

Tennessee's Tiniest Babies: The Prevention of Necrotizing Enterocolitis (NEC)
A Tennessee Initiative for Perinatal Quality Care Collaborative
Inter-institutional Improvement Project



Project Development Leaders

Scott Guthrie, MD
State Project Leader & Past TIPQC Infant Medical Director

Eva Dye, MSN, DNP
State Project Leader

Jack Owens, MD
State Project Leader

Patricia A. Scott, DNP, APRN, NNP-BC, C-NPT
TIPQC Infant Quality Improvement Specialist

Brenda Barker, MEd, MBA
TIPQC Executive Director

Alicia Mastronardi, MPH
TIPQC Data Manager

Mary Catherine Burke
Patient & Family Partner

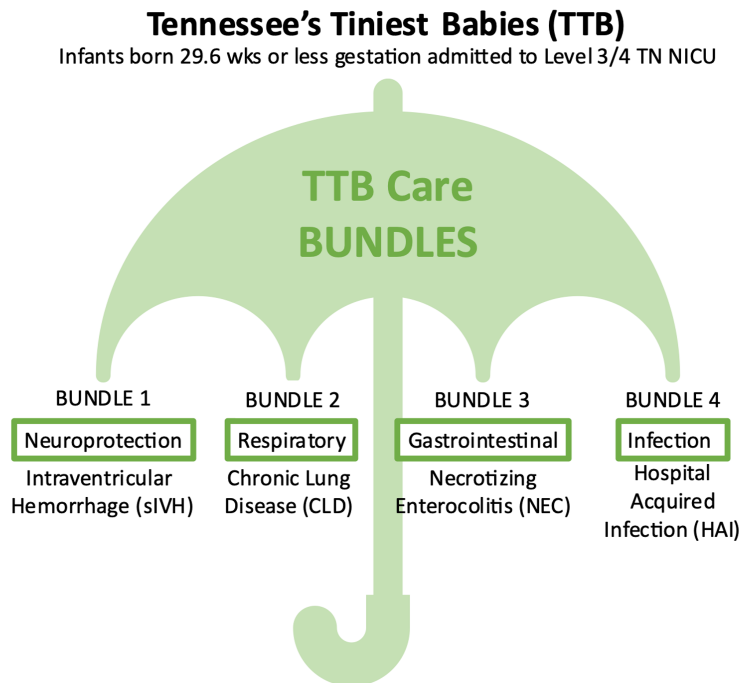
Overview

We are seeking to lower Tennessee’s infant mortality rate to 5 deaths per 1,000 live births by focusing on the implementation of potentially better practices which can improve the survival rates and the outcomes of preterm infants born at less than 29.6 or less weeks gestation.

The development and implementation of the “Tennessee's Tiniest Babies” (TTB) project will occur from Q3 2022 to Q3 2027. The project has been developed and will be launched in phases determined by specific care *bundles* – see Figure 1. The intent is to have participating hospitals implement the care bundles *cumulatively* – incorporating the potentially better practices from each bundle into their unit. *This toolkit is focused on the Necrotizing Enterocolitis (NEC) care bundle.* The project is proposed to end in Q2 2026, with final data Q3 2026.

This quality improvement project will be carried out in individual hospitals with collaborative coordination through the Tennessee Initiative for Perinatal Quality Care (TIPQC).

Figure 1:



Background

Preterm birth is a multi-factorial problem that, despite national and state efforts remains relatively unchanged^{1,2}. Specifically, an increase in the number of the earliest preterm births (infants with birth weights of <750 g and gestational age of <28 weeks) has been implicated as the primary contributor to infant mortality rates³. Very preterm births, defined as <32 weeks and birth weight <1500g, represented 33% of all infant deaths in one report. In this study, more than two thirds of deaths attributable to preterm birth occurred during the first day of life and 27% of deaths occurred within the next 27 days⁴.

Protocol
TIPQC: Collaborative Framework for Statewide QI Project Implementation
Tennessee's Tiniest Babies: Prevention of Necrotizing Enterocolitis (NEC)

Variation in outcomes among NICUs have also been reported^{5 6 7}. Practice variation, even amongst providers in the same group, can be a contributing factor to these varied outcomes^{8 9}. We have fortunately witnessed significant progress in the care of preterm infants over the past few decades. These advances have gradually moved from new technologies and medicines to how we care for these infants. This has led to improved survival rates and outcomes by the centers who have focused on improving the delivery of care¹⁰.

Preliminary Data from Tennessee and Evidence of a Performance Gap

Tennessee has thirteen level 3 and 4 NICUs across the state who care for infants <32 weeks and a birth weight <1500g. In 2020, 1,352 babies, or 1.7% of live births, were born very preterm in Tennessee and cared for at these facilities¹¹. Statistically, this group of infants represents approximately one-third of our state's infant deaths. To lower Tennessee's infant mortality rate, meet the goal as put forth in the "2030 Healthy People" objectives, and improve these outcomes, a collaborative approach to the care along with the implementation of effective care strategies for Tennessee's Tiniest Babies should be undertaken.

Rationale for TIPQC Improvement: Many state collaboratives have worked on decreasing the rate of necrotizing enterocolitis in their respective states. Tennessee has not yet worked on this area of improvement. With state support, education, monthly huddles, learning sessions and data capture, teams should be able to better adopt potentially better practices. These potentially better practices will improve care for Tennessee's Tiniest Babies.

Project Design

Each participating facility/team will:

- Hold regular, at least monthly, team meetings.
- Regularly review and revise your goals, current system, opportunities for improvement, and barriers.
- Plan and conduct tests of the recommended changes detailed in this toolkit.
- After successful testing and adaptation, implement the changes in your facility.
- Attend and actively participate in the monthly huddles, quarterly learning session, and annual statewide meetings.
- Capture and submit the defined project data as required (with minimal to no data lag).
- Submit a monthly report that includes data as well as information on changes being tested and/or implemented.
- Strive to achieve the project aim and the project's process and structure measure goals:
 - At least 90% compliance on all defined process measures.
 - Have all structures (defined by the structure measures) in place by the end of the project.

TIPQC: Collaborative Framework for Statewide QI Project Implementation
Tennessee's Tiniest Babies: Prevention of Necrotizing Enterocolitis (NEC)

Aim

- To reduce the mortality in infants less than or equal to 29.6 weeks gestational age by 25% of the Tennessee state baseline. There should be a dose response effect seen with the implementation of bundles which address broader global aims.

The aim of this NEC care bundle is:

- 25% relative reduction (over last 3 years institutional baseline) in necrotizing enterocolitis in infants less than or equal to 29.6 weeks gestational age in participating TN NICUs by Q2 2026, with final data on Q3 2026.

The proposed aims of the previous and forthcoming care bundles are:

- 25% relative reduction (over last 3 years institutional baseline) in chronic lung disease in infants less than or equal to 29.6 weeks gestational age in participating TN NICUs by Q2 2025, with final data on Q3 2025.
- 25% relative reduction (over last 3 years institutional baseline) in intraventricular hemorrhage in infants less than or equal to 29.6 weeks gestational age in participating TN NICUs by Q2 2024, with final data on Q3 2024.
- 25% relative reduction (over last 3 years institutional baseline) in Hospital Acquired Infections in infants less than or equal to 29.6 weeks gestational age in participating TN NICUs by Q2 2027, with final data on Q3 2027.

Charter

Tennessee's Tiniest Babies: Prevention of Chronic Lung Disease was selected by an interdisciplinary team of Tennessee neonatal care providers. Units representing multiple Tennessee perinatal regions indicated their willingness to fully participate in the project if implemented on a statewide basis. By completing the project application, each participating unit agrees to fully implement the project as designed, collect and submit the required monthly data in a timely manner, and participate in monthly webinars and statewide face-to-face meetings.

Toolkit

For this project, the *Tennessee's Tiniest Babies: Prevention of Necrotizing Enterocolitis (NEC)* Tool Kit was written by experts in neonatal care from across the state. The information within the tool kit was developed using the most recent evidence. A comprehensive reference list for further reading is included.

Measures

Target population: Infants born 29.6 or less weeks gestation admitted to one of the participating NICUs for care. This includes all infants including transfers admitted within 24 hours of birth.

TIPQC: Collaborative Framework for Statewide QI Project Implementation
Tennessee's Tiniest Babies: Prevention of Necrotizing Enterocolitis (NEC)

Outcome measures:

- #1. Percent necrotizing enterocolitis (NEC)* among targeted infants born 29.6 or less weeks gestation admitted to one of the participating NICUs for care
- #2. Percent mortality of targeted infants with NEC
- #3. Percent mortality by hospital discharge or 40 weeks corrected gestational age, whichever comes first (among targeted infants)

These outcome measures will be calculated from the captured "TIPQC TTB-NEC Clinical Care Checklist form in Simple QI - see Appendix.

Baseline data: Retrospective data source: VON criteria.

- Participating NICUs will retrospectively capture and report **annual** baseline data for the previous 3 years (2021, 2022, 2023) including:
 - Annual NEC rates among infants born ≤ 29.6 weeks.
 - Annual mortality rate of NEC among infants born ≤ 29.6 weeks
 - Percent mortality by hospital discharge or 40 weeks corrected gestational age, whichever comes first (among targeted infants born ≤ 29.6 weeks)
- This baseline data will serve as the "institutional baseline" for measuring a planned relative reduction in rates.

NEC is diagnosed by radiographic and clinical definition 10 days of life or later and includes at least one of the following clinical findings:

- Bilious gastric aspirate, residual or emesis
- Abdominal distension or discoloration
- Occult or gross blood in stool (no fissure)

AND at least one of the following diagnostic imaging findings:

- Pneumatosis
- Portal venous gas
- Pneumoperitoneum

Process Measures:

- Percent of targeted infants receiving mother's own milk at any point during hospitalization
- Percent of targeted infants receiving mother's own milk from day 21-28 of their hospitalization
- Percent of targeted infants receiving oral immune therapy at any point during hospitalization
- Percent of targeted infants with cord clamped ≥ 60 seconds after birth

These Process measures will be calculated from the captured "TIPQC TTB-NEC Clinical Care Checklist form in Simple QI - see Appendix.

Structure Measures:

In addition, participating NICUs will report the following Structure measures quarterly:

- Policy & Procedure
 - Standardized policy and procedure updated last 2-3 years for each of the following:
 - Feeding,
 - Transfusion practices,
 - Antibiotic stewardship, and
 - Oral immune therapy.
- Provider and Nursing Education
 - Addressing non-evidence-based practices and FDA approved medication and updates,
 - Feeding Intolerance,
 - Care of feeding tubes, residuals.

Participating NICUs will report progress for these structure measures in 10% increments (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%) quarterly.

These Structure measures will be calculated from the captured “TIPQC TTB-NEC Quarterly Capture of Structure Measures” in Simple QI .

Balancing Measures:

- Days on TPN first month of life
- Number of blood cultures drawn until 40 weeks’ CGA and number of positive blood cultures
- NPO first month of life for greater than 24 hours related to “feeding intolerance”

These Balancing measures will be calculated from the captured “TIPQC TTB-NEC Clinical Care Checklist form in Simple QI - see Appendix.

Data Entry

Participating NICU 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 the SimpleQI platform for all measures. Details of the system, data handling and security, compliance and oversight measure are specified in the TIPQC Framework protocol and the TIPQC Participation and Data Use Agreement. No changes in data management are anticipated.

QI Data Reports

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

Protocol

TIPQC: Collaborative Framework for Statewide QI Project Implementation

Tennessee's Tiniest Babies: Prevention of Necrotizing Enterocolitis (NEC)

- A report consisting of only local facility's/center's data. Participants will not be able to download or see other participating center's local reports, nor will other participating centers have access to other hospital local report. This report can be used to present each facility's / center's performance at each monthly huddle.
- A report comparing the performance of 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 of 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 course of the project will be made.

Record Retention

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

Recruitment of participating centers

The recruitment strategy described in the TIPQC Framework protocol will be used.

Procedures for participating centers

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 centers

No changes in the training plan outlined in the TIPQC Framework protocol are anticipated for this QI project.

Duration of the project

The duration of the project is at least 12 months. 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 have the opportunity to 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 member's 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.

Finally, the Oversight Committee controls extensions of project duration, or changes in progress scope. The Oversight Committee 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

- ¹Gupta, R. & Froeb, K. (2020). Preterm birth. *The Journal of Perinatal & Neonatal Nursing*, 34(2), 99-103. doi: 10.1097/JPN.0000000000000469
- ²March of Dimes. *Preterm Birth: Tennessee, 2010-2020*. March of Dimes. Retrieved July 6, 2022, from <https://www.marchofdimes.org/peristats/data?reg=99&top=3&stop=60&lev=1&slev=4&obj=1&sreg=47>
- ³MacDorman, M. F., Martin, J. A., Mathews, T. J., Hoyert, D. L., Ventura, S. J. (2005). Explaining the 2001–02 infant mortality increase: Data from the linked birth/infant death data set. *Natl Vital Stat Rep.*, 53(12), 1–22.
- ⁴Callaghan, W. M., MacDorman, M. F., Rasmussen, S. A., Qin, C., & Lackritz, E. M. (2006). The contribution of preterm birth to infant mortality rates in the United States. *Pediatrics*, 118(4), 1566–1573. <https://doi.org/10.1542/peds.2006-0860>
- ⁵Horbar, J. D., Badger, G. J., Lewit, E. M., Rogowski, J., & Shiono, P. H. (1997). Vermont Oxford

Tennessee's Tiniest Babies: Prevention of Necrotizing Enterocolitis (NEC)

Network. Hospital and patient characteristics associated with variation in 28-day mortality rates for very low birth weight infants. *Pediatrics*, 99(2), 149–156.

⁶Lee, S. K., McMillan, D. D., Ohlsson, A., & et al. (2000). Variations in practice and outcomes in the Canadian NICU network: 1996-1997. *Pediatrics*, 106(5), 1070–1079.

⁷Vohr, B. R., Wright, L. L., Dusick, A. M., & et al. (2004). Neonatal Research Network. Center differences and outcomes of extremely low birth weight infants. *Pediatrics*, 113(4), 781–789.

⁸Institute of Medicine - Committee on Quality of Health Care in America. (2001). *Crossing the quality chasm: A new health system for the 21st century*. National Academies Press.

⁹Aziz, K., McMillan, D. D., Andrews, W., & et al. (2005). Canadian Neonatal Network. Variations in rates of nosocomial infection among Canadian neonatal intensive care units may be practice-related. *BMC Pediatr.*, 5(1), 22–34.

¹⁰Bell, E. F., Hintz, S. R., Hansen, N. I., Bann, C. M., Wyckoff, M. H., DeMauro, S. B., Walsh, M. C., Vohr, B. R., Stoll, B. J., Carlo, W. A., Van Meurs, K. P., Rysavy, M. A., Patel, R. M., Merhar, S. L., Sánchez, P. J., Laptook, A. R., Hibbs, A. M., Cotten, C. M., D'Angio, C. T., Winter, S., & et al. (2022). Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Mortality, in-hospital morbidity, care practices, and 2-year outcomes for extremely preterm infants in the US, 2013-2018. *JAMA*, 327(3), 248–263. <https://doi.org/10.1001/jama.2021.23580>

¹¹March of Dimes. *Infant Mortality Rates: Tennessee*. Retrieved July 6, 2022, from <https://www.marchofdimes.org/peristats/>

Appendices

- TIPQC Participation and Durable Data Use Agreement (TIPQC Participation and Durable Data Use Agreement.pdf)
- TIPQC Project Application
- TIPQC TTB-NEC Clinical Care Checklist form
- TIPQC TTB-NEC Quarterly Capture of Structure Measures