**Protocol: Conditions in Obstetric Care (CCOC) Project**

In Association with The American College of Obstetricians and Gynecologists’ (ACOG)

Alliance for Innovation in Maternal Health (AIM)

**Tennessee Initiative for Perinatal Quality Care (TIPQC)**

**Inter-Institutional Quality Improvement Project**

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Funded under a grant from the Tennessee Department of Health (TDH

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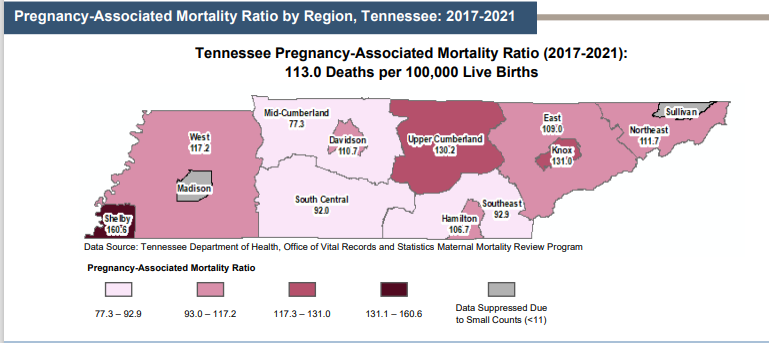
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**EXECUTIVE SUMMARY**

*This Executive Summary defines the 5 W’s (and 1 H) of the TIPQC Cardiac Conditions in Obstetric Care Project.*

***WHY:*** Cardiac conditions are the leading cause of pregnancy-related deaths and disproportionately affect non-Hispanic Black people [1]. Nationally, multidisciplinary maternal mortality review committees have found that birthing people who died from cardiac conditions during pregnancy and postpartum were not diagnosed with a cardiovascular disease prior to death. These committees also found that more than 80% of all pregnancy-related deaths were preventable, regardless of cause. Obstetric complications such as preeclampsia and gestational diabetes are associated with future cardiovascular disease (CVD) risk. Studies show that those with cardiac risk factors and those with congenital and acquired heart disease require specialized care during pregnancy and postpartum to minimize risk of preventable morbidity and mortality [1]. Common risk factors for CVD-related mortality include race and ethnicity, age, hypertension during pregnancy, and obesity [2].

In Tennessee (TN), from 2017 to 2021, 455 Tennessee birthing people have died during pregnancy or within a year of pregnancy [3]. Over the past five years, Black birthing people in Tennessee were 2.4x as likely to die from pregnancy-related causes as White birthing people. Tennessee’s maternal mortality review (MMR) noted race-specific causes of death such as the higher incidence of Black women with pregnancy-related cardiovascular deaths. For Black birthing people, 91% of pregnancy related deaths were determined to be preventable. The main causes of pregnancy-related deaths among Black birthing people were preeclampsia, eclampsia, cardiovascular conditions, embolism, and homicide. Just over 1 in 3 (36%) deaths were pregnancy-related and over half of pregnancy-associated deaths (57%) occurred between 43-365 days postpartum. Among all pregnancy-associated deaths, about 3 in 4 deaths (77%) could have been prevented with the appropriate resources and/or interventions [3].



***WHAT****:*TIPQC has chosen to partner with the American College of Obstetricians and Gynecologist (ACOG) in their Alliance for Innovation on Maternal Health (AIM) safety program to improve care for pregnant people with cardiac conditions. In addition to ACOG, AIM Core Partners include American College of Nurse Midwives (ACNM), Association of State and Territorial Health Officials (ASTHO), Association of Women’s Health, Obstetric, and Neonatal Nursing (AWHONN), California Maternal Quality Care Collaborative (CMQCC), Preeclampsia Foundation, Society for Maternal-Fetal Medicine (SMFM). Additional collaborators will include the TN Dept of Health, the TN Regional Perinatal Centers, and other state PQC initiatives.

***WHO:***This project will engage members of the obstetric care teams, emergency departments (ED), birthing centers, and Intensive care units (ICUs). In addition, hospital administration support for this project is essential to provide team leadership, process development, implementation oversight, and quality measurement.

***WHERE:***This project will target all delivering hospitals and birthing centers in Tennessee, as well as emergency settings.

***HOW:***This bundle provides guidance for health care teams to develop coordinated, multidisciplinary care for pregnant and postpartum people with cardiac conditions and to respond to cardio-obstetric emergencies. This bundle is one of several core patient safety bundles developed by the AIM that provides condition- or event-specific clinical practices for implementation in appropriate care settings [1]. This project will improve outcomes by addressing Readiness, Recognition and Prevention, Response, and Reporting. These 5 R’s provide a framework for tackling the numerous barriers and gaps to optimal care for pregnant people [4].

***Readiness***focuses plans for every unit that cares for birthing people by training all obstetrical care providers to perform a basic Cardiac conditions screening; establish a protocol for rapid identification of potential pregnancy-related cardiac conditions in all practice settings to which pregnant and postpartum people may present; develop a patient education plan based on the pregnant and postpartum person’s risk of cardiac conditions; establish a multidisciplinary “Pregnancy Heart Team” or consultants appropriate to their facility’s designated Maternal Level of Care to design coordinated clinical pathways for people experiencing cardiac conditions in pregnancy and the postpartum period; establish coordination of appropriate consultation, co-management and/or transfer to appropriate level of maternal or newborn care; develop trauma-informed protocols and training to address health care team member biases to enhance quality of care; and develop and maintain a set of referral resources and communication pathways between obstetric providers, community-based organizations, and state and public health agencies to enhance quality of care [4].

***Recognition and Prevention***emphasizes the importance of care for every patient by obtaining a focused pregnancy and cardiac history in all care settings, including emergency department, urgent care, and primary care. In all care environments, providers should assess and document if a patient presenting is pregnant or has been pregnant within the past year. Providers should assess if there are any escalating warning signs for an imminent cardiac event present; utilize standardized cardiac risk assessment tools to identify and stratify risk and conduct a risk-appropriate work-up for cardiac conditions to establish diagnosis and implement the initial management plan and screen each person for condition associated risk factors and provide linkage to community services and resources; and screen each person for condition associated risk factors and provide linkage to community services and resources [4].

The***Response***aspect of the bundle focuses on every event. There should be facility-wide standard protocols with checklists and escalation policies for management of cardiac symptoms and standard protocols with checklists and escalation policies for management of people with known or suspected cardiac conditions. Healthcare providers should coordinate transitions of care including the discharge from the birthing facility to home and transition from postpartum care to ongoing primary and specialty care. Obstetrical providers and facilities should offer reproductive life planning discussions and resources, including access to a full range of contraceptive options in accordance with safe therapeutic regimens. Finally, the providers will need to provide patient education focused on general life-threatening postpartum complications and early warning signs, including instructions of who to notify if they have concerns, and time and date of a scheduled postpartum visit [4].

***Reporting/Systems Learning***supports processes in place for every birthing facility to monitor outcomes and process data related to cardiac conditions, with disaggregation by race and ethnicity due to known disparities in rates of cardiac conditions experienced by Black and Indigenous pregnant and postpartum people. For pregnant and postpartum people at high risk for a cardiac event, establish a culture of multidisciplinary planning, admission huddles and post-event debriefs. Finally, perform multidisciplinary reviews of serious complications (e.g. ICU admissions for other than observation) to identify systems issues [4].

***Respectful Care*** provides essential best practices to support respectful, equitable, and supportive care to all patients. Further health equity considerations are integrated into elements in each domain. Every unit, birthing facility, provider, and team member should screen for structural and social drivers of health that might impact clinical recommendations for treatment plans and provide linkage to resources that align with the pregnant or postpartum person’s health literacy, cultural needs, and language proficiency. The care team should be prepared to engage in open, transparent, and empathetic communication with pregnant and postpartum people and their identified support network to understand diagnoses, options, and treatment plans. Finally, this team will include each pregnant or postpartum person and their identified support network as respected members of and contributors to the multidisciplinary care team [4].

The overall format for coordination of the project, like other TIPQC projects, will be via a web-based conference tool. There will be monthly maternal web conferences. The purpose of the conferences is to share “what works and what does not work in our setting” as we realize that any global plan or protocol must work within the context of the local hospital, considering resources, staffing, time commitment, etc. This sharing will assist TIPQC to develop useful guidelines and management protocols/bundles that can be applied in most clinical settings. The final product will be a living product, undergoing constant modification as needed based on the context into which it is applied.

***WHEN:***A limited number of hospitals will participate in the obstetric pilot phase of implementation beginning in January 2024. A full kick off for all state hospital teams will be in late March 2024.

**AIMS, POPULATION, AND MEASURES**

**GLOBAL PROJECT AIM**: Decrease Severe Maternal Morbidity Among People with Cardiac Conditions & Decrease Pregnancy-Related Deaths Due to Cardiac Conditions (utilizing state surveillance monitoring) by 10% across the state by Summer 2026.

**Statewide AIM:** Improve care of patients with cardiac conditions in hospital and/or urgent or emergency care settings by increasing screening and appropriate referrals for at least 90% of all birthing people thereby reducing NTSV C-sections & reducing preterm rates by 10% by June 2026.

**TARGET POPULATION**: Birthing people in TN hospitals and urgent/emergent care departments within the hospital setting.

Measurement Statement: For this bundle, cardiac conditions refer to disorders of the cardiovascular system which may impact maternal health. Such disorders may include congenital heart disease, cardiac valve disorders, cardiomyopathies, arrhythmias, coronary artery disease, pulmonary hypertension, and aortic dissection. An ICD-10 codes list of cardiac conditions will be used when calculating outcome and ***state surveillance data***.

**MEASURES**

**I. Outcome Measures**

***Frequency of collection & reporting: monthly***

1. Percent of NTSV Cesarean Birth Rate Among People with Cardiac Conditions

* Denominatorٰ¹: Among people with cardiac conditions, those with live births who have their first birth ≥ 37 completed weeks gestation and have a singleton in vertex (Cephalic) position
* Numerator: Among the denominator, those with a cesarean birth

2. Percent of Preterm Birth Rate Among People with Cardiac Conditions

* Denominator¹: Singleton live births among people with cardiac conditions
* Numerator: Among the denominator, preterm live births (<37 completed weeks gestation)

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¹ Reference: the AIM “Data collection Plan” for the Cardiac conditions in Obstetric Care Bundle. The definition has been directly copied and pasted.

**II. Process Measures:**

*Frequency of collection & reporting: monthly and quarterly*

**\*Process Measure #1, #2 and #3 should be reported monthly**

#1. Percent of Standardized Pregnancy Risk Assessments for People with Cardiac Conditions

* Denominator: Patients with cardiac conditions diagnosed prior to birth admission
* Numerator: Among the denominator, those who received a pregnancy risk classification using a standardized cardiac risk assessment tool by time of birth admission.

#2. Percent of Cardiovascular Disease (CVD) Assessment among Pregnant and Postpartum Women

* Denominator: All birth admissions
* Numerator: Among the denominator, those with documentation of a cardiovascular disease assessment using a standardized tool

#3. Percent of Multidisciplinary Care Plan for Pregnant People with Cardiac Conditions

* Denominator: Patients with cardiac conditions diagnosed prior to birth admission
* Numerator: Among the denominator, those who had a multidisciplinary care plan for birth established by time of birth admission

**\*Process Measure #4 - #8**

*Frequency of collection & reporting: and quarterly*

#4. OB Provider Education – Cardiac Conditions

* + - Cumulative proportion of delivering physicians, midwives who have completed an education program on cardiac conditions
    - Report estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#5. Nursing Education – Cardiac Conditions

* + - Cumulative proportion of nursing staff who have completed an education program on cardiac conditions
    - Report estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#6. OB Provider Education – Respectful and Equitable Care

* + - Cumulative proportion of delivering physicians, midwives who have completed an education program on Respectful and Equitable Care
    - Report estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#7. Nursing Education – Respectful and Equitable Care

* + - Cumulative proportion of nursing staff who have completed an education program on Respectful and Equitable Care
    - Report estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#8. ED Provider Education – Cardiac Conditions

* + - Cumulative proportion of ED providers and mid-level providers who have completed an education program on cardiac conditions in pregnant and Postpartum people.
    - Report estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#9. ED Nursing Education – Cardiac Conditions

* + - Cumulative proportion of ED nursing staff who have completed an education program on cardiac conditions in pregnant and Postpartum people.
    - Report estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

**III. Structure Measures**

*Frequency of collection & reporting: quarterly.*

#1. Multidisciplinary Pregnancy Heart Team (PHT)

* + Does your hospital have a multidisciplinary Pregnancy Heart team appropriate to the Maternal Level of Care to coordinate clinical pathways for people experiencing cardiac conditions in pregnancy and the post-partum period including cardiologist, anesthesiologist, maternal fetal medicine (MFM), obstetrics, obstetric anesthesia, cardiac anesthesia, pharmacy, emergency medicine, intensive care, cardiac surgeons, interventional cardiologists, electrophysiologists, HF Specialists, nursing, and social workers.
  + Establish a multidisciplinary Pregnancy Heat Team
    - Report completion estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#2. ED Screening for Current or Recent Pregnancy

* + Integrate standardized screening for current or recent pregnancy into the ED
    - Report completion estimates in 10% increment s(0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#3. Patient Education Materials on Urgent Postpartum Warning Signs

* + Has your hospital integrated patient education on urgent postpartum warning signs into discharge teaching (or other times)?
  + Do these education materials provided to parents encourage discussion with providers?
    - Report completion estimates in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#4. Multidisciplinary Case Reviews for CCOC Bundle

* + - Care providers should establish a process and perform multidisciplinary case reviews of specific cases, including:
      * Critical care/ICU admissions for other than observation
      * Those at the highest levels of risk, such as Modified World Health Organization (mWHO) risk levels III and IV
    - Report completion estimate in 10% increments(0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

#5. Patient Event Debriefs

* + Has your hospital developed and implemented a standardized process to conduct debriefs with patients after a severe event?
    - Report completion estimates in 10% increments(0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%)

**CHARTER**

An inter-professional team of Tennessee obstetric providers selected Cardiac Conditions in Obstetric Care (CCOC), along with TIPQC’s maternal arm, in conjunction with the Alliance for Innovation on Maternal Care (AIM). Additionally, TIPQC noticed deficits in statewide maternal care for cardiac screening and referral networks for birthing people.

The TIPQC Maternal Arm with AIM collaborated to bring this project to fruition in Tennessee. AIM is a national data-driven maternal safety and quality improvement initiative based on proven implementation approaches to improving maternal safety and outcomes in the US. AIM’s goal is to eliminate preventable maternal mortality and severe morbidity across the United States (US). AIM works through state teams and health systems to align national, state, and hospital level quality improvement efforts to improve overall maternal health outcomes. AIM is funded through a cooperative agreement with the Maternal and Child Health Bureau (MCHB)-Health Resource Services Administration.

Stakeholders at the 2023 TIPQC Annual meeting selected the Cardiac Conditions in Obstetric Care (CCOC) project as the focus of 2023 Quality improvement efforts. Participating institutions will agree to the following: implementing the project as designed, collecting, and submitting the monthly data in a timely manner, and participating in monthly webinars (conferences) and statewide meetings. The TIPQC Maternal Arm’s goals are to work with the medical leaders across the state to implement policies, procedures, and protocols in delivering facilities within the state of Tennessee.

**TOOLKIT**

A tool kit has been developed by the TIPQC Maternal Arm in conjunction with the AIM Bundle.

**DATA COLLECTION & REPORTS**

**Data Entry**

Participating hospital teams will complete data entry training provided by TIPQC. Team members identified in the project application will be granted access to the project’s SimpleQI data resources and enter data in the SimpleQI platform. Details, data handling and security, compliance and oversight measures in this platform are in the TIPQC application and DUA (as listed). No changes in data management are anticipated.

**Security:** SimpleQI is hosted in Microsoft Azure’s Secure Cloud Platform as a Service (PaaS) infrastructure and is continuously monitored for security breaches. Azure would notify SimpleQI upon any such breach affecting the platform. SimpleQI would assess the impact and work with Azure to remedy the situation and would also assess if any data was compromised and notify the affected customers of such a breach within 24 hours.

**Data Handling:** SimpleQI uses an SSL Protocol to secure the Platform. SimpleQI employs industry standard precautions designed to protect your information from unauthorized access. SimpleQI ensures that data is encrypted at rest. SimpleQI will make any legally required disclosures of any breach of the security, confidentiality, or integrity of unencrypted electronically stored personal data via email or conspicuous posting on this Platform in the most expedient time possible and without unreasonable delay, consistent with (i) the legitimate needs of law enforcement or (ii) any measures necessary to determine the scope of the breach and restore the reasonable integrity of the data system. No method of transmission over the internet or method of electronic storage is 100% secure. Simple QI cannot promise, nor should it be expected, that personal data or private communications will always remain private. SimpleQI cannot guarantee complete security. SimpleQI currently stores user information via secure cloud-based web hosting services, provided by Microsoft Azure and the information is stored on servers located within the United States.

**Retention of Data:** SimpleQI retains personal data when there is an ongoing legitimate business, legal, or compliance need to do so. Retention periods will vary depending on the type of personal data. The general factors considered in determining whether to retain personal data are:

* Whether there is a legal or contractual need to retain the information
* Whether the information is necessary to provide services or for functionality of Platform features
* Whether the account holding users have the ability to access and delete the information from their accounts

When SimpleQI has no ongoing legitimate business need to process personal data, data will either be deleted or anonymized or, if this is not possible (for example, when personal data has been stored in backup archives), SimpleQI will securely store such personal data until deletion of such information is possible.

**QI Data Reports**

The various types of periodic reports utilized for this project may include:

- A report consisting of only a local facility’s/center’s data. Teams will not be able to download or see other participating center’s local reports. Teams will use this report to present the facility's/center’s performance at each monthly huddle.

- A report comparing the performance of a local facility/center to the performance of the other participating teams. The other participating teams will be de-identified in this report.

- A report consisting of aggregate data from the collaborative as a whole. The TIPQC state leaders will present this report at each monthly huddle to share the overall performance of all the participating facilities/centers. This report will only be available to TIPQC state leaders.

- A confidential report that compares the overall performance of all of the participating teams. The participating teams will be identified in this report and thus will contain sensitive content. This report will only be made available to the TIPQC state leaders for coaching and improvement purposes.

The core contents of the periodic reports will be determined by group consensus, once data instruments are finalized, no revisions during the project will be made.

Simple QI will upload data into the AIM Data Center on behalf of each participating hospital. The AIM Data Center is a secure online system used to capture data from every state participating in any of the AIM maternal safety bundles. The identity of each participating hospital is masked in the Data Center – only TIPQC and each participating hospital will know the identity of each masked hospital. Each participating hospital will be able to generate any number of reports in the Data Center on their data. Capture of the defined measures in the AIM Data Center is required for participation in this Maternal Safety Bundle.

**RECORD RETENTION**

Record retention described in the TIPQC Framework protocol will be followed.

**RECRUITMENT OF PARTICIPATING INSTITUTIONS**

The recruitment strategy described in the TIPQC Framework protocol will be used and is open to all birthing hospitals and care teams across the state.

**PROCEDURES FOR PARTICIPATING INSTITUTIONS**

The data procedures described in the TIPQC Framework protocol will be used. From the protocol: “Each team will be encouraged to develop procedures to support project implementation, data reporting, and change analysis by the local project team. Substantial local latitude is provided to allow flexibility for integration of TIPQC activities into local workflow and schedules, though a minimum frequency and timeliness of data entry is required and is outlined in the project application and data agreement. In this all-voluntary collaborative, multiple data reporting systems and paradigms will be supported to facilitate the broadest possible participation.”

**TRAINING PLAN FOR PARTICIPATING INSTITUTIONS**

In addition to the TIPQC Framework protocol, teams will be offered additional training at the TIPQC Annual Meeting in March 2024.

**DURATION OF THE PROJECT**

Several pilot teams will begin implementation for several months prior to the project kickoff for all teams. The duration of the project is 2 years. Participants or the TIPQC membership at large may ask the Oversight Committee to extend the project or use it as a building block for future projects with complimentary endpoints.

**ROLE OF THE TIPQC OVERSIGHT COMMITTEE**

The critical role of the TIPQC Oversight Committee is not anticipated to change during this QI project. From the protocol:

* “Throughout the selection, development, pilot testing, and implementation of a project the TIPQC Oversight Committee plays a vital role. The Committee oversees the selection process at the state meeting and is tasked with ensuring that stakeholders who are present can contribute to the selection process. Following project development and pilot testing, the pilot toolkit is reviewed and approved by the Oversight Committee. Upon completion of pilot testing and incorporation of pilot directed modifications, the Oversight Committee reviews and approves the final toolkit for release to potential participants.”
* “Throughout all phases of the project, the Oversight Committee will be informed of any concerning trends in balancing measures and of any potential safety issues. Further the Oversight Committee is empowered to halt any quality improvement project at any time. A project will be stopped if a simple majority of the entire Oversight Committee votes to halt the project. Should a majority of the Oversight Committee vote to stop a project, a message will be sent to all participating centers directing them to stop the project and data collection will be suspended. The message will include both a detailed explanation of the Committee’s concerns and a roll call listing of Committee members' votes- yes, no, abstain, or not present. Given the multiple levels of evidence-based review employed prior to statewide release of the toolkit, early termination of a project by the Oversight Committee is not expected, but a formal mechanism is included should events arise that warrant pausing or halting project participation.
* “The Oversight Committee controls extensions of project duration, or changes in progress scope and is charged with balancing the cost vs. value of any proposed extension or change within the confines of the resources and mission of TIPQC. The Oversight Committee may vote, again by simple majority, to extend project duration or scope or opt to extend the project until the next state meeting for a general membership vote.”

**REFERENCES**

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2. American College of Obstetricians and Gynecologists' Presidential Task Force on Pregnancy and Heart Disease and Committee on Practice Bulletins—Obstetrics. “ACOG Practice Bulletin No. 212: Pregnancy and Heart Disease.” Obstetrics and gynecology vol. 133,5 (2019): e320-e356. doi:10.1097/AOG.0000000000003243
3. Tennessee Department of Health. (2023). 2021 Maternal Mortality Review (MMR). <https://www.tn.gov/content/dam/tn/health/program-areas/maternal-mortality/Racial-Inequities-Providers-2021.pdf>
4. Alliance for Innovation on Maternal Health (2021). Cardiac conditions in obstetric care. <https://saferbirth.org/psbs/cardiac-conditions-in-obstetric-care/>

**ATTACHMENTS**

* TIPQC Participation and Durable Data Use Agreement (TIPQC Participation and Durable Data Use Agreement.pdf)
* TIPQC Project Application
* SimpleQI and REDCap data entry tool
* TIPQC Toolkit