**Protocol: Promotion of Vaginal Delivery (PVD):**

**Optimizing Obstetrical Care**

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**

****

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

**Project Development Team Leaders**

Danielle Tate, MD, MFM

State Project Leader & TIPQC Maternal Medical Director

Connie Graves, MD, MFM

TIPQC State HTN Project Co-Leader

Bonnie Miller, MSN, RN

TIPQC Maternal Quality Improvement Specialist

Brenda Barker, MEd, MBA

TIPQC Executive Director

Theresa Scott, MS

TIPQC Data Manager

 Rolanda Lister, MD

TIPQC Health Equity Officer

**Pilot Teams**

Ascension St. Thomas Midtown

 Ascension St Thomas Rutherford

Baptist Memorial Hospital for Women
Centennial Medical Center

Regional One Health Medical Center

Stonecrest Medical Center

University of Tennessee Medical Center in Knoxville

**EXECUTIVE SUMMARY**

*This Executive Summary defines the 5 W’s (and 1 H) of the TIPQC “Promotion of Vaginal Delivery (PVD): Optimizing Obstetric Care” quality improvement (QI) project. The PVD care aspects of the overall project are also described.*

***WHY:*** Nationally, and throughout Tennessee (TN) there remain unmet needs for Nulliparous, Term, Singleton, and Vertex (NTSV) pregnant person. From 1998 to 2008, cesarean birth rates in the United States rose from 22% to 33% of all births, making it the nation’s most common hospital surgery [1]. The extraordinary rise and remarkable variation in rates of cesarean birth create concern for both the quality and cost of maternity care. As well, the overuse of cesarean birth has proven to be a consistent barrier to providing high-value, high-quality maternity care.

Even though rates of primary and total cesarean birth have recently leveled, there was a rapid rise in cesarean birth rates from 1996 to 2011 specifically. Thirty states and the District of Columbia have Cesarean delivery rates for first-time mothers with low-risk deliveries that are above the Health People 2020 goal of 23.9% [2]. Nationally, Tennessee is in the highest quartile of cesarean birth rates at 34.2%. [3]. Based on 2015-2019 Tennessee Department of Health Vital Statistics data, 75% of TN hospitals have a cesarean birth rate above 20% [4]. There is notable variation in cesarean birth rates among the birthing hospitals in Tennessee, with 31 percentage points separating the facilities with the highest and lowest cesarean rates, 42% versus 11%. According to Leapfrog data [5], the rate of cesarean births among nulliparous, term, singleton, vertex (NTSV) pregnancies range from 11% to 42% among responding TN birthing hospitals.

In addition, the percent of non-Hispanic Black low-risk cesarean birth rates remain higher than all other ethnic groups in Tennessee. According to the recently released 2022 Tennessee Maternal Mortality Report, “Non-Hispanic Black women were 2.5 x more likely to die than white women” during pregnancy or up to one year after pregnancy [6]. Disparities in care are noted in multiple factors such as cesarean birth rates, preterm births, breastfeeding rates, and other areas TIPQC will continue to address through QI hospital team engagement in projects.

The most important group to focus on for cesarean birth reduction (vaginal birth promotion) and labor support are pregnancies that are considered Nulliparous, Term, Singleton, and Vertex (NTSV). NTSV is defined as the first pregnancy beyond 20 weeks gestation (Nulliparous) with a >37 weeks gestation or full-term (Term) single baby in utero (Singleton) in the head down presentation (Vertex). These factors represent the most favorable set of conditions for successful vaginal birth while simultaneously carrying the highest rate of labor complications. It is also the largest contributor to the rise in cesarean rates and exhibits the greatest variation for all subpopulations of cesarean births for both hospitals and providers. However, the NTSV population that can be compared between states, hospitals, and even providers.

***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 women for the safe reduction of primary cesarean birth. 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) and collaboration with the TN Dept of Health, the TN Regional Perinatal Centers, and other state initiatives.

***WHO:***The maternal arm will consist of all members of the obstetric care teams, emergency departments (ED), birthing centers, and Intensive care units (ICUs). In addition, hospital administration support for the promotion of vaginal delivery in NTSV project is essential to provide team leadership, process development, implementation oversight, and quality measurement.

***WHERE:****The maternal arm involves inpatient delivering hospitals and birthing centers in Tennessee.*

***HOW:*** *The maternal arm will improve outcomes by addressing Readiness, Recognition and Prevention, Response, and Reporting. These 4 R’s provide a framework for tackling the numerous barriers and gaps to optimal care for pregnant people.****Readiness****focuses on patient, provider, and community education as well as development of institutional guidelines and protocols.****Recognition and Prevention****emphasizes the importance of standard protocol for standardized admission criteria, triage management, education, and support for women presenting in spontaneous labor. To offer standardized techniques for pain management, and comfort measures that promote labor progress and prevent dysfunctional labor. To offer protocols for timely identification of specific patient problems who would benefit from proactive intervention before labor to reduce the risk for cesarean birth. The****Response****aspect of the bundle focuses on access to treatment, education on facility-wide standard protocols with checklists and escalation policies for management of every labor challenge by standardizing induction scheduling, evidence-based labor algorithms, polices, and techniques, which allow for prompt recognition and treatment of dystocia. This includes the development of protocols in diagnosis in conjunction with timely medical intervention and treatment. Finally,* ***Reporting/Systems Learning****supports the development of mechanisms to collect data and outcomes.*

*A major focus of the maternal arm will be a needs assessment, review of existing maternal protocols for the population, and extensive education for the care team on the overall safe reduction of primary cesarean birth. 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 is applied.*

***WHEN:****A limited number of hospitals will participate in the obstetric pilot phase of implementation beginning in October 2022. A full kick off for all state hospital teams will be in January -March 2023.*

**AIMS, POPULATION, AND MEASURES**

**GLOBAL PROJECT AIM**: To promote safe vaginal delivery for ALL in the birthing population presenting with a nulliparous, term, singleton, vertex pregnancy (NTSV) and thus decrease NTSV cesarean delivery rates to <23.6% (Healthy People Goal 2030) [7] in all participating Tennessee birthing facilities by Summer 2024. This project will include a special focus on the BIPOC (Black, Indigenous, and People of Color) population which data shows has greater disparities in this outcome.

**TARGET POPULATION**: Nulliparous birthing patients with a term, singleton baby in a vertex presentation.

● Nulliparous = first delivery/birth or Para Zero

● Term = ≥37 weeks gestation,

● Singleton = no twins or beyond,

● Vertex position = Cephalic position; no breech or transverse positions.

*This population is also known as the NTSV population.*

**MEASURES**

**I. Outcome Measures**:

*Frequency of collection & reporting*: monthly

**#1. Cesarean delivery rate among NTSV population**

* Denominator[[1]](#footnote-1) = women with live births who are having their first birth ≥37 weeks and have a singleton in vertex (Cephalic) position
* Numerator = among the denominator, all cases with a cesarean birth
* *This is equivalent to the Joint Commission PC-02 measure*

**#2. Cesarean delivery rate among NTSV population after labor induction**

* Denominator1 = women with live births who are having their first birth ≥37 weeks and have a singleton in vertex (Cephalic) position *and with a labor induction*
	+ Induction of labor is defined (by ACOG) as
		- The use of pharmacologic and/or mechanical methods to *initiate* labor.
		- Examples of methods include but are not limited to artificial rupture of membranes, balloons, oxytocin, prostaglandin, laminaria, or other cervical ripening agents
		- Includes both elective AND medically indicated inductions.
	+ A birth would still be counted in the denominator even if any of the following are performed:
		- Unsuccessful attempts at initiating labor
		- The use of pharmacologic and/or mechanical methods to initiate labor following spontaneous ruptured membranes without contractions
* Numerator: among the denominator, all cases with a cesarean birth

**II. Process Measures:**

*Frequency of collection & reporting*: quarterly

**#1. Provider education**

* Cumulative proportion of OB physicians and midwives who have completed (within the last 2 years) an education program on the ACOG/SMFM labor management guidelines that includes teaching on the Safe Reduction of Primary C/S: Support for Intended Vaginal Births bundle and the unit-standard protocol?
	+ Report estimates in 10% increments (0-9%, 10-19%, 20-29%, 30-39%, 40-49%, 50-59%, 60-69%, 70-79%, 80-89%, 90-100%)

**#2. Nursing education**

* Cumulative proportion of OB nurses has completed (within the last 2 years) an education program on the ACOG/SMFM labor management guidelines that includes teaching on the Safe Reduction of Primary Cesarean Section: Support for Intended Vaginal Births bundle and the unit-standard protocol
	+ Report estimates in 10% increments (0-9%, 10-19%, 20-29%, 30-39%, 40-49%, 50-59%, 60-69%, 70-79%, 80-89%, 90-100%)

**III. Structure Measures**

*Participating hospitals to report the date each structure measure has been completed.*

**#1. Patient, family, & staff support**

* Has your hospital developed OB specific resources and protocols to support patients, and family through an unexpected/ traumatic Cesarean?

**#2. Policy & Procedure**

* Does your hospital have an up-to-date new labor guidelines policy and procedure (reviewed and updated in the last 2-3 years) that provides a unit-standard approach for providing labor support, freedom of movement, and management protocols for labor challenges?

**#3. EMR Integration**

* Were any of the recommended tools for the Safe Reduction of Primary Cesarean Section bundle (i.e., order sets, protocols, and/or documentation) integrated into your hospital’s Electronic Medical Record system?

**#4. Multidisciplinary case reviews**

* Has your hospital established a process to perform multidisciplinary bundle reviews on a random sample of 10-20 charts/monthly (depending on hospital size) for NTSV C/S?

**CHARTER**

An inter-professional team of Tennessee obstetric providers selected promotion of vaginal delivery. TIPQC’s maternal arm, in conjunction with the Alliance for Innovation on Maternal Care (AIM). Additionally, TIPQC noticed “gaps” in statewide maternal care for supporting vaginal birth and reducing fist birth cesareans. Although cesarean births can be lifesaving for mother and baby, and medically needed, the rapid rise and extreme variation suggests that the “grey-areas” indications seem to be driving much of these trends. Recent data indicates that term newborn outcomes have not improved in the last 20 years. This rise in cesarean rates has resulted in significant health, social, and economic cost for American women.

The Joint Commission subsequently adopted this metric in 2010 and now requires all hospitals with more than 300 births report their results as part of the Perinatal Core Measure Set. The metric has also been adopted by the Leapfrog Group and Centers for Medicare and Medicaid Services. Several states also require hospital reporting as part of their Medicaid quality initiatives. The NTSV Cesarean Birth measure was re-endorsed as one of NQF’s Perinatal and Reproductive Health measures in 2016, and The Joint Commission is now the steward of the measure. 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. Additionally, TIPQC noticed “gaps” in rate of NTSV cesarean deliveries in birthing facilities across Tennessee.

Stakeholders at the 2022 TIPQC Annual meeting selected the promotion of vaginal delivery (PVD) project as the focus of 2022 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**

See “Appendices.” In addition, the maternal PVD teams will be utilizing resources in the AIM Bundle.

**Data COLLECTIOn & REPORTS**

Participating teams will be capturing the defined Outcome, Process, and Structure Measures in the AIM Data Center. 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. Specific team member’s from each hospital will be granted access to the Data Center. They will be responsible for entering their team’s outcome, process, and structure measures. 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.

Additional Severe Maternal Morbidity (SMM) outcome measures are also required to be captured in the AIM Data Center for participation. This data will be calculated by the Tennessee Hospital Association (THA) for each participating hospital team using specific ICD-10 codes pulled from claims data. TIPQC will receive the tallied counts from THA (on a 2-quarter lag basis) and upload them into the AIM Data Center on behalf of each participating hospital. TIPQC will provide THA with the list of participating hospitals. The participating hospital teams have granted permission for THA to calculate the required measures and for TIPQC to submit the measures to the AIM Data Center. TIPQC will label each participating hospital teams’ data with their masked identifier prior to uploading.

**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.

**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 2023.

**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 1.5 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**

1. Smith H, Peterson N, Lagrew D, Main E. 2016. Toolkit to Support Vaginal Birth and Reduce Primary Cesareans: A Quality Improvement Toolkit. Stanford, CA: California Maternal Quality Care Collaborative.
2. Safe prevention of the primary cesarean delivery. Obstetric Care Consensus No. 1. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:693-711.
3. America's Health Rankings analysis of America's Health Rankings composite measure, United Health Foundation, AmericasHealthRankings.org, accessed 2022.
4. TDH. (n.d.) *Infant Mortality.* Retrieved from Tennessee Department of Health. [*https://urlisolation.com/browser?clickId=A85293A7-2ED1-41DC-8D6D-871DD5C6A1F4&traceToken=1654229408%3Bregionalone\_hosted%3Bhttps%3A%2F%2Fwww.tn.gov%2Fhealth%2Fhealth&url=https%3A%2F%2Fwww.tn.gov%2Fhealth%2Fhealth-program-areas%2Ftennessee-vital-signs%2Fredirect-tennessee-vital-signs%2Fvital-signs-actions%2Finfant-mortality.html*](https://urlisolation.com/browser?clickId=A85293A7-2ED1-41DC-8D6D-871DD5C6A1F4&traceToken=1654229408%3Bregionalone_hosted%3Bhttps%3A%2F%2Fwww.tn.gov%2Fhealth%2Fhealth&url=https%3A%2F%2Fwww.tn.gov%2Fhealth%2Fhealth-program-areas%2Ftennessee-vital-signs%2Fredirect-tennessee-vital-signs%2Fvital-signs-actions%2Finfant-mortality.html)
5. LEAPFROG. (2022). Hospital Safety Grade. Retrieved from The LEAPFROG Group: <https://www.leapfroggroup.org/ratings-reports>
6. TDH. (2022, April 13.) *Maternal Mortality in Tennessee 2017-2020: 2022 Report to the Tennessee General Assembly*. Retrieved from the Tennessee Department of Health (TDH): “2022 Maternal Mortality Annual Report.” Maternal Mortality in Tennessee 2017-2020. Nashville: Tennessee Department of Health, 22 April 2022.
7. HHS. (2022). Reduce cesarean births among low-risk women with no prior births—MICH-06; Healthy People 2030. Retrieved from US Department of Health and Human Services.

Joint Commission. (2019). Specifications Manual for Joint Commission National Quality Measures (v2019A). Perinatal Care (PC-02).

**Appendices**

* TIPQC Participation and Durable Data Use Agreement (TIPQC Participation and Durable Data Use Agreement.pdf)
* TIPQC Project Application
* Redcap data entry tool
* TIPQC Toolkit
1. Reference: the AIM “Data Collection Plan” for the C-section Bundle. The definition has been directly copied and pasted. [↑](#footnote-ref-1)