A Program Evaluation to Measure the Feasibility of the Team Birth Project

NCT03529214

August 20, 2019

STUDY PROTOCOL

Team Birth Project

A Partnership to Improve Vaginal Delivery Rates while Enhancing the Safety and Experience of Care

TABLE OF CONTENTS

1. Background and Significance

Supporting and caring for women in labor often requires making difficult decisions with imperfect information. Among the most challenging decisions is when to deliver via cesarean. Modern maternal healthcare systems have the capacity to save lives by performing cesarean deliveries but we sometimes overuse this capacity in ways that can be harmful.[1,2] The national cesarean delivery rate in the United States has increased by 500% since the early 1970s without proportional benefit to mothers or term infants.[3] This shift is not well explained by demographic changes, women's preferences, reimbursement or malpractice policies.[2,4-7] Furthermore, cesarean delivery rates vary 10-fold, from 7% to 70% at the hospital-level, suggesting a significant opportunity for improvement with hospital-based quality improvement programs.[8-10] The WHO has recently advocated for programs that move away from rigid adherence to labor progress protocols towards enhanced models of team communication.[11]

This project will evaluate and support the implementation of a process improvement program that is designed to improve vaginal delivery rates to enhance the safety and experience of care. The program was developed through a one-year design effort at Ariadne Labs that included literature review, expert validation, workflow mapping, feature selection, prototyping and rapid cycle testing.

2. Statement of the Problem

The goal is to improve vaginal delivery rates to enhance the safety and experience of care. Cesarean delivery rates have been selected as the primary patient safety indicator because overuse of cesarean deliveries is a national concern and cesarean reduction is a top priority among the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American College of Nurse Midwives.

To date, professional efforts to safely reduce cesarean rates focus on improving clinical knowledge. Policymakers, payers and purchasers tackle addressing misaligned incentives through payment and malpractice reforms. However, emerging research at Ariadne Labs suggest a third, previously unaddressed root cause -- unintentional errors due to system complexity.[12]

This project aims to mitigate errors rooted in system complexity by addressing three types of challenges that can influence team performance:

I. Timing of Key Decisions

Optimizing the timing of when to admit patients to a labor and delivery room or when to deliver operatively has a substantial impact on the likelihood of cesarean delivery independent of other risks and preferences. Guidelines on when to do a cesarean delivery are imprecise. In emergent situations, obstetric clinicians (nurses, midwives and doctors) agree about when to perform a cesarean delivery, but reasonably disagree about when to act *to prevent* an emergency. In the absence of a communication process to ensure appropriate decision makers are considering all of the pertinent information *and* using a common decision

framework, disagreements can go unrecognized or unresolved. As a result, even well-intended, well-trained and board-certified clinicians perform surgeries that appear to be potentially avoidable, and even harmful, in retrospect.

II. Shared Information and Decision Making

When deciding which actions should be taken to ensure the safety of the mother and baby, obstetric clinicians are often presented with disconnected pieces of information, uncertainty and time pressures when synthesizing large volumes of data. Women have a unique insight into their preferences, symptoms, energy, mood, and motivation during labor. Labor nurses often spend the most time with the laboring woman collecting objective and subjective data, and tracking labor progress. Obstetricians and midwives typically have the most technical proficiency at intervening during labor. Nonetheless, each person often evaluates the status of labor tacitly and clinicians make decisions with limited accountability to each other or to the laboring woman.

Clinical decisions are generally based on trend data. The present is analyzed in the context of the past to predict the future. There is no reliable process to ensure all members of the team are reviewing the same information together with a shared mental model of how this data should inform their actions. These factors can lead to inaccurate decision making since it is difficult to keep track of timelines and activities in a clinician's working memory, particularly as they may also be responsible for other patients simultaneously.

III. Conflation of risk

Labeling risk in obstetrics (e.g. hypertension, advanced maternal age, gestational diabetes etc.) is important to identify those pregnancies that have an increased risk of poor outcome for either the mother or the baby. However, these labels can be used sub-optimally during labor where "high risk pregnancy" is often conflated with "high risk labor". For example, a pregnant woman with hypertension may be at high risk during her pregnancy but can still be expected to have a routine and labor deliver vaginally. Moreover, clinicians can sometimes conflate maternal, fetal and labor progress status when making decisions, meaning that care plans may not always be specific to the concern identified, leading to inaccurate decision making.

3. Process Improvement Program

I. Program Description

Ariadne Labs has developed a process improvement program called the "Team Birth Project" that consists of 1) a set of three tools to designed to improve team communication and decision making during labor, 2) training and coaching to support sustained implementation of these tools and 3) data collection for assurance of implementation fidelity.

Our program is designed to achieve four behaviors that support team performance. We identified these behaviors and designed tools to support them through a one-year human-centered design process that included expert validation and rapid cycle testing.

The team behaviors are as follows:

> Behavior 1: Promote the roles of the laboring woman, nurse, and delivering provider as members of the care team with equally valuable input for decision-making
>
> Behavior 2: Elicit laboring woman's preferences, symptoms, and subjective experiences to inform care plans
>
> Behavior 3: Distinguish between maternal, fetal, and labor progress statuses and care plans
>
> Behavior 4: Set shared expectations for next planned evaluation

These behaviors will be carried out by the "**minimum care team**," which consists of three individuals: the laboring woman, the labor nurse, and the provider (obstetrician or midwife).

The minimum care team will come together during a team huddle (structured conversation about care and corresponding plans) to carry out these behaviors. Other individuals may also be involved in these huddles depending on the circumstance (e.g. anesthesiologist, labor support individuals, doula, neonatologist), but at least the minimum care team must be physically present to be considered a complete huddle.

Huddles should ideally take place during the following key moments:

1) Before or soon after a laboring woman is admitted to a labor and delivery room
2) At any time during the active phase of labor (when cervical dilatation is >4-6cm)
3) When the laboring woman commences pushing (cervical dilation = 10cm)
4) When clinicians are considering operative delivery (cesarean or instrumental)
5) When any member of the care team has concerns that may require a change of plan

The care team may also wish to come together as a team huddle at other times, including when there are changes in shift of either the labor nurse, provider, or should any member of the care team request a team huddle. These are not prescribed and not mandatory in this process improvement program.

II. Tools

The four team behaviors are the basis of the tools that have been designed for implementation in labor and delivery units across the country to increase vaginal delivery rates. The development of these tools is described in Appendix 2. These tools act in concert during the childbirth encounter to promote optimal timing of admission to the labor and delivery unit, generate reliability during clinical assessments in labor and precision when distinguishing concerns in labor and to foster accuracy when making decisions to deliver operatively.

i) Shared Labor and Delivery Planning Board (Appendix 1a)

The Shared Labor and Delivery Planning Board is a patient facing whiteboard which will be located all labor and delivery rooms in the hospital. Components of the board include: designated spaces for names of the care team (behavior 1), preferences (behavior 2), plans across the maternal, fetal, and progress categories (behavior 3), and next steps in care (behavior 4).

The care team will be constructed uniquely each time, but *at a minimum* the names of the laboring woman, the labor nurse and provider should be documented on the whiteboard. The purpose of the board is to act as a fulcrum for the care team to come together and huddle at defined key moments. The huddles will involve collating shared information, clearly distinguishing between maternal, fetal, and progress statuses, developing corresponding care plans, and setting expectations for future evaluations.

ii) Admission Decision Aid (Appendix 1b)

The Admission Decision Aid is a one-page tool intended to be used primarily by the triaging clinician to prevent premature admission of laboring women to a labor and delivery bed. The triaging clinician may choose to involve the laboring woman or other clinicians in using the tool, but how this is done will not be prescribed by Ariadne Labs Project Team. The tool defines a new category of indication, *deferred admission for women in early labor*, for clinicians to identify those women who are unable to return home but can be supported with care options which do not require admission to a labor and delivery room.

Specifically, the Admission Decision Aid 1) **improves precision** by separating the reasons for admission into three distinct categories: maternal, fetal, and progress, 2) **improves accuracy** by distinguishing between patients who need to be admitted versus those whose admission can be deferred and 3) **organizes the care options** which can be reviewed with other members of the care team when constructing care plans to manage the care of laboring women.

iii) Delivery Decision Aid (Appendix 1c)

The Delivery Decision Aid is a one-page tool intended to improve the accuracy of decisions to intentionally deliver a baby (via cesarean or operative vaginal delivery) instead of allowing labor and delivery to proceed. The tool is to be used by the labor nurse and delivering provider in front of the laboring woman during a team huddle when clinicians are considering

whether an operative delivery is indicated or when any member of the care team would like to review the care options.

The Delivery Decision Aid 1) improves **precision** by separating the reasons for performing an operative delivery into three distinct categories: maternal, fetal, and progress), 2) **requires reliability and accountability** (ensuring the minimum criteria to deliver have been confirmed each time this decision is made, and requiring that this confirmation and decision process occurs verbally with the nurse, delivering provider, and woman all present), and 3) **organizes the care options** which can be reviewed with other members of the care team when constructing care plans to manage the care of laboring women.

III. Sites

Four sites have been selected to partner with Ariadne Labs to trial this process improvement program. We have aimed for diversity in the choice of site which includes the following variables: geography, rural/urban mix, facility type (academic health canter, community hospital, critical access hospital etc.) delivery volume, provider mix and patient demographics. Overlying these parameters, we have used four criteria -- specifically high need (facility cesarean rates have room for improvement), willingness to engage in the improvement program with capacity to support the implementation of the program and broader relationships that can lead to spread of the program regionally and nationally.

The criteria are described in more detail below.

NEED: Hospitals with NTSV 1 cesarean rates above the HealthyPeople 2020 target of 23.9%

WILL: Site leadership commitment at the executive, service line, and front-line levels

CAPACITY: Site infrastructure to support quality improvement activity, including oversight responsibility for quality, data tracking for quality assurance, and standing quality assurance committees

RELATIONSHIPS: Site has relationships with state perinatal quality collaborative department of public health, or other stakeholders to facilitate spread.

SITE	SPECIFICS	LAUNCH
CONFIRMED		
South Shore Hospital, South Weymouth, Massachusetts	Community hospital, annual delivery volume ~3000, 40% NTSV rate	April 2018
Saint Francis Hospital, Tulsa, Oklahoma	Catholic, not-for-profit health system, annual delivery volume ~4000, NTSV rate 36%	September 2018
Eastside Health Alliance – Overlake Medical Center and Evergreen Health, Puget Sound, Washington	Alliance between a regional non-profit hospital and a public district hospital	January 2019

IV. Implementation Plan

Table 1: Study activities

Activity	Lead team	QI or research	Pre-implementation	Implementation period																	Ongoing
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
Identify super-users and champions	Site	QI	✓																			
Small scale implementation	Both	QI	✓																			
Training the trainers	Ariadne	QI	✓																			
Training the observers	Ariadne	QI	✓																			
Installation of tools	Site	QI	✓																			
Widespread training	Site	QI	✓																			
Ongoing coaching & support	Both	QI		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Training evaluation	Site	QI	✓																			
Observations	Site	QI																				
Four 12-hour shifts per week				✓	✓	✓																
Three 6-hour shifts per week							✓	✓	✓	✓	✓											
Three 4-hour shifts every other week												✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ad hoc as needed for sustainability																						✓
Patient record data extraction	Both	Both		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Management Surveys	Site	Research	✓																		✓	
Clinician Practice Surveys	Site	Research		✓							✓				✓							
Clinician Acceptability and Feasibility Surveys	Site	Research				✓					✓				✓							
Clinician in-depth interviews	Ariadne	Research									✓				✓							
Focus Group Discussions	Ariadne	Research		✓							✓				✓							
Patient Postpartum Surveys (daily)	Site	Research		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Data use agreement	Both	Both	✓																			
Collect and store data for analysis	Both	Both		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Monitor data for quality and changes in outcomes	Both	Both		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Data analysis	Ariadne	Research														✓	✓	✓	✓			
Publications	Both	Research																✓	✓	✓	✓	

The implementation plan will be co-developed by the local site and the Ariadne Labs Project Teams (see Appendix 4 for a list of project team members). All clinicians (labor nurses, and obstetricians and midwives) in the unit will participate in the initiative as a component of the hospital process improvement effort.

The tools will be used for all women other than those who have 1) a scheduled cesarean delivery or 2) are being induced for fetal loss.

i) Local Site Implementation Team

A core local team will be identified to embed the program and socialize the tools to generate buy-in from frontline staff. Key site leaders include: 1) local leaders (e.g. chair of obstetrics and gynecology, nurse manager, head of midwifery) to champion the project in the labor and delivery unit, 2) executive sponsor (e.g. chief medical officer) to support implementation at the administrative and board level, and 3) day to day clinical champions among physicians, midwives, and nurses to troubleshoot and propel the program forward. This implementation team will direct local implementation processes with support from the Ariadne Labs Project Team.

ii) Ariadne Labs Implementation Team

The Ariadne Labs Team will support each local site implementation team with initial clinician training to introduce the behaviors and tools and subsequently ongoing coaching. The team will include implementation specialists, clinical coaches and trainers.

iii) Implementation Schedule

1. Small scale implementation: Preceding widespread training, the Ariadne Labs Project Team will train a small group of clinician champions and "super-users" in the program and tool use. These clinicians will be identified by the local site implementation team and will include labor nurses, obstetricians and midwives as appropriate for the context. They will trial the tools and behaviors to identify ideas for site-specific adaptations and build a library of local testimonials to help generate buy-in among their peers during socialization and widespread training.

2. Training the trainers: super-users will be trained to train and coach their peers to help build their capacity to deliver widespread training to all frontline clinical staff at each site with assistance from the Ariadne Labs Implementation Team. Super-users will become "experts' in the use of the tools and provide technical assistance and support to other clinicians using the tools. Both champions and super-users will help to troubleshoot any challenges in implementing the tools.

3. Training the observers: Each local site will allocate local staff to be observers in both triage and labor and delivery unit. Observers will be trained to use a structured observation form by the Ariadne Labs Project Team to ensure consistency of data

collection. The observers may also be trained as coaches to be able to provide feedback to the clinicians they are observing about areas for improvement.

4. Installation of tools: The Ariadne Labs Project Team will share the most updated versions of the tools via a shared folder. Each local site implementation team will be responsible for printing and distributing materials and positioning the labor and delivery planning board to ensure accessibility, visibility and ease of use in labor and delivery rooms. The Ariadne Labs Project Team and local site implementation team will work together to determine location and accessibility of the decision aids. Should versions of the decisions aids change during implementation, the Ariadne Labs Project Team will be responsible for incorporating the changes into the tool and distributing updated tools to each local site implementation team in an organized and timely manner.

5. Widespread training: Each local site will expect all of the clinicians involved in childbirth care with hospital practice privileges (nurses, midwives, and obstetricians) to participate in the training, but the format will be dependent on their availability. The training will be conducted by the local site implementation team with support from the Ariadne Labs Implementation Team and will include a combination of didactic and interactive sessions. The didactic sessions will aim to generate buy in for the initiative and introduce the key behaviors and tools. Learning objectives will include understanding the conceptual framework of dividing statuses and care plans into maternal, fetal, and labor progress categories and the categorization of delivery indications based on clinical urgency. Interactive sessions will include reflections, discussions, and roleplays to allow clinicians to react to the behaviors and tools and begin to practice implementing them in hypothetical, simulated scenarios.

6. Ongoing coaching & support: Once all local staff have been trained in the use of the tools and the quality improvement program has gone “live” across the site, the Ariadne Labs Implementation Team will support local implementers, champions and super-users through weekly calls. The Ariadne Labs Project Team may also conduct site visits to identify any contextual or mitigating factors that are affecting the implementation of the tools with the intent to co-produce solutions.

V. Local Quality Assurance

Each local site team, with support from the Ariadne Labs Project Team, will conduct routine quality assurance to assess the fidelity of program implementation using a mixed methods approach. These data will help identify potential adaptations to improve the implementation of the behaviors and tools. Quality assurance data collection methods will include the following components: training evaluations, observations, patient record data, and weekly coaching calls.

1. Training evaluations will assess the experience and quality of the training.
    a) Training evaluations will be administered by trainers following the initial training as an electronic survey.
    b) The local site will administer the electronic survey to all clinicians' email addresses.
    c) All clinicians involved in the training will be invited to participate in the evaluations.
    d) All surveys will be anonymous.
    e) Only data that defines the clinician role of respondents will be collected. No individual identifiers will be collected.
    f) Participation will be voluntary and uncompensated.

2. Observations will document the use of the three tools (admission decision aid, delivery decision aid, planning whiteboard) as well as the nature of the interactions and conversations that occur during huddles.
    a) Observations will be conducted by trained members of the local teams, including nurse managers, nurse educators and other individuals involved in quality administrative roles. Local observers will receive training from the Ariadne Labs Project Team to support reliable and actionable observations.
    b) Local staff will use a paper observation checklist to capture quantitative and qualitative data about the huddles.
    c) No identifiable information about the patient or the participating clinicians will be collected by the observers.
    d) Observers will transfer data from the paper observation checklist into an electronic format. Local site observers will decide how to store or dispose of paper checklists.
    e) Observer shifts frequency will be as follows:
        i. Month 1-3: four 12-hour shifts (2 weekday, 1 night and 1 weekend)
        ii. Month 4-8: three 6-hour shifts (1 weekday, 1 weekend, 1 night)
        iii. Month 9-18: three 4-hour shifts on alternate weeks (1 weekday, 1 weekend, 1 night)
        iv. Ongoing: ad hoc as needed for sustainability and training new staff
    f) Observers will be alerted to when a key moment is occurring by the care team or by the charge nurse on the labor and delivery unit. If two key moments are happening simultaneously for two patients, observers may use their discretion

about which observation to make to capture a range of key moments and types of laboring women.

g) The clinicians will introduce the observer and explain the purpose of the observation to the laboring woman and her family and ask the laboring woman if she agrees to the observation or wishes to opt out.

3. Patient record data collected by each local site for tracking quality and reporting including cesarean delivery rates and adverse outcomes will be used to assess if the project is having any impact on these measures.
    a) Patient record data will be extracted from the medical record system by the data and quality team at each local site.
    b) The indicators that will be collected and analyzed for the project have been identified based on the measures used for other cesarean birth reduction projects and the measures of greatest interest to site leadership (see Appendix 3 for more details).
    c) The Ariadne Labs Project Team will support each local site team with designing a system to extract any data required for the project that is not currently being regularly collected.
    d) The Ariadne Labs Project Team will analyze the data and produce reports to share with the local site implementation team and frontline clinicians to track progress with project implementation and key outcomes of interest.

4. Weekly coaching calls will include conversations on the facilitators, barriers, and adaptations the local teams are encountering throughout the implementation process.
    a) The Ariadne Labs Project Team will take detailed notes on the coaching calls to capture the lessons and challenges experienced by the local site teams.
    b) The Ariadne Lab Project Team will qualitatively analyze the notes within and across calls to identify common themes to inform future coaching and implementation problem solving.

Monitoring and analyses for implementation fidelity will be conducted by the local site team and Ariadne Labs Project Team. These analyses will include quantitative analyses of the training evaluations, observations, and patient record data and qualitative analyses of the observations and weekly coaching calls. The analyses will be shared with each local site implementation team and frontline clinicians through regular reports.

4. Research Project: South Shore Program Evaluation

The Ariadne Labs Project Team will evaluate the feasibility and acceptability of implementing the process improvement program at each local site, as well as the potential benefits and harms of the program, for generalizable lessons for broader implementation.

I. Aims and Endpoints

This study has four aims:

1. Adaptation of the tools and implementation strategy to optimize practice of the four core behaviors
2. Documentation of the feasibility and acceptability of tools and implementation strategy to clinician and patient participants
3. Detection of any unintended consequences associated with the tools or implementation of the tools
4. Collection of preliminary data on the relationship between the tools and subsequent implementation on patient outcomes between the use of the tools and corresponding implementation with cesarean delivery rates

As the Quality Improvement Program progresses at each local site, we will collect additional data toward the above aims (Table 4). The three primary endpoints relate to the implementation of the intervention (Primary 1), its acceptability to various groups (Primary 2), and any unintended consequences, including adverse events that could impact patient safety (Primary 3). Additionally, cesarean delivery rates will be monitored at each site to identify any decline as a secondary endpoint. Since this is not an effectiveness trial, the study is not intentionally powered or designed to detect this reduction. The two exploratory endpoints will measure the specific adaptations of the program and any information on how the program succeeds or struggles in various contexts.

Table 4: Endpoints

Primary	1	High fidelity Implementation of the program
	2	Acceptability and feasibility of the program
	3	Patient safety
Secondary		Patient benefit, including program effectiveness at improving vaginal delivery rates
Exploratory	1	Adaptation of the program for improvement
	2	Determinants of how program successes and failures

The aims and endpoints will be measured with a variety of outcome measures, as shown in Table 5. Each aim maps to an endpoint, which is paired with a specific research question. The table also lists the specific measures and data sources we will use to address each question and the domains covered in each data source.

Table 5: Aims, endpoints, outcomes, data sources, and domains

Aim	Endpoint	Implementation question	Outcome measures	Data sources	Domains
1. Adaptation of the tools and implementation strategy to optimize practice of the four behaviors	Primary 1	How are the four core behaviors implemented?	Quantity and quality of core behaviors performed	Observations Clinician Practice Surveys Clinician Knowledge and Attitudes Survey Clinician Interviews Patient Surveys	Involvement of minimum team Incorporation of woman's input Precision of MFP distinction Shared expectations
	Primary 1	Are the tools implemented?	Quantity of tool use	Observations Clinician Practice Surveys Patient Surveys	Team huddle occurrence Whiteboard use Admission decision aid use Delivery decision aid use
	Exploratory 1	What adaptations are made to the intervention?	Adaptations	Clinician Interviews Implementation Focus Groups Discussions	Site-specific adaptations Generalizable adaptations
2. Documentation of the feasibility and acceptability of the tools and implementation strategy to clinician and patient participants	Primary 2	Do clinicians find the tools acceptable and feasible to implement?	Clinician reports	Clinician Acceptability and Feasibility Surveys Clinician Interviews Implementation Focus Group Discussions	Perceived value of behaviors, including collaboration Ease of integration in workflow Adaptations and suggestions for improvement
	Primary 2	Are the tool and implementation strategy acceptable to patients?	Patient reports	Patient Surveys	Role in care Communication with team Timing of care
	Primary 2	Do site teams find the tools acceptable and feasible to implement?	Site team reports	Implementation Focus Group Discussions	Facilitators Barriers

Table 5: Aims, endpoints, outcomes, data sources, and domains

Aim	Endpoint	Implementation question	Outcome measures	Data sources	Domains
					Adaptations
					Coaching and support
3. Detection of any harms to associated with the tools or implementation of the tools	Primary 3	Has there been any harm to patients as a result of the tools and implementation strategy?	Patient outcomes and care processes	Patient Level Data	Intervention rates
					Maternal morbidity and mortality
					Neonatal morbidity and mortality
			Patient experience	Patient Postpartum Surveys	Role in care
					Communication with team
					Disempowerment
					Timing of care
4. Collection of preliminary data on the relationship between the tools and subsequent implementation on patient outcomes between the use of the tools and corresponding implementation with cesarean delivery rates	Secondary	Have there been any benefits to patients as a result of the tools and implementation strategy?	Patient outcomes & care processes	Patient Level Data	Intervention rates
					Delivery indications
					Admission timing
					Admission indications
			Patient experience	Patient Postpartum Surveys	Role in care
					Communication with team
					Empowerment
					Timing of care
	Exploratory 2	What contextual factors may be related to cesarean delivery?	Contextual factors	Management Surveys	Other contextual factors
				Site Implementation Team focus group discussions	

II. Research Eligibility Criteria

The following participants are eligible for this research project.

1. Clinician participants
    i. Inclusion criteria
        a) All clinicians (nurses, obstetricians and midwives as appropriate) who have practice privileges at each local site
    ii. Exclusion criteria
        a) None
2. Implementation Team participants
    i. Inclusion criteria
        a) Each local site implementation team which includes site champions, super-users and others who have been involved in the implementation of the process improvement program at each of the local sites
    ii. Exclusion criteria
        a) None
3. Patient participants
    i. Inclusion criteria
        a) 18 years or older (15 years or older at St. Francis Hospital only)
        b) Live birth (spontaneous or induction of labor)
            - Vaginally *or*
            - With an instrument (forceps/vacuum) *or*
            - Unscheduled cesarean delivery
    ii. Exclusion criteria
        a) Scheduled cesarean delivery
        b) Experienced intrapartum, stillbirth, or neonatal death

At no time during the course of the study will the Ariadne Labs Project Team directly interact with patient participants for the purpose of data collection. All patient participant interaction will be the responsibility of local site staff.

III. Data Collection

We will use the data we collect to assess how the tools have been implemented, any adaptations that have been made to the tools for greater acceptability and feasibility of the program in order to deriver generalizable lessons for future implementation efforts. Data will be used to assess any unintended consequences and benefits of using the tools in clinical practice. The data collection approach is based upon the logic model we developed (Appendix 2) and Consolidated Framework for Implementation Research (CFIR).

All data collected will not include any identifiers for the participating clinicians or patients. Clinicians, the implementation team and patients will be invited to participate in surveys, interviews and focus group discussion as relevant. All participation will be voluntary. There will be no penalty for not choosing not to complete surveys or interviews.

1. Management Surveys will provide background information about contextual factors, including delivery volume, bed occupancy rates, nurse staffing levels and other organizational information.

    a) This survey will be administered digitally using either a Word document or the online survey service Qualtrics.
    b) Data will be collected at baseline and at the end of the project through an electronic form designed by the Ariadne Labs Project Team.
    c) The local site Implementation Team will fill out this survey at each data collection point to ensure consistency of data collection.

2. Clinician Practice Surveys will provide insight into current practices of team decision making and their frequency of occurrence. This survey will be administered at baseline, midpoint and endpoint to assess any longitudinal change in practices related to the key behaviors.

    a) The local site team will administer the survey three times to all clinicians' email addresses.
    b) All clinicians with practicing privileges in the unit will be invited to participate and will be sent a hyperlink which will direct them to the Qualtrics survey.
    c) All surveys will be confidential
    d) Consent text is available in the consent language attachments.
    e) Consent will be affirmed with an agreed statement, stating that moving forward with the survey, the participant is providing consent to participate.
    f) Participation will be voluntary and uncompensated for completion of multiple surveys.
    g) The survey will take no more than 15 minutes to complete.

3. Clinician Acceptability and Feasibility Surveys will provide insight into feasibility and acceptability of use of the tools for clinicians and leading indicators of issues to investigate further through in-depth interviews. Surveys will be conducted at month, 3, 8 and 12 of the project.

    a) The local site team will administer the survey to all clinicians' email addresses.
    b) All clinicians with practicing privileges in the unit will be invited to participate and will be sent a hyperlink which will direct them to the Qualtrics survey.
    c) All surveys will be confidential.
    d) Consent text is available in the consent language attachments.
    e) Consent will be affirmed with an agreed statement, stating that moving forward with the survey, the participant is providing consent to participate.
    f) Participation will be voluntary and uncompensated for completion of multiple surveys.
    g) The survey will take no more than 15 minutes to complete.

4. Clinician Interviews will be used to provide deeper insights related to the Team Birth project including implementation. Interviews will be conducted at the project midline

and end line leading to a total of 15-35 interviews per site. Interviews will no longer be conducted monthly. Additional interviews may also be conducted ad hoc if key issues are raised in the surveys and further information is needed to inform adaptations to the tools or implementation Each interview is expected to last about 45-60 minutes.

a) Maximum variation purposive sampling will be used to identify a subset of clinicians who have a range of receptiveness to the project and the tools.
b) The local site implementation team will identify clinicians in-depth interviews, using selection criteria such as responsiveness to the intervention (i.e. positive, neutral, negative), clinician type (doctor, midwife, nurse), and potentially other criteria to be identified. The Ariadne Labs Team will select interviewees based upon this list.
c) Local sites will invite the selected participants via their email address or site teams will utilize a interview sign up sheet. The sheet will be kept securely on site by the implementation team. Participation will be voluntary and uncompensated for completion of multiple surveys.
d) The Ariadne Labs Team will be responsible for scheduling of interviewees with participants.
e) One-to-one semi-structured interviews will be conducted by the Ariadne Labs Project Team and will be audio recorded.
f) Interviews will be conducted using a combination of methods (in person, over the telephone or both) depending on preference of the interviewees. In person interviews will be conducted at a designated location which will be guided by the local site.
g) Consent text is available in the consent language attachments.
h) Verbal consent will be obtained by the Ariadne Labs interviewer either in person or by telephone prior to conducting the interview.
i) The audio files will originate with Ariadne Labs Project Team and the audio files will be transcribed.
j) These interviews will not be anonymous, but no identifying information about the participants will be noted or recorded and all audio-recordings and transcripts will be kept confidential.
k) General themes from the interviews will be shared with local site implementation teams.

5. Clinician Knowledge and Attitudes Survey will be conducted to evaluate knowledge and skills related to the core behaviors, use of the tools and attitudes toward reducing cesarean delivery rates and implementing the intervention. This survey will no longer be administered.

    a) The local site team will administer the survey to all clinicians' email addresses.
    b) All clinicians with practicing privileges in the unit will be invited to participate and will be sent a hyperlink which will direct them to the Qualtrics survey.

c) All surveys will be confidential.
d) Consent text is available in the consent language attachments.
e) Consent will be affirmed with an agreed statement, stating that moving forward with the survey, the participant is providing consent to participate.
f) Participation will be voluntary and uncompensated for completion of multiple surveys.
g) The survey will take no more than 15 minutes to complete.

6. Focus Group Discussions will be conducted to identify successes, challenges and other contextual factors that are impacting the implementation of the tools, identify adaptations that have been made, why they have been made and how to improve the tools or the implementation program. The majority of focus group participants will fill all three roles (i.e. super-users, champions and implementers). Consequently, focus group discussions will address issues relevant to all three roles. In the event that some individuals only have one role, separate role-specific focus groups will be conducted with these individuals (e.g. some individuals may be super-users but not champions or implementers). Focus group discussions will be held at beginning of project, project midline and end line at each study site leading to 3-5 focus groups per site.

    a) Ariadne Labs Team will invite local site implementation teams to participate in focus group discussions.
    b) Four to six members of the implementation team, champions and super users will be invited to participate in each focus group discussion.
    c) A fact sheet, with all elements of informed consent, will be provided to participants during the scheduling process and at the time of the focus group.
    d) Participants will be given the opportunity to ask questions and asked to confirm their consent to participate in the focus groups.
    e) A semi-structured guide will be used. Focus groups that only include one role, will use a subset of questions from that guide.
    f) These discussions will audiotaped.
    g) Discussions will happen either in-person, at a location designated by the local site, or by video conference.
    h) Participation will be voluntary and uncompensated for completion of multiple focus group discussions.
    i) The audio files will originate with Ariadne Labs Project Team and the audio files will be transcribed.
    j) These focus groups will not be anonymous, but no identifying information about the participants will be noted or recorded and all audio-recordings and transcripts will be kept confidential.
    k) General themes from the interviews will be shared with each local site implementation team.

7. Patient Postpartum Surveys will be conducted by the local site team on the postpartum ward to provide an insight into patient experience of the tools.

a. Convenience sampling will be used.
b. Members of local staff will offer the survey electronically using an online survey service, Qualtrics, to all women who meet inclusion criteria while recovering from their delivery on the postpartum ward.
c. The survey will be administered daily on a tablet device which will be offered to postpartum women by local staff.
d. Any women who have experienced an intrapartum, stillbirth or neonatal death will not be asked to complete this survey.
e. The survey will be completed once per eligible postpartum woman.
f. There will be no incentives presented to postpartum women or surveys administered after discharge form the postpartum ward.
g. Consent text is detailed in the consent language attachments and postpartum women will have the opportunity to ask questions to local staff prior to proceeding with completion of the survey.
h. Consent will be affirmed with an agreed statement, stating that moving forward with the survey, the participant is providing consent to participate.
i. Participation is voluntary and uncompensated, and women may stop taking the survey at any time.
j. The survey will last no longer than ten minutes.
k. Survey data will be analyzed and reported in aggregate on a monthly basis.
l. Demographic data will be collected to assess the impact of the tools on different groups of women.
m. Demographics that will be collected include: age, race/ethnicity, education, and parity.
n. Any demographic data that is collected will not be shared unless there are at least five individuals in that category.

8. Patient Postpartum Interviews will be conducted by study team on the postpartum ward to provide an insight into the patient's care experience. Interviews will be conducted during the final month of data collection. Patients will also be screened to participate in interviews during the final month of data collection.

    a. Convenience sampling will be used.
    b. Members of the study team will offer patients the option to complete an interview and/or survey to all women who meet inclusion criteria while recovering in the postpartum ward. This is a one-time interview. There will be no invitations presented to patients after the patient has been discharged from the postpartum care unit.
    c. Any women who have experienced an intrapartum, stillbirth or neonatal death will not be asked to complete this interview.
    d. Participation is voluntary and uncompensated, and women may stop the interview at any time.
    e. The interview will last no longer than fifteen minutes and collectively no more than 30 minutes if completed with a survey.

f. One-to-one semi-structured interviews will be conducted by the Ariadne Labs Study Team and will be audio recorded.
g. The audio files will originate with Ariadne Labs Study Team and the audio files will be transcribed.
h. No identifying information about the participants will be noted or recorded and all audio-recordings and transcripts will be kept confidential.
i. Interview will be analyzed and reported in aggregate by the Ariadne Labs Study Team.
j. Demographic data will be collected to assess the impact of the care on different groups of women.
k. Demographics that will be collected include: age, race/ethnicity, education, and parity.
l. Any demographic data that is collected will not be shared unless there are at least five individuals in that category.
m. If a patient participant completes both the survey and the interview, a code will be place on the interviewer's questions sheet and the survey which will link the demographic information. This is to avoid the participant having to complete this section twice. Demographic questions will mirror those presented in the patient survey.

9. Patient Level Data will be collected from patient records through a partnership between the Ariadne Labs and each local site team.

    a) Patient record data will be extracted from the medical record system by the data and quality team at each local site.
    b) The indicators that will be collected and analyzed for the project have been identified based on the measures used for other cesarean birth reduction projects and the measures of greatest interest to site leadership (see Appendix 3 for more details).
    c) The Ariadne Labs Project Team will support each local site team to design a system to extract any data required for the project that is not currently being regularly collected.
    d) All data will adhere to data protection agreements as described in Section 8.

10. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey data will be shared with Ariadne Labs by site's study teams.
    a) HCAHPS is a standardized, publicly reported survey of patients' perspectives of their hospital care and experience. All sites / hospitals are required to collect HCAHPS by the Centers of Medicare and Medicaid Services (CMS). The data from the survey will be used to allow study staff to better understand the patient experience in aggregate and compare with the patient surveys.
    b) HCAHPS survey report will be shared securely with Ariadne Labs via email.
    c) The survey reports will be sent on a quarterly basis including the quarter before launch as baseline data.

d) This information does not contain any protected health information and displays quantitative data in aggregate.
e) The survey is a standardized, publicly reported survey of patients' perspectives of their hospital care and experience. All sites / hospitals are required to collect HCAHPS by the Centers of Medicare and Medicaid Services (CMS). However, Ariadne Labs will only be sent HCAHPS reports specific to the Obstetrical unit.
f) The HCAHPS reports are a general hospital quality metric captures that Ariadne Labs will use to compare to the results of the patient postpartum surveys.

IV. Analysis

The Ariadne Labs Project Team will analyze all data with the goal of addressing the specific aims and endpoints associated with each data source. A thorough statistical analysis plan and table shells will be drawn up before the final data analysis, but at a minimum it will include both quantitative and qualitative approaches, as well as specific attention to longitudinal changes in endpoints over time.

Quantitative approaches will include basic descriptive statistics such as means, percentages, and standard deviations over time. Because this study is not designed as a test of effectiveness and because our study populations will not be representative, no statistical tests for causal inference are anticipated. Analyses will be performed in SAS 9.4 or equivalent platform.

Qualitative approaches will include rapid thematic analysis of the qualitative sections of the observation form, the weekly coaching calls, clinician interview transcripts and focus group transcripts. Thereafter, all interviews will be transcribed and could be used for secondary analysis with data from other sites. This secondary analysis would be coded thematically using QSR NVivo or equivalent program qualitative analysis software to identify commonalities and differences. Secondary analysis of the qualitative fields from observation forms used in the quality improvement program at South Shore may be conducted at a later date to identify lessons for key implementation lessons for South Shore and future sites.

V. Outputs

The research evaluation will create the three key outputs:

1. Improved versions of the tools and implementation package that could be applied to successfully implement the program more broadly in the future.

2. Peer-reviewed publications co-authored with local site teams describing the feasibility and acceptability of the intervention and qualitative experiences of implementation.

3. White paper on generalizable lessons for implementation of solutions to address clinical complexity in childbirth.

5. Benefits

Possible benefits of participating in the quality improvement program are described as below:

1. Clinician Participants
   As a result of participation in the quality improvement program, clinician-participants may experience improved team communication, greater reliability and accuracy for decisions making at key moments related to either admission or labor and delivery at their site.

2. Patient Participants
   As a result of participation, laboring women may feel their preferences were reflected in the care they received, they were involved in key decisions and have a better experience of childbirth.

There are no benefits of the research project to either the clinician participants or the patient participants. However, insights gained from this program evaluation may contribute to the development of new improved methods of clinician-patient communication and scalable implementation lessons to support the spread of the program to other sites.

6. Risks

The quality improvement program focuses on processes of care and does not specify care plans and does not include any treatment-decision directives. All guidance conforms with evidence-based and nationally endorsed guidelines from obstetrics professional organizations, including the American College of Obstetricians and Gynecologists, the Society for Maternal-Fetal Medicine, the American College of Nurse-Midwives, and the Association of Women's Health, Obstetric and Neonatal Nurses.

For clinician participants, attending trainings, using the tools and being observed are part of the hospital's quality improvement process, so any risks would be associated with that effort and not the research. For patient participants, it is possible that the quality improvement program could be associated with a rise in complications associated with vaginal delivery, including 3rd/4th degree perineal lacerations and postpartum hemorrhage. Patients may also feel uncomfortable with having their care observed or with being explicitly included in the care team, especially during labor.

For clinician participants, the research components, voluntary participation in surveys, individual interviews and focus groups, carry very low risk of criminal or civil liability, financial standing, employability, insurability or reputation discomfort because the surveys, interviews, and focus groups do not contain sensitive topics. For patient surveys, there are no anticipated any risks to patients' criminal or civil liability, financial standing, employability, insurability, or reputation from taking the survey because the surveys do not contain sensitive topics.

7. Data Monitoring and Adverse Events

I. Data and Outcomes Monitoring

The principal investigator will assess the quality and completeness of patient level data regularly over the course of the study, and consistent problems will be identified and corrected as needed. Safety of subjects will be discussed actively and longitudinally as required during the period that the study is active, both with the participating site and also as an Ariadne Labs Project Team. Progress and potential safety or other concerns for subject will be discussed at protocol meetings to be held as needed during the duration of the protocol activity.

II. Adverse Events Reporting Guidelines

The proposed research will comply with the regulations set forth in 45 CFR Part 46, Protection of Human Subjects. The Ariadne Labs Project Team are educated on the protection of human research participants. They have been educated regarding HIPAA regulations and fully understand their responsibility to safeguard the personal health information of every participant involved in the research.

A communication plan has been developed to report adverse events for either patient-participants or clinician-participants (see Appendix 3 for a list of possible adverse events). All events will be reported to the site investigator, who will then report all events to the Principal Investigator. The site investigator will be responsible for notifying their local IRB, and the principal investigator will promptly notify the HMS IRB in necessary instances, as determined by the Principal Investigator, within 5 business days. The Ariadne Labs Project Team will then meet, in conjunction with the site investigator, to discuss the adverse event and decide on strategies to avoid such events from recurring.

8. Data Security & Privacy

I. Data Security

All data will be stored on an Amazon Web Services server in a secure environment approved by Harvard University Information Technology (HUIT).

The following measures will be taken to ensure the data is stored securely: 1) all data will be encrypted in transit and at rest, 2) servers containing sensitive data will not be exposed to the internet and 3) access only to authorized personnel by role via proxy servers using AWS security groups and private subnets.

Users will be required to login and passwords will be a minimum of 8 characters and be alphanumeric. Vulnerability scanning will be performed daily and all user activity will be logged.

Additionally, data may be stored on the secure Harvard shared drive. Only the Ariadne Labs Project Team will have access to data and will remain up to date on Human Subjects Protection training.

II. Data Privacy

Prior to data collection, a data use agreement will be executed between Harvard TH Chan School of Public Health and each local site. The data use agreement will include 1) the purpose, 2) a description of the data and data parameters, and 3) key Ariadne Labs and site contacts. The signed data use agreement will be uploaded to the IRB systems as soon as it is available.

Surveys will not be linked to any names or personal information. Interview data will be kept confidential. Observation data will not include any names or protected health information. Electronic medical record data that will be provided will include identifiable elements but no names or dates of birth will be included.

9. References

1. Witt WP, Wisk LE, Cheng ER, et al. Determinants of Cesarean Delivery in the US: A Lifecourse Approach. *Matern Child Health J*. 2014:84-93. doi:10.1007/s10995-014-1498-8.

2. Declercq ER, Sakala C, Corry MP, Applebaum S, Herrlich A. Major Survey Findings of Listening to MothersSM III: Pregnancy and Birth. *J Perinat Educ*. 2014;23(1):9-16. doi:10.1891/1058-1243.23.1.9.

3. Hamilton BE, Hoyert DL. Annual Summary of Vital Statistics: 2010-2011. *Pediatrics*. 2013;131:548-558. doi:10.1542/peds.2012-3769.

4. Declercq E, Menacker F, MacDorman M. Rise in "no indicated risk" primary caesareans in the United States, 1991-2001: cross sectional analysis. *BMJ*. 2005;330(7482):71-72. doi:10.1136/bmj.38279.705336.0B.

5. Ecker J. Elective cesarean delivery on maternal request. *JAMA*. 2013;309(18):1930-1936. doi:10.1001/jama.2013.3982.

6. Yang YT, Mello MM, Subramanian S V., Studdert DM. Relationship Between Malpractice Litigation Pressure and Rates of Cesarean Section and Vaginal Birth After Cesarean Section. *Med Care*. 2009;47(2):234-242. doi:10.1097/MLR.0b013e31818475de.

7. Gimm GW. The impact of malpractice liability claims on obstetrical practice patterns. *Health Serv Res*. 2010;45(1):195-211. doi:10.1111/j.1475-6773.2009.01062.x.

8. Kozhimannil KB, Law MR, Virnig BA. Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. *Health Aff (Millwood)*. 2013;32(3):527-535. doi:10.1377/hlthaff.2012.1030.

9. Kozhimannil KB, Arcaya MC, Subramanian S V., et al. Maternal Clinical Diagnoses and Hospital Variation in the Risk of Cesarean Delivery: Analyses of a National US Hospital Discharge Database. Smith GC, ed. *PLoS Med*. 2014;11(10):e1001745. doi:10.1371/journal.pmed.1001745.

10. Cáceres IA, Arcaya M, Declercq E, et al. Hospital Differences in Cesarean Deliveries in Massachusetts (US) 2004–2006: The Case against Case-Mix Artifact. Young RC, ed. *PLoS One*. 2013;8(3):e57817. doi:10.1371/journal.pone.0057817.

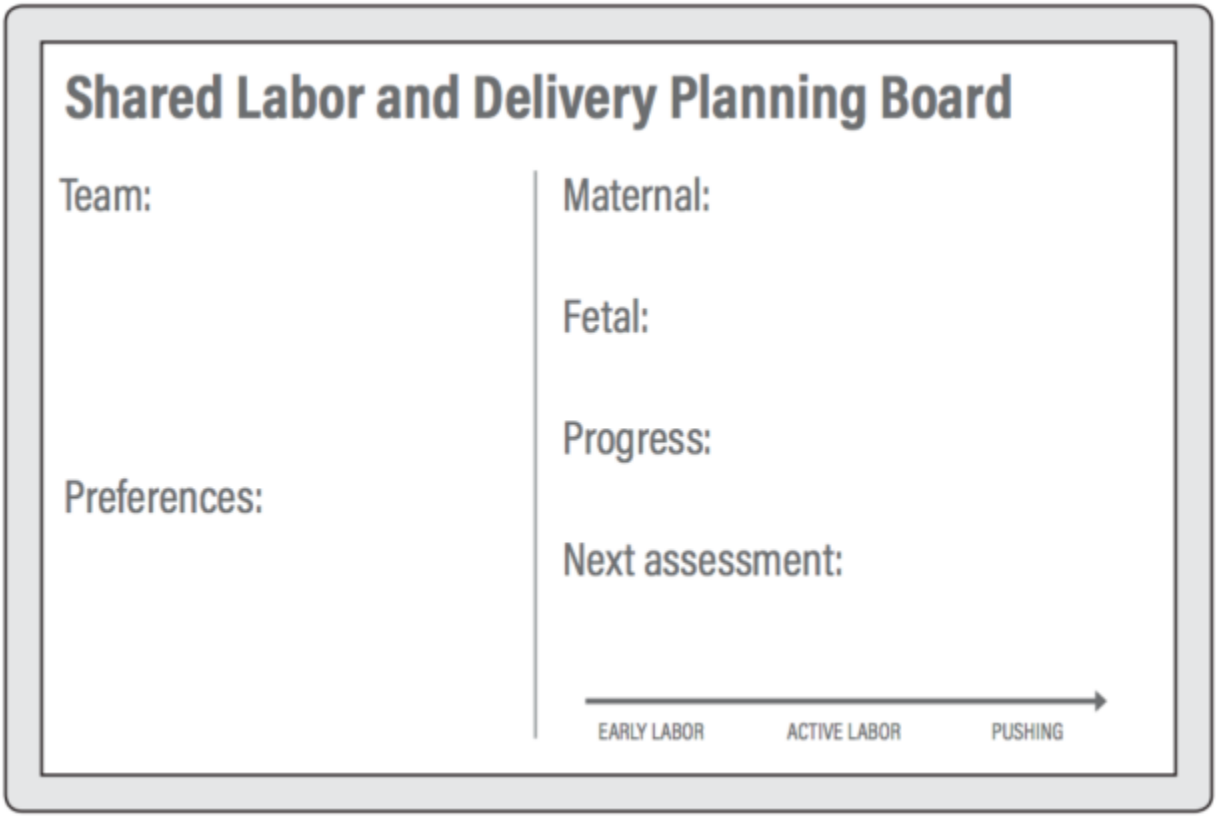
11. WHO | WHO recommendations: intrapartum care for a positive childbirth experience. *WHO*. 2018.

12. Plough AC, Galvin G, Li Z, et al. Relationship Between Labor and Delivery Unit Management Practices and Maternal Outcomes. *Obstet Gynecol*. 2017;130(2):358-365. doi:10.1097/AOG.0000000000002128.

10. Appendices

Appendix 1: Tools

Appendix 1a: Shared Labor and Planning Delivery Board



Appendix 1b: Admission Decision Aid

Admission Decision Aid

Use this tool after assessment to help confirm whether admission is necessary.

1 Consider: **Is admission currently indicated?**

CATEGORY	REASONS TO ADMIT	REASONS TO DEFER ADMISSION
MATERNAL	• Observation requires a labor and delivery room • Not coping well with early labor *and* ambulatory strategies are not effective • Pain relief requires admission (regional anesthesia) • Inducing labor	• Observation does not require a labor and delivery room • Not coping well with early labor *but* ambulatory strategies are effective • Previous history of precipitous labor • Social considerations about sending home
FETAL	• Observation requires a labor and delivery room • Membranes have ruptured – any gestation < 37 weeks – gestation ≥ 37 weeks *and* GBS positive • Inducing labor	• Observation does not require a labor and delivery room • Membranes have ruptured – gestation ≥ 37 weeks *and* GBS negative
PROGRESS	• In active labor – regular contractions *and* ≥ 4 – 6 cm dilated	• Not in active labor *but* has documented cervical change with regular contractions

2 Consider: **Which options can support the laboring person if deferred?**

COUNSELING	PHYSICAL	CLINICAL
• Explain the benefits of deferred admission • Provide encouragement • Provide advice on relaxation and breathing techniques	• Provide an alternate labor space (if available) • Facilitate position change, movement, ambulation • Provide hydrotherapy (tub/bath/shower if available) • Offer hydration and nutrition • Provide tools to aid labor (birth ball or rebozo if available)	• Administer pain relief – non-pharmacological (water injections, TENS, hot and cold therapy, acupuncture, massage) – pharmacological (non-opioid analgesia, therapeutic sleep) • Consider laboratory testing or imaging

Appendix 1c: Delivery Decision Aid

Delivery Decision Aid

Use this tool to guide team discussion when considering operative delivery.
All team members should be present.

1. Ask aloud: **"What is the reason for considering delivery?"**

2. Confirm aloud: **Have the minimum criteria for that indication been met?**

CATEGORY	INDICATION	MINIMUM CRITERIA
MATERNAL	Request	
FETAL	Intolerance of labor	*Any of:* • Bradycardia • Recurrent decelerations *and* absent variability • Recurrent decelerations that do not improve with resuscitation *and* remote from delivery • Tachycardia that does not improve with resuscitation *and* remote from delivery
PROGRESS	Failed induction of labor	*Either:* • Latent phase lasted ≥ 24 hours • Oxytocin administration ≥15 hours *with* ruptured membranes
	Active phase arrest	No cervical change with ruptured membranes *and* ≥ 6 cm dilated… *with either:* • Adequate contractions (>200 MVU) ≥ 4 hours • Oxytocin administration ≥ 6 hours
	Second stage arrest	*Either:* • Multiparous and pushing ≥ 2 hours • Nulliparous and pushing ≥ 3 hours

3. Ask aloud: **"Are there options that will allow more time for labor?"**
(see other side for suggested options)

Yes: Discuss options and make a plan.

No: Discuss risks and benefits of operative delivery and answer any questions.

Delivery Decision Aid: Options for more time

The following options may offer reassurance and provide additional time for labor and vaginal delivery.

CATEGORY	OPTIONS
MATERNAL	• Provide emotional support (communication with the mother, encouragement, breathing and relaxation techniques) • Provide physical support (movement, positional change, hydrotherapy, acupuncture, touch techniques, massage) • Adjust environment (decrease stimuli) • Administer pain relief – non-pharmacological (hydrotherapy, TENS, hot and cold therapy) – pharmacological (non-opioid analgesia, nitrous oxide, opioid analgesia, regional anesthesia) • Order laboratory testing or imaging • Consult with additional clinicians
FETAL	• Facilitate movement and positional change • Assess well being (change fetal heart monitoring method, perform scalp stimulation) • Pause augmenting agent (stop oxytocin) • Reverse augmenting agent (administer tocolytic) • Resuscitate (hydration, oxygen, amnioinfusion) • Consult with additional clinicians
PROGRESS	• Facilitate movement, ambulation, or relaxation (rebozo, walking path, birthing ball, hydrotherapy, reduce environmental stimuli) • Augment labor • Adjust dose of oxytocin • Confirm contraction strength (IUPC) • Consult with additional clinicians

Appendix 2: Tool Development and Adaptation

Tool Development

This program was developed using a year-long, rigorous human-centered design process that included expert validation and rapid cycle testing. Through a comprehensive review of the peer-reviewed literature, gray literature, and professional organization guidelines evidence-based strategies were identified to reduce harm from overuse of cesarean deliveries. Using expert consultation with approximately fifty key leaders from clinical obstetrics (nurses, midwives, obstetricians, anesthesiologists), patient advocacy, health services research, and implementation science, we prioritized the strategies based on their strength of evidence, impact, ability to be operationalized through simple tools, and sensitivity to context. As a result of this process, strategies that preserved labor progress and minimize preemptive cesareans for inadequate labor progress in the absence of other concerns were prioritized.

Clinical workflow process maps and logic models were developed to identify opportunities to operationalize these strategies, including the specific opportunity to improve team decision-making. A second expert consultation session surfaced four previously described behaviors. Using interviews with clinicians, and rapid cycle testing in simulation, a set of care planning and decision aids to support these behaviors at admission, during labor, and at delivery were developed.

The tools organize available pertinent data and care management options using a patient facing shared planning board that can create accountability between the laboring woman, nurse and delivering provider and two decision aids to support the decisions to admit a woman to a labor and delivery room and to deliver her baby operatively. The decision aids embed guidelines for labor management from national professional organizations, but do not direct specific care management options. In addition to use of these aids by the care teams, an implementation model has been developed which will be evaluated for implementation fidelity and track progress towards patient safety goals.

Tool Adaptation

Throughout the implementation process, the local site implementation team will make adaptations to the tools and implementation processes based upon their context, resources, and early experiences with training on, coaching about, and using the tools. There are three categories of adaptations that can be made while maintaining implementation fidelity:

1. No Adaptation: Features that are essential to the four behaviors that constitute the program objectives and therefore cannot be adapted without altering the program objectives.

2. Ariadne Labs-Guided Adaptation: Features that have major impact on core behaviors but can be adapted by local sites with Ariadne Labs support to ensure adequate implementation, tracking, and measurement of the changes.

3. Site Guided Adaptation: Features that are not essential to the core behaviors and will be best adapted to local contexts and preferences.

Tool	**No Adaptation**	**Ariadne Labs-Guided Adaptation**	**Site Guided Adaptation**
Labor and Delivery Planning Board	Conversations between laboring woman, nurse, and provider Conversations in MFP format Updating of whiteboard at each key moment conversation	In person vs. phone conversations Identifying critical moments for conversations Modifying elements of the labor and delivery planning board	Lead roles for different elements of conversations Location of whiteboard in the labor room
Admission Decision Aid		Indications for admission may vary with site and context	Plan options may vary according to availability at sites
Delivery Decision Aid	Indications for delivery		Lead roles for different elements of verification Team members present for verification Plan options if do not meet verification indications

Ariadne Labs-Guided Adaptations will be discussed with the Ariadne Labs Project Team and local site teams before implementation and will be rolled out at set points in time to facilitate measurement of the changes and acceptability. Site Guided Adaptations will be allowed to happen organically based on the preferences of the local champions, super-users, and frontline staff. All adaptations will be tracked by the Ariadne Labs Project Team along with the justifications for each adaptation as part of our program evaluation.

Appendix 3: Patient Record Data Measures

Patient level data and/or calculated measures may come from ICD-10 codes or from other fields in the clinical record, depending on the variable and the existing data infrastructure and analysis processes at the hospital. The Ariadne Labs Project Team will request that the hospital team provides these data on a monthly basis.

The Ariadne Labs Project Team will use these data to calculate indicators, such as rates and counts, to include in reports for the study team, managers, clinicians, and any other people at the hospital involved in the project. The reports will focus on primary outcomes for impact of the quality improvement initiative, including cesarean delivery rates and other related indicators (i.e. operative delivery rates). We will also monitor selected maternal and neonatal adverse events and co-morbidities in order to identify other potential benefits or harms and provide context to interpret the primary outcome results.

Below are examples of the types of indicators we will report based on the patient level data the hospital team provides. Further below is a full list of the patient level data elements we will request to calculate these indicators.

Procedures

- Cesarean delivery rate
- Operative delivery rate
- Vaginal delivery rate
- Induction rate
- Episiotomy rate

Maternal Adverse Events

- 3rd/4th degree laceration rate
- Hemorrhage rate
- Infection rate
- ICU admission
- Maternal death

Neonatal Adverse Events

- Birth trauma rate
- Rate of Apgar ≤ 7 at 5 minutes
- Intubation rate
- NICU admission rate
- Neonatal death

Patient Comorbidities

- Rate of diabetes
- Rate of hypertension
- Cholestasis of pregnancy
- Placenta previa
- Placenta accreta

Other

- Indications for cesarean or operative deliveries
- Indications for admission
- Length of labor

Maternal Variables
Maternal ID
Month of delivery
Year of delivery
Maternal age
Gestational age
Parity
Prior cesarean delivery
Scheduled cesarean delivery
TOLAC
Cesarean indication
Induction
Scheduled induction
Admission indication
Dilation at admission
Labor length
First stage of labor length
Postpartum stay length
Episiotomy
Third/fourth degree laceration
Maternal death
Maternal ICU admission
Postpartum hemorrhage
Massive obstetric hemorrhage
Blood transfusion
Placenta accreta
Placenta previa
Unplanned hysterectomy
Infection
Sepsis
Cholestasis
Chorioamnionitis
Uterine rupture
Abruption
Acute fatty liver of pregnancy
Acute renal failure
Amniotic fluid embolism
Cardiac arrest
Ventricular fibrillation
Disseminated intravascular coagulation
Deep vein thrombosis
Ileus
Acute heart failure
Pulmonary edema
Pulmonary embolism
Substance misuse
Pre-gestational diabetes
Gestational diabetes
Chronis hypertension
Gestational hypertension
Preeclampsia
Eclampsia
Sickle cell disease
Epidural

Neonatal Variables
Baby ID
Maternal ID
Mode of delivery
Presentation
Ventilation resuscitation within the first 72 hours
Cardiopulmonary resuscitation within the first 72 hours
Cardiac arrest
Cephalohematoma
Hypoglycemia
Stillbirth
Neonatal death
NICU admission
Neonatal transfer
Unexpected newborn complications
Apgar at 1 min
Apgar at 5 min
Meconium aspiration syndrome
Birth trauma
Intracranial hemorrhage
Encephalopathy
Hypotension
Pneumonia
Seizures
Sepsis
Transfusion
Preexisting condition
Intubation
Continuous positive airway pressure (CPAP)

Appendix 4: Local Site Teams and Ariadne Labs Project Team

1. Site 1: South Shore Hospital Team

South Shore Team Role	Named individual
Executive Sponsor	Kimberly Dever, MD, President of the Medical Executive Committee and Associate CMO
Co-Directors of Project	Kimberly Dever, MD Chair of the Department of Obstetrics and Gynecology Julie Paul, CNM, Co-Director of Midwifery
Day-to-Day Champions	Rachel Ballester, Certified Nurse Midwife Judy Berk, Certified Nurse Midwife Faye Weir, MSN, cDNP, RN and Director Child Parent Services Luke Poppish, Senior Service Line Manager Kathleen Bruce, Labor and Delivery Nurse Manager Kathleen Cahill, Parent/Child Services
Hospital Quality Improvement Team	Karen Baxter, JD, RN, Director, Risk Management Brett Corrigan, Performance Management Specialist Noreen MacLean, MSN, RN Administrative Clinical Coordinator Christine Just, MSN, RN, CNM Director of Provider Council
Data Analyst	Pamela Patterson, BSN, RN Perinatal Outcomes Nurse
Research Coordinator	Maureen DeMenna, MSN, RN, Clinical Research Program Manager

2. Site 2: Saint Francis Hospital Team

South Shore Team Role	Named individual
Executive Sponsor	Shannon Filosa, RN, PhD, Executive Director of Women's and Children's Services
Director(s) of Project	Donald Loveless, MD, Section Chief of Obstetrics and Gynecology Karen Duncan, BSN, RNC-OB, Clinical Manager of Labor and Delivery
Day-to-Day Champions	Lisa Early, APRN-CNS, MS, C-OB, Clinical Educator Trisha Short, BSN, RN, Perinatal Safety Nurse
Hospital Quality Improvement Team	Brenda Nance, RN, Executive Director for the Quality Department Bonnie Parks, Manager of Outcomes Measurement
Data Analyst	Maggie Smith, IT representative for Stork
Research Coordinator	Amber Hood, IRB and Compliance Manager