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Idealized Design of Perinatal Care

The Institute for Healthcare Improvement thanks Ascension Health and Premier, Inc., our colleagues in this important work to improve the safety and effectiveness of perinatal care.

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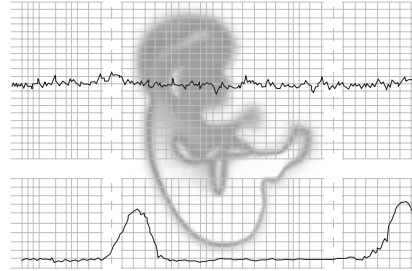
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Idealized Design of Perinatal Care

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Thank you to our colleagues in this important work:

Premier Healthcare Informatics and Insurance Management Services staff have provided invaluable leadership throughout the Idealized Design of Perinatal Care project. Premier's mission, to improve the health of communities, drove its involvement in the project. Through its clinical databases and risk management offerings, Premier's focus on improving health care quality and outcomes is well aligned with IHI. Premier thanks the ten Premier owner organizations that served as the participants in Phase I and the additional five Premier owners that joined the project in Phase II. Together, IHI and Premier are advancing the imperative for quality improvement.

Ascension Health (www.ascensionhealth.org) is the nation's largest Catholic and nonprofit health system, with more than 105,000 associates serving in 20 states and the District of Columbia. Consistent with its mission to serve all people with special attention to those who are poor and vulnerable, Ascension Health is an innovative leader in transforming health care through patient-centered, holistic care of the highest clinical quality. Ascension Health's Alpha Ministries have been involved in transforming care in perinatal safety for almost two years as part of the Clinical Excellence goal of no preventable deaths or injuries by 2008. The Perinatal Safety Alpha Ministries added the IHI innovation work in this area as part of a broad approach to develop high-reliability units and claims prevention strategies. With five new teams now participating in the IHI innovation project, Idealized Design of Perinatal Care, Ascension Health is pleased to continue to support important endeavors such as this.

The Institute for Healthcare Improvement also acknowledges the contributions made by **Kaiser Permanente** in the field of perinatal safety, especially in the areas of teamwork and communication training, including the SBAR technique, some of which is incorporated in the Idealized Design of Perinatal Care project.

Executive Summary

Idealized Design of Perinatal Care is an innovation project based on the principles of reliability science and the Institute for Healthcare Improvement's (IHI's) model for applying these principles to improve care.¹ The project builds upon similar processes developed for other clinical arenas in three previous IHI Idealized Design projects. The Idealized Design model focuses on comprehensive redesign to enable a care system to perform substantially better in the future than the *best* it can do at present. The goal of Idealized Design of Perinatal Care is to achieve a new level of safer, more effective care and to minimize some of the risks identified in medical malpractice cases.

The model described in this white paper, Idealized Design of Perinatal Care, represents the Institute for Healthcare Improvement's best current assessment of the components of the safest and most reliable system of perinatal care. The four key components of the model are: 1) the development of reliable clinical processes to manage labor and delivery; 2) the use of principles that improve safety (i.e., preventing, detecting, and mitigating errors); 3) the establishment of prepared and activated care teams that communicate effectively with each other and with mothers and families; and 4) a focus on mother and family as the locus of control during labor and delivery.

Reviews of perinatal care have consistently pointed to failures of communication among the care team and documentation of care as common factors in adverse events that occur in labor and delivery. They are also prime factors leading to malpractice claims.²

Two perinatal care “bundles”—a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually—are being tested in this Idealized Design project: the *Elective Induction Bundle* and the *Augmentation Bundle*. Experience from the use of bundles in other clinical areas, such as care of the ventilated patient, has shown that reliably applying these evidence-based interventions can dramatically improve outcomes.³ The assumption of this innovation work is that the use of bundles in the delivery of perinatal care will have a similar effect.

The authors acknowledge that other organizations have also been working on improving perinatal care through the use of simulation training and teamwork and communication training. IHI's model includes elements of these methods.

The Idealized Design of Perinatal Care project has two phases. Sixteen perinatal units from hospitals around the US participated in Phase I, from February to August 2005. The goals of Phase I were identifying changes that would make the most impact on improving perinatal care, selecting elements for each of the bundles, learning how to apply IHI's reliability model to improve processes, and improving the culture within a perinatal unit. This white paper provides detail about the Idealized Design process and examines some of the initial work completed by teams.

Phase II, which began in September 2005, expands on this work. This phase focuses particularly on managing second stage labor, including common interpretation of fetal heart monitoring, developing a reliable tool to identify harm, and ensuring that patient preferences are known and honored.

Introduction

Adverse events occurring during labor and delivery are rare relative to the number of births, but when they do occur they can result in significant harm. The effects of an adverse event—physical, psychological, and financial—take a heavy toll on the child, the family, and the clinicians involved. Families may be left to care for a child who has enormous needs, and their only recourse for obtaining financial assistance to meet these needs may be to pursue legal action.

Malpractice claims in obstetrics and gynecology are not uncommon. According to the American College of Obstetricians and Gynecologists (ACOG), obstetricians and gynecologists have an average of 2.6 claims filed against them during their career. Of these, 61 percent are obstetrics-related cases.⁴ Claims related to a brain-damaged infant were among the top five conditions for which compensation was sought during the period from 1985 to 2003, with an average indemnity of \$509,280.⁵ According to the 2003 National Practitioner Data Bank report, obstetrics-related cases (totaling 1,255) generated 8.1 percent of all physician malpractice payment reports, had the highest median (\$290,000) and mean (\$475,880) payment amounts, and took the longest amount of time to resolve compared with anesthesia-related cases (the mean delay between incident and payment in obstetrics was 5.66 years, median 4.74 years; compared with 3.67 and 3.30 years, respectively, in anesthesia). The median malpractice award for a childbirth-related claim involving obstetricians and hospitals was \$2.5 million for the period from 1997 to 2003.⁶ In part because of these statistics, liability insurance premiums for obstetricians and hospitals with large OB services have risen dramatically.

The best defense against malpractice claims—and indeed for providing the best care for patients—is prevention or minimization of harm whenever possible, through adherence to evidence-based practice guidelines. Professional organizations such as ACOG and the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) have developed a number of practice guidelines and position statements (Figure 1). The challenge is ensuring that these guidelines are used consistently. Guidelines also evolve, based on new research, and must be revisited periodically by clinicians to determine their impact on local practice. Further, the Idealized Design project recognizes that evidence-based care must be provided by a care team that works together smoothly and effectively (a high-functioning team, as described below), complemented by complete and accurate documentation of that care.⁷

Figure 1. Examples of Position Statements and Bulletins Related to the Idealized Design of Perinatal Care

AWHONN Clinical Position Statements

- Fetal Assessment, Revised and Reaffirmed, April 2000
- Professional Nursing Support of Laboring Women, Approved by the Executive Board, April 2000

ACOG Practice Bulletins

- Induction of Labor, ACOG Practice Bulletin, Number 10, November 1999
- Intrapartum Fetal Heart Rate Monitoring, ACOG Practice Bulletin, Number 70, December 2005

Additional ACOG References

- ACOG Committee Opinion, Patient Safety in Obstetrics and Gynecology, Number 286, October 2003
- ACOG Practice Bulletin, Fetal Macrosomia, Number 22, November 2000
- ACOG Practice Bulletin, Shoulder Dystocia, Number 40, November 2002
- ACOG Practice Bulletin, Dystocia and the Augmentation of Labor, Number 49, December 2003

Poor documentation of care not only impedes communication among providers, but often complicates defense against malpractice claims. Incomplete or absent documentation may be interpreted as indicating a lack of planning for a particular course of action, and gaps in documentation make it difficult to determine the rationale behind a decision. Another potential problem with documentation can occur when the medical record contains contradictory statements, due to differences in interpretation, recorded by different providers. The wide variation in the way obstetricians and nurses interpret the fetal monitoring strip may be due to the absence of a common language for interpretation, lack of multidisciplinary training in teamwork and communication, and variability in processes of care.

Reviews of perinatal care (from individual cases and claims analysis) show that poor communication among providers and with patients contributes to care that is less than optimal and may increase the risk of a malpractice claim. In one study of closed claims in obstetrics and gynecology, more than one-third of adverse events were associated with communication problems ranging from basic miscommunication among providers, to misunderstanding because of a lack of common terminology, to delays in communication, and to a total absence of communication.⁸

The clinical processes in the Idealized Design project are designed to decrease the incidence of communication problems. The two perinatal care bundles are based on reliability science and provide a common language for team members, in order to improve teamwork and communication.

The Idealized Design of Perinatal Care Model

Idealized Design of Perinatal Care is the fourth Idealized Design model developed by IHI. (The first three models are Idealized Design of Clinical Office Practices,⁹ Idealized Design of Medication Systems, and Idealized Design of the Intensive Care Unit.) Each of these designs has resulted in improved outcomes in their respective clinical arenas.¹⁰ The goal of Idealized Design is to develop the best possible “ideal” care system that its designers can conceive at that time. Furthermore, Idealized Designs are capable of being improved and of improving themselves.¹¹

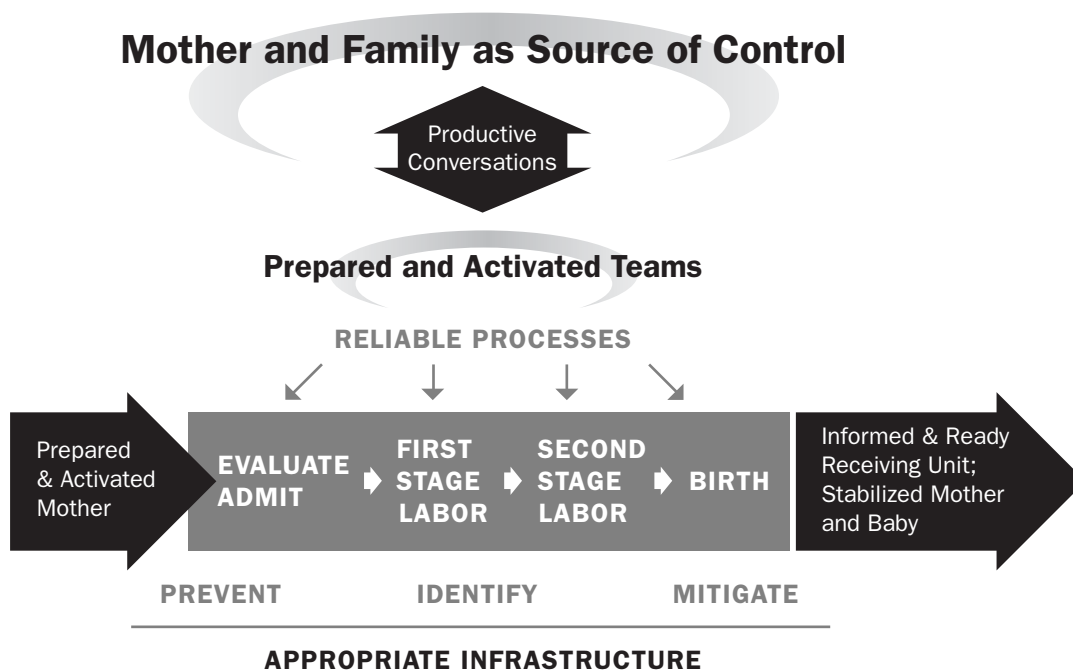
Idealized Design of Perinatal Care is based on reliability science (failure-free operation over time), including both *what* and *how* care is delivered. The *what* consists of the best science, the soundest evidence, upon which to base practice. This evidence spans a wide spectrum, from the results of randomized trials to expert opinion. The ACOG Practice Bulletins are examples of guidelines based on peer-reviewed research.

The *how* is the method by which that evidence-based care is delivered (e.g., by using standardized order sets). At present, the execution of best practices is highly variable, as demonstrated by chart review and malpractice claims analysis. To improve safety and reliability, *what* we do and *how* we do it must come together as the *way* we provide effective perinatal care.

The Model for Improvement¹² is an effective methodology to test changes in processes that result in the reliable delivery of the highest level of care. Delivering ideal care is based on reliable design and a specific goal for each process that will make the greatest difference in care.

Simply improving current processes cannot achieve acceptable levels of reliability.¹³ Idealized Design is based instead on a comprehensive redesign of the care system: determining what the best perinatal care would look like, and how all the parts and players involved in its complex processes would best fit together, in a “best possible world” scenario. Components include clinical processes, communication and teamwork, and acknowledging and honoring the expressed preferences of the mother and the family. Idealized Design of Perinatal Care is a method of marrying these factors to produce a theory, an “educated best guess,” about the best perinatal care system.

Figure 2. Idealized Design of Perinatal Care



Components of the Model

The Idealized Design of Perinatal Care model (Figure 2) consists of eight basic components:

- A prepared and activated mother and family;
- The mother and family as the source of control (patient preferences);
- Productive conversations between the mother, family, and the care team;
- High-functioning care teams (prepared and activated);
- Reliable processes used to evaluate and manage labor and delivery (the perinatal care “bundles”);
- Reliable processes to prevent, detect, and mitigate problems;
- An appropriate infrastructure that underlies the system of care; and
- A stabilized mother and baby, given into the care of an informed and ready patient care unit.

The *mother and family as the source of control* means the mother has the information she needs to make informed decisions about her care, and is the source of control in the birth process. She, in collaboration with the care team, is able to make good decisions about the selection and delivery of her care. These shared goals create the conditions for delivering the safest and most reliable care. Mothers and partners are provided with information in a way that takes into account health and cultural literacy issues.

Productive conversations are defined as communications between the patient, her family, and the care team that honor *patient preferences* and emphasize the safety of both mother and fetus, and are continually evaluated and updated during the birth process. For example, patients have opportunities to list their preferences regarding delivery, pain management, and responses to their emotional needs.

A prepared and activated team that works together is a prerequisite for providing safe and reliable care. Effective communication among team members is critical for the team to be highly functional. SBAR (Situation-Background-Assessment-Recommendation)⁴⁴ is an effective tool to help team members communicate clearly and respectfully with each other in a focused and effective manner, especially in urgent or critical situations. All relevant facts are communicated in a cogent, methodical manner; concerns, recommendations, and requests are made specifically and clearly. Building on the work in crew resource management, communication training includes education in appropriate assertiveness and development of conflict resolution skills. Examples of applying these models can be found in Kaiser Permanente's work and in the Department of Defense/Agency for Healthcare Research and Quality (AHRQ) teamwork training curricula. Effective oral communication then translates into comprehensive written documentation that includes reasons for treatment decisions, monitoring information, and indications of treatment plans.

Reliable processes are used to evaluate the mother and fetus, and to manage the labor and delivery process. The Idealized Design of Perinatal Care bundles (described in more detail below) incorporate processes that help create a culture of patient safety, and processes that clinicians believe are important in contributing to good care for both the mother and the baby. By implementing the bundles and measuring their effect, IHI anticipates being able to reduce harm in labor and delivery, as well as being able to document that reduction.

These same reliable processes are also used to *prevent, detect, and mitigate* problems.⁴⁵ Prevention is, of course, preferable to anything else, but when problems cannot be prevented, providers must be able to detect them and mitigate their effects quickly. In labor and delivery, for example, this might mean collaborative interpretation of fetal monitoring based on common language and team response.⁴⁶ A common language is one in which descriptions of monitoring strips and desired actions are the same for both obstetricians and nurses, without inconsistencies or ambiguities. Once a problem is detected, action is taken based upon the results of detection. For example, the interpretation of fetal monitoring might mean the mother needs to be repositioned to improve

oxygenation to the fetus, thereby mitigating the problem detected. This cycle—prevent, detect, mitigate—underpins the principles of safety in the Idealized Design.

An appropriate infrastructure in the perinatal unit is another prerequisite for providing safe and reliable care. This infrastructure includes standard elements of multidisciplinary staff education and preparation, ensuring staff competency, privileging, and adoption of common standards.

Finally, *a stabilized mother and baby are given into the care of an informed and ready patient care unit.*

Design Targets

To determine the effectiveness of the Idealized Design of Perinatal Care model, the expert faculty established specific design targets—measurable raise-the-bar goals that indicate a dramatic improvement in results for patients beyond the best known in health care today—that include the following:

1. Birth trauma (i.e., neonatal injury as defined in the AHRQ Patient Safety Indicators)²⁷ is reduced to a maximum of 3.3 adverse events per 1,000 live births. According to AHRQ, the national estimate of birth trauma per 1,000 live births was 7.358 in 2001.²⁸
2. Patients (mothers) state that 95 percent of the time their wishes are known to the entire care team and respected.
3. Perinatal units report a 50 percent improvement in their culture survey scores. One example of a culture survey tool is AHRQ's Hospital Survey on Patient Safety Culture (HSOPSC).²⁹
4. All claims or allegations may be defended because they meet each institution's internal standards for defense (e.g., consistent documentation, no lapses in documentation, no lapses in communication).

Implementation of the Perinatal Care Bundles

Idealized Design uses reliability principles to support the application of the “bundle” concept to clinical processes.²⁰ A bundle is a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually. The selection of the evidence-based elements comprising the bundles is based on sound science and local knowledge, and an agreement among clinicians that patients should receive all elements of care unless medically contraindicated. Experience from the use of bundles in other clinical areas, such as care of the ventilated patient, has shown that reliably applying these evidence-based interventions can dramatically improve outcomes.²⁴ The assumption of this innovation work is that the use of bundles in the delivery of perinatal care will have a similar effect.

Bundles themselves do not improve outcomes, but the ability of the team to reliably implement every element of the bundle for all patients, unless medically contraindicated, advances care in such a way as to achieve the improved outcomes. The most important idea underlying bundles is the “all or none” concept: A team gets credit for implementing the bundle only if *every* element of the bundle is delivered for each patient, unless medically contraindicated. This goal serves as a catalyst to move teams toward a design that achieves a 10^{-2} level of reliable performance (i.e., 95 percent of the time patients receive all elements of the bundle).²² Providing care in the usual manner will not accomplish this goal.

Implementation of the two bundles, the Elective Induction Bundle and the Augmentation Bundle, is the focus of Phase I of the Idealized Design of Perinatal Care. Successful implementation requires that teams comply with all components of the respective bundle for each patient, establishing effective systems and a common language to ensure that obstetricians, nurses, and other caregivers interpret the same clinical scenario in the same way.

Elective Induction Bundle

Review of medical malpractice claims reveals that oxytocin, which stimulates uterine contractions and induces labor, is involved in more than 50 percent of the situations leading to birth trauma. To minimize the opportunity for harm, it is necessary to understand the pharmacology of the drug and its impact on the fetus, and to have protocols to guide its appropriate use. Based on findings from reviews of adverse events, medical malpractice claims, and guidelines provided by professional organizations, the expert faculty selected four elements that must be considered when using oxytocin for labor induction:

- Assessment of gestational age (ensuring that gestational age is greater than or equal to 39 weeks);
- Monitoring fetal heart rate for reassurance;
- Pelvic assessment; and
- Monitoring and management of hyperstimulation.

Before the elective induction of labor is initiated, it must be determined that the fetus has a gestational age of greater than or equal to 39 weeks, and this determination must be documented according to agreed upon standards. Determining which care team member is responsible for establishing gestational age and the method by which it is established are decisions that are left up to individual sites. Although babies have been delivered before 39 weeks of gestational age, ACOG guidelines²³ and other research report that the likelihood of harm to the baby from elective delivery is greater before 39 weeks. In the event of an adverse outcome, plaintiffs’ attorneys may use non-compliance with this guideline as an indicator of poor care.

Likewise, monitoring fetal heart rate for reassurance before induction, in accordance with specific definitions (detailed below), must be documented. Clinicians monitor fetal heart rate and the effects of uterine stimulants on the fetus, and ensure the availability of a physician capable of performing an emergency cesarean section, should it be necessary. For the first time, two major governing organizations, ACOG and AWHONN, have accepted the definitions of fetal monitoring developed by the National Institute for Child Health and Human Development (NICHD). This adoption is based on the goal of using a standard terminology to describe fetal heart rate monitoring and then developing an agreed upon plan of action to ensure compliance with this element of the bundle. According to ACOG, “The presence of fetal heart rate accelerations generally ensures that the fetus is not acidemic and provides reassurance of fetal status.”^{24,25} Because the positive predictive value of reassuring fetal assessment is high (>99 percent), it is vital that definitions are accepted and used by all members of the care team.²⁶

Pelvic examination to determine dilation, effacement, station, cervical position and consistency (Bishop’s Score), and fetal presentation should be performed and documented. This confirms the patient as a candidate for induction and allows a measure and evaluation of her progress in labor. Again, pelvic assessment should be performed and documented by pelvic examination before the induction is initiated.

Finally, because it is a frequent and potentially consequential occurrence during induced labor, hyperstimulation must be identified using a standard definition and documented, and a plan for a consensus response to the hyperstimulation must be made. The overall goal is to monitor for hyperstimulation and respond appropriately. In this Idealized Design project, teams worked together to develop a definition of hyperstimulation (generally agreed to be more than 5 contractions in 10 minutes), using information from the literature and guidelines from professional associations.²⁷

Augmentation Bundle

Augmentation of labor is a coordinated effort to enhance uterine contractions for a woman who is already in labor. One reason to augment labor is inadequate contractions in terms of strength or frequency, resulting in inadequate progress of labor. Oxytocin is used to augment uterine contractions. As with induction, four critical elements must be considered:

- Estimated fetal weight;
- Monitoring fetal heart rate for reassurance;
- Pelvic assessment; and
- Monitoring and management of hyperstimulation.

Estimation of fetal weight replaces gestational age in this bundle. It is important to know the size of the fetus to determine whether a continued attempt at vaginal delivery is appropriate. Monitoring for fetal reassurance and for uterine hyperstimulation and the teams' responses to both have the same implications as in the Elective Induction Bundle. Again, pelvic assessment should be performed and documented by pelvic examination before the augmentation is initiated.

Phase I: Lessons Learned

Of the perinatal/infant adverse events reported to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 84 percent cited poor or no communication among care providers as a common factor in those events.²⁸ The lack of a common language increases the chances of miscommunication among providers when they share information about maternal and fetal status and expected action. Nurses may have been trained using AWHONN language, and obstetricians trained using ACOG language. Further investigation has shown that even if a common language was adopted by both nurses and obstetricians, they continue to train independently. As a result, communication involving the description of the fetal heart rate tracings is not consistent among providers and this inconsistency may result in an action different from the one desired. Highly reliable perinatal teams have adopted a common language (the recently adopted NICHD language) and train nurses and obstetricians together. During the training, differences in interpretation are addressed and consensus is obtained regarding the desired action or response to specific interpretations.

A good example of the lack of consensus around nomenclature is “electronic fetal monitoring,” or EFM. According to one study, “Complete consensus on EFM nomenclature has not been achieved within the United States and Canada and is dependent on the descriptive terminology of various researchers, authors, and equipment manufacturers. Since communication is the essence of quality and safety, common nomenclature should be established among the members of the same perinatal healthcare team. This assures that all members comprehend the meaning of pattern implication.”²⁹ In another example, in AWHONN's Perinatal Nursing textbook (1996), Display 9-4, “Variability Nomenclature,” lists seven different authors with differing definitions of “variability.” The adoption by AWHONN and ACOG of the NICHD terminology has now supported one common language for pattern interpretation — something that has been missing since the first commercially available electronic fetal monitor was introduced in 1968. Another example of the need for one common language is the definition of “short- and long-term variability.” Prior to the adoption of the NICHD terminology in 1997, each individual care provider, physician, or nurse used their own working definition, developed by researchers such as Parer, Schiffrin, Tucker, and Murray.³⁰ The ACOG Technical Bulletin (Number 207), “Fetal Heart Rate Patterns: Monitoring, Interpretation and Management,” was in place until May 2005, but did not provide a definition of short- or long-term variability in terms of beats per minute (bpm). Figure 3 illustrates various definitions and

the evolution to the currently accepted NICHD guideline that no longer differentiates between short- and long-term variability, and instead uses baseline variability.³¹

Figure 3. Various Definitions of “Variability”

AWHONN Principles and Practices (1993)

Short-term variability:

- Absent
- Present

Long-term variability:

- Decreased/minimal (0–5 bpm)
- Average/within normal limits (6–25 bpm)
- Marked/saltatory (>25 bpm)

Murray et al. (1996)

Short-term variability:

- Absent
- Present

Long-term variability:

- Absent (0–2 bpm)
- Decreased/minimal (3–5 bpm)
- Average/within normal limits (6–25 bpm)
- Marked/saltatory (>25 bpm)

NICHD (1997) [Currently accepted by ACOG and AWHONN]

Baseline variability:

Visually quantified as the amplitude of peak-to-trough in beats per minute

- Absent (amplitude range undetectable)
- Minimal (amplitude range detectable but 5 bpm or fewer)
- Moderate [normal] (amplitude range 6–25 bpm)
- Marked (amplitude range >25 bpm)

Three elements of the two bundles proved difficult to adopt during Phase I: a policy of no elective deliveries before 39 weeks of gestational age, definition and management of hyperstimulation, and estimation and documentation of fetal weight. Teams will continue to test different processes to ensure reliable compliance with each of the bundle elements. In the case of limiting elective induction to instances in which gestational age is at least 39 weeks, teams in the Idealized Design project encountered issues related to physician preferences, workload and coverage issues, and demands from patients. To address these issues, teams presented guidelines and scientific information supporting the 39-week limit to the obstetricians practicing at the institutions to reinforce this element of the bundle. Some organizations set an expectation that there would be no elective inductions before 39 weeks. Once the expectation was set, staff at the hospital were instructed not to schedule elective inductions if the gestational age was determined to be less than 39 weeks.

Documentation of hyperstimulation proved more elusive, as the definition was more difficult to pin down. After consultation with expert faculty and internal discussions within their own organizations,

teams agreed to use one definition for hyperstimulation. The next hurdle was to determine the clinical response to hyperstimulation. Physicians were reluctant to document estimated fetal weight, even when it was agreed that this was an estimate and could be listed as a range—LGA (large for gestational age), AGA (average for gestational age), and SGA (small for gestational age). The concern for some was the risk associated with estimating incorrectly. Some teams, however, were able to move ahead successfully by emphasizing that the estimated fetal weight is a range.

The role of leadership, both administrative and clinical, also proved to be essential to success. Adoption of the elements of the perinatal care bundles, especially the 39-week gestational age limit, was achieved more readily in organizations where leaders set the expectation that the bundles would be adopted.

Looking Ahead: Phase II

During Phase II, teams will continue to work on applying IHI's reliability model to the implementation of the perinatal care bundles. In addition, Phase II will focus on developing systems to ensure that a mother's preferences are known and honored. Teams will also focus on testing their response to crisis situations by simulating these situations and making changes to improve those processes. The Idealized Design project also focuses on improving the safety culture of the perinatal unit, which will be measured using available safety attitude survey tools.³² A Perinatal Trigger Tool will be used to determine rate of perinatal harm. Another component of the model, the handoff to a receiving unit, is in development. Additional work in this project will focus on management of second stage labor and increasing the reliability of the selected processes.

IHI, Ascension Health, and Premier, Inc., remain committed to pursuing this valuable work to achieve improved outcomes.

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