

Optimal Cord Clamping

Tennessee Initiative for Perinatal Quality Care

Inter-Institutional Quality Improvement Project

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Project Development Leaders

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

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

Ashley Lerro, RN, CCM, CLC
TIPQC Program Manager

Brenda Barker, MEd, MBA
TIPQC Executive Director

Theresa A Scott, MS
TIPQC Data Manager

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Members of the Optimal Cord Clamping Development Faculty

Brenda Barker, M Ed, MBA
Kirk Bass, MD
Natalie Blaché , MD
Jenn Gibson, MD
Scott Guthrie, MD
Howard Herrell, MD
Claire Leezer, CNM
Ashley Lerro, RN, CCM, CLC
Kim Patterson, DNP, APRN, NNP-BC
Marcelo Rains, MD
Walter Schoutke, MD
Patti Scott, DNP, APRN, NNP-BC, C-NPT
Theresa A Scott, MS
Darshan Shah, MD
Grant Studebaker, MD
Christopher Welsch, MD
Parul Zaveri, MD

Project Pilot Teams

Bristol Regional Medical Center
Erlanger Health System
Greenville Community Hospital
Jackson Madison County General Hospital
Johnson City Medical Center/Niswonger Children’s Hospital
TriStar Hendersonville Medical Center
Regional One Medical Center
University of Tennessee Medical Center in Knoxville
Vanderbilt University Medical Center

Specific Acknowledgments

Howard Herrell, MD
State Project Leader

Jessica Young, MD, MPH
TIPQC Maternal Medical Director

Danielle Tate, MD
TIPQC Maternal Medical Director Elect

Bonnie Miller, MSN, RN
TIPQC Maternal Quality Improvement Specialist

Rolanda Lister, MD
TIPQC Health Equity Officer

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Introduction: *What are we trying to accomplish?*

Problem

Delayed cord clamping is an intended period of time after the delivery of the baby which allows for continued placental circulation and further transfusion of fetal blood to the infant. This delay in cord clamping is typically defined as one minute and has many benefits for the baby. This is a practice that has been recommended by the World Health Organization, the American College of Obstetrics and Gynecology, and the American Academy of Pediatrics. Despite this, hospitals and health care providers in Tennessee are not consistently practicing delayed cord clamping.

No data exists on the rate of delayed cord clamping in newborns born in Tennessee hospitals. The California Perinatal Quality Care Collaborative (CPQCC) reported only 23% of newborns in their PQC received at least 60 seconds of delay prior to clamping. Rates amongst hospitals in the California PQC ranged from 0-74.5%. Tennessee's rate of delayed cord clamping is expected to be similar or worse than what has been reported by the CPQCC.

Finally, recent data show that compared to White neonates, Black and Hispanic neonates are less likely to receive the benefits of delayed cord clamping at the time of birth. Additionally, Black toddlers are more likely to develop iron deficiency anemia which can have a negative impact on normal development and can potentially be ameliorated with a delay in cord clamping¹.

Project Description (*what*)

We are seeking to increase the rate of delayed umbilical cord clamping (defined as clamping the cord 60 seconds after birth) in all infants born at participating delivery hospitals in Tennessee. This is referred to as **optimal cord clamping** since it represents the appropriate time the cord should be clamped based on physiological parameters.

The Optimal Cord Clamping (OCC) project was selected by stakeholders at the 2021 TIPQC Annual Meeting. Project development occurred in Q3 and Q4 2021. The pilot phase of the project was Q1 2022. The start of the statewide roll-out of the project is planned for March 2022. The project is proposed to end in March 2023.

TIPQC agrees to the following:

- Provide this toolkit and other resources to participating teams.
- Offer monthly huddles, quarterly learning sessions, and annual statewide meetings.
- Facilitate the sharing between participating teams, allowing them to learn from each other.
- Facilitate the capture of data metrics and provide reports to participating teams which show their progress towards improvement.
- Provide guidance and feedback to participating teams, facilitating their achievement of the project aim.

Participating teams will agree to the following:

- 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.

Rationale (*why*)

A recent study has suggested that every 10% increase in the rate of the delay in umbilical cord clamping among **preterm infants** at a hospital was associated with a 5% lower hospital mortality rate among neonates².

Participating in the TIPQC OCC Project will help your facility meet recent recommendations from WHO, ACOG, and AAP. This is a low-cost project that does not require new equipment or skills. It will also have a minimal data collection requirement. This is an ideal project for any birthing institution whether a larger center which has participated in multiple TIPQC efforts before, or a smaller hospital interested in their first TIPQC project.

Expected Outcomes and Benefits

If successful, this project is expected to decrease infant mortality rates in Tennessee. Currently Tennessee ranks 42 out of 50 states with an infant mortality rate of 7.1 per 1000 live births³. Based on current evidence, even term babies may have an improvement in neurodevelopmental outcomes. Preterm infants are expected to have a decreased need for blood transfusions, a decreased risk of intraventricular hemorrhage, a decreased incidence of late onset sepsis, and we hope to see an overall impact on mortality rates.

Aim Statement

The aim of this state-wide quality improvement (QI) project is

- To increase to 90% the percentage of infants born in participating TN delivering facilities that do not have their umbilical cord clamped until at least 60 seconds after birth by March 2023.

This project specific aim supports broader global aims:

- To promote Optimal Cord Clamping in all infants born in Tennessee to support better outcomes.
- To eliminate any racial and ethnic disparities that may exist in the practice of cord management in Tennessee with this evidence-based project.

OCC: Evidence, Contraindications, & Special Circumstances

OCC is an evidence-based, simple, and effective non-intervention for improving newborn outcomes.

Summary of Evidence

Term Newborns

A 2011 study weighing babies with the cord intact revealed that these infants received an additional 30-40% of blood volume due to OCC⁴. Other evidence documents an increase in hemoglobin concentration and improved iron status for up to six months after birth. This increase in hemoglobin concentration decreases the risk of early neonatal anemia and iron deficiency without anemia^{5, 6, 7, 8}.

The risk of hyperbilirubinemia and the need for phototherapy is a concern related to delayed cord clamping. This hypothetical concern has not been addressed in the literature. A recent RCT found no significant difference in mean serum bilirubin levels, development of neonatal jaundice, or the need for phototherapy in babies who experienced OCC^{5, 6, 8}.

There is also no evidence that delayed cord clamping negatively affects other neonatal outcomes such as rates of NICU admission, rates of respiratory distress, or lower Apgar scores^{6, 7, 8, 9}. Furthermore, meta-analysis has not demonstrated an increased risk for hypothermia in preterm babies who receive OCC¹⁰.

Preterm Newborns

Preterm infants frequently do not receive the benefits of delayed cord clamping due to the fear that it would impede the initiation of resuscitation. This concern, however, is not validated in the literature and there is accumulating evidence that these babies benefit the most from delayed cord clamping. Neonatal outcomes such as Apgar scores, incidence of respiratory distress syndrome, incidence of jaundice requiring phototherapy, or mortality were not found to be increased in preterm infants who experienced delayed cord clamping^{6, 10, 11, 12}.

It has been reported that a delay of 30-45 seconds in cord clamping in the preterm infant resulted in an increase in blood volume by 8 to 19.3 mL/kg as compared to babies who did not receive delayed cord clamping¹⁰. Benefits for this population include a decreased need for blood transfusions by increasing blood volume and hemoglobin concentration at birth, a decreased risk of intraventricular hemorrhage, and a decreased risk of late-onset sepsis^{6, 10, 12, 13}.

A Cochrane Analysis has found that a delay in cord clamping can reduce the incidence of mortality in preterm infants by nearly a third. The number needed to treat to prevent one death is 30-50 infants and the number needed to treat to prevent a death in infants less than 1500 grams is only 20 infants. The Cochrane Analysis also concluded that “early cord clamping probably causes harm^{9, 14}.”

Benefits found by Andersson et al and Rabe et al^{9, 14, 15} include:

- Reduced need for blood transfusion
- Reduced need for treatment of hypotension
- Reduced incidence of late onset sepsis
- No change in Apgar scores
- Increased number of iron stores
- Improved developmental outcomes

Parents

Qualitative studies using interviews with parents have reported overall positive feedback and support for OCC¹⁶. Mothers report that they felt they could contribute to their preterm baby’s care when they received OCC¹⁷. Parents who are present during stabilization with the cord intact report that they feel reassured by the procedure and that communication is improved¹⁸.

Contraindications

There are almost no indications for early cord clamping, nor contraindications to OCC.

- The need for maternal resuscitation in the face of massive, acute hemorrhage would be a rare, justifiable reason to proceed with early clamping of the cord.
- A ruptured vasa previa, snapped cord, or other trauma to the cord vessels which will result in hemorrhage from the baby are also reasons for early cord clamping.

Special Circumstances

- Complete Placental Abruption
When the placenta is delivered at the same time as the baby, it could be held above the baby, with gentle application of pressure to the placenta, and then clamped at 60 seconds before the placenta is lowered.
- Short Cord Length
A short cord length might interfere with the management of the mother or baby but can usually be addressed with optimal positioning. It should not be considered as an automatic indication for early cord clamping, nor a contraindication to OCC.
- Umbilical Cord Milking
In view of current evidence showing harm for cord blood milking for preterm infants, ACOG and others have recommended against it in the context of preterm deliveries. It is also clear that OCC is preferable to milking in term infants. Where delayed cord clamping is not possible, the potential benefit to milking in term infants is unclear. Therefore, we recommend against cord milking in all cases unless there has been discussion between the obstetric and neonatal providers prior to delivery where a theoretic benefit might exist given a specific clinical circumstance in term or near term newborns¹⁹.
- Multiple Gestation
Studies of multiple births have demonstrated the feasibility of providing OCC to twins and triplets^{20, 21, 22}. Thus, multiple births should not be routinely excluded from OCC. The plan for delivery should be considered on an individual basis with a decision made by an experienced perinatal team ahead of birth.
- Prolonged Stabilization During Fetal to Neonatal Transition
Studies examining initial stabilization during OCC have included widely varying methodologies. Therefore, no firm conclusion can be made at this time regarding safety or benefits^{9, 15}. Over 90% of preterm babies will start to breath during OCC with or without gentle stimulation^{23, 24}. However, some units now undertake initial stabilization with the cord intact routinely (mother-baby dyad intact) and have reported favorably on feasibility and safety^{25, 26}. Where concerns about neonatal wellbeing during OCC cannot be addressed by comprehensive staff education and support at the time of birth, units may wish to explore providing stabilization with the cord intact by collaborating with other teams who already have standard operating procedures and data to support implementation and safety.

SIDE NOTE:

Cord Banking

No consideration was given to cord banking for this project as this is not a very widespread practice. If cord banking has been requested, the course of action should be decided by the physician and the family. An occasional exclusion because of cord banking would fall under the 10% that is allowed for contraindications and would not grossly affect the OC performance of that facility. Theoretically enough blood should still be available to bank after a one-minute delay.

How to Use This Toolkit

This toolkit focuses on providing support and resources to facilitate the implementation of OCC in all babies born in Tennessee, regardless of gestational age.

Included in this toolkit are:

- The rationale for OCC in all babies.
- An overview of quality improvement (QI), specifically in the context of OCC.
- The details regarding the data measures to collect and monitor to see the impact of your changes.
- The guidelines and best practices for OCC as outlined by the American College of Obstetricians and Gynecologists, American Academy of Pediatrics, the World Health Organization, and the British Association of Perinatal Medicine.

We recommend that you review the toolkit in whole. We then suggest focusing on the change ideas and potentially better practices listed in the Key Driver Diagram. It is recommended that all the change ideas and best practices be implemented by the end of the project.

Research your current system and identify the opportunities for improvement. From this, we suggest creating a draft 30-60-90-day plan, which will help your team decide where to start and identify what you want to accomplish in the next 3 months. Thus, allowing your team to determine your first PDSA cycles.

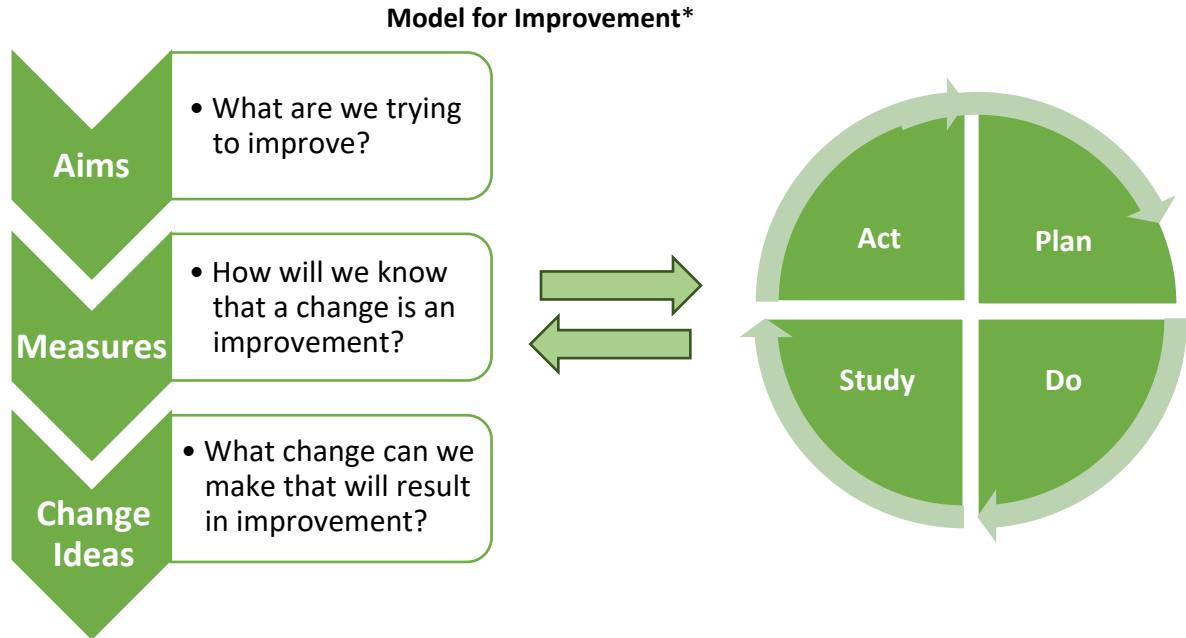
The order of the change ideas on the Key Driver Diagram is the order we suggest (from top to bottom). As you conduct tests of change and accomplish individual change ideas, return to the Key Driver Diagram for your “roadmap” of which change idea to work on next.

This toolkit is intended for application in conjunction with the learning opportunities and webinars offered and facilitated by TIPQC.

Any success realized from this toolkit is in part due to the generosity and collaborative spirit of the team that developed this toolkit, the practices that participated in the TIPQC pilot projects, and from the British Association of Perinatal Medicine who provided ideas and direction.

QI Overview: *The Journey to Optimal Cord Clamping*

All TIPQC inter-institutional QI projects are designed based on the IHI Model for Improvement, which provides the framework for developing, testing, and implementing changes that lead to improvement.



For more information, see <https://tipqc.org/jit-pdsa/>. *Used by permission and adapted from: Langley, Nolan, Nolan, Norman, Provost. *The Improvement Guide*. San Francisco: Jossey-Bass Publishers; 1996.⁷

The following sections provide a more general overview of quality improvement – placed in the context of achieving OCC practices at your facility.

Phase 1: Define the Problem

Where are we now? And how did we get here?

It is important to understand your local data and to consider it in the context of regional, national, and international standards observing any changes over recent years. To achieve this, your team should understand how to look at your local data, what questions to ask and where to access benchmarking data such as the Vermont Oxford Network (VON). The ability to convey these data to the wider team clearly and concisely will facilitate a stronger commitment to the implementation of quality improvement interventions.

Project aim

To increase the percent of infants born in participating TN delivering facilities that have their umbilical cord clamped at least 60 seconds (or more) after birth to 90% by March 2023.

Questions to ask:

1. What proportion of babies at your facility have their cord clamped *at or* after 1 minute?
2. What proportion of babies at your facility have their cord clamped *earlier* than 1 minute?
3. Are the indications for early clamping documented, what are they, and are they appropriate?
4. Has your normothermia data changed?

Understanding barriers and enablers and finding solutions

In this section we describe some of the commonly described barriers and enablers to Optimal Cord Management (OCM). Optimal Cord Management is the process of care which surrounds optimal cord clamping (OCC). This section will provide you with quality improvement tools to integrate your own context and processes, giving examples to get the discussion within your team rolling. We suggest solutions that have worked elsewhere but encourage you to find solutions which are appropriate for your local setting as a solution which works for one team may not be successful in another.

In general, barriers fall into one of these categories:

1. Lack of awareness of benefits of Optimal Cord Management:
 - Carry out a rolling program of education about Optimal Cord Management and its benefits: this may include face to face sessions, online tutorials, posters, safety briefs, and parent hand-outs.
 - Develop a shared guideline for the perinatal team.
 - Identify champions for Optimal Cord Management for both neonatal and maternity teams.
2. Resistance to change:
 - Establish midwifery, obstetric, and neonatal leads for Optimal Cord Management and build a culture of shared responsibility.
 - Identify and empower champions for Optimal Cord Management for both neonatal and maternity teams.
 - Encourage and share parental feedback about their experience of Optimal Cord Management.
 - Ask high performing units to share their improvement journey for Optimal Cord Management.
 - Start small, one birth at a time, and build confidence.
 - Provide regular feedback, invite feedback, and address concerns of staff.
 - Invite this individual or group to join the project team and find ways of working with and not against them.
3. Concerns that Optimal Cord Management may harm the mother:
 - Educate with the evidence that shows Optimal Cord Management is safe for the mother.
 - Encourage maternity and anesthetic staff 'call out' during Optimal Cord Management if concerns arise.
 - Make prebirth huddles with neonatal team routine, where plan is agreed, and actions rehearsed if challenges encountered.
 - If the woman is bleeding, initial obstetric management for e.g., assessing for trauma, clamping of bleeding vessels/applying pressure can continue during Optimal Cord Management.
 - Ensure the team respects and maintains a sterile operating field during OCC.
4. Concerns that Optimal Cord Management may harm the baby:
 - Educate with the evidence that shows Optimal Cord Management is safe for baby and that 'too early' cord clamping is harmful.
 - Provide neonatal support for maternity staff during Optimal Cord Management, either by simply attending the birth of the baby, by providing gentle stimulation to the baby, or where guidelines and training exist, in providing respiratory support.
 - Ensure a package of normothermia care accompanies Optimal Cord Management.
5. Logistical concerns and human factors in carrying out Optimal Cord Management particularly under sterile conditions:
 - Develop a shared guideline for the perinatal team that walks people through the actions and tasks required.
 - Walk through the process and identify risk and logistical issues including human factors (Figure 1).
 - Sketch out a diagram such as a positioning diagram relevant to your unit's layout to guide attendees at birth (Figure 2).
 - Conduct drills and simulation to improve confidence of staff.

Figure 1: Issues to consider when walking through the process of Optimal Cord Management
(Example modified from the British Association of Perinatal Medicine toolkit)

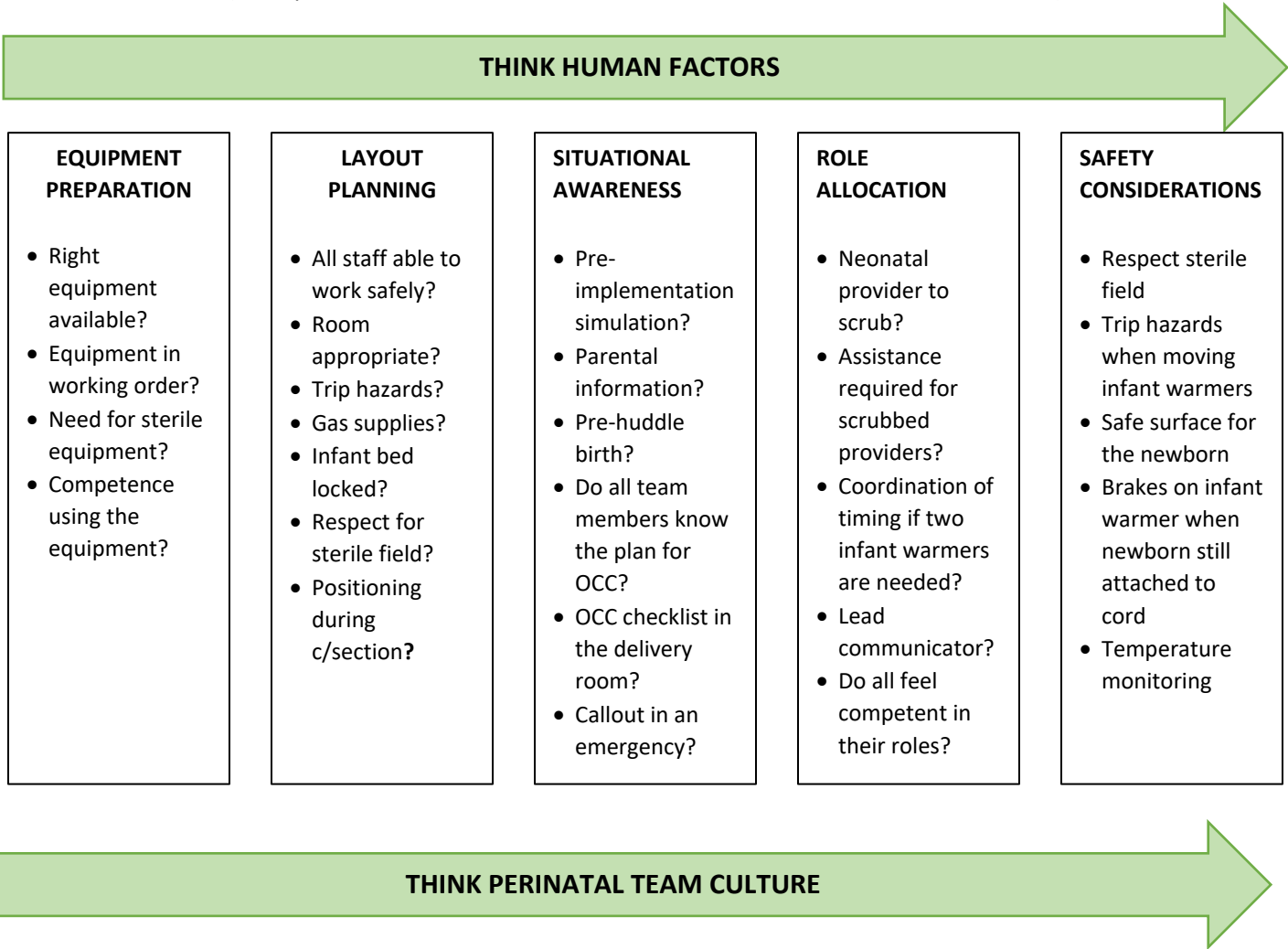


Figure 2: Example positioning for optimal cord clamping at a cesarean section birth
(Provided courtesy of Regional One Health System in Memphis, Tennessee)



Use some of these improvement tools to survey barriers and enablers in your own service:

1. **Forcefield analysis**- this tool balances the positive and negative drivers influencing Optimal Cord Management, with scores assigned to describe the strength of each force. Study, plan, and act to strengthen the weaker positive forces and diminish the resisting forces (Figure 3). Resource: <https://tipqc.org/jit-force-field/>
2. **Pareto Chart**- in categorizing the underlying problem, a Pareto chart gives a visual depiction of the frequency of problems in graphical form, allowing you to target the areas that offer the greatest potential for improvement (Figure 4). Resource: <https://tipqc.org/jit-pareto-chart/>
3. **Fishbone diagram**- cause and effect analysis tool. This is a useful tool for categorizing factors which influence the ability to deliver optimal cord management (Figure 5). Resource: <https://tipqc.org/jit-cause-effect/>
4. **Case review** – take the last 10-20 cases where Optimal Cord Management was not achieved and use a structured review tool to identify any common themes. The BAPM Toolkit has an example case review tool here: https://hubble-live-assets.s3.amazonaws.com/bapm/redactor2_assets/files/831/OCM_Toolkit_Full_For_Launch.pdf (pages 46-48). Consider reviewing 10 cases where optimal cord management was achieved and identify strengths.
5. **Process mapping** – walk through the journey that a preterm baby takes before birth, during birth and immediately after birth and think about the factors within the process and the environment that may contribute to optimal cord management. Resource: <https://tipqc.org/jit-flowcharts/>

Figure 3: Example force field analysis for Optimal Cord Management

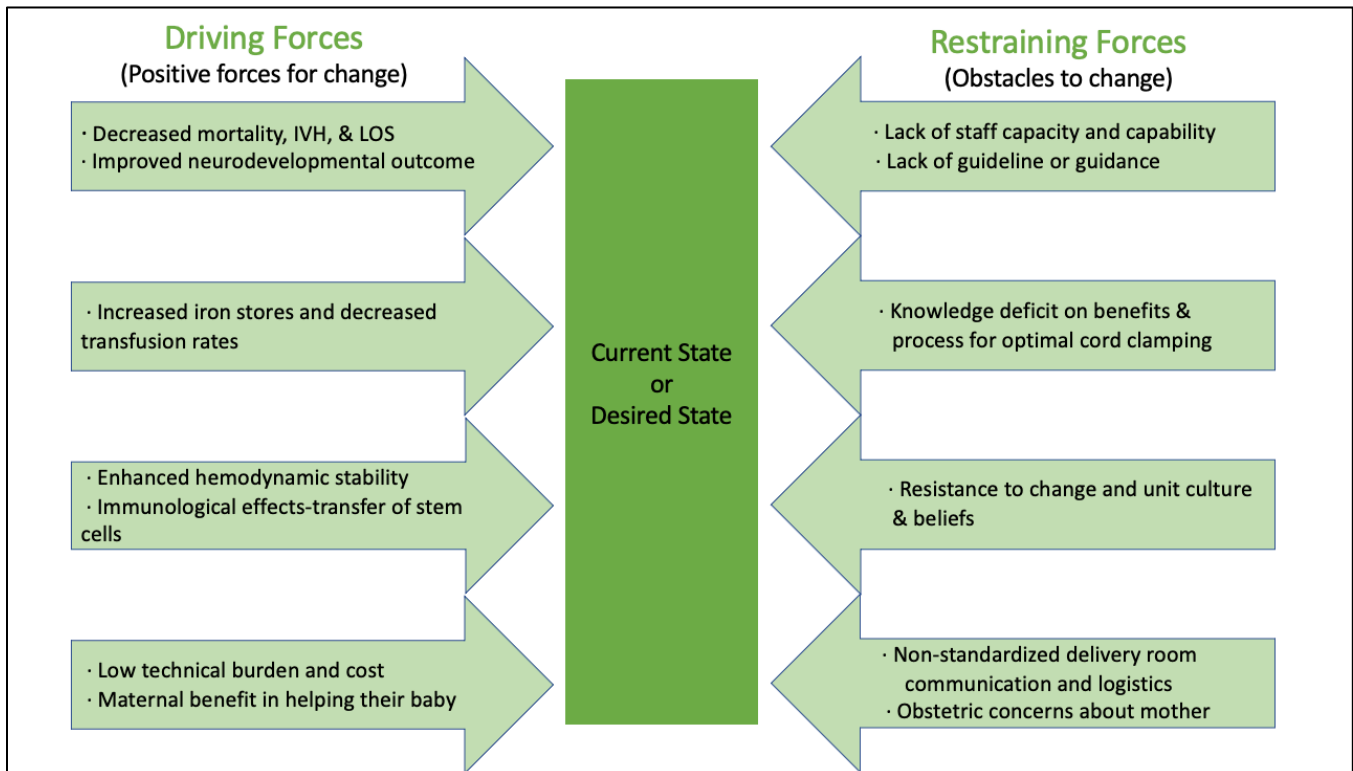


Figure 4: Example Pareto chart for Optimal Cord Management
(Example from the British Association of Perinatal Medicine toolkit)

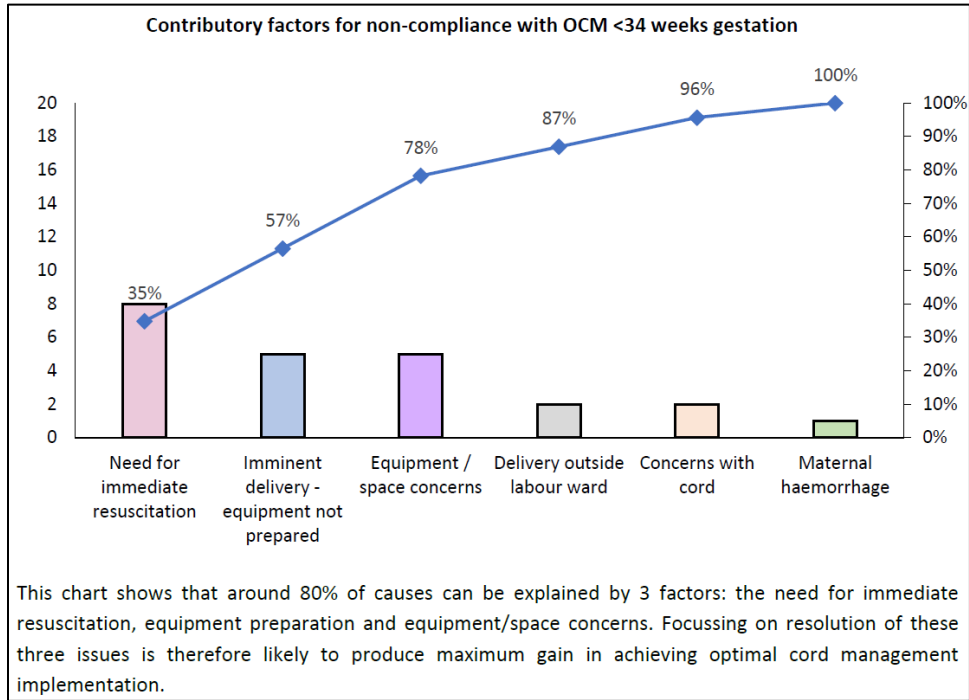
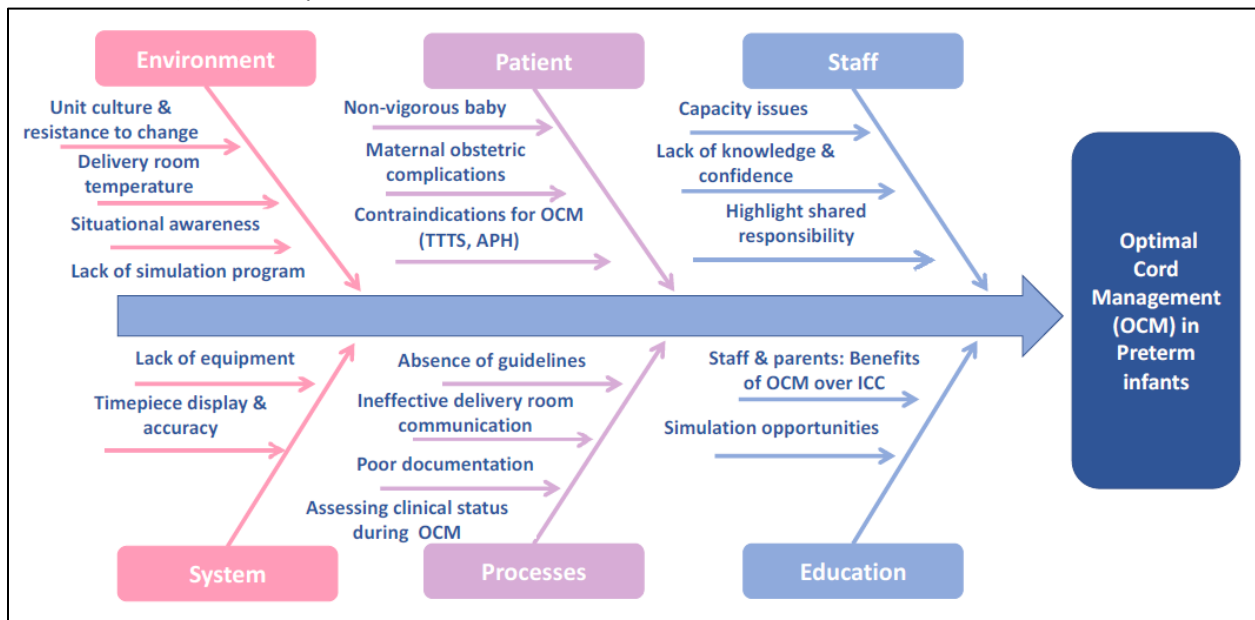


Figure 5: Example fishbone diagram for Optimal Cord Management
(Example from the British Association of Perinatal Medicine toolkit)



Phase 2: Develop a Shared Purpose

The evolution of the perinatal team

Obstetric and neonatal teams all have an important role to play in the safe delivery of care for women in labor and the subsequent care of their baby. This care at times may be delivered in professional silos which has the potential to lead to poor communication and missed opportunities for antenatal interventions which may lead to suboptimal outcomes. Developing a strong perinatal team within your workplace will help facilitate communication, understanding and collaboration across departments and allow more cohesive implementation and embedding of antenatal interventions. Having shared goals, a shared vision and sharing experience ensures your project has momentum and that barriers and enablers can be best appreciated and tackled.

One key component to any successful project is having a team that is engaged, resilient, enthusiastic, and committed to working together to create the right culture for change. Teams should ideally be around 5-8 members. Suggested team composition includes:

- Project champion
- Physician champion
- Nursing champion
- Unit medical director
- Unit nursing management
- Front line nursing
- Nursing educators
- Nurse practitioners
- Midwives
- Physicians
- Patient/family members
- Patient safety officer
- Quality improvement office
- IT/EMR implementation experts
- Depending on the project – pharmacy, anesthesia providers, operating room leader, lactation, physical therapy, etc.

When forming your team consider:

- **Who** are the most influential people within the maternity/neonatal/pediatric team? These may not be the most senior staff members. Consider inviting those who are unsure or oppositional to understand perspective and secure buy in from the outset.
- **Where** are the areas likely to be affected by any changes? Consider staff in these areas.
- **Why** should people want to be involved in your project? Not everyone understands the benefits of OCC, so take the time to educate the staff. Consider how you are going to engage people and maintain their commitment.
- **What** is your expectation of team members? What will they be required to do in terms of time and effort? How will you manage team members who do not deliver on tasks/actions?
- **When** are people available and are the project's time commitments realistic?
- **How** often are you going to meet? Keep up momentum for change, short but frequent meetings.
- **What else** is going on? Are there existing workstreams with overlapping agendas that could be pulled together to prevent duplication. Are there other QI projects which take priority?

Find out if your facility has a central quality improvement team who can facilitate projects and provide valuable skills and knowledge in designing and implementing improvement work. Local data analysts are valuable in helping to collect, analyze, and display data.

Stakeholder engagement

Who else needs to be involved? Start by brainstorming the groups of people likely to be affected by the proposed change. Within the topic of optimal cord management, they are likely to include:

- pediatricians and neonatologists
- neonatal and obstetrical nurses
- obstetricians
- advance practice nurses – practitioners, midwives, CRNAs
- parent groups
- anesthesiologists

Resources:

<https://tipqc.org/jit-teams/>

Phase 3: Plan and Implement Changes

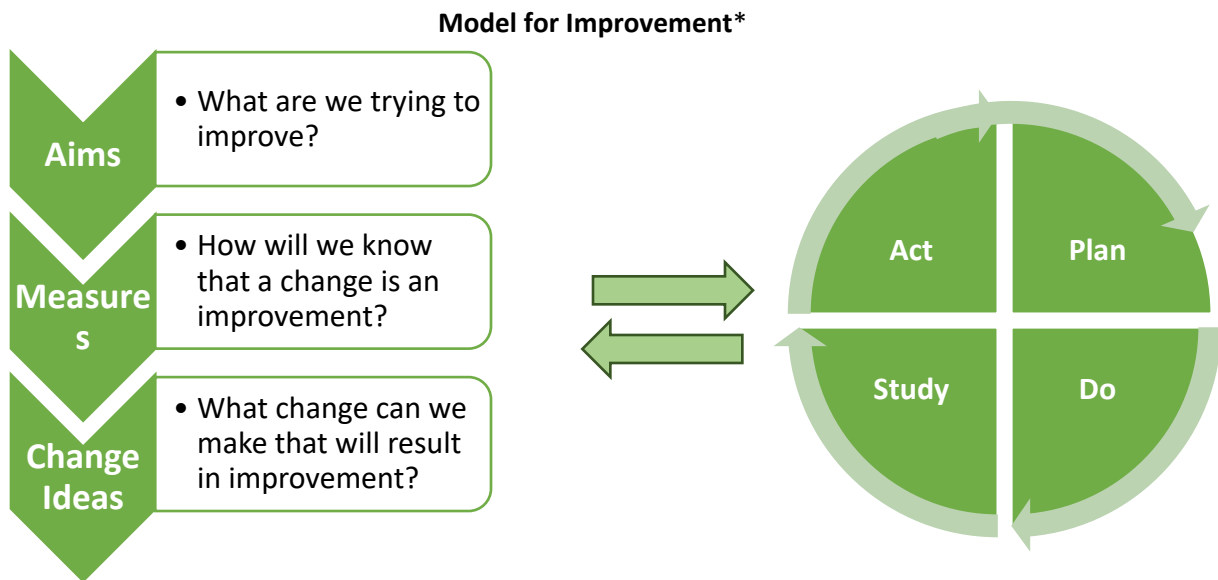
Project Charter

The quality improvement project charter provides a rationale for the team’s work. It can help to clarify the team’s thinking about what needs to be done and why. The charter helps the team keep the focus on a specific problem. The charter also identifies members of the project’s team. An example charter and template can be found here:

<http://www.ihl.org/resources/Pages/Tools/QI-Project-Charter.aspx>

Formulate, prioritize, and test solutions

As mentioned, all TIPQC inter-institutional QI projects are designed based on the IHI Model for Improvement, which provides the framework for developing, testing, and implementing changes that lead to improvement.



For more information, see <https://tipqc.org/jit-pdsa/>. *Used by permission and adapted from: Langley, Nolan, Nolan, Norman, Provost. The Improvement Guide. San Francisco: Jossey-Bass Publishers; 1996.⁷

The Model for Improvement

The IHI Model for Improvement consists of the 3 questions and the Plan-Do-Study-Act (PDSA) cycle. With PDSA cycles, the main idea is a mindset of continuous monitoring and testing of change ideas over time.

Plan

Which intervention(s) will you try first? This may be the intervention most likely to make an impact, the easiest to implement or the one that will best win hearts and minds. How will this intervention be introduced into clinical practice? Who and what will be required to make this happen? Predict what you think the change might be?

Do

When and how will this plan be carried out? A timescale is important. Document problems and unexpected observations.

Study

Use established tools to analyze your data (see Phase 4). Has your change idea resulted in improvement? Is this a real improvement? Does your data suggest your change idea needs to be modified? Why might this be so? Compare your data to your predictions.

Act

Identify and carry out any modifications needed to this change idea to make it more effective, using further PDSA cycles as needed i.e., Adapt, Adopt or Abandon, Repeat. Start with rapid testing your change on a small scale for example small numbers of patients or a specific subgroup of patients. If effective, increase the numbers or widen to include other groups of patients. Test and repeat with increasing scale until you can show effectiveness throughout your patient group.

Resources:

<https://tipqc.org/jit-model-for-improvement/>

<http://www.ihl.org/resources/Pages/HowtoImprove/default.aspx>

Phase 4: Test and Measure Improvement

In this phase, improvements are tested, reviewed, and re-tested (using PDSA cycles) to find a solution.

Measures

Measuring for improvement is different than the data collected for research or to prove whether clinical interventions work or not. This type of measurement asks the questions “how do we make it work in our context?” and “how do we know that a change is an improvement?” It is important that you collect the right data for your project.

Groups of measures collected include

- Outcome measures
 - Reflect the impact on the patient. This may include things like: survival, late onset sepsis, intraventricular hemorrhage, requirement for blood transfusion during the first six weeks of life etc.
- Process measures
 - The way systems and processes work to deliver the desired outcome, e.g., number of babies receiving optimal cord management with cord clamping at or greater than 60 seconds.
- Balancing measures

- This is what may be happening elsewhere in the system because of the change, e.g., the number of babies admitted with a temperature outside the normothermic range.

The measures defined for this TIPQC OCC Project are detailed in the “Measures: How will we know that a change is an improvement?” section.

Data analysis and display

How will any change be measured, assessed, and displayed in your unit or network? Common tools to present and analyze your data include run charts and statistical process control (SPC) charts. All require a level of knowledge and skill to collate and interpret correctly. Importantly, measurement should not be a ‘before and after’ audit which is unreliable in measuring true change, but a continuous process over time during which your changes can be evaluated and modified.

Note that you may choose a different type of chart to be understood by your audience. Run charts and statistical process control charts should always be used by the QI project team in understanding data and assessing change, while other charts and tools may be used to prepare your data in a format which is best understood by frontline staff. You may need an easy-to-read key to explain your chart or provide a summary interpretation.

Resources:

<http://www.ihl.org/resources/Pages/Measures/default.aspx>

<https://tipqc.org/jit-types-of-measures/>

<https://tipqc.org/jit-run-charts/>

<https://tipqc.org/jit-control-charts/>

<http://www.ihl.org/resources/Pages/Tools/RunChart.aspx>

<http://www.ihl.org/resources/Pages/Publications/TheRunChartASimpleAnalyticalToolforLearningfromVariationHealthcareProcesses.aspx>

Phase 5: Implement, Embed, and Sustain

This phase involves the wider implementation of improvements so that change becomes embedded in routine practice throughout the system.

Spread

This can involve formal methods such as *dissemination* that includes presentations, publications, leaflets, learning boards, social media, or informal methods of *diffusion* where word of mouth, champions, and opinion leaders can accelerate your message. Consider carefully what is required for the embedding of changes within your system. It is also important to consider how to disseminate this information to non-participating centers. This could be done through local and regional conferences and at professional organization meetings.

Exception reporting

We recommend that neonatal units undertake a case review when optimal cord management is not achieved using the facility’s risk reporting mechanisms. A case review or audit tool can be used or adapted for this purpose. In this project since we are targeting every delivery, it might be helpful to review the deliveries from every shift or choose a priority gestational age cutoff.

Sustainability

The ability of a service to implement and sustain change is dependent on various strengths and weaknesses of any one project. These can be assessed and addressed from the outset of a project and be reviewed regularly throughout the time course to improve the likelihood of sustaining improvement beyond its lifespan. A useful tool to guide sustainment efforts is available through the IHI at:<http://www.ihl.org/resources/Pages/Tools/HowtoGuideSustainabilitySpread.aspx>.

Barriers and loss of motivation

It is not unusual to find the size of a previous improvement decreases over time. It is important to understand why, so that solutions can be tailored to the problem. Different approaches will be effective for different people and different situations. The following activities may be useful: talk to key individuals, observe clinical practice in action, use a questionnaire to survey staff, and/or brainstorm with a focus group. Education is a key element of overcoming barriers particularly within an interactive forum; using opinion leaders to influence others within your staffing structure; reminder systems to prompt clinicians; and ensuring feedback of data to staff in a format that they find useful; and proper use of parent stories. All these can help to reinvigorate and embed your changes for improvement.

Resources:

<http://www.ihl.org/resources/Pages/IHIWhitePapers/AFrameworkforSpreadWhitePaper.aspx>

<http://www.ihl.org/resources/Pages/Tools/Sustainability-Planning-Worksheet.aspx>

<https://tipqc.org/jit-spread/>

<https://tipqc.org/jit-holding-gains/>

Measures: How will we know that a change is an improvement?

Target population

- All infants born in participating Tennessee delivering facilities.

Outcome measure

- Percent of infants who had their umbilical cord clamped at least 60 seconds (or more) after birth (percent of OCC)
 - Denominator = total number of live births in the month
 - Numerator = among the denominator, number of infants who had their umbilical cord clamped at least 60 seconds (or more) after birth

WORKING DEFINITIONS FOR THIS PROJECT:

Live birth

“Live birth” is defined as the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes, or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

For this project, this should include all viable babies for which active resuscitation was decided upon and/or attempted, regardless of outcome or gestation. It is recommended that all babies ≥ 22 weeks gestation should be reviewed. Active resuscitation would be indicated by an attempt of Bag Mask Ventilation (BMV), an attempted and/or placed endotracheal Tube (ETT), and/or occurrence of chest compressions.

If your facility is utilizing ICD-10 codes for data extraction and capture, the Z37 code for “Outcome of delivery” can be utilized – specifically Z37.0 (Single live birth), Z37.2 (Twins, both liveborn), Z37.3 (Twins, one liveborn and one stillborn), Z37.5 (Other multiples, all live born), and Z37.6 (Other multiple births, some liveborn). In the case of Z37.6, the infant records should be reviewed to determine the exact number of live born for each set of multiples.

- *Frequency of collection & reporting:* monthly
- **NOTE:** “Overall” numerator and denominator counts will be captured as well as counts disaggregated by mother’s race/ethnicity.
 - Defined as Non-Hispanic (NH) White, NH Black, Hispanic
 - The denominator would translate to (for example), the number of live births for mothers who self-identified as White Non-Hispanic. The numerator would then count the number of these *White Non-Hispanic live births* where the infant had their umbilical cord clamped at least 60 seconds (or more) after birth.
 - If mother’s race/ethnicity is not one of these values or is missing in her medical record, the infant will be included in the “overall” numerator/denominator counts, but excluded from the disaggregated counts.

Balancing measures

- Percent of 5-minute APGAR score ≤ 3
 - Denominator = total number of live births in the month
 - Numerator = among the denominator, number of infants with 5-minute APGAR score ≤ 3
- Percent of hypothermia on first temperature
 - Denominator = total number of live births in the month
 - Numerator = among the denominator, number of infants with first temp $< 97.7^{\circ} \text{ F} / 36.5^{\circ} \text{ C}$

ADDITIONAL GUIDANCE:

First temperature

An infant's temperature should be recorded within 15 to 30 minutes of age, or per existing hospital policy, irrespective of the infant's location (eg, newborn nursery or NICU). Hospital policy should be followed regarding method of first temperature (ie, rectal or axillary). If no policy exists, an *axillary* temperature is recommended.

- *Frequency of collection & reporting:* monthly

Process measures

- Provider education
 - Cumulative proportion of infant care providers, including delivering physicians, midwives, Neonatologists, Pediatricians, and NNPs, who have completed an education program on OCC that includes the unit-standard protocols
 - Report estimate in 10% increments (0-9%, 10-19%, 20-29%, 30-39%, 40-49%, 50-59%, 60-69%, 70-79%, 80-89%, 90-100%)
- Nursing education
 - Cumulative proportion of OB, Newborn Nursery, and Neo nurses who have completed an education program on OCC that includes the unit-standard protocols
 - Report estimate in 10% increments (0-9%, 10-19%, 20-29%, 30-39%, 40-49%, 50-59%, 60-69%, 70-79%, 80-89%, 90-100%)
- Percent of infants who had their cord clamping documented in their medical record (i.e., no missing data)
 - Denominator = total number of live births
 - Numerator = among the denominator, number of infants who had complete (no missing) OCC data in their medical record
 - *Not to be reported until after "EMR integration" Structure measure (see below) has been completed.*
- *Frequency of collection & reporting:* quarterly

Structure measures

- Parent engagement & education
 - Has your hospital developed education materials to provide to parents on the benefits of OCC and to encourage discussion with providers?
 - Report Completion Date
- Policy & Procedure
 - Does your hospital have an OCC policy and procedure (reviewed and updated in the last 2-3 years)?
 - The policy and procedure should include (1) what infants are eligible for OCC, and (2) Delivery Room Optimization (equipment [timers] and personnel available in every delivery room at every delivery to accurately measure time to cord clamping)
 - Teams should review and revise/update their policy and procedure if it already exists
 - Report Completion Date

- OCC Flowchart
 - Is a best practice OCC flow chart (based on the developed protocol) available for reference in every delivery room?
 - The OCC flow chart should include (1) the pre-birth “Huddle” between providers in the delivery room, and (2) components of Delivery Room Optimization.
 - Report Completion Date
- EMR Integration
 - Has your hospital integrated proper documentation of OCC (based on guidelines) into your hospital’s EMR?
 - Report Completion Date
 - GOAL: Six (6) months after the start of the project.
 - The documentation should include the following data fields (at minimum):
 - Was delayed cord clamping performed? (Y/N)
 - If N,
 - Why not? (Provide list of reasons, including contraindication; check all that apply)
 - If Y,
 - Seconds delayed (from birth)
- Reporting of performance
 - Does your hospital track and share OCC performance metrics?
 - Report Completion Date
 - Recommendations:
 - The reporting of the metrics can help guide provider education and QI activities within your facility.
 - Overall metrics should be reported as well as the metrics disaggregated by mother’s race/ethnicity.
 - The reporting should include run charts – graphing the metrics over time.
 - Optimally, performance metrics are shared at both the institution and provider level.
 - Reporting should continue after completion of the TIPQC QI project.
 - The metrics could also be determined in term and preterm live births.
 - Other metrics that could be monitored and reported.
 - The reason an umbilical cord was not clamped (e.g., contraindications)
 - Whether the documentation of cord clamping was “complete” (i.e., no missing data)
 - Time to cord clamping (in seconds)
 - NOTE: Capturing this metric accurately is critical. Hospitals will need to determine the device to use (APGAR timer, separate timer, etc.), who will capture the time, and how the capture of the time will be incorporated into the workflow to minimize burden (but still ensuring accuracy).
 - If clamping was <60 seconds, why?
 - Concern for the newborn, including respiratory effort (infant not spontaneously breathing prior to clamping the cord)
 - Concern for the mother
 - In conjunction with reporting, OB and Neo care providers should establish a process and perform multidisciplinary case reviews of specific cases, including:
 - Cases where the umbilical cord was clamped at less than 60 seconds after birth.
 - Cases with major complications, including postpartum hemorrhage, placental abruption, maternal collapse, maternal seizure, etc.
 - Cases where whether cord clamping was performed was not documented.
 - The British Association of Perinatal Medicine (BAPM) Toolkit includes an example case review reporting tool (pgs 46-48; available here: <https://hubble-live->

assets.s3.amazonaws.com/bapm/redactor2_assets/files/831/OCM_Toolkit_Full_For_Launch.pdf

- Frequency of collection & reporting: quarterly

Data Collection

Your team should determine the process in which your team will collect and capture the outcome, balancing, process, and structure measure for this project.

- Is any of the data available in your EMR? If yes,
 - Can a report be generated on the existing fields to provide the monthly counts you need?
 - Do the fields need to be revised to meet the suggested data fields?
- If the data is not currently captured in your EMR, how could you (manually) capture the needed data on each live birth to then provide the monthly counts?
 - A suggested method of data capture (until data capture fully integrated into a hospital’s EMR) is to utilize your (paper) delivery log. If you have the room in the log, you could add the following columns of data to be captured on every delivery. If the log is already full, you could consider taping an additional piece of paper to each page in the log that could be folded out of the way. You could also consider having a separate “OCC Log” that would reside with the delivery to capture the necessary fields.
 - We suggest a “Cord clamped ≥60 secs?” column be captured – in the delivery log, on an extra sheet of paper, or in a separate data collection instrument/binder.
 - The data should be captured as Y / N / N/A, where N/A = cord clamping not appropriate (i.e., contraindication)
 - The field should be captured for each delivery captured in the log
 - After the close of each month, the numerator and denominator counts should be tallied (manually) from the paper data collection.
 - Still births should be deducted from the number of deliveries in each month
 - TIPQC will be providing EMR directions for common platforms so that your facility’s information technology service can easily make the changes needed to your EMR as rapidly as possible.

Whether you capture the needed OCC data on each live birth via paper or in your EMR, the monthly counts could easily be entered and stored in a Microsoft Excel spreadsheet using the following layout, where D = denominator and N = numerator.

	<u>Outcome Measure</u>								<u>Balancing Measures</u>			
	OCC (umbilical cord clamped ≥ 60 sec after birth)								5 min APGAR ≤ 3			
	Overall		NH White		NH Black		Hispanic		Hypothermia on first temp			
Month	D	N	D	N	D	N	D	N	D	N		

NOTE: The 5 min APGAR score and/or 1st temp may be *missing* (ie, not documented) for some of the infants born in a given month. If you find your infant charts contain missing data for either of the Balancing Measures, we recommend breaking up the Numerator value for each Balancing Measure into two components: “Missing N” = among the denominator, the number of infants with missing data for the corresponding Balancing Measures; and “Non-missing N” = among the denominator, the number of infants that do not have missing data and meet the Balancing Measure’s Numerator definition criteria.

Participating teams will capture the outcome and balancing measures each month via an electronic survey. A second electronic survey will be used to capture the process and structure measures every quarter. Each participating team will be sent an email (each month / quarter) that contains a link to the appropriate survey. TIPQC will maintain the surveys and the data captured in the surveys. Participating teams will be provided with blank paper versions of the monthly and quarterly data capture surveys, which they can choose to use.

TIPQC will generate and provide each team with a monthly data report that will include the data they have captured (to date). The outcome, balancing, and process measures will be plotted over time in run charts, which will visually illustrate any improvement in the measures.

SIDE NOTE:

Tracking 30 versus 60 second cord clamping

Any facility is welcome to capture and track 30 second cord clamping in addition to 60 second cord clamping. As a state, we have chosen to only capture and track the 60 second cord clamping outcome. The additional 30 second cord clamping outcome will need to be captured and tracked *internally* at a facility – statewide data support will not be provided.

Change Ideas: *What changes can we make that will result in an improvement?*

All improvement requires change. And while there are many kinds of changes that will lead to improvement, the specific changes are developed from a limited number of *change concepts*. As described in the IHI Model for Improvement, “A change concept is a general notion or approach to change that has been found to be useful in developing specific ideas for changes that lead to improvement.” These change concepts are used to design and run tests of change (i.e., Plan-Do-Study-Act (PDSA) cycles) to see if they result in improvement.

A similar idea to change concepts are *Potentially Better Practices* (PBP's), which are a set of clinical practices that have the potential to improve the outcomes of care. They are labeled ‘potentially better’ rather than ‘better’ or ‘best’ because until the practices are evaluated, customized, and tested in your own institution, you will not know whether the practices are truly ‘better’ or ‘best’ (or ‘worse’). Depending on the circumstances in your facility, you may have to implement other practices or modify existing ones to successfully improve outcomes. The PBP's in this collection are not necessarily the only ones required to achieve the improved outcomes targeted. Thus, this list of PBP's is not exhaustive, exclusive, or all inclusive. Changes in practice, guided by these PBPs, will require testing and adaptation to your circumstances and context to achieve measured improvements in outcomes.

Core Strategies to Support Optimal Cord Clamping

The following core strategies provide a framework that is best designed to achieve a high rate of OCC with a low rate of adverse consequences. Each of these core strategies should be reviewed to identify how to achieve best practice.

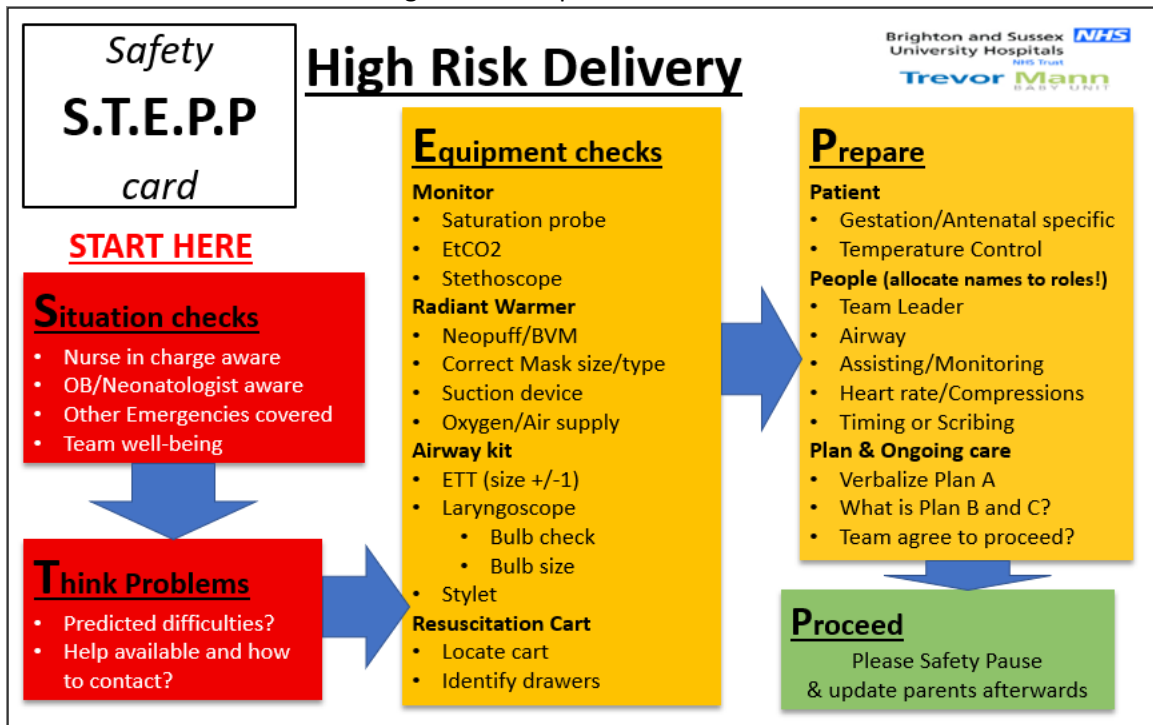
1. Human factors and multidisciplinary perinatal team working
2. Provision of normothermia care
3. Supporting the onset of spontaneous breathing and lung inflation
4. Parent information and involvement

1. Human factors and multidisciplinary perinatal team working

A multidisciplinary team approach with high quality communication across the perinatal team is essential at the birth of a baby, especially if that baby is preterm. Team performance in such high acuity situations is important to outcomes, and team behaviors such as information sharing, vigilance, management of workload and leadership correlate strongly with the quality of resuscitation²⁷. Situational awareness training using the Situational Awareness Program for Everyone (SAFE) Toolkit may be a valuable activity for perinatal teams to undertake²⁸.

At birth, OCC and ongoing stabilization require multiple inputs from multiple individuals and perinatal teams may find it useful to employ a pit-stop model with checklists and well-orchestrated tasks to improve efficiency and safety in the delivery room²⁹. Situational awareness can be ensured by performing a pre-resuscitation huddle. Checklists such as a STEPP card (Figure 6) can be used to guide the team huddle prior to birth.

Figure 6: Example of a STEPP card



2. Provision of normothermia care

Meta-analysis does not demonstrate an increased risk for hypothermia in preterm babies who receive Optimal Cord Management⁹. Although not statistically significant, admission temperature is slightly higher compared to those who have early cord clamping (<60 seconds after birth). A study of OCC in near-term lambs reported better temperature control in those undergoing OCC versus early cord clamping³⁰.

The first minute after birth is a potential risk period for thermoregulation as there may be a delay in transferring a wet baby to an external heat source. Both evaporation and convection can be important properties of heat loss during the period of OCC. Nevertheless, rapidly transferring a baby who is relatively more 'hypovolemic' by clamping the cord too early may also add to hypothermia. OCC is consistent with good thermal practices, such as putting the baby in a bag, drying, putting a hat on, and/or bringing an external heat source to the bedside. Teams should identify the risks, undertake a risk assessment before birth, and put in place measures to minimize hypothermia as below.

Key measures to assist normothermia during OCC:

- Ensure a warm draft-free environment of 75-79°F: this may require increasing the temperature in the delivery room in anticipation of OCC.
- Ensure warmed (sterile) towels are available for stimulating/holding the baby during OCC and for later transfer to the stabilization area.
- Ensure (sterile) plastic bag or thermal suit available for use if gestation requires it.
- Ensure that the heat source is activated on the radiant warmer.
- Ensure chemical mattress or other thermal mattress is activated at the appropriate time and used in the manner recommended by the manufacturer.
- Cover the baby's head as soon as possible using a hat or the relevant part of the plastic thermal suit.
- Check temperature after OCC is complete and maintain normothermia thereafter.

SIDE NOTE:***Skin to skin care***

Facilities should not be discouraged to use skin to skin care immediately after birth while waiting to clamp the umbilical cord. Skin to skin care for the first full minute or longer is a very effective way to keep the baby warm and begin the bonding process. Obstetricians at some of our TN facilities utilize skin to skin contact for 3-5 minutes.

3. Supporting the onset of spontaneous breathing and lung inflationObservations on the physiologic onset of breathing at birth

Once born, the preterm baby should receive multiple stimuli by the obstetric care provider to encourage the onset of breathing while still attached to the umbilical cord. The neonatal care provider should be closely observing the transition and providing verbal feedback to the obstetric care provider.

The World Health Organization (WHO) recommends using a minimum interval of one minute for deferring cord clamping. Stabilization should start with gentle but deliberate stimulation, good thermal care, and optimal positioning so that the airway is patent and does not get obstructed, while actively encouraging the onset and maintenance of spontaneous respiration. The goal is to support the onset of spontaneous breathing and lung inflation during OCC^{31, 32}.

Providing respiratory support at birth

The infant is delivered and placed on the mother's thighs or abdomen. Clamping and cutting the umbilical cord will be delayed for at least 60 seconds.

During the 60 seconds, the obstetrician (obstetric provider) can perform initial resuscitation steps, including:

- Drying the newborn and removing the wet linen.
- Provide warmth by placing the infant skin-to-skin with the mother or by covering the infant with dry linen (consider the use of a chemical warming mattress under sterile drapes for c/section deliveries in infants < 32 weeks' gestation).
- Newborn repositioning (airway patency should be ensured by optimizing head position).
- Suctioning is not necessary unless the secretions are copious, or the airway is obstructed by the secretions
- Gentle but deliberate stimulation while keeping the head relatively motionless.

There are situations in which early cord clamping is indicated. This should be a discussion between obstetric and neonatal/pediatric providers prior to delivery whenever possible. These situations include:

- Infants who do not show any response to the initial resuscitation efforts or are non-vigorous for their gestational age should probably have the cord clamped and cut at or after 30 seconds and certainly by 60 seconds.
- If the placental circulation is not intact, such as in the case of abnormal placentation, placental abruption, or umbilical cord avulsion, the cord should be clamped immediately.
- Maternal hemodynamic instability or the need for immediate resuscitation of the newborn on the warmer would be an indication for immediate umbilical cord clamping³³.

Trials comparing intact cord resuscitation with early cord clamping have not reported improved neonatal outcomes and did not include a sufficient number of Extremely Low Birth Weight infants³⁴. At present, there are two large randomized clinical trials underway to address this issue.

4. Parental information and involvement

Parents should receive information about OCC during their prenatal care, along with information about the benefits of breast milk, the stabilization process, and the start of their neonatal journey. Some units have developed educational

materials for parents regarding OCC. During OCC, parents should be given reassurance regarding their baby's well-being and be encouraged to touch or even hold their baby when possible. If touching and holding are not possible, photographs should be offered.

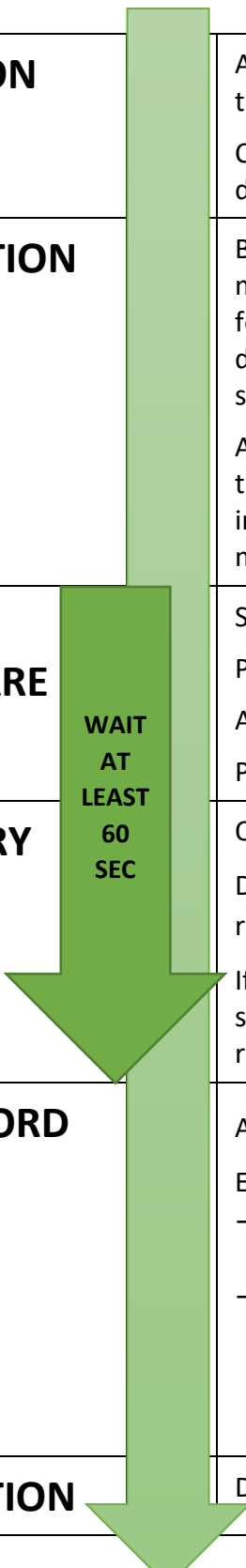
Best Practices Flowchart for Optimal Cord Clamping

The flowchart shown on the following page has been adapted from the Best Practice Flowchart in the BAPM Toolkit.

BEST PRACTICES FLOWCHART FOR OPTIMAL CORD CLAMPING

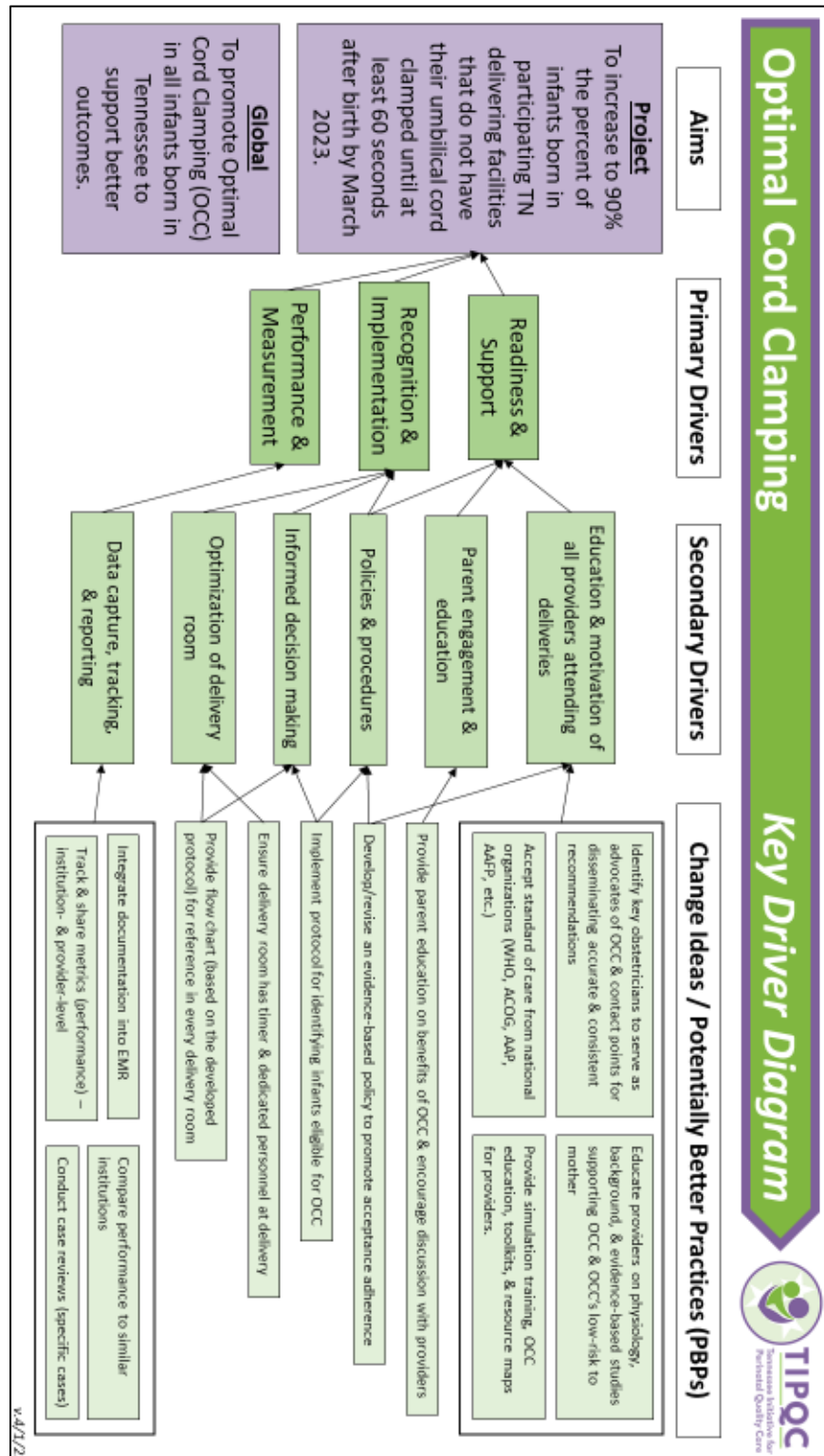


<p>PREPARATION</p>	<p>Assemble equipment/supplies per NRP guidelines, including thermal support depending on gestational age.</p> <p>Consider any monitoring (SaO2, CRM) that may be needed during the time from birth to when cord is clamped.</p>
<p>COMMUNICATION</p>	<p>Before birth, ensure that all team members caring for the mother-infant dyad and the parents are engaged with the plan for optimal cord management (this can be accomplished during the pre-birth huddle for a vaginal delivery or during the safety checklist before a c/section).</p> <p>Assign roles for optimal cord management (OCM) (starting the timer, ensuring airway patency, providing gentle stimulation of infant's respiratory efforts, providing thermal support, monitoring, and providing maternal support).</p>
<p>BIRTH & THERMAL CARE</p>	<p>Start clock as soon as infant is delivered.</p> <p>Place the infant on mother's abdomen.</p> <p>Administer Oxytocin to mother as part of the delivery routine.</p> <p>Provide appropriate thermal care.</p>
<p>RESPIRATORY SUPPORT</p>	<p>Optimizing airway patency.</p> <p>Deliberate and gentle stimulation of the baby and his/her own respiratory effort.</p> <p>If baby does not have adequate respiratory effort after 30 seconds, consider cord clamping to provide appropriate respiratory support.</p>
<p>CLAMP THE CORD</p>	<p>After at least 60 seconds, clamp the umbilical cord.</p> <p>Evaluate the newborn:</p> <ul style="list-style-type: none"> → If infant is crying/breathing and has appropriate tone, continue STS with mother → If the infant has labored breathing, is hypotonic, or needs further evaluation move the infant to the radiant warmer for care per NRP guidelines. After stabilization has occurred, prepare to transfer the infant to the NICU if required.
<p>DOCUMENTATION</p>	<p>Document the provision of OCM in the medical record.</p>



Optimal Cord Clamping Key Driver Diagram

A driver diagram is a visual display of a QI collaborative's (or team's) theory of what "drives," or contributes to, the achievement of the project aim – that is, the project's "theory of change." The far-right column of the driver diagram lists the specific *change ideas to test* using PDSA cycles.



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