subset of the denominator, and each eligible patient who delivers during a given quarter or year can be assigned as numerator-yes or numerator-no.</p>	<p>pregnancy with each visit or procedure billed separately. This Code Book includes all relevant billing codes.</p> <p>For outpatient prenatal and postpartum visits, patients may be identified through an active/open pregnancy episode, which is established in the patient's medical record during their first prenatal visit at a designated clinic or health care facility. This episode remains open for a duration of 60-90 days post-delivery, facilitating comprehensive identification of all pregnant and postpartum patients.</p> <p>Patients who have undergone a comprehensive CVD risk assessment using a standardized tool, subsequently have their risk score, "At Risk" or "Not at Risk," documented in their medical record. Importantly, if a patient is determined to be "Not at Risk," the assessment does not need to be repeated unless the patient reports new symptoms at a later appointment. It is crucial to conduct a CVD risk assessment at least once during pregnancy or the postpartum period. The implementation of the proposed quality measure at the clinic and healthcare facility levels is intended for more frequent monitoring, tailored to the specific patient volume of each setting and determined at the discretion of the Accountable Entity. For high volume obstetric clinics, the proposed measure may be useful to calculate monthly whereas a family medicine clinic with a low volume and pregnant and postpartum patients may choose to calculate the measure bi-annually. A strength of the proposed measure is its flexible timing for calculating the measure as well as the workable use of a standardized tool, not limited to only the CMQCC algorithm but future iterations and enhanced instruments for assessing CVD risk among pregnant and postpartum individuals.</p>
<p><b>Code List Errors:</b> Finally, the code lists have very severe errors and limitations, which I fully describe in comments attached (to share with the developers). The developers need to start from the code book to identify the relevant codes rather than from whatever data they happened to use. To cite the most obvious example, many codes for diabetes and heart failure are omitted, including all codes for type 1 and MODY diabetes.</p>	<p>ICD-10 and CPT codes were meticulously evaluated for inclusion in the Code Book by measure developers, co-investigators, and our Technical Expert Panel (TEP) prior to any data abstraction. Throughout several meetings, the panel assessed and validated the relevance of each code. We are not opposed to incorporating the codes suggested by the reviewer, despite the fact that they fall under O90.3 – Cardiomyopathy during the puerperium, which serves as the primary code for all patients with cardiomyopathy in the pregnancy and postpartum periods. The I codes function as secondary codes, aligning with standard obstetric coding practices.</p>

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	Again, we apologize for any resulting confusion caused due to the incorrect Code Book attached to our submission.

