TIPQC Quality Improvement Project Application:
Optimizing Care of the 35-36 Week Infant
in the Newborn Nursery

PROJECT DETAILS

The challenge: The late preterm infant (LPI) is an infant born between 34 0/7 weeks and 36 6/7 weeks gestation. LPIs account for approximately 75% of the preterm births in the US and for approximately 20% of the NICU admissions.[1] The LPIs are often referred to as the "great imposter" because their size is misleading, often being metabolically and physiologically immature. The morbidity rate approximately doubles for every week below 38 weeks gestational age at birth. They are also more likely to be re-hospitalized within 2 weeks of discharge, usually due to hyperbilirubinemia or feeding difficulties.[2] A large Kaiser cohort in 1998-2000 showed readmission occurred in 4.4% of LPIs compared to 2.0% of term infants; 26% of the time due to poor feeding.[3]

Charter: The TIPQC "Improving the Care and Outcomes of the Late Preterm Infant" Project (i.e., the "LPI Project") was selected by an interdisciplinary team of Tennessee 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.

Aim: Improve the care and outcomes for infants born between 35 0/7 to 36 6/7 weeks by systematically implementing evidence-based practices to achieve a 10% reduction in readmission rates (within one week of discharge) by March 2019.

Immediate AIM: Improve practice reliability of 35-36 week newborns by 15% by March 2019, by systematically developing and implementing evidence-based practices focused on delivery room care, transition, infection, nutrition, parent education, and discharge readiness.

References:
[1] McCormick MC, Escobar GJ, Zheng Z, Richardson DK. (2006). Place of birth and variations in management of late preterm ("near-term") infants Semin Perinatol. 2006;30;44–47.
[2] Shapiro-Mendoza CK, Tomashek KM, Kotelchuck M, Bar eld W, Nannini A, Weiss J, et al Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk Pediatrics. 2008;121:e223–232.
[3] Escobar GJ, Clark RH, Greene JD Short-term outcomes of infants born at 35 and 36 weeks gestation: we need to ask more questions Semin Perinatol. 2006;30:28–33.

APPLICATION SUMMARY

The Tennessee Initiative for Perinatal Quality Care (TIPQC) is a statewide Quality Improvement Collaborative founded in 2008 that is funded by the Tennessee Department of Health. TIPQC is charged with improving health outcomes for mothers and infants in Tennessee by engaging key stakeholders in a perinatal quality collaborative that will identify opportunities to optimize birth outcomes and implement data-driven, provider and community-based performance improvement initiatives. Please visit www.TIPQC.org for more information.

This document is designed to facilitate the successful participation of a multi-disciplinary local QI team working in your center on the
    "Improved Care and Outcomes of the Late Preterm Infant" (i.e., "Late Preterm") project.
Completion of this document
    1. specifies the composition of your improvement team;
    2. identifies executive sponsorship and medical oversight of your team's work;
    3. specifies personnel authorized to submit local data and receive local QI reports, and/or authorize and request a download a team's data; and
    4. confirms that your improvement team's collection of local data and execution of this QI project will be reviewed and monitored in accordance with local governance policies and procedures for QI projects in your center.

Requirements:
  ▪ Execution of a TIPQC Data Use Agreement between your facility or practice with the Tennessee Department of Health is required *prior* to review of this Project Application.
  ▪ Completion of this entire Project Application is required before your team can participate in the project.

Please contact Brenda.barker@tipqc.org with questions.

APPLICATION

Forming the local Quality Improvement Team

Convening your quality improvement team is a critical first step to success. Typically the core team membership will include 5-8 members who "own" critical components or are direct stakeholders in the process or processes involved in the improvement project. Suggested team composition includes Project Champion, Physician Champion, Nursing Champion, Unit Medical Director, Unit Nursing Management, Front Line Nursing, Respiratory Therapists, Nursing Educators, Infection Control Practitioners, Nurse Practitioners, Midwives, Physicians, Pharmacists, Family Members, Patient Safety Officer, Quality Improvement Office, Joint Commission Data Extraction and Reporting Office, Pharmacy, CPOE and EMR Implementation Experts. *Please provide your team information and indicate each team member using the table provided at the end of this application.*

Team expectations include:

1. Create a core team, and designate a *Project Champion* for day-to-day management of the project. Each team will need a *Physician* and *Nursing Champion* as well as *Patient/Family member*.
2. Obtain local executive support for the project and schedule frequent executive champion updates on project progress, challenges and opportunities.
3. Obtain local review and approval for QI project initiation and continuation in compliance with local guidelines and policies (e.g. IRB, Quality Council, Practice Board etc.)
4. Conduct frequent (consider weekly, but at least monthly) team meetings.
5. Keep up to date on data collection and resolution of potential data entry errors in the TIPQC/TDH REDCap system.
6. Implement changes using a PDSA methodology - *ask the 3 questions, then PDSA.*
7. Participate in all TIPQC webinars, and regional and State meetings by sharing your team's REDCap reports and lessons learned from your PDSA implementation of Potentially Better Practices in the Project Toolkit. *Everyone teaches, everyone learns!*

Local Oversight and Governance for this QI Project – IRB or Quality Council Approval

Substantial inter-institutional variation is recognized for the review and approval process for QI projects. *Please indicate which governance model is used in your facility or practice, and confirm that this project has been reviewed and participation has been approved by the appropriate entity in your setting:*

Governance model: This project has been reviewed by (initial by appropriate entity):

- _____ Our facility or practice's IRB

- _____ Our facility or practice's Quality Council or similar QI governance entity

- _____ Other (please describe): _____

Confirmation of review and approval: This project has been reviewed in compliance with local policies and procedures for the governance of QI projects. The team has received approval to participate in the project. Documentation of local review and approval will be maintained in our facility or practice throughout our participation in the project, and for at least one year after the project concludes.

Signature of *Project Champion*:_____

Print Name: _____Date:_____

Acknowledgment of Local Medical Oversight & Approval from Medical Director, Service Chief, Chief of Medical Staff, or Chief Medical Officer

This project seeks to effectively and efficiently implement evidence-based practice in an active clinical care setting. QI tests of change that introduce new processes or modify existing processes require assurance of local medical oversight of the work of the improvement team. This application requires identification of the physician champion who will be responsible for medical oversight of your institution or practice's implementation of this project. The Physician Champion is also responsible for gaining approval from the Medical Director, Service Chief, Chief of the Medical Staff, or Chief Medical Office (as appropriate) for participation in this project. *Please have the Physician Champion complete this section (initial and signature).*

- ▪ _____ I have read the project application and tool kit.

- ▪ _____ I agree to provide medical oversight for the work of the improvement team in my facility or practice.

- ▪ _____ I have gained approval from the Medical Director, Service Chief, Chief of the Medical Staff, or Chief Medical Office (as appropriate) for participation in this project.

Signature of *Physician Champion*: _____

Print Name: _____Date:_____

Project Data and Reports: Completion and Security Assurance

This project will be completed under your facility or practice's Data Use Agreement with the Tennessee Department of Health for TIPQC QI Projects. Data and quality improvement reports will be transmitted, analyzed and stored using hardware and software maintained by the Tennessee Department of Health who will be responsible for the security and maintenance of the systems as outlined in the DUA.

Your facility is responsible for maintaining the safety and security of all systems and software that are used in your facility and by your team members. Additionally, your facility is responsible for ensuring that local handling of quality improvement data and reports for this project are in compliance with the DUA and all federal and state regulations.

Additionally, your center agrees to collect and report the data set described in the toolkit, including future collaborative wide modifications to the data set that may become necessary as the project moves forward.   All data will be submitted for purposes of quality improvement, and all participants agree no data or information obtained during this project will be used for promotional or marketing purposes. Private Health Information (PHI) will be used to the minimum extent possible consistent with efficiently and effectively achieving the projects stated Aim.

Data entry and report generation training will be conducted as part of the project kick-off. The responsibility for ensuring the quality and accuracy of the data reported to TIPQC as part of this project resides solely with the individual participating facility or practice. Validation of data and correction of potential data errors that may become apparent during subsequent analysis is likewise, the responsibility of the individual participating center or practice. Questions about data entry, report generation, and data error notifications for this project should be directed to TIPQC.

Should communication regarding specific data records be necessary, this communication will be based on the unique TIPQC record identification number or the assigned date of entry of the field in question.   Participating centers and practices specifically agree they will not provide patient or provider level information to TIPQC that could potentially identify any patients, providers, or provider groups that have been de-identified as part of the project data collection and reporting plan outlined in the project toolkit.

Quality improvement data and report security is a shared responsibility in a large-scale quality improvement collaborative. Three groups of end-users must be identified for your facility or practice to participate in this project: 1) personnel authorized to enter project data, 2) personnel authorized to request/receive standardized reports of QI data, and 3) personnel authorized to request/receive downloads of the your QI data. *Please read the following carefully and then indicate which team members should be granted which access rights related to data entry, reports, and data downloads. IMPORTANT: your center is responsible for contacting TIPQC promptly for any required changes to the listed personnel and/or their access rights.*

1) Data entry: A variety of strategies to optimize data entry have been successfully employed by different centers ranging from a very small number of data entry end-users, to all improvement team members listed above, to multiple clinical end-users. Each approach has its strengths and weaknesses. If you are unsure or would like further consultation on designing your approach, please contact the TIPQC office.

2) QI data reports: Project reports are essential for successful quality improvement using a PDSA methodology. Standardized periodic reports for this project may be downloaded on-demand by authorized personnel at your center using a secure link though the REDCap

interface, or they may be sent to authorized personnel through a secure system *depending on the type of report*. The various types of periodic reports utilized may include:

- A report consisting of only your local facility's/center's data. You will not be able to download or see other participating center's local reports, nor will other participating centers have access to your local report. You will use this report to present your facility's/center's performance at each monthly huddle.
- A report comparing the performance of your 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, but flexibility is available to modify reports as needed in the future.

Potentially better practices to consider for managing QI project data and reports:

- Include at least two people who are authorized to both enter data and review reports. Some data entry error warnings can only be generated in the report. Investigating and correcting this type of data error is easier if the end-user is authorized to enter data and generate reports.
- Grant report generation authorization to senior leaders or executive champions to allow closer monitoring and to facilitate ownership of the outcome of the improvement effort.
- Review authorized personnel periodically as some may have left the project, your facility, or your practice and continued access may no longer be appropriate.

Any external requests to TIPQC for reports where your center is individually identifiable will be referred to your facility or practice's authorized representative listed above.

3) Downloads of QI data: From time to time, TIPQC has received requests to provide downloads of a participating center's project data.   As your center or practice considers whether to authorize this option, we would like to emphasize several critical limitations of this potentially valuable feature.

- TDH software will ensure that the requestor has provided the required authentication credential (username and password), and then will securely transmit the requested data to the device presenting the correct authentication credentials.
- Your center is responsible for the security of the authentication credentials, the device requesting the data download, and for any and all subsequent use, storage and/or transmission of the data. Your responsibility includes continued compliance with the

TDH/TIPQC DUA, the HIPAA/HITECH Act and other Federal regulations as well as local policy and guidelines for the downloaded material.

- Neither TDH, nor personnel working under the TIPQC contract can be responsible for the proper handling, security, or usage of your downloaded data.

While this is a potentially powerful feature that can greatly accelerate QI success, it is not without its risks that require careful consideration and local planning before authorization. *Please check the approach your center prefers for downloading your centers data.*

      No data downloads are authorized.

      Data downloads are only to be completed when one of the authorized personnel indicated contact TIPQC and request a one-time data download. (Note this does not preclude multiple requests over time, but a request must be made for each individual download event.)

Any requests made to TIPQC for direct access to your data as part of a legal, judicial or regulatory action will be referred to the Tennessee Department of Health.

Project Data and Reports: Use and Release
Local project reports based on your local data are prepared by TIPQC for your center or practice's improvement work on this project. Sharing the results, (data, analysis, intervention, and implementation strategy) from local PDSA cycles is essential in order to harness the power of a collaborative approach to data-driven quality improvement. However, local reports where the local center is identifiable will only be prepared for the identified center. Thus, the decision to share your results in an identifiable fashion *within the collaborative* project is left to your institution's change team.

Using your TIPQC analyses or data for purposes other than collaborative quality improvement, specifically using TIPQC analyses or data for contracting, marketing, or promotional purposes, is expressly excluded by the TDH/TIPQC DUA, and is re-confirmed by completion of this agreement.

State level reports will be prepared and distributed by TIPQC, and represent a collaborative patient safety and/or quality improvement work product, and are the intellectual property of TIPQC. State reports may include statewide and regional aggregate analyses, as well as de-identified center comparisons (e.g. center A, center B, center C…). Local centers will be provided with their center identification code in order to compare their performance to other de-identified participants within the state when de-identified center comparisons are prepared. *Release of your center's comparative performance is not permitted, and participants expressly agree they will not use comparative analyses or data for contracting, marketing or promotional purposes*.

In summary, local center or practice reports are provided by TIPQC for the internal use of the individual center or practice and can only be released or published in any form with the written

consent of the individual center (owner of the individual center's data,) *and* the written consent of TIPQC (convener or the collaborative and owner of the aggregate data.)

Unauthorized public release of a TIPQC report where a center is identified may be actionable by the individual center or practice that is identified, by the other non-identified centers and practices that contributed to the aggregated data, and/or by TIPQC.

Recognition of Participation in this TIPQC Project
Completion of this project application serves as authorization to list your center as a participant in this TIPQC project and a contributor to the aggregate result. Such listing may occur in conjunction with data presentations, on the TIPQC website, and when TIPQC is queried about which centers are participating in a given project.

Continued listing as a participant requires timely data entry for monthly summary statistics. This provides TIPQC with sufficient time to analyze the data and prepare reports for each collaborative meeting.

Likewise, accurate data entry (prompt resolution and correction of any automated data checks) is essential, and must be completed by the data entry deadline each month. This helps ensure that aggregate reports prepared by TIPQC for all participants are both up-to date and representative.

Failure to maintain the timeliness and accuracy of your data can result in temporary or permanent removal of your local data from the TIPQC project, as well as removal of your center's name as a participant in this project at the discretion of the Medical Director of TIPQC.

Publication and Presentation of Results
Publication or presentation of results and/or experiences derived from this project may be valuable to others who face similar challenges in implementation of evidence-based Potentially Better Practices. Any contemplated release of data or presentation of collaborative experience should conform to the principles of data ownership and collaborative sharing as outlined above. Permission for data release must be obtained from the data's respective owner(s) before the data is released in any public forum. Specifically, publication of any identifiable center data requires written permission from that center and publication of any aggregate data requires written permission from TIPQC. As this project is by design a collaborative effort, authorship of any publication would ideally reflect the collaborative contribution of each center, each center's project leader, other significant contributors as designated by each center's project leader, and TIPQC. For this collaborative project, authorship will minimally include the primary author of the report. Additional authors will be included based on guidance from the TIPQC Oversight Committee's Projects Subcommittee, and the editorial policies of the venue where the report is submitted.

Statement of Good Faith

We agree that the data submitted by individual centers or practices is the individual property of the submitting center or practice. We agree to collaborate with other participating centers by contributing our data for aggregation and analysis by TIPQC for the purpose of improving our center's delivery of perinatal healthcare. We agree other uses of this data and analysis do not conform to the spirit of collaborative improvement, and we further agree to limit our uses of this data accordingly. Specifically, *we agree we will not use TIPQC project data for contracting, advertising, publicity, or marketing campaigns*.

Senior Leader Authorization and Support

Please have your Senior Leader confirm the following (using initials) and sign.

_____ I have reviewed this application and understand the commitment, objectives and expectations involved in the TIPQC statewide improvement project being carried out in my facility or practice.

_____ I will support the team and will work with them to remove any barriers and/or provide the resources necessary for them to achieve success.

Signature of *Senior Leader*: _____

Title: _____

Print Name: _____Date:_____

Please return this form by date to Brenda Barker, TIPQC Project Manager via FAX at 615-936-8766 or scan to Brenda.Barker@TIPQC.org.   Please keep the original on file in your facility.

TEAM INFORMATION

Facility/Practice Name:

_____

Street Address: Mailing Address:

_____   _____

_____   _____

_____   _____

_____   _____

Describe *the group's* previous experiences with quality improvement projects:

_____

_____

_____

What does the team hope to achieve by participating in this Improvement Project?

_____

_____

_____

TEAM MEMBERS *(page 1)*

IMPORTANT: By being listed below, the individual acknowledges their expected participation in this project.

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

TEAM MEMBERS *(page 2)*
IMPORTANT: *By being listed below, the individual acknowledges their expected participation in this project.*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

TEAM MEMBERS *(page 3)*
IMPORTANT: *By being listed below, the individual acknowledges their expected participation in this project.*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

TEAM MEMBERS *(page 4)*
IMPORTANT: *By being listed below, the individual acknowledges their expected participation in this project.*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*

Name: _____

Title: _____

Email: _____

Phone: _____

Role: **REDCap rights:**
_____ Project Champion   _____ Data entry
_____ Physician Champion   _____ Project reports
_____ Nursing Champion   _____ Data download authorization/
_____ Patient/family member   request *(limit 2)*