

# MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through National Quality Forum's (NQF) Consensus Development Process (CDP). The information submitted by the measure developers/stewards is included after the *Brief Measure Information* and *Preliminary Analysis* sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

# **Brief Measure Information**

NQF #: 3716

# **Corresponding Measures:**

**Measure Title:** CVD Risk Assessment Measure- Proportion of Pregnant/Postpartum Patients That Receive CVD Risk Assessment with a Standardized Tool

Measure Steward: University of California, Irvine

**sp.02. Brief Description of Measure:** The University of California, Irvine (UCI) implemented and tested a CVD risk assessment algorithm that can be integrated into the electronic health record (EHR) system that immediately identifies patients who are at increased risk for CVD.

The unit of measurement is individual patients, and the population will include any patient who has a prenatal or postpartum visit in the hospital system. This includes pregnant and postpartum emancipated minors. The denominator in the CVD Risk Assessment Measure is all patients seen for pregnancy or postpartum care at a health care facility or hospital system. A hospital system includes Labor and Delivery (L & D), outpatient care in hospitals or at affiliated clinics, and private providers contracted with hospitals for delivery. The measure excludes patients with a preexisting heart problem, and patients who have another reason for visiting a clinic [not prenatal or postpartum care] and have a positive pregnancy test but plan to terminate the pregnancy or seek prenatal services elsewhere.

This measure determines the percentage of pregnant or postpartum patients at a clinic who were assessed for CVD risk with a standardized tool, such as the CVD risk assessment algorithm developed by the California Maternal Quality Care Collaborative (CMQCC). The aim is to perform a CVD risk assessment using a standardized tool on all (100 %) eligible pregnant/postpartum patients. Every single patient should be assessed for CVD risk at least once during their pregnancy and, if needed, additional times when new symptoms present during the pregnancy and/or postpartum period. A threshold has still to be determined ("at least xxx % of patients who received risk assessment"). The measure can be calculated on a quarterly or annual basis.

# 1b.01. Developer Rationale:

**sp.12. Numerator Statement:** The percentage of all pregnant and postpartum patients who received a CVD risk assessment with a standardized tool.

**sp.14. Denominator Statement:** Pregnant and Postpartum Office visit assess the CVD risk of patients who are pregnant or postpartum (group B "Pregnant and Postpartum Office Visit" in the CPT-ICD 10 Code Book). Any

person who is pregnant or postpartum who attends a pregnant or postpartum clinic visit at any participating site should undergo risk assessment. See the excel attachment "CPT – ICD 10 Code Book" for the full list of CVD confirmation CPT codes.

**sp.16. Denominator Exclusions:** 1) Patients who have another reason for visiting the clinic and 2) Prior history of known cardiac disease

Measure Type: Process

sp.28. Data Source: Electronic Health Records and Paper Medical Records

sp.07. Level of Analysis: Clinician: Group/Practice

IF Endorsement Maintenance – Original Endorsement Date:

**Most Recent Endorsement Date:** 

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?:

# **Preliminary Analysis: New Measure**

# Criteria 1: Importance to Measure and Report

# 1a. Evidence

1a. Evidence. The evidence requirements for a *structure, process, or intermediate outcome* measure are that it is based on a systematic review (SR) and grading of the body of empirical evidence in which the specific focus of the evidence matches what is being measured. For measures derived from a patient report, the evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

# The developer provides the following description for this measure:

- This is a new process measure at the clinician group practice level that measures the percent of patients who were assessed for cardiovascular disease (CVD) risk with a standardized tool.
- The developer provides a <u>logic model</u> that demonstrates the importance of risk assessment for pregnant or postpartum patients. The risk assessment assists providers in distinguishing between signs and symptoms of cardiac disease and those of normal pregnant and postpartum patients who may have cardiovascular disease.
- Follow-up care for those identified at risk leads to increased patient awareness, behavior change and ultimately change in maternal mortality and birth outcomes.

## The developer provides the following evidence for this measure:

SR of the evidence specific to this measure?
Quality, Quantity, and Consistency of evidence provided?
Yes
No

• Evidence graded?

# Summary:

- The California Maternal Quality Care Collaborative (CMQCC) Cardiovascular Disease in Pregnancy and Postpartum Task Force developed the risk assessment algorithm based on risk factors, symptoms, vital sign abnormalities, and physical examination findings commonly identified in patients who die of various types of cardiovascular disease.
- The literature establishes that CVD is the leading cause of maternal mortality in the United States and California. CVD accounts for greater than 33 percent of all pregnancy-related deaths in the US and 25 percent of pregnancy deaths in California.
- The developer cites evidence that the risk assessment was able to accurately identify pregnant or postpartum patients at risk for CVD.
  - The authors assessed the triage algorithm retrospectively on 64 CVD related deaths in CA for 2002-2006. They found that the use of the algorithm would have identified 56 of the 64 cases (88%) of CVD. The proportion of cases increased to 93% when they restricted it to the 60 cases of patients who were symptomatic or had sufficient documentation.
  - A prospective cohort study of obstetrical patients from April 2018 to July 2019 at academic medical centers in CA and NY was conducted with 846 patients. The overall risk assessed positive rate was 8% (5% in CA, 19% in NY). CVD was confirmed in 30% with positive risk assessments with complete follow-up.

# Exception to evidence

• N/A

# **Questions for the Standing Committee:**

- What is the relationship between this measure and patient outcomes?
- How strong is the evidence for this relationship?
- Is the evidence directly applicable to the process of care being measured?
- Does the target population value the measured outcome and find it meaningful?

# **Guidance From the Evidence Algorithm**

Not an outcome measure (Box 1) -> Process measure without a systematic review of evidence (Box 3) -> Empirical evidence presented (Box 7) -> All studies included (Box 8) -> Benefits outweigh undesirable effects (Box 9) -> Moderate. The highest possible rating is moderate.

Preliminary rating for evidence:	🛛 High	🛛 Moderate	🗆 Low	Insufficient
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# 1b. Gap in Care/Opportunity for Improvement and Disparities

**1b. Performance Gap.** The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- CVD risk assessment rates were provided from 23 measured entities with 31,309 patients from 9/1/2021 to 2/28/2022.
- Mean performance was 63.8% and interquartile range (IQR) was 45%.

• The 10th decile performance was 24.9% and the 90th decile performance was 100%.

# Disparities

- The developer provided rates for patients segmented by age, race, ethnicity, insurance status, and timing.
- Differences were shown by age (20-29 [92.2%], 40+ [83.6%], race (Black [95.3%] and White [91.7%]), ethnicity (Non-Hispanic [93.3%], Hispanic [82.0%]), race/ethnicity (Non-Hispanic White [94.7%], Non-Hispanic Black [95.3%], Hispanic [82.0%]), insurance status (private [93.4%] and public [85.8%]), and timing (prenatal [91.0%], postpartum [90.6%]).
- However, the developer reports an overall rate of 90.8%, which is inconsistent with the mean 63.8% reported for the performance gap above.

# **Questions for the Standing Committee:**

• Is there a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement:	🗆 High	🛛 Moderate	🗆 Low	
Insufficient				

# Criteria 2: Scientific Acceptability of Measure Properties

# Complex measure evaluated by the Scientific Methods Panel (SMP)? Yes No

# 2a. Reliability: Specifications and Testing

**2a1. Specifications** require the measure, as specified, to produce consistent (i.e., reliable) and credible (i.e., valid) results about the quality of care when implemented.

2a2. Reliability testing demonstrates whether the measure data elements are repeatable and producing the same results a high proportion of the time when assessed in the same population in the same time period, and/or whether the measure score is precise enough to distinguish differences in performance across providers.

# **Specifications:**

• Large facilities are excluded from the signal to noise analysis for reliability testing, but are not mentioned in the exclusions. The developer states that these facilities were excluded for the purpose of parameter estimation.

# **Reliability Testing:**

- Reliability testing conducted at the Accountable Entity Level:
  - The developer excluded facilities with a large sample size (N>75<sup>th</sup> percentile +1.5\*IQR) from the analysis. The rationale for this exclusion is unclear, as the developer states that these facilities were excluded due to "a relatively large sample size that could have a disproportionate influence." Additionally, three clinics were removed "for the purpose of the parameter estimation."
  - Reliability testing was done using signal to noise ratio. Median reliability was 0.992 with a minimum reliability of 0.839 and a maximum of 1.000.

# Questions for the Standing Committee regarding reliability:

• Do you have any concerns that the measure cannot be consistently implemented (i.e., are the measure specifications adequate)?

# **Guidance From the Reliability Algorithm**

Box 1 -> Box 2 -> Box 4 -> Box 5 -> Box 6 -> Box 6b

Preliminary rating for reliability: 
☐ High 
☐ Moderate 
☐ Low 
☐ Insufficient

2b. Validity: <u>Validity Testing</u>; <u>Exclusions</u>; <u>Risk Adjustment</u>; <u>Meaningful Differences</u>; <u>Comparability</u>; <u>Missing Data</u>

2b2. Validity testing should demonstrate that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

# **2b2-2b6.** Potential threats to validity should be assessed/addressed.

## **Validity Testing**

- Validity testing conducted at the Patient/Encounter Level:
  - The developer conducted a Kappa analysis between automated extracted electronic health record (EHR) data and a manual reviewer (n=2,535 charts) to determine whether those patients had the risk assessment completed and a risk score. The developer found 100% agreement between the EHR data extraction and chart documentation.
  - However, the developer did not provide testing results for all key data elements (e.g., numerator, denominator, exclusions). Nor did the developer provide any sensitivity or specificity statistics, nor any positive predictive values or negative predictive values with some other source of the same information considered to be valid.
- Validity testing conducted at the Accountable Entity Level:
  - They examined the correlation of the risk assessment measure and the percent of confirmed CVD cases for 23 entities. The relationship was positive (0.424) and significant (p=0.0437), as hypothesized.
  - Face validity testing was conducted with a technical expert panel (TEP) of 14 experts with varied backgrounds: Measure Developers, Clinical Content Cardiology, Clinical Content OB/GYN/MFM, Clinical IT, Patient Representatives. The developer reports that the TEP reached consensus with a 10 out of 10 vote that:
    - There should not be any upper or lower age limit,
    - Private providers who contract with the hospital for labor and delivery services can be included in the denominator,
    - How to calculate the measure if the algorithm was administered more than once during a pregnancy episode, and
    - Whether the final performance measure scores can be used to differentiate good from poor quality of care
  - It is difficult to determine if the face validity results of "10 out of 10" was for all the items above together or separately. The list of individuals who were on the TEP is available in the submission's Additional section.

- The following exclusions are applied to the measure:
  - Patients who have another reason for visiting a clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as an OB provider (plan to terminate the pregnancy or seek prenatal services elsewhere).
  - Prior history of known cardiac disease. If CVD confirmation falls on a date prior to CVD algorithm use with a patient who has completed the algorithm, it is considered an exclusion and does not require CVD algorithm evaluation.
  - The developer states that it did not test the exclusions because they are necessary for the measure to be clinically valid. Per NQF's validity criterion, all threats to validity that are relevant should be empirically assessed. This was not done.

# **Risk Adjustment**

• The measure is not risk-adjusted or stratified. The developer argued that because Black race is one of the variables that contributes to the CVD risk score it is not necessary to include it in a risk adjustment model.

# Meaningful Differences

- The rate for CVD risk assessment in the three hospital systems was 54.4%, 71.6%, and 100% (p<0.0001), suggesting a meaningful difference in performance and the need for quality improvement among the hospital networks.
- Rates of CVD risk assessment at 23 clinical sites were 44.2% (25<sup>th</sup> percentile), 67.1% (median), and 89.2% (75<sup>th</sup> percentile). Five clinics were in the first quartile and considered to be low performing and 6 clinics were above the third quartile and considered to be high performing.

# **Missing Data**

- All variables to calculate the measure are retrieved from the EHR. There are no missing variables in the records that would impact the calculation of the score.
- Some providers started but did not sign and close the chart, hence a score was calculated but not officially completed (reviewed and signed by a clinician). These charts were not included in the numerator.

# Comparability

• The measure only uses one set of specifications for this measure.

# Questions for the Standing Committee regarding validity:

• Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk adjustment approach, etc.)?

# **Guidance From the Validity Algorithm**

Box 1 -> Box 2 -> Box 5 -> Box 6 -> Box 7 -> Box 7b

Preliminary rating for validity:  $\Box$  High  $\boxtimes$  Moderate  $\Box$  Low  $\Box$  Insufficient

# Criterion 3. Feasibility

**3. Feasibility** is the extent to which the specifications, including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- The developer notes all data elements are in defined fields in the electronic claims.
- The developer highlighted that IT departments are prioritizing the transition to telehealth services resulting in delays in processing reliance agreements for IRB approval.

# **Questions for the Standing Committee:**

- Are the required data elements routinely generated and used during care delivery?
- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: 

High
Moderate
Low
Insufficient

# Criterion 4: Use and Usability

# 4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.

**4a.1. Accountability and Transparency.** Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If they are not in use at the time of initial endorsement, then a credible plan for implementation within the specified time frames is provided.

# Current uses of the measure

Publicly reported?	🗆 Yes 🛛	No
Current use in an accountability program?	🗆 Yes 🖂	No 🗆 UNCLEAR
Planned use in an accountability program?	🛛 Yes 🛛	No 🗌 NA

# Accountability program details

• The measure was submitted to CMS in April 2022 for the public reporting program for hospital outpatient and inpatient quality reporting programs.

**4a.2. Feedback on the measure by those being measured or others.** Three criteria demonstrate feedback: (1) Those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; (2) Those being measured, and other users have been given an opportunity to provide feedback on the measure performance or implementation; and (3) This feedback has been considered when changes are incorporated into the measure.

# Feedback on the measure provided by those being measured or others

• The developer provided summaries to clinical sites about their performance and reviewed with the clinicians their performance over time and in comparison to other sites.

• The measures were reviewed with the co-investigators at each site and semi-structured interviews were conducted with five clinicians at each site. Overall, clinicians appreciated the ability to monitor their performance and get a benchmark of their peer's performance.

# **Questions for the Standing Committee:**

- How have (or can) the performance results be used to further the goal of high quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: 🛛 Pass 🗌 No Pass

# 4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

**4b. Usability** evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.

**4b.1 Improvement.** Progress toward achieving the goal of high quality, efficient healthcare for individuals or populations is demonstrated.

# Improvement results

• Improvement results are not available because the developer only reports baseline results.

**4b2. Benefits versus harms.** The benefits of the performance measure in facilitating progress toward achieving high quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

# Unexpected findings (positive or negative) during implementation

- Patients and clinicians commented on improved patient awareness of the immediate and lifetime risk of developing CVD.
- The consistent use of the tool has raised awareness of the importance of CVD risk assessment among obstetricians.

# **Potential harms**

None noted.

# Additional Feedback:

• At the time of this preliminary analysis development, MAP recommendations for this measure were not available.

# **Questions for the Standing Committee:**

- How can the performance results be used to further the goal of high quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability: 🛛 High 🛛 Moderate 🖓 Low 🖓 Insufficient

# Criterion 5: Related and Competing Measures

# **Related Measures**

• NQF #0608 Pregnant women that had HBsAg testing

# Harmonization

• The developer states that these measures are harmonized to the extent possible, noting that the measures have the same target population, but their focus is different.

# Criteria 1: Importance to Measure and Report

## 1a. Evidence

## 1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

## [Response Begins]

The following is the logic model of our CVD risk assessment measure that describes the process and outcome of our measure.



## [Response Ends]

# 1a.02. Select the type of source for the systematic review of the body of evidence that supports the performance measure.

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

## [Response Begins]

Other (specify)

[Other (specify) Please Explain]

The CMQCC Cardiovascular Disease in Pregnancy and Postpartum Task Force was charged with developing a toolkit that includes an overview of clinical assessment and management strategies based on risk factors and presenting signs and symptoms. The key components of the Toolkit include an algorithm developed to guide stratification and initial evaluation of symptomatic or high-risk pregnant or postpartum patients.

The goal of the algorithm is to assist providers in distinguishing between signs and symptoms of cardiac disease and those of normal pregnancy and to guide clinicians in the triage of further cardiac evaluation, appropriate referrals, and followup of pregnant and postpartum patients who may have cardiovascular disease. Drawing from the literature and analysis of cardiovascular deaths reviewed in the California Pregnancy Associated Mortality Review (CA-PAMR), the authors created this algorithm based on risk factors, symptoms, vital sign abnormalities, and physical examination findings commonly identified in patients who die of various types of cardiovascular disease.

## [Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.

## Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins] N/A [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins] N/A [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins] N/A [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins] N/A [Response Ends] 1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins] N/A [Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins] N/A [Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins] N/A [Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins] N/A [Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins]

N/A

[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins] N/A [Response Ends]

1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]

**Empirical Evidence** 

## 1a.14. Briefly synthesize the evidence that supports the measure.

# [Response Begins]

Cardiovascular disease (CVD) is the leading cause of maternal mortality in the United States, accounting for over onethird of all pregnancy-related deaths.<sup>1</sup> *Peripartum cardiomyopathy (PPCM) constitutes the largest group among CVDrelated deaths.* **24%** of ALL CVD pregnancy-related deaths (and 31% of cardiomyopathy deaths) were determined to be **potentially preventable.**<sup>2</sup>

CVD also accounts for many folds higher maternal morbidity, a longer length of hospital stays, intensive care unit (ICU) admissions, and future pregnancy risks.<sup>3</sup>

Racial/ethnic disparities in pregnancy-related mortality have also been well established.<sup>4, 5</sup>, African American patients exhibit 3-12 times higher mortality <sup>1, 6, 7</sup> as they are more likely to have pre-existing CVD,<sup>3</sup> hypertensive disorders of pregnancy <sup>3, 5</sup> and peripartum cardiomyopathy (PPCM) <sup>5,8</sup> when compared to patients from other racial /ethnic groups.

Timely diagnosis of CVD is critical; however, this may be challenging due to:

- 1. Pregnancy is a state of hemodynamic stress that may lead to signs and symptoms that are very similar to those of CVD, such as shortness of breath, fatigue, and swelling.<sup>9</sup>
- 2. Healthcare providers generally do not suspect CVD when evaluating pregnant or postpartum patients with symptoms that may signify an underlying diagnosis of CVD.

There is a need to establish a standardized CVD risk assessment tool to triage pregnant and postpartum patients and provide standardized options of appropriate follow-up. This population-wide risk assessment is likely to reduce CVD-related morbidity and mortality, particularly among African American patients. The proposed measure will monitor follow-up to universal cardiovascular risk assessment in all pregnant patients at their first encounter with an obstetrics provider.<sup>10</sup> The tool facilitates clinicians to evaluate pregnant or postpartum patients presenting with symptoms such as shortness of breath, cough, or excessive fatigue in the context of risk factors, vital sign abnormalities, and abnormal physical examination findings.<sup>1</sup> Use of this measure improves the accurate diagnosis of heart failure rather than attributing symptoms of persistent cough and shortness of breath and bilateral infiltrates on chest X-ray to pneumonia or pregnancy-related.

# [Response Ends]

# 1a.15. Detail the process used to identify the evidence.

# [Response Begins]

Cardiovascular disease (CVD) is the leading cause of maternal mortality in the United States and California. CVD accounts for >33% of all pregnancy-related deaths in the US and 25% of pregnancy-related deaths in CA (2002-2006). Data from the California Pregnancy Associated Mortality Review (CA-PAMR)<sup>1</sup> of deaths occurring from 2002-2006 show the following:

- Only a small fraction of these patients had a known diagnosis of cardiovascular disease prior to death.<sup>2</sup>
- Most patients who died had presented with symptoms either during pregnancy or after childbirth.
- A significantly higher proportion of patients sustain short- and long-term morbidity due to undiagnosed or delayed diagnosis of cardiovascular disease, as evidenced by the fact that one of every three intensive care admissions in pregnancy and postpartum period are related to cardiac disease.<sup>3,4</sup>
- 25% of these deaths may have been prevented if heart disease was diagnosed earlier.<sup>2,3,5</sup>

Pregnant and postpartum patients who die from CVD represent the most extreme consequence of missed or delayed recognition of CVD. Accordingly, any triage algorithm should be able to detect the most serious cases and not return a 'false negative' assessment in a patient with underlying CVD. To assess how well the triage algorithm would have identified pregnant and postpartum patients with the most need of further work-up, we compared the 64 cardiovascular disease deaths identified by CA-PAMR for 2002-2006, using the seven critical risks and abnormalities, including heart rate, systolic blood pressure, respiration rate, oxygen saturation, tachypnea, cough and wheezing. We found that the use of the algorithm would have identified 56 out of 64 (88%) cases of CVD.<sup>1</sup> The proportion of patients identified increased to

93% when we restricted comparison to the 60 cases of patients who were symptomatic or had sufficient documentation with which to compare to the algorithm.<sup>1</sup>

To address these issues, CMQCC together with the California Department of Public Health: Maternal, Child and Adolescent Health Division published the *Improving Health Care Response to Cardiovascular Disease in Pregnancy and Postpartum* Toolkit in 2017.<sup>2</sup> The California Maternal Quality Care Collaborative (CMQCC) developed a CVD risk assessment algorithm, that guides stratification and initial clinical evaluation of symptomatic or high-risk pregnant or postpartum patients. The toolkit includes a risk assessment algorithm, which guides stratification and initial evaluation of symptomatic or high-risk pregnant or postpartum patients. The algorithm risk stratifies patients using 18 parameters including patient's history, abnormal symptoms, vital signs, and physical examination findings to identify patients who warrant further cardiac work-up. The CMQCC Cardiovascular disease in pregnancy toolkit also includes resources for providers, infographics for patients on signs and symptoms of CVD, future CVD risk and long-term health issues, contraception options and planning a pregnancy with known CVD. The toolkit also includes a discussion on racial and ethnic disparities in CVD prevention and diagnosis.

The Alliance for Innovation on Maternal Health Cardiac Conditions in Obstetrical Care includes the CMQCC CVD Assessment Algorithm for Pregnant and Postpartum Patients in the Cardiac Conditions in Obstetrical Care Bundle (COCC).<sup>6</sup> In the bundle, cardiac conditions refer to disorders of the cardiovascular system which may impact maternal health. Such disorders may include congenital heart disease or acquired heart disease, including but not limited to cardiac valve disorders, cardiomyopathies, arrhythmias, coronary artery disease, pulmonary hypertension, and aortic dissection despite limitations, recognized as an emerging best practice and an important tool for assessing symptoms and risk in a standardized way.

The American College of Obstetricians and Gynecologists (ACOG) recently endorsed the California (CA) cardiovascular disease (CVD) risk assessment algorithm for pregnant and postpartum patients. The aim is to prospectively determine risk-assessed-positive and true-positive rates of CVD among patients across two populations.

For the initial implementation, a prospective cohort study of obstetrical patients from April 2018 to July 2019 at academic medical centers in CA and New York (NY) was conducted.<sup>7</sup> There were 846 patients who had a risk assessment. There was an attempt to complete a risk assessment for all patients at least once during their pregnancy care (prenatal or postpartum). Patients who had a positive risk assessment ("Red Flags," >3–4 moderate risk factors, abnormal physical examination, and persistent symptoms) underwent further testing. The primary outcome was the risk assessed-positive rate. Secondary outcomes included the true-positive rate and the strength of each moderate factor in predicting a positive CVD risk assessment.

The overall risk assessed-positive rate was 8% (5% in CA vs. 19% in NY). The sites differed in ethnicity, that is, African American patients (2.7% in CA vs. 35% in NY, p < 0.01) and substance use (2.7 vs. 5.6%, p < 0.04). The true-positive rate was 1.5% at both sites. The percentage of risk assessed-positive patients who did not complete follow-up studies was higher in NY (70%) than in CA (27%). CVD was confirmed in 30% with positive risk assessments with complete follow-up.<sup>7</sup> Combinations of moderate factors were the main driver of risk assessment-positive rates in both populations. This is the first data describing the performance of the CVD risk assessment algorithm in the general obstetric population. Factors, such as the proportion of African American patients affect the likelihood of a positive risk assessment. The CVD risk assessment algorithm highlights patients at higher lifetime risk of CVD and may identify a group that could be targeted for more direct care transitions postpartum. Data may be used to design a larger validation study.

[Response Ends]

## 1a.16. Provide the citation(s) for the evidence.

## [Response Begins]

## References for 1a.14):

1. Creanga AA, Syverson C, Seed K, Callaghan WM. Pregnancy-Related Mortality in the United States, 2011–2013. *Obstet Gynecol*. 2017;130(2):366-373. doi:10.1097/AOG.00000000002114.

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- 4. Say L, Pattinson RC, Gülmezoglu AM. WHO systematic review of maternal morbidity and mortality: the prevalence of severe acute maternal morbidity (near miss). *Reprod Health*. 2004;1(1). doi:10.1186/1742-4755-1-3.
- 5. Petersen EE, Davis NL, Goodman D, et al. Racial/Ethnic Disparities in Pregnancy-Related Deaths United States, 2007–2016. *MMWR Morb Mortal Wkly Rep.* 2019; 68:762–765. doi:10.15585/mmwr.mm6835a3.
- 6. Hameed AB, Lawton ES, McCain CL, et al. Pregnancy-related cardiovascular deaths in California: beyond peripartum cardiomyopathy. *Am J Obstet Gynecol*. 2015;213(3):379.e1-379.e10. doi:10.1016/j.ajog.2015.05.008.
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# [Response Ends]

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

# 1b.01. Briefly explain the rationale for this measure.

*Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.* 

# [Response Begins]

The implementation of metrics on the adherence to standards signals to clinicians the endorsement of management and value of the metric as a signal to provide quality care to obstetric patients. The measure is easy to understand and can be calculated for the unit or even individual clinician performance (if the patient is assigned to one clinician) in addition to a systemwide basis. The measure allows for the identification of low-performing sites or clinicians and to address modifiable gaps in diagnostic excellence.

The training for the use of the tool has raised awareness of the importance of CVD risk assessment among obstetricians. The easy use (takes less than 1 minute to complete CVD risk assessment) of the tool allows obstetricians to systematically identify patients who are at risk for CVD and need follow-up on more thorough monitoring during the pregnancy. Additionally, we have anecdotal evidence that administration of the tool and providing patients with a risk score has improved patient awareness of the immediate and lifetime risk of developing CVD, which drives changes in health behavior. We have not seen any evidence that the follow-up of patients who were deemed at high risk for CVD led to inappropriate use of resources.

[Response Ends]

# 1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

## [Response Begins]

### Performance scores on the Measure at the Specified Level of Analysis, September 2020- February 2022

Level of Analysis	Performance Score
Min	0.0%
Max	100.0%
Mean	63.8%
SD	29.3%
Median	67.1%
IQR	45.0%
Score by Decile	*
10th Pctl	24.9%
20th Pctl	42.2%
30th Pctl	46.8%
40th Pctl	55.8%
50th Pctl	67.1%
60th Pctl	74.1%
70th Pctl	88.2%
80th Pctl	89.8%

Level of Analysis	Performance Score
90th Pctl	100.0%

\*Cell intentionally left empty

[Response Ends]

**1b.03.** If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

N/A

[Response Ends]

# 1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

# [Response Begins]

The proportion of pregnant/postpartum patients at three hospital networks who received a CVD risk assessment by demographic variables, the timing of assessment, and three six-month time periods, September 2020 – February 2022

Population Group	Total n	Column %	Completed Risk Assessment <i>n</i>	Row %	Chi square test p- value**
Overall	31309	100.0%	28419	90.8 %	*
Hospital Network	*	*	*	*	<.0001
UCI	2611	8.3%	1421	54.4 %	*
UCSD	5985	19.1%	4285	71.6 %	*
UTENN	22713	72.5%	22713	100. 0%	*
Age group	*	*	*	*	<.0001
<20	1257	4.0%	1208	96.1 %	*

Population Group	Total n	Column %	Completed Risk Assessment n	Row %	Chi square test p- value**
20-29	14042	44.8%	12946	92.2 %	*
30-39	14702	47.0%	13172	89.6 %	*
40+	1308	4.2%	1093	83.6 %	*
Race	*	*	*	*	<.0001
Black	3829	12.2%	3649	95.3 %	*
White	18633	59.5%	17079	91.7 %	*
ΑΑΡΙ	1501	4.8%	1166	77.7 %	*
Others	7346	23.5%	6525	88.8 %	*
Ethnicity	*	*	*	*	<.0001
Hispanic	7180	22.9%	5891	82.0 %	*
Non-Hispanic	23424	74.8%	21849	93.3 %	*
Unknown	705	2.3%	679	93.3 %	*
Race/Ethnicity	*	*	*	*	<.0001
Non-Hispanic White	16256	51.9%	15388	94.7 %	*
Non-Hispanic Black	3769	12.0%	3593	95.3 %	*
Hispanic	7180	22.9%	5891	82.0 %	*
ΑΑΡΙ	1476	4.7%	1148	77.8 %	*
Others/unknown	2628	8.4%	2399	91.3 %	*
Insurance	*	*	*	*	<.0001
Public (Medicaid, Military, government)	9330	29.8%	8005	85.8 %	*

Population Group	Total n	Column %	Completed Risk Assessment	Row %	Chi square test p- value**
Private (Commercial, Managed care)	20332	64.9%	18994	93.4 %	*
Self-pay	323	1.0%	322	99.7 %	*
Unknown	1324	4.2%	1098	82.9 %	*
Timing	*	*	*	*	<.0001
Prenatal	12424	39.7%	11300	91.0 %	*
Postpartum	18885	60.3%	17119	90.6 %	*
Period	*	*	*	*	<.0001
09/01/20 - 02/28/21	6867	21.9%	6055	88.2 %	*
03/01/21-08/31/21	12316	39.3%	11363	92.3 %	*
09/01/21- 02/28/22	12126	38.7%	11001	90.7 %	*

\*\* Chi square test testing different distribution of screening status by social-demographic category

\*Cells intentionally left empty,

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

N/A

[Response Ends]

# 1c. Composite – Quality Construct and Rationale

# Criteria 2: Scientific Acceptability of Measure Properties

## sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see <u>What Good Looks Like</u>).

# [Response Begins]

CVD Risk Assessment Measure - Proportion of pregnant/postpartum patients that receive CVD Risk Assessment with a standardized tool.

[Response Ends]

## sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

# [Response Begins]

The University of California, Irvine (UCI) implemented and tested a CVD risk assessment algorithm that can be integrated into the electronic health record (EHR) system that immediately identifies patients who are at increased risk for CVD.

The unit of measurement is individual patients, and the population will include any patient who has a prenatal or postpartum visit in the hospital system. This includes pregnant and postpartum emancipated minors. The denominator in the CVD Risk Assessment Measure is all patients seen for pregnancy or postpartum care at a health care facility or hospital system. A hospital system includes Labor and Delivery (L & D), outpatient care in hospitals or at affiliated clinics, and private providers contracted with hospitals for delivery. The measure excludes patients with a preexisting heart problem, and patients who have another reason for visiting a clinic [not prenatal or postpartum care] and have a positive pregnancy test but plan to terminate the pregnancy or seek prenatal services elsewhere.

This measure determines the percentage of pregnant or postpartum patients at a clinic who were assessed for CVD risk with a standardized tool, such as the CVD risk assessment algorithm developed by the California Maternal Quality Care Collaborative (CMQCC). The aim is to perform a CVD risk assessment using a standardized tool on all (100 %) eligible pregnant/postpartum patients. Every single patient should be assessed for CVD risk at least once during their pregnancy and, if needed, additional times when new symptoms present during the pregnancy and/or postpartum period. A threshold has still to be determined ("at least xxx % of patients who received risk assessment"). The measure can be calculated on a quarterly or annual basis.

# [Response Ends]

# sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure. Please do not select:

• Surgery: General

# [Response Begins]

Cardiovascular Perinatal Health Perinatal Health: Labor and Delivery Perinatal Health: Post-Partum Care Perinatal Health: Prenatal Care [Response Ends]

## sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

## [Response Begins]

Disparities Sensitive Health and Functional Status: Total Health Screening [Response Ends]

## sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result. Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure. Please do not select:

• Populations at Risk: Populations at Risk

[Response Begins] Adults (Age >= 18) Children (Age < 18) Women [Response Ends]

## sp.07. Select the levels of analysis that apply to your measure.

## Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- Clinician: Clinician
- Population: Population

[Response Begins] Clinician: Group/Practice [Response Ends]

#### sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Ambulatory Care

Inpatient/Hospital

**Outpatient Services** 

# sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

## [Response Begins]

https://sites.uci.edu/cvdriskassessmentmeasures/implementation/

[Response Ends]

# sp.12. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, <u>contact staff</u>. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins] Available in attached Excel or csv file [Response Ends]

Attachment: 3716\_3716\_Data Dictionary For IRB 2020-5693-508.xlsx Attachment: 3716\_3716\_CPT-ICD 10 Code Book-508.xlsx

## sp.13. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome). DO NOT include the rationale for the measure.

DO NOT include the rationale for the measure

## [Response Begins]

The percentage of all pregnant and postpartum patients who received a CVD risk assessment with a standardized tool. [Response Ends]

## sp.14. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

## [Response Begins]

The CVD algorithm consists of 18 variables and is integrated in the electronic medical record (EMR), including demographics, vital signs, and any risk factors. The algorithm is administered at the first visit of women who receive an obstetric visit (prenatal, labor and delivery, postpartum). It is repeated at presentation of clinical symptoms during the pregnancy. Most of the data are automatically pulled from the medical record (age, race, vital signs, symptoms). See the excel attachment "CPT – ICD 10 Code Book" for the full list of CVD confirmation CPT codes. Completion of the algorithm takes about 30 seconds.

The EMR calculates an immediate score of women. Charts of patients who screen positive are flagged with a banner and smartset orders with recommendations for follow-up (labs/imaging/consults). A completed CVD risk algorithm will have a calculated risk score and clinician signature (group E "Cardiovascular Screening Completed" in the CPT-ICD 10 Code Book).

The total population in which data was collected is OB patients: patients who have an active pregnancy or postpartum episode with at least 1 visit. This includes pregnant and postpartum minors; visits include hospital system: Labor and Delivery; outpatient care at the hospital or in affiliated clinics; private providers contracting with the hospital for delivery. Exclusion criteria include: Patients with a prior history of known cardiac disease and women who have another reason for visiting the clinic [not prenatal or postpartum care] and have a positive pregnancy test but plan to terminate the pregnancy or seek prenatal services elsewhere. This total number of patients is the denominator for the risk assessment measure.

The numerator consists of patients with a completed risk assessment. Individual CVD risk scores will be calculated automatically once the algorithm is completed and will be part of the patient's medical record.



## Flow Chart of CVD Risk Assessment Measure Calculation

The clinic IT system can provide regular updates of the CVD screening and follow-up measures (quarterly, yearly) by clinic site, unit, or the complete hospital network to the medical director.

Medical and demographic data on the patients allow to calculate the measure for subgroups and identify the need for targeted interventions. IT can extract clinical data on the cohort to identify subgroups in need of targeted interventions.

# [Response Ends]

# sp.15. State the denominator.

Brief, narrative description of the target population being measured.

# [Response Begins]

Pregnant and Postpartum Office visit assess the CVD risk of patients who are pregnant or postpartum (group B "Pregnant and Postpartum Office Visit" in the CPT-ICD 10 Code Book). Any person who is pregnant or postpartum who attends a pregnant or postpartum clinic visit at any participating site should undergo risk assessment. See the excel attachment "CPT – ICD 10 Code Book" for the full list of CVD confirmation CPT codes.

[Response Ends]

## sp.16. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

# [Response Begins]

Any patient who is pregnant or postpartum who attends a pregnant or postpartum clinic visit at any participating site should undergo a risk assessment.

Patients (a) who have an office visit for prenatal or postpartum care at the intervention site (regardless of gestational age or prior prenatal care at other sites), (b) Any age (including pregnant and postpartum minors), (c) Outpatient OB visit at the hospital or in affiliated clinics; Labor and Delivery including private providers contracting with the hospital for delivery.

[Response Ends]

## sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

## [Response Begins]

[a] Patients who have another reason for visiting the clinic

[b] Prior history of known cardiac disease

[Response Ends]

## sp.18. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

# [Response Begins]

[a] 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 OB provider (plan to terminate the pregnancy or seek prenatal services elsewhere).

[b] Prior history of known cardiac disease. CVD confirmation is identified if the patient has one or more ICD codes in their medical chart during the data abstraction period. If CVD confirmation falls on a date prior to CVD algorithm use with a patient who has completed the algorithm, it is considered an exclusion and did not require CVD algorithm evaluation. See the excel attachment "CPT – ICD 10 Code Book" for the full list of CVD confirmation CPT codes.

## [Response Ends]

## sp.19. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the riskmodel covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field. [Response Begins] N/A [Response Ends]

## sp.20. Is this measure adjusted for socioeconomic status (SES)?

[Response Begins] No [Response Ends]

## sp.21. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins] No risk adjustment or risk stratification [Response Ends]

## sp.22. Select the most relevant type of score.

Attachment: If available, please provide a sample report. [Response Begins] Rate/proportion [Response Ends]

# sp.23. Select the appropriate interpretation of the measure score.

*Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score* 

[Response Begins] Better quality = Higher score [Response Ends]

## sp.24. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

## [Response Begins]

The total population includes the number of OB patients with at least one pregnancy or postpartum episode recorded in their medical records. See *Group A* - *Live birth in Codebook and Group B* – *Pregnancy and Postpartum Office Visits Inclusion criteria:* 

[a] pregnant and postpartum minors;

[b] Visits: Labor and Delivery; outpatient care at a hospital or in affiliated clinics; private providers contracting with hospitals for delivery.

Exclusion criteria:

[a] Patient with a prior history of known cardiac disease *Group C - ICD-10 Exclusion Codes* for CVD Screening. If a patient presents these conditions during subsequent prenatal or postpartum visits, she should be referred directly for follow-up, rather than being rescreened.

[b] 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 (plan to terminate the pregnancy or seek prenatal services elsewhere).

Sample Size: The algorithm can be calculated for clinician groups/practice sites and individual clinicians regardless of their patient volume.

*Time and Period of Data:* Depending on the patient volume, the measure can be calculated on an annual or quarterly basis.

*Data extraction*: The Information Technology (IT) department extracts the number of eligible patients (Medical Record Number, visit date, denominator) and the number of patients who received a risk assessment (Date risk assessment was completed, numerator). Additional data for stratification can be clinic site, clinician, race/ethnicity of mother, insurance, gestational age, and date of birth of infant (to identify whether the assessment was completed during pregnancy or postpartum.

## [Response Ends]

sp.27. If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

## Examples of samples used for testing:

- Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.
- The sample should represent the variety of entities whose performance will be measured. The <u>2010 Measure</u> <u>Testing Task Force</u> recognized that the samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.
- The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.
- When possible, units of measurement and patients within units should be randomly selected.

## [Response Begins]

N/A

[Response Ends]

## sp.30. Select only the data sources for which the measure is specified.

# [Response Begins]

Electronic Health Records

Paper Medical Records

## sp.31. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

## [Response Begins]

### **Electronic Health Records: EPIC and Cerner**

The CVD risk assessment algorithm, developed by the California Maternal Quality Care Collaborative (CMQCC), is an initial step that guides the stratification and initial evaluation of symptomatic or high-risk pregnant or postpartum patients. The acceptability of the measure is further strengthened by the support it has received from ACOG and its inclusion in the CVD bundle by the Alliance for Innovation for Maternal Health.

The algorithm can be used manually or integrated into the electronic health record. The integration of the algorithm was successfully completed in EPIC and Cerner as a Smartset. From the algorithm we can collect several items: date of the finished algorithm, algorithm signed by the clinician, algorithm items (YES/NO), algorithm calculated risk, and follow-up tests ordered. All other data is collected directly from patient records.

[Response Ends]

#### sp.32. Provide the data collection instrument.

### [Response Begins]

Available at measure-specific web page URL identified in sp.09

[Response Ends]

## 2a. Reliability

## 2a.01. Select only the data sources for which the measure is tested.

[Response Begins] Electronic Health Records Paper Medical Records [Response Ends]

## 2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

#### [Response Begins]

EHR data in EPIC from University of California Irvine, University of California, San Diego EHR data in Cerner from St. Thomas/University of Tennessee [Response Ends]

## 2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

# [Response Begins]

09-01-2020 - 02-28-2022

[Response Ends]

# 2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- Clinician: Clinician
- Population: Population

# [Response Begins]

Clinician: Group/Practice

[Response Ends]

# 2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

# [Response Begins]

# The proportion of pregnant/postpartum patients at three hospital networks who received a CVD risk assessment by clinic site, September 2020 – February 2022

Clinical Sites	Total n	Column %	Completed Risk Assessment <i>n</i>	Row %	Туре
UCI Health System	*	*	*	*	*
UCI CM OB/GYN	27	1.0%	1	3.7%	Obstetrics & Gynecology
UCI FQHC ANA FAM MED	76	2.9%	51	67.1%	Family Medicine
UCI FQHC ANA OB/GYN	382	14.7%	273	71.5%	Obstetrics & Gynecology

Clinical Sites	Total n	Column %	Completed Risk Assessment n	Row %	Туре
UCI FQHC SA FAM MED	16	0.6%	6	37.5%	Family Medicine
UCI FQHC SA OB/GYN	906	34.8%	499	55.1%	Obstetrics & Gynecology
UCI MAN MFM	564	21.7%	353	62.6%	Maternal- Fetal Medicine
UCI MAN OB/GYN	362	13.9%	90	24.9%	Obstetrics & Gynecology
UCI PLAZA FAM MED	11	0.4%	10	90.9%	Family Medicine
UCI TUSTIN OB/GYN	172	6.6%	96	55.8%	Obstetrics & Gynecology
UCI YORBA LND OBGYN	95	3.6%	42	44.2%	Obstetrics & Gynecology
UCSD Health System	*	*	*	*	*
AMP WOMENS HEALTH SVCS	102	1.7%	43	42.2%	Women's Health Services
CNV WOMENS HEALTH SVCS	712	11.9%	389	54.6%	Women's Health Services
DIR WOMENS HEALTH SVCS	525	8.8%	389	74.1%	Women's Health Services
MOS OB HOSPITALIST	317	5.3%	0	0.0%	Obstetric Hospitalist
MOS WOMENS HEALTH SVCS	846	14.1%	396	46.8%	Women's Health Services
PHR WOMENS HEALTH SVCS	102	1.7%	91	89.2%	Women's Health Services

Clinical Sites	Total n	Column %	Completed Risk Assessment n	Row %	Туре
UNC WOMENS HEALTH SVCS	161	2.7%	142	88.2%	Women's Health Services
VLJ WOMENS HEALTH SVCS	2724	45.4%	2392	87.8%	Women's Health Services
VTC WOMENS HEALTH SVCS	470	7.8%	422	89.8%	Women's Health Services
ZZZ VLJ WOMENS HEALTH	26	0.4%	21	80.8%	Women's Health
UTENN Health System	*	*	*	*	*
ST Midtown	13627	60.0%	13627	60.0%	General
ST River Park	1340	5.9%	1340	5.9%	General
ST Rutherford	7746	34.1%	7746	34.1%	General

\*Cells intentionally left empty

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

## [Response Begins]

Number and descriptive characteristics of patients who received a CVD risk assessment compared to total patients, September 2020 – February 2022

Descriptive Characteristics	Total n	Column %	Completed Risk Assessment <i>n</i>	Row %
UCI Health System	*	*	*	*
Overall	2611	100.0%	1421	54.4%
Age group	*	*	*	*
<20	52	2.0%	28	53.8%
20-29	1043	40.1%	579	55.5%
30-39	1324	50.9%	705	53.2%

Descriptive Characteristics	Total n	Column %	Completed Risk Assessment	Row %
40+	192	7.4%	109	56.8%
Race	*	*	*	*
Black	106	4.1%	57	53.8%
White	1778	68.3%	990	55.7%
AAPI	375	14.4%	206	54.9%
Others	352	13.5%	168	47.7%
Ethnicity	*	*	*	*
Hispanic	1483	57.0%	858	57.9%
Non-Hispanic	1121	43.0%	559	49.9%
Race/Ethnicity	*	*	*	*
Non-Hispanic White	563	21.6%	267	47.4%
Non-Hispanic Black	102	3.9%	54	52.9%
Hispanic	1483	57.0%	858	57.9%
ΑΑΡΙ	371	14.3%	204	55.0%
Others/unknown	92	3.5%	38	41.3%
Insurance	*	*	*	*
Public (Medicaid, Military, government)	1371	52.7%	722	52.7%
Private (Commercial, Managed care)	887	34.1%	406	45.8%
Self-pay	1	0.0%	0	0.0%
Unknown	352	13.5%	293	83.2%
Timing	*	*	*	*
Prenatal	970	37.3%	382	39.4%
Postpartum	1641	63.0%	1039	63.3%
UCSD Health System	*	*	*	*
Overall	5985	100.0%	4285	71.6%
Age group	*	*	*	*
<20	53	0.9%	28	52.8%
20-29	1973	32.9%	1341	68.0%
30-39	3549	59.2%	2638	74.3%
40+	410	6.8%	278	67.8%
Race	*	*	*	*

Descriptive Characteristics	Total n	Column %	Completed Risk Assessment <i>n</i>	Row %
Black	353	5.9%	222	62.9%
White	3087	51.5%	2321	75.2%
ΑΑΡΙ	731	12.2%	565	77.3%
Others	1814	30.3%	1177	64.9%
Ethnicity	*	*	*	*
Hispanic	1753	29.8%	1089	62.1%
Non-Hispanic	4122	70.1%	3109	75.4%
Race/Ethnicity	*	*	*	*
Non-Hispanic White	2574	42.9%	2002	77.8%
Non-Hispanic Black	339	5.7%	211	62.2%
Hispanic	1753	29.2%	1089	62.1%
ΑΑΡΙ	721	12.0%	560	77.7%
Others/unknown	598	10.0%	423	70.7%
Insurance	*	*	*	*
Public (Medicaid, Military, government)	1953	32.6%	1277	65.4%
Private (Commercial, Managed care)	3096	51.6%	2239	72.3%
Unknown	936	15.6%	769	82.2%
Timing	*	*	*	*
Prenatal	1947	32.5%	1411	72.5%
Postpartum	4038	67.4%	2874	71.2%
UTENN Health System	*	*	*	*
Overall	22713	100.0%	22713	100.0%
Age group	*	*	*	*
<20	1152	5.1%	1152	5.1%
20-29	11026	48.5%	11026	48.5%
30-39	9829	43.3%	9829	43.3%
40+	706	3.1%	706	3.1%
Race	*	*	*	*
Black	3370	14.8%	3370	14.8%
White	13768	60.6%	13768	60.6%
ΑΑΡΙ	395	1.7%	395	1.7%

Descriptive Characteristics	Total n	Column %	Completed Risk Assessment <i>n</i>	Row %
Others	5180	22.8%	5180	22.8%
Ethnicity	*	*	*	*
Hispanic	3944	17.4%	3944	17.4%
Non-Hispanic	18181	80.1%	18181	80.1%
Race/Ethnicity	*	*	*	*
Non-Hispanic White	13119	57.8%	13119	57.8%
Non-Hispanic Black	3328	14.7%	3328	14.7%
Hispanic	3944	17.4%	3944	17.4%
ΑΑΡΙ	384	1.7%	384	1.7%
Others/unknown	1938	8.5%	1938	8.5%
Insurance	*	*	*	*
Public (Medicaid, Military, government)	6006	26.4%	6006	26.4%
Private (Commercial, Managed care)	16349	72.0%	16349	72.0%
Self pay	322	1.4%	322	1.4%
Unknown	36	0.2%	36	0.2%
Timing	*	*	*	*
Prenatal	9507	41.9%	9507	41.9%
Postpartum	13206	58.1%	13206	58.1%

\*Cells intentionally left empty

## [Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

## [Response Begins]

We used the same data sets for empirical validity tests. However, for SNR reliability testing, we used the same data set but excluded VLI WOMENS HEALTH SVCS (n=2724), ST Midtown (n=13627), and ST Rutherford (n=7746) for the purpose of parameter estimation.

#### [Response Ends]

#### 2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

# [Response Begins]

We are limited to social risk factors that are included in the electronic medical record. Most of these risk factors are part of the risk assessment tool; these include age over 40 years, black race, substance use, and medical risk factors (obesity, diabetes, hypertension, history of chemotherapy). Stratifications can be performed by insurance status (commercial/private insurance vs. public insurance) as a proxy for socio-economic status and by geographic location (rural/urban, medically underserved area) using zip code. Patient zip codes also allow us to gauge patient community characteristics.

We conducted a logistic regression analysis with age, race/ethnicity, insurance status, and timing. We found statistically significant differences among those social risk factors (see table below).

Risk Factors	Total n	Column %	Completed Risk Assessment	Row %	Chi square test p- value**
			n		
Age group	*	*	*	*	<.0001
<20	1257	4.0%	1208	96.1%	*
20-29	14042	44.8%	12946	92.2%	*
30-39	14702	47.0%	13172	89.6%	*
40+	1308	4.2%	1093	83.6%	*
Race	*	*	*	*	<.0001
Black	3829	12.2%	3649	95.3%	*
White	18633	59.5%	17079	91.7%	*
ΑΑΡΙ	1501	4.8%	1166	77.7%	*
Others	7346	23.5%	6525	88.8%	*
Ethnicity	*	*	*	*	<.0001
Hispanic	7180	22.9%	5891	82.0%	*
Non-Hispanic	23424	74.8%	21849	93.3%	*
Unknown	705	2.3%	679	93.3%	*
Race/Ethnicity	*	*	*	*	<.0001
Non-Hispanic White	16256	51.9%	15388	94.7%	*
Non-Hispanic Black	3769	12.0%	3593	95.3%	*
Hispanic	7180	22.9%	5891	82.0%	*
ΑΑΡΙ	1476	4.7%	1148	77.8%	*
Others/unknown	2628	8.4%	2399	91.3%	*
Insurance	*	*	*	*	<.0001
Public (Medicaid, government)	9330	29.8%	8005	85.8%	*
Private (Commercial, Managed care)	20332	64.9%	18994	93.4%	*

**Table 1: Logistic Regression Analysis** 

Risk Factors	Total	Column %	Completed	Row %	Chi square test p-
	n		Risk		value**
			Assessment		
			n		
Self pay	323	1.0%	322	99.7%	*
Unknown	1324	4.2%	1098	82.9%	*
Timing	*	*	*	*	<.0001
Prenatal	12424	39.7%	11300	91.0%	*
Postpartum	18885	60.3%	17119	90.6%	*

\*\* Chi square test testing different distribution of screening status by social-demographic category

\*Cells intentionally left empty

## [Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or encounter-level data; in 2a.010 enter "see validity testing section of data elements"; and enter "N/A" for 2a.11 and 2a.12.

# 2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins] Accountable Entity Level (e.g., signal-to-noise analysis) [Response Ends]

# 2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

# [Response Begins]

We used Signal to Noise analysis. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in performance. A reliability of zero implies that all the variability in a measure is attributable to measurement errors. Reliability of one implies that all the variability is attributable to real differences in performance.

We eliminated clinics with a relatively large sample size (Denominator, or n) that could have a disproportionate influence. Then excluded if n>75<sup>th</sup> percentile+1.5\*(interquartile range).

• Calculate the 25<sup>th</sup> at 75<sup>th</sup> percentile of n across the 23 clinics.

25<sup>th</sup> percentile: 95

75<sup>th</sup> percentile: 846

interquartile range: 748

75<sup>th</sup> percentile+1.5\*(interquartile range)=1968

• VLI WOMENS HEALTH SVCS (n=2724), ST Midtown (n=13627), and ST Rutherford (n=7746) are removed for the purpose of the parameter estimation.

Next, we used empirical Bayes shrinkage with n<sup>2</sup> weighting to estimate the signal and noise variances as outlined in Section 5. of Morris<sup>1</sup>:

 $\hat{A} = \sigma_{provider-to-provider}^{2}$  $S_{i}^{2} = \sigma_{error}^{2}$ 

Then we calculated using  $Reliability = \frac{\sigma_{provider-to-provider}^2}{\sigma_{provider-to-provider}^2 + \sigma_{error}^2}$  for each clinic.

## [Response Ends]

## 2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, <u>NQF Measure Evaluation Criteria</u>).

### [Response Begins]

k: 20 A (Signal Variance): 0.0655 SD: 0.2558 b-hat (Mean): 0.714 V-bar: 0.000230 Median Reliability: 0.992 Min SNR: 0.839 Max SNR: 1.000

## [Response Ends]

#### 2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

## [Response Begins]

The median reliability for our measure is 0.992 (close to 1), which means that almost all the variability is attributable to real differences in performance.

## [Response Ends]

## 2b. Validity

#### 2b.01. Select the level of validity testing that was conducted.

## [Response Begins]

Patient or Encounter-Level (data element validity must address ALL critical data elements)

## Empirical validity testing

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

[Response Ends]

## 2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

### [Response Begins]

**Patient Or Encounter Level:** We conducted a Kappa analysis between automated extracted EHR data and manual reviewer. We conducted weekly audits to monitor adoption. NPs are early adopters and MDs tend to be slower in integrating tool in clinical practice. To address this, we revised and customized the implementation plan at each institution to foster interest and use of the tool by clinicians. In total, we reviewed 2,535 charts at UCI whether they had the risk assessment completed and a risk score. A risk gets only calculated if all the data elements are completed. We identified 100% consistency between the EHR data extraction and the chart documentation.

**Empirical Validity Testing:** The CVD risk assessment measure and the percent of confirmed CVD cases were calculated for 23 entities. We hypothesized them to be positively correlated. Pearson Correlation Coefficient (r) was calculated to test the correlation between the measure and the % of confirmed CVD cases. The Pearson chi-square test p<0.0001 indicates that measure 1 rates in different clinics are significantly different.

**Face Validity:** A vote was conducted among the Technical Expert Panel and patients/caregivers on whether the final performance measure scores can be used to differentiate good from poor quality of care for Face Validity. The 14member Technical Expert Panel (TEP) represented diverse stakeholders (Measure Developers, Clinical Content – Cardiology, Clinical Content – OB/GYN/MFM, Clinical IT, Patient Representatives). TEP members met virtually every 2-3 months and provided input on the individual elements of the algorithm, the integration of the algorithm in the EHR and discussed additional clinical criteria such as the appropriate BNP cutoff. Per consensus vote, TEP members agreed that: i) There should not be any upper or lower age limit (so adolescent pregnancies and patients with IVF and pregnancy loss/stillbirths are included), ii) Private providers who contract with the hospital for L&D services can be included in the denominator, and iii) How to calculate the measure if the algorithm was administered more than once during a pregnancy episode. TEP members also discussed the benefits and drawbacks of a 60-day window for follow-up of a positive risk assessment and agreed that a shorter time period might not allow for system or patient-initiated rescheduling of appointments and a larger window might make it difficult to assume that the test was done as a result of the positive risk score.

[Response Ends]

#### 2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins] Patient or Encounter Level: 1.0 Empirical Validity: 0.424 Face Validity: 10 out of 10 [Response Ends]

# 2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

# [Response Begins]

**Patient or Encounter Level:** We are confident to be able to identify prenatal and postpartum patients. We are confident that we can identify those who have a positive CVD risk assessment score and who are not. We checked the data extracted by the UCI IT department with results from the manual review of a subset of charts. There were no discrepancies between manual and EHR extraction for this measure.

**Empiric Validity:** The r=0.424 (p-value=0.0437) shows that the CVD risk assessment measure and percent of confirmed CVD cases have a moderate positive correlation with a statistically significant p-value.

**Face Validity:** 100% of experts and patients/caregivers voted in agreement that the measure could differentiate good from poor quality care among accountable entities.

## [Response Ends]

# 2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

## [Response Begins]

The CVD Risk assessment measures were implemented at three large hospital networks in September 2020 over an eighteen-month period. We reviewed all 31,309 pregnant or postpartum patients who had a visit to any of the hospital units. We collected data of the CVD risk assessment from the clinician groups/practices of the hospital networks. We performed bivariate analyses using the Chi-square test to test the difference in categorical variables. Subset analysis was done for each clinician group/practice as well.

## [Response Ends]

# 2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

## [Response Begins]

The cohort consisted of 31,309 patients in which UCI had 2,611, UCSD had 5,985, and UTENN having 22,713 total population sample size. The rate for CVD risk assessment in the three hospital systems was 54.4%, 71.6%, and 100% (p<0.0001), suggesting a meaningful difference in performance and the need for quality improvement among the hospital networks.

The analysis by clinician group/practice revealed significant variation in the CVD risk assessment rates. Differences were identified in the successful completion of CVD measures between the clinical sites, which were primarily based on the size of the clinic (number of patients seen) and specialty. The majority of the clinics at UTENN had a hard stop in their EHR which forced the completion of the algorithm yielding 100% compliance with CVD risk assessment. Within each hospital system, performance on the measure varied widely by the clinical site.

# 2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

## [Response Begins]

The measure could provide meaningful and actionable data on the percentage of patients who received a CVD risk assessment at each clinic site. In each hospital system, we identified low-performing and high-performing sites. A review of low performance resulted in the identification of root causes such as clinicians not signing the screen with the risk assessment score before closing the chart or lack of training on the risk assessment of new clinicians and achieving an improvement in the score in the next reporting period.

The measure is a percentage and the range was from 0% to 100%. The performance quartiles are as follows: Q1: 44.2%, Q2: 67.1%, and Q3: 89.2%. The IQR is 45%. Of the 23 clinical sites, 5 clinics were in the first quartile and are considered to be low performing and 6 clinics were in the third quartile and considered to be high performing.

## [Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

# [Response Begins]

All variables to calculate the measure are retrieved from the electronic health record. There are no missing variables in the records that would impact the calculation of the score. If the risk assessment is not done, it will be part of the measure calculation. Missing risk assessments will be analyzed by patient demographics as part of the measure reporting. However, we identified a group of risk assessments that were initiated but not completed and compared this group with the group of completed charts by client age, insurance status, race-ethnicity, and clinic site. We found that UCSD had a larger percentage of incomplete charts ("missing" values) than UCI but that the missingness did not vary by patient demographics. We also found that UCSD had significant differences in completed risk assessments by race/ethnicity. Further analysis will have to explore to what extent this finding is associated with the clinic site (higher rate of completion at postpartum clinics, white patients more likely to return to postpartum clinics, etc.) Significant differences were identified by clinic sites suggesting differences in the adoption of the measure. Furthermore, we observed that after additional training on how to complete the charts, the number of incomplete risk assessments decreased. Therefore, we do not believe that there is a systematic bias in the use of the risk assessment tool and that the differences rather show differences in measure implementation.

## [Response Ends]

# 2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

# [Response Begins]

Frequency of missing data and distribution by the hospital systems, September 2020- February 2022

Health System	Total	Started, but did not	Completed Risk
	n	n	n
UCI Health System	2611	254	1421
UCI CM OB/GYN	27	0	1
UCI FQHC ANA FAM MED	76	18	51
UCI FQHC ANA OB/GYN	382	53	273
UCI FQHC SA FAM MED	16	8	6
UCI FQHC SA OB/GYN	906	91	499
UCI MAN MFM	564	27	353
UCI MAN OB/GYN	362	23	90
UCI PLAZA FAM MED	11	1	10
UCI TUSTIN OB/GYN	172	31	96
UCI YORBA LND OBGYN	95	2	42
UCI Time Period	*	*	*
09/01/20 - 02/28/21	844	109	590
03/01/21- 08/31/21	847	79	495
09/01/21- 02/28/22	920	66	336
UCSD Health System	5985	759	4285
AMP WOMENS HEALTH SVCS	102	3	43
CNV WOMENS HEALTH SVCS	712	95	389
DIR WOMENS HEALTH SVCS	525	43	389
MOS OB HOSPITALIST	317	230	0
MOS WOMENS HEALTH SVCS	846	185	396
PHR WOMENS HEALTH SVCS	102	5	91
UNC WOMENS HEALTH SVCS	161	7	142
VLJ WOMENS HEALTH SVCS	2724	165	2392
VTC WOMENS HEALTH SVCS	470	23	422
ZZZ VLJ WOMENS HEALTH	26	3	21
UCSD Time Period	*	*	*
09/01/20 - 02/28/21	1836	299	1278
03/01/21- 08/31/21	2093	278	1492
09/01/21- 02/28/22	2056	182	1515
UTenn Health System	22713	0	22713

Health System	Total n	Started, but did not complete n	Completed Risk Assessment <i>n</i>
ST Midtown	13627	0	13627
ST River P	1340	0	1340
ST Rutherf	7746	0	7746
UTENN Time Period	*	*	*
09/01/20 - 02/28/21	4187	0	4187
03/01/21- 08/31/21	9376	0	9376
09/01/21- 02/28/22	9150	0	9150

\*Cells intentionally left empty

We noticed that some providers started but did not sign and close the chart, hence a score was calculated but not officially completed (reviewed and signed by a clinician). These charts were not included in the numerator, lowering the measure score (percentage of patients who completed a risk assessment). This gap was due to lapses in the clinical flow, particularly in the Labor and Delivery division of one of the networks where zero charts were completed. We have been working with the clinic groups/providers to improve the completion of the risk assessment and reduce the percentage of incomplete risk assessments over time.

## [Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

# [Response Begins]

We do not believe that the data is biased. One health care system has mandatory risk assessment for all pregnant and postpartum patients. There were no differences in client demographics *within* the clinic sites.

Any differences in opened but not completed risk assessments seemed to be due to implementation challenges and misunderstanding from clinicians on how to use the risk assessment screen. After additional training of clinicians at low-performing sites, the measure improved in the next six-month measurement period. We assume that these implementation challenges were largely due to the limited ability of in-person training and monitoring of risk assessment completion due to the COVID-19 safety measures at clinics.

# [Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not

demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

### 2b.11. Indicate whether there is more than one set of specifications for this measure.

### [Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins] [Response Ends]

**2b.13.** Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins] [Response Ends]

**2b.14.** Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins] [Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins] Yes, the measure uses exclusions. [Response Ends]

## 2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

# [Response Begins]

The exclusion criteria are:

[a] Patients who have another reason for visiting a clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as an OB provider (plan to terminate the pregnancy or seek prenatal services elsewhere).

[b] Prior history of known cardiac disease. CVD confirmation is identified if the patient has one or more ICD codes in their medical chart during the data abstraction period. If CVD confirmation falls on a date prior to CVD algorithm use with a patient who has completed the algorithm, it is considered an exclusion and did not require CVD algorithm evaluation. See the attached word document [CPT – ICD 10 Code Book] for a full list of CVD confirmation CPT codes.

When we extract data for analysis from the EHR, we ask our Information Technology department to exclude patients with a prior history of known cardiac disease based on our CPT-ICD 10 code list. These exclusion criteria are ICD-10 codes that can be abstracted to see if they pre-exist in the patient record and used along with the CPT office visit codes to see how many patients with pre-existing conditions unnecessarily completed a risk assessment.

[Response Ends]

## 2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

# [Response Begins]

We did not perform statistical tests because the exclusions are necessary for the measure to be clinically valid.

[Response Ends]

# 2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

# [Response Begins]

The exclusions are necessary for the measure to be clinically valid. The reason for the exclusion is that patients with already known CVD do not require to be screened for this condition but should be flagged for enhanced monitoring as part of regular prenatal care. Patients who do not plan to receive prenatal care at the site need to be excluded because they would not receive the required follow-up in case they are identified to be at risk for CVD.

[Response Ends]

# 2b.19. Check all methods used to address risk factors.

[Response Begins] No risk adjustment or stratification [Response Ends] 2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins] [Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

## [Response Begins]

It is not risk-adjusted or stratified, because Black race is one of the variables that contribute to the risk score.

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins] [Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins] [Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins] [Response Ends]

## 2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins] [Response Ends] 2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

## [Response Begins]

[Response Ends]

### 2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins] [Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins] N/A [Response Ends]

## 2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins] [Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins] [Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins] [Response Ends]

# 2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins] [Response Ends]

# 2c. Composite – Empirical Analysis

# Criterion 3. Feasibility

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

## [Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)

Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

[Response Ends]

## 3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

## [Response Begins]

ALL data elements are in defined fields in electronic claims

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins] N/A [Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

N/A

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

## [Response Begins]

The main challenge during implementation was caused by the COVID-19 pandemic, which resulted in IT departments having to prioritize the transition to telehealth services. As we gathered data from different health systems, we faced delays in processing reliance agreements for IRB approval for data transmission to UCI and processing of EMR data not included in the CVD algorithm Smart Sets. During the testing and validation of the extracted data, we had to revise data specifications with our IT team. For example, we noticed that the criterion "office visit at MFM" is meaningless if the patient was already considered a high-risk patient and seen at MFM for other reasons (for example, having twins). We are exploring whether we can use only tests and labs as follow-up procedures rather than office visits. In addition, we had to closely monitor the data extraction. For example, at first, IT pulled all follow-up procedures that were done after the risk assessments. We had to make sure that the IT data extractions indicated the time whether a follow-up laboratory test was performed within 60 days after a positive risk assessment (as outlined in the data dictionary) or after the 60-day period (presumably due to new symptoms).

## [Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

## [Response Begins]

Programming code is needed to implement the algorithm and the associated measure is freely available from UCI. [Response Ends]

# Criterion 4: Use and Usability

## 4a. Use

4a.01. Check all current uses. For each current use checked, please provide:

- Name of program and sponsor
- o URL
- Purpose
- o Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

#### [Response Begins]

Quality Improvement (Internal to the specific organization)

## [Quality Improvement (Internal to the specific organization) Please Explain]

Our measures were tested at geographically and ethnically diverse hospital networks: UCI (1,500 births per year), UCSD (3,000 births per year), and UTENN (11,000 births per year). The hospital networks UCI and UCSD are located in Southern California and UTENN in Tennessee. They include regional Level 3 birthing centers with the full scope of inpatient and outpatient hospital services and affiliated community and private medical clinics. All hospitals have Obstetrics/Gynecology (OB/GYN) residency training programs, a high volume of Medicaid patients, and a diverse racial/ethnic demographic mixture. The information on the measure is used for staff training at other additional sites that have adopted the measure, such as Albert Einstein College and the University of Missouri. The Saint Luke's Hospital System is a non-profit 11-hospital system affiliated with the University of Missouri-Kansas City School of Medicine. Five hospitals within the system have obstetrical units that service approximately 5000 deliveries per year. Montefiore Medical Center (MMC), an affiliate of Albert Einstein College, provides a full range of services at more than 20 locations in the Bronx and Westchester County. Its diverse patient population includes mainly Latino (40%) and Black populations (30%). There is an anticipated 5000 births per year at MMC.

## **Current Users:**

- University of Tennessee/ St. Thomas Health, Tennessee
- University of California, San Diego/UC San Diego Health
- University of California, Irvine/UC Irvine Health
- Albert Einstein College/Montefiore Medical Center, New York
- University of Missouri, Kansas City/St. Luke's Health System, Kansas City

## [Response Ends]

### 4a.02. Check all planned uses.

## [Response Begins]

Public reporting Quality Improvement (internal to the specific organization)

## [Response Ends]

# 4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

## [Response Begins]

We submitted to the CMS for the Measures Under Consideration (MUC) list in April 2022 and applied to the public reporting program for hospital outpatient and inpatient quality reporting programs. If it is accepted, the measure will be publicly reported three years after acceptance.

## [Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

## [Response Begins]

We submitted to the CMS for the Measures Under Consideration (MUC) list in April 2022 and applied to the public reporting program for hospital outpatient and inpatient quality reporting programs. If it is accepted, the measure will be publicly reported three years after acceptance.

Each clinic site or unit can calculate its own measure manually or with the support of its Information Technology department annually or semi-annually. UCI is working with two additional health care systems (Albert Einstein College/Montefiore Medical Center and St. Luke's Health/University of Missouri, Kansas City) to implement risk assessment at their obstetric sites for the period 2022-2024. UCI is also advising the University of Pennsylvania on a four-year project (2022-2026) that will implement the algorithm in its health care network and evaluate the use of the risk assessment in emergency room departments. Conversations with additional hospital networks are ongoing.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

## [Response Begins]

During 2020-2022, we worked with three sites: the University of California, Irvine (UCI), the University of California, San Diego (UCSD), and the University of Tennessee/St. Thomas Health (UTENN). Each hospital system implemented a risk assessment tool and calculated the quality measure. Individual sites calculated their measures and provided feedback about the completion rate to their staff through e-mails or at staff meetings.

In addition, individual patient data for the measures were uploaded to UCI, and measures for three to six-month periods were calculated by clinic site and patient demographics. The calculated measures were shared with UTENN and UCSD and site differences in performance of the clinic sites were addressed by the site investigators. For example, one site had zero percent of patients screened, which was due to clinicians not signing the risk assessment prior to closing the chart. We also found in the first round of measure calculations statistical differences by completed risk assessment by race/ethnicity at UCSD and a higher rate of risk assessment among postpartum patients than prenatal patients. Upon further inspection, the UCSD site investigator identified that the clinic site with the best performing risk assessment rate was a clinic that served mainly white postpartum patients. Quality improvement was performed at the other UCSD sites. Similarly, UCI observed a drop in CVD risk assessment in the third 6-month reporting period which led to another round of refresher training.

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

## [Response Begins]

The respective sites provided initial data for the first 6-month period after integrating the algorithm. Thereafter, we collected an 18-month period and calculated the measure for three to six-month periods. We provided summaries to UCI clinic sites about their performance and reviewed with the clinicians their performance over time and, in comparison to the other sites. Similarly, we provided summaries to UCSD and UTENN via clinic sites that were shared and reviewed with

the individual sites. Graphs and bar charts have been disseminated with each data run showing the overall performance of risk assessment completion in the various clinical sites within each hospital system.

[Response Ends]

# 4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

## [Response Begins]

The measures of the three hospital systems were reviewed by the co-investigators during virtual co-investigator meetings. Each site co-investigator individually contacted medical directors and/or clinicians with low CVD risk assessment rates to identify any implementation barriers. In addition, UCI conducted semi-structured interviews with five clinicians at each site (n=15) in May 2021 to elicit the value of the measure and barriers to its use. Barriers to the performance of CVD risk assessment were identified as busy clinics, competing priorities, the complexity of medical conditions, and lack of immediate access to stethoscopes to perform cardiovascular examination. Overall, clinicians appreciate the ability to monitor their performance and get a benchmark of their peer's performance.

#### [Response Ends]

### 4a.08. Summarize the feedback obtained from those being measured.

### [Response Begins]

Clinicians appreciated the ability to monitor their performance and get a benchmark of their peer's performance. The measure provided insightful discussions at Safety and Quality meetings.

[Response Ends]

#### 4a.09. Summarize the feedback obtained from other users.

#### [Response Begins]

We did not obtain any other systematic feedback. However, we collaborated with one additional health system on the integration of the tool in their electronic health systems (University of Missouri-Kansas City/St. Luke's Hospital System). The feedback from management and clinicians was consistent with the feedback already reported.

#### [Response Ends]

# 4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

#### [Response Begins]

We formed a 14-member Technical Expert Panel (TEP) representing diverse stakeholders (Measure Developers, Clinical Content – Cardiology, Clinical Content – OB/GYN/MFM, Clinical IT, Patient Representatives). TEP members met virtually every 2-3 months and provided input on the individual elements of the algorithm, and the integration of the algorithm in the EHR and discussed additional clinical criteria such as the appropriate BNP cutoff. The TEP members agreed that:

- i. There should not be any upper or lower age limit (so adolescent pregnancies and women with IVF are included).
- ii. Private providers who contract with the hospital for L&D services can be included in the denominator.
- iii. How to calculate the measure if the algorithm was administered more than once during a pregnancy episode.

## 4b. Usability

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

## [Response Begins]

We could address the completeness of risk assessment at different clinic sites and address it through quality improvement activities. We also observed a decrease in the measure in the third six-month period at one of the hospital networks (UCI) which are also being addressed through quality improvement interventions.

## [Response Ends]

# 4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

## [Response Begins]

We found an unexpected positive impact on general awareness of cardiovascular health in the obstetric setting. Patients and clinicians commented on improved patient awareness of the immediate and lifetime risk of developing CVD that drives changes in health behavior. The implementation of the risk assessment also highlighted the need for clinician training on risk communication. While for most patients the result of the risk assessment may not produce any strong emotions, some patients may have had prior high-risk pregnancies (themselves or family/friends) or overall anxiety about the birth outcome or may have anxiety or other mental health problems that are exacerbated by being labeled "at risk." Physicians need to be alerted in the training that the standard explanation of conveying risk may not suffice for all patients.

## [Response Ends]

## 4b.03. Explain any unexpected benefits realized from implementation of this measure.

#### [Response Begins]

The consistent use of the tool has raised awareness of the importance of CVD risk assessment among obstetricians. Training of clinicians on how to counsel patients about their CVD risk and address potential concerns to avoid negative emotional reactions related to CVD risk with patients.

[Response Ends]

# **Criterion 5: Related and Competing Measures**

# 5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

### [Response Begins]

0608: Pregnant women that had HBsAg testing.

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

# [Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

N/A

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQFendorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins] Yes [Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

## [Response Begins]

The measures have the same target group of pregnant patients. However, their focus is not on risk assessments for CVD. Measures that address cardiovascular health are not focusing on the obstetric population and are secondary preventive measures (assessing treatment of individuals already identified with cardiovascular health issues).

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

# [Response Begins]

Our measure is used for standardized identification of individuals with previously unknown CVD who are suspected to have or to be at risk of developing CVD. A CVD risk assessment distinguishes patients with a high probability of disease by analyzing several variables indicated by the algorithm.

For a universal use of cardiovascular risk assessment in pregnant and postpartum women, a reliable clinical screening approach that monitors the hospital and clinician performance is lacking. The implementation of a measure to monitor universal CVD risk assessment in the obstetric population will lead to timely identification and follow-up of women at risk of CVD and reduce maternal morbidity and mortality and lifetime onset of CVD.