Implementation of Safe Reduction of Primary Cesarean Birth Patient Safety Bundle: Review Article

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Abstract

Cesarean births and associated morbidity and mortality have reached near epidemic proportions. The National Partnership for Maternal Safety under the guidance of the Council on Patient Safety in Women's Health Care responded by developing a patient safety bundle to reduce the number of primary cesarean births. Safety bundles outline critical practices to implement in every maternity unit. This National Partnership for Maternity Safety bundle, as with other bundles, is organized into four domains: *Readiness, Recognition and Prevention, Response,* and *Reporting and Systems Learning*. Bundle components may be adapted to individual facilities, but standardization within an institution is advised. Evidence-based resources and recommendations are provided to assist implementation.

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Introduction:

In many countries, cesarean section is the most common major surgical procedure. Globally, the rate of cesarean birth increased by 3.7% annually from 2000 to 2015.Exceptionally wide practice variation characterizes use of cesarean birth both across and within countries. Cesarean rates of less than 10%, considered an indication of underuse, have recently been identified in 28 nations. However, most world nations have cesarean rates of 15% or higher, which is considered an indication of overuse (**1**).

As overuse is associated with myriad types of excess harm in women and cesarean-born children and with excess cost, policymakers, purchasers, payers, clinical leaders, researchers, advocates and women themselves seek ways to minimize unneeded cesarean births **(2, 3).**

In the United States, following a steep rise between 1996 and 2007, the cesarean rate has plateaued for a decade at nearly one in three. The American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine concluded that the steep rise was not accompanied by discernible benefits for women and newborns, and they have jointly issued guidance for safely reducing primary cesarean births **(4).**

Many effective strategies for cesarean reduction have been identified. Pre-labor practices that have been associated with reduced likelihood of cesarean birth include choosing individual care providers and birth settings with lower cesarean rates, choosing types of care providers and birth settings with lower cesarean rates (e.g., midwives and birth centers), childbirth training workshops, being physically active and staying fit during pregnancy, arranging for the labor support of a doula and attempting external cephalic version with non-cephalic presentation at term **(4, 5).**

After the onset of labor, factors that have been associated with reduced likelihood of cesarean birth include: delaying hospital admission until labor is well established, continuous labor support by someone in a doula role, intermittent auscultation rather than either on-admission or continuous electronic fetal monitoring,

discontinuation of synthetic oxytocin for induction after onset of labor, avoiding labor epidural (associated with cesarean for non-reassuring fetal heart status), remaining upright and mobile during the first stage of labor versus lying in bed, and following guidelines related to cervical status and elapsed time for use of synthetic oxytocin and cesarean birth **(6, 7, 8).**

Clinician interventions associated with lower likelihood of cesarean birth include clinical practice guidelines coupled with education by opinion leaders, audit and feedback, or mandatory second opinion**(3, 9, 10)**. Characteristics of women associated with lower likelihood of cesarean birth include lower body mass index, younger age and having Medicaid/public assistance versus private insurance coverage **(11, 12).**

Cesarean rates vary across racial/ethnic groups, and further within specific ethnic sub-groups **(13, 14).** Changes over time in primary cesarean rates have not been associated with changes in maternal risk profiles **(15)**. Assessment of factors that may be associated with cesarean rates commonly use vital statistics, administrative and/or medical records as data sources.

Surveys of childbearing women themselves enable us to examine the possible impact of women's beliefs and behaviors, as well as their care arrangements and labor experiences that may not be systematically recorded in other sources **(16, 17).**

Here we use data from the recent population based Listening to Mothers in California Survey to examine mother-reported factors that may be associated with lower likelihood of cesarean birth. These include factors not previously reported in the literature, such as women's attitudes, behaviors, knowledge and preferences, as well as previously reported factors, such as members of the woman's care team and labor management practices. It was also used the low-risk first birth cesarean rate at the woman's birth hospital as a proxy for local practice style **(18).**

To contribute to discussions about optimal ways to safely reduce the rate of cesarean birth, we carried out an adjusted analysis to examine possible associations between women's likelihood of cesarean birth and their attitudes, behaviors, knowledge and preferences, as well as their experiences with health professionals, the composition of their care team, and labor management and communication practices they experienced. In 2011, 1 in 3 women who gave birth in the United States did so by cesarean delivery**(19**). Even though the rates of primary and total cesarean delivery have plateaued recently, there was a rapid increase in cesarean rates from 1996 through 2011 . Although cesarean delivery can be lifesaving for the fetus, the mother, or both in certain cases, the rapid increase in the rate of cesarean births without evidence of concomitant decreases in maternal or neonatal morbidity or mortality raises significant concern that cesarean delivery is overused.Therefore, it is important for health care providers to understand the short-term and long term tradeoffs between cesarean and vaginal delivery, as well as the safe and appropriate opportunities to prevent overuse of cesarean delivery, particularly primary cesarean delivery **(20**).

Balancing risks and benefits

Childbirth by its very nature carries potential risks for the woman and her baby, regardless of the route of delivery. The National Institutes of Health has commissioned evidence-based reports over recent years to examine the risks and benefits of cesarean and vaginal delivery**(21**). For certain clinical condition such as placenta previa or uterine rupture cesarean delivery is firmly established as the safest route of delivery. However, for most pregnancies, which are low-risk, cesarean delivery appears to pose greater risk of maternal morbidity and mortality than vaginal delivery. It is difficult to isolate the morbidity caused specifically by route of delivery (**22**).

For example, in one of the few randomized trials of approach to delivery, women with a breech presentation were randomized to undergo planned cesarean delivery or planned vaginal delivery, although there was crossover in both treatment arms (**23**). In this study, at 3-month follow-up, women were more likely to have urinary, but not fecal, incontinence if they had been randomized to the planned vaginal delivery group. However, this difference was no longer significant at 2-year follow-up. Because of the size of this randomized trial, it was not powered to look at other measures of maternal morbidity (**24**).

A large population-based study from Canada found that the risk of severe maternal morbidities defined as hemorrhage that requires hysterectomy or transfusion, uterine rupture, anesthetic complications,

shock, cardiac arrest, acute renal failure, assisted ventilation, venous thromboembolism, major infection, or in-hospital wound disruption or hematoma was increased 3-fold for cesarean delivery as compared with vaginal delivery (2.7% vs 0.9%, respectively). There also are concerns regarding the long-term risks associated with cesarean delivery, particularly those associated with subsequent pregnancies (**25**).

The incidence of placental abnormalities, such as placenta previa, in future pregnancies increases with each subsequent cesarean delivery, from 1% with 1 prior cesarean delivery to almost 3% with 3 prior cesarean deliveries. In addition, an increasing number of prior cesareans is associated with the morbidity of placental previa: after 3 cesarean deliveries, the risk that a placenta previa will be complicated by placenta accreta is nearly 40%(**26**).

This combination of complications not only significantly increases maternal morbidity but also increases the risk of adverse neonatal outcomes, such as neonatal intensive care unit admission and perinatal death(**21, 26, 27**). Thus, although the initial cesarean delivery is associated with some increases in morbidity and mortality, the downstream effects are even greater because of the risks from repeat cesareans in future pregnancies(**28**).

Indications for primary cesarean

There is great regional variation by state in the rate of total cesarean delivery across the United States, ranging from a low of 23% to a high of nearly 40% . Variation in the rates of nulliparous term singleton vertex cesarean births indicates that clinical practice patterns affect the number of cesarean births performed. There also is substantial hospital-level variation. Studies have shown a 10-fold variation in the cesarean delivery rate across hospitals in the United States, from 7.1- 69.9%, and a 15-fold variation among low-risk women, from 2.4-36.5%.(**29**).

Studies that have evaluated the role of maternal characteristics, such as age, weight, and ethnicity, have consistently found these factors do not account fully for the temporal increase in the cesarean delivery rate or its regional variations.(**30,31**).

These findings suggest that other potentially modifiable factors, such as patient preferences and practice variation among hospitals, systems, and health care providers, likely contribute to the escalating cesarean delivery rates. To understand the degree to which cesarean deliveries may be preventable, it is important to know why cesareans are performed. In a 2011 population-based study, the most common indications for primary cesarean delivery included, in order of frequency, labor dystocia, abnormal or indeterminate (formerly, no reassuring) fetal heart rate tracing, fetal malpresentation, multiple gestation, and suspected fetal macrosomia. Arrest of labor and abnormal or indeterminate fetal heart rate tracing accounted for more than half of all primary cesarean deliveries in the study population. Safe reduction of the rate of primary cesarean deliveries will require different approaches for each of these indications. For example, it may be necessary to revisit the definition of labor dystocia because recent data show that contemporary labor progresses at a rate substantially slower than what has been historically taught. Improved and standardized fetal heart rate interpretation and management also may have an effect. Increasing women's access to nonmedical interventions during labor, such as continuous labor support, also has been shown to reduce cesarean birth rates. External cephalic version for breech presentation and a trial of labor for women with twin gestations when the first twin is in cephalic presentation also can contribute to the safe lowering of the primary cesarean delivery rate (**32**).

What is the appropriate definition of abnormally progressing first-stage labor?

The first stage of labor has been historically divided into the latent phase and the active phase based on the work by Friedman in the 1950s and beyond. The latent phase of labor is defined as beginning with maternal perception of regular contractions. On the basis of the 95th percentile threshold, historically, the latent phase has been defined as prolonged when it is >20 hours in nulliparous women and >14 hours in multiparous women The active phase of labor has been defined as the point at which the rate of change of cervical dilation significantly increases. Active-phase labor abnormalities can be categorized either as protraction disorders (slower progress than normal) or arrest disorders (complete cessation of progress). Based on Friedman's work, the traditional definition of a protracted active

phase (based on the 95th percentile) has been cervical dilatation in the active phase off<1.2cm/h for nulliparous women and <1.5 cm/h for multiparous women.19 Active-phase arrest traditionally has been defined as the absence of cervical change for 2 h in presence of adequate uterine contractions and cervical dilation of at least 4 cm. In this retrospective study conducted at 19 US hospitals, the duration of labor was analyzed in 62,415 parturient women, each of whom delivered a singleton vertex fetus vaginally and had a normal perinatal outcome. In this study, the 95th percentile rate of active-phase dilation was substantially slower than the standard rate derived from Friedman's work, varying from 0.5e0.7 cm/h for nulliparous women and from 0.5e1.3 cm/h for multiparous women the ranges reflect that at more advanced Second, the maximal slope in the rate of change of cervical dilation over time (ie, the active phase) often did not start until at least 6 cm. The Consortium on Safe Labor data do not directly address an optimal duration for the diagnosis of active-phase protraction or labor arrest, but do suggest that neither should be diagnosed < 6 cm of dilation. Because they are contemporary and robust, it seems that the Consortium on Safe Labor data, rather than the standards proposed by Friedman, should inform evidence based labor management (**33**).

How should abnormally progressing first-stage labor be managed?

Although labor management strategies predicated on the recent Consortium on Safe Labor information have not been assessed yet, some insight into how management of abnormal first-stage labor might be optimized can be deduced from prior studies. The definitions of a prolonged latent phase are still based on data from Friedman and modern investigators have not particularly focused on the latent phase of labor. Most women with a prolonged latent phase ultimately will enter the active phase with expectant management. With few exceptions, the remainder either will cease contracting or, with Amniotomy or oxytocin (or both), achieve the active phase . Thus, a prolonged latent phase (eg, >20 hours in nulliparous women and >14 hours in multiparous women) should not be an indication for cesarean delivery. When the first stage of labor is protracted or arrested, oxytocin is commonly recommended. Several studies have evaluated the optimal duration of oxytocin augmentation in the face of labor protraction or arrest. A prospective study of the progress of labor in 220 nulliparous women and 99 multiparous women who spontaneously entered labor evaluated the benefit of prolonging oxytocin augmentation for an additional 4 hours (for a total of 8 hours) in patients who were dilated at least 3 cm and had unsatisfactory progress (either protraction or arrest) after an initial 4-hour augmentation period(**34**).

The researchers found that of women who received at least 4 additional hours of oxytocin, 38% delivered vaginally, and none had neonates with 5-minute Apgar scores of 500 women found that extending the minimum period of oxytocin augmentation for active-phase arrest from 2 hours to at least 4 hours allowed the majority of women who had not progressed at the 2-hour mark to give birth vaginally without adversely affecting neonatal outcome. The researchers defined active-phase labor arrest as 1 cm of labor progress over 2 hours in women who entered labor spontaneously and were at least 4 cm dilated at the time arrest was diagnosed. The vaginal delivery rate for women who had not progressed despite 2 hours of oxytocin augmentation was 91% for multiparous women and 74% for nulliparous women. For women who had not progressed despite 4 hours of oxytocin (and in whom oxytocin was continued at the judgment of the health care provider), the vaginal delivery rates were 88% in multiparous women and 56% in nulliparous women. Subsequently, the researchers validated these results in a different cohort of 501 prospectively treated women . An additional study of 1014 women conducted by different authors demonstrated that using the same criteria in women with spontaneous labor or induced labor would lead to a significantly higher proportion of women achieving vaginal delivery with no increase in neonatal complications (**35**).

Of note, prolonged first stage of labor has been associated with an increased risk of chorioamnionitis in the studies listed, but whether this relationship is causal is unclear (ie, evolving chorioamnionitis may predispose to longer labors). Thus, although this relationshipneeds further elucidation, neither

chorioamnionitis nor its duration should be an indication for cesarean delivery. Given these data, as long as fetal and maternal status are reassuring, cervical dilation of 6 cm should be considered the threshold for the active phase of most women in labor (Box). Thus, before 6 cm of dilation is achieved, standards of active-phase progress should not be applied. Further, cesarean delivery for active-phase arrest in the first stage of labor should be reserved for women ≥6 cm of dilation with ruptured membranes who fail to progress despite 4 hours of adequate uterine activity, or at least 6 hours of oxytocin administration with inadequate uterine activity and no cervical change (**36**).

What is the appropriate definition of abnormal second-stage labor?

The second stage of labor begins when the cervix becomes fully dilated and ends with delivery of the neonate. Parity, delayed pushing, use of epidural analgesia, maternal body mass index, birth weight, occiput posterior position, and fetal station at complete dilation all have been shown to affect the length of the second stage of labor (**35**).

Further, it is important to consider not just the mean or median duration of the second stage of labor but also the 95th percentile duration. In the Consortium on Safe Labor study discussed earlier, although the mean and median duration of the second stage differed by 30 minutes, the 95th percentile threshold was approximately 1 hour longer in women who received epidural analgesia than in those who did not. Defining what constitutes an appropriate duration of the second stage is not straightforward because it involves a consideration of multiple short-term and long-term maternal and neonatal outcomes some of them competing. Multiple investigators have examined the relationship between the duration of the second stage of labor and adverse maternal and neonatal outcomes in an attempt to define what should constitute a “normal” duration of the second stage. In the era of electronic fetal monitoring, among neonates born to nulliparous women, adverse neonatal outcomes generally have not been associated with the duration of the second stage of labor.In a secondary analysis of a multicenter randomized study of fetal pulse oximetry, of 4126 nulliparous women who reached the second stage of labor, none of the following neonatal outcomes was found to be related to the duration of the second stage, which in some cases was 5 hours: 5-minute Apgar score of <4, umbilical artery pH <7.0, intubation in the delivery room, need for admission to the neonatal intensive care unit, or neonatal sepsis. Similarly, in a secondary analysis of 1862 women enrolled in an early vs delayed pushing trial, a longer duration of active pushing was not associated with adverse neonatal outcomes, even in women who pushed for≥ 3 hours (**35**)

This also was found in a large, retrospective cohort study of 15,759 nulliparous women even in a group of women whose second stage progressed >4 hours(**37**).The duration of the second stage of labor and its relationship to neonatal outcomes has been less extensively studied in multiparous women. In 1 retrospective study of 5158 multiparous women, when the duration of the second stage of labor was >3 hours, the risk of a 5-minute Apgar score of <7, admission to the neonatal intensive care unit, and a composite of neonatal morbidity were all significantly increased (**38**).

A population-based study of 58,113 multiparous women yielded similar results when the duration of the second stage was ≥ 2 hours. A longer duration of the second stage of labor is associated with adverse maternal outcomes, such as higher rates of puerperal infection, third-degree and fourth-degree perineal lacerations, and postpartum hemorrhage. Moreover, for each hour of the second stage, the chance for spontaneous vaginal delivery decreases progressively. Researchers have found that after a ≥3-hour second stage of labor, only 1 in 4 nulliparous women and 1 in 3 multiparous women give birth spontaneously, whereas up to 30-50% may require operative delivery to give birth vaginally in the current second stage of labor threshold environment (**38**).

Thus, the literature supports that for women, longer time in the second stage of labor is associated with increased risks of morbidity and a decreasing probability of spontaneous vaginal delivery. However, this risk increase may not be entirely related to the duration of the second stage per se, but rather to health care provider actions and interventions in response to it (eg, operative delivery and the associated risks of perineal trauma). With appropriate monitoring,

however, the absolute risks of adverse fetal and neonatal consequences of increasing second-stage duration appear to be, at worst, low and incremental). For example, in the study of 58,113 multiparous women cited earlier, although the risk of a 5-minute Apgar score of <7 and birth depression was increased when the second stage of labor lasted >2 hours, the absolute risk of these outcomes was low (<1.5%) with durations <2 hours and was not doubled even with durations >5 hours. Moreover, the duration of the second stage of labor was unrelated to the risk of neonatal sepsis or major trauma. Thus, a specific absolute maximum length of time spent in the second stage of labor beyond which all women should undergo operative delivery has not been identified. Similar to the first stage of labor, a prolonged second stage of labor has been associated with an increased risk of chorioamnionitis in the studies listed, but whether this relationship is causal is unclear (ie, evolving chorioamnionitis may predispose to longer labors). Again, neither chorioamnionitis nor its duration should be an indication for cesarean delivery (**39**).

How should abnormally progressing second-stage labor be managed?

Giventhe available literature, before diagnosing arrest of labor in the second stage and if the maternal and fetal conditions permit, at least 2 hours of pushing in multiparous women and at least 3 hours of pushing in nulliparous women should be allowed.Longer durations may be appropriate on an individualized basis (eg, with the use of epidural analgesia or with fetal malposition) as long as progress is being documented. For example, the recent Eunice Kennedy Shriver National Institute of Child Health and Human Development document suggested allowing 1 additional hour in the setting of an epidural, thus, at least 3 hours in multiparous women and 4 hours in nulliparous women be used to diagnose second-stage arrest, although that document did not clarify between pushing time or total second stage (**40**).

What other management approaches may reduce cesarean deliveries in the second stage of labor?

In addition to greater expectant management of the second stage, 2 other practices could potentially reduce cesarean deliveries in the second stage: (1) operative vaginal delivery; and (2) manual rotation of the fetal occiput for malposition (**40**).

Operative vaginal delivery

In contrast with the increasing rate of cesarean delivery, the rates of operative vaginal deliveries (via either vacuum or forceps) have decreased significantly during the past 15 years. (**40**).Yet, comparison of the outcomes of operative vaginal deliveries and unplanned cesarean deliveries shows no difference in serious neonatal morbidity (eg, intracerebral hemorrhage or death).

In a large, retrospective cohort study, the rate of intracranial hemorrhage associated with vacuum extraction did not differ significantly from that associated with either forceps delivery (odds ratio [OR], 1.2; 95% confidence interval [CI], 0.7e2.2) or cesarean delivery (OR, 0.9; 95% CI, 0.6e1.4)(**41**). In a more recent study, forceps-assisted vaginal deliveries were associated with a reduced risk of the combined outcome of seizure, intraventricular hemorrhage, or subdural hemorrhage as compared with either vacuum-assisted vaginal delivery (OR, 0.60; 95% CI, 0.40e0.90) or cesarean delivery (OR, 0.68; 95% CI, 0.48e0.97), with no significant difference between vacuum delivery or cesarean delivery.Fewer than 3% of women in whom an operative vaginal delivery has been attempted go on to deliver by cesarean.(**42**).

Although attempts at operative vaginal delivery from a midpelvic station (0 and +1 on the e5 to +5 scale) or from an occiput transverse or occiput posterior position with rotation are reasonable in selected cases(**43**), these procedures require a higher level of skill and are more likely to fail than low (+2) or outlet (scalp visible at the introitus) operative deliveries. Performing low or outlet procedures in fetuses not believed to be macrosomic is likely to safely reduce the risk of cesarean delivery in the second stage of labor. However, the number of health care providers who are adequately trained to perform forceps and vacuum deliveries is decreasing. In one survey, most (55%) resident physicians in training did not feel competent to perform a forceps delivery upon completion of residency(**44**).

Thus, training resident physicians in the performance of operative vaginal deliveries and using simulation for retraining and ongoing maintenance of

practice would likely contribute to a safe lowering of the cesarean delivery rate. In sum, operative vaginal delivery in the second stage of labor by experienced and well-trained physicians should be considered a safe, acceptable alternative to cesarean delivery. Training in, and ongoing maintenance of, practical skills related to operative vaginal delivery should be encouraged (**45)**.

Manual rotation of the fetal occiput

Occiput posterior and occiput transverse positions are associated with an increase in cesarean delivery and neonatal complications(**46, 47**). Historically, forceps rotation of the fetal occiput from occiput posterior or occiput transverse was common practice. Today this procedure, although still considered a reasonable management approach, has fallen out of favor and is rarely taught in the United States. An alternative approach is manual rotation of the fetal occiput, which has been associated with a safe reduction in the risk of cesarean delivery and is supported by the Society of Obstetricians and Gynaecologists of Canada(**48, 49**).

For example, in a small prospective trial of 61 women, those who were offered a trial of manual rotation experienced a lower rate of cesarean delivery (0%) compared with those treated without manual rotation (23%, P ¼.001)(**50**).

A large, retrospective cohort study found a similar large reduction in cesarean delivery (9% vs 41%, P <.001) associated with the use of manual rotation. Of the 731 women in this study who underwent manual rotation, none experienced an umbilical cord prolapse. Further, there was no difference in either birth trauma or neonatal academia between neonates who had experienced an attempt at manual rotation vs those who had not (**48**).

To consider an intervention for a fetal malposition, the proper assessment of fetal position must be made. Intrapartum ultrasonography has been used to increase the accurate diagnosis of fetal position when the digital examination results are uncertain. Given these data, which are limited for safety and efficacy, manual rotation of the fetal occiput in the setting of fetal malposition in the second stage of labor is a reasonable intervention to consider before moving to operative vaginal delivery or cesarean delivery. To safely prevent cesarean deliveries in the setting of malposition, it is important to assess the fetal position in the second stage of labor, particularly in the setting of abnormal fetal descent (**51**).

Which fetal heart tracings deserve intervention, and what are these interventions?

The second most common indication for primary cesarean is an abnormal or indeterminate fetal heart rate tracing. Given the known variation in interpretation and management of fetal heart rate tracings, a standardized approach is a logical potential goal for interventions to safely reduce the cesarean delivery rate. Category III fetal heart rate tracings are abnormal and require intervention (**44**).

The elements of category III patternse which include either absent fetal heart rate variability with recurrent late decelerations, recurrent variable decelerations, or bradycardia or a sinusoidal rhythme have been associated with abnormal neonatal arterial umbilical cord pH, encephalopathy, and cerebral palsy. Intrauterine resuscitative efforts including maternal repositioning and oxygen supplementation, assessment for hypotension and tachysystole that may be corrected, and evaluation for other causes, such as umbilical cord prolapse should be performed expeditiously; however, when such efforts do not quickly resolve the category III tracing, delivery as rapidly and as safely possible is indicated (**52**).

The American Congress of Obstetricians and Gynecologists (ACOG) recommends preparations for imminent delivery in the event that intrauterine resuscitative measures do not improve the fetal heart rate pattern**.**In contrast, category I fetal heart tracings are normal and do not require intervention other than ongoing assessment with continuous or intermittent monitoring, given that patterns can change over time. Moderate variability and the presence of accelerations, which are features of category I patterns, have proved to be reliable indicators of normal neonatal umbilical cord arterial pH (7.20) **(53).**

Most intrapartum fetal heart rate tracings are category II**(54, 55**).Category II tracings are indeterminate and comprise a diverse spectrum of fetal heart rate patterns that require evaluation, continued surveillance, initiation of appropriate corrective measures when indicated, and reevaluation(**44**). Based

on the high rate of first cesarean deliveries performed for the indication of "no reassuring fetal heart rate" (also known as an "abnormal or indeterminate fetal heart rate") and the rarity of category III patterns, it can be deduced that category II tracings likely account for most cesarean deliveries performed for no reassuring fetal status(**10**).

Thus, one important consideration for health care providers who are making the diagnosis of no reassuring fetal status with the intent to proceed with cesarean delivery is to ensure that clinically indicated measures have been undertaken to resolve the concerning elements of the category II tracing or provide reassurance of fetal well-being. Scalp stimulation to elicit fetal heart rate acceleration is an easily employed tool when the cervix is dilated and can offer clinician reassurance that the fetus is not acidotic. Spontaneous or elicited heart rate accelerations are associated with a normal umbilical cord arterial pH (7.20).Recurrent variable decelerations, thought to be a physiologic response to repetitive compression of the umbilical cord, are not themselves pathologic. However, if frequent and persistent, they can lead to fetal academia over time. Conservative measures, such as position change, may improve this pattern. Amnioinfusion with normal saline also has been demonstrated to resolve variable fetal heart rate decelerations and reduce the incidence of cesarean delivery for a no reassuring fetal heart rate pattern. Similarly, other elements of category II fetal heart rate tracings that may indicate fetal academia, such as minimal variability or recurrent late decelerations, should be approached with in utero resuscitation(**44**).

Prolonged fetal heart rate decelerations (which last >2 minutes) often require intervention. They can occur after rapid cervical change or after hypotension (ie, in the setting of regional analgesia). Prolonged decelerations also may be a sign of complications, such as abruptio placentae, umbilical cord prolapse, or uterine rupture; because of their potential morbidity, these complications should be considered in the differential diagnosis to allow for appropriate evaluation and intervention Uterine tachysystole, defined as ≥ 5 contractions in 10 minutes averaged over 30 minutes, can occur spontaneously or because of uterotonic agents (ie, oxytocin or prostaglandins) and can be associated with fetal heart rate changes, such as prolonged or late decelerations. Reduction or cessation of the contractile agent or administration of a uterine relaxant, such as a beta-mimetic agent, can resolve uterine tachysystole and improve the fetal heart rate tracing(**56**).

In contrast, there are no current data to support interventions specifically for decelerations with "atypicalfeatures" (eg, shoulders, slow return to baseline, or variability only within the deceleration) because they have not been associated with fetal academia (**52, 55**).There is not consistent evidence that ST-segment analysis and fetal pulse oximetry either improve outcomes or reduce cesarean delivery rates**(57, 58**). Despite the evidence that fetal scalp sampling reduces the risk of cesarean deliveryand the poor ability of electronic fetal heart rate monitoring patterns to predict pH, intrapartum fetal scalp sampling has fallen out of favor in the United States. This predominantly is due to its invasive nature, the narrow clinical presentations for which it might be helpful, and the need for regulatory measures to maintain bedside testing availability (**59, 60**).

Currently, this testing is not performed in most US centers and a fetal blood sampling "kit" that is approved by the US Food and Drug Administration is not currently manufactured. The unnecessary performance of cesarean deliveries for abnormal or indeterminate fetal heart rate tracings can be attributed to limited knowledge about the ability of the patterns to predict neonatal outcomes and the lack of rigorous science to guide clinical response to the patterns(**55**).

Supplemental oxygen, intravenous fluid bolus, and tocolytic agents are routine components of intrauterine resuscitation that have extremely limited data for effectiveness or safety. Performance of these interventions without a subsequent change in fetal heart rate pattern is not necessarily an indication for cesarean delivery. Medication exposure, regional analgesia, rapid labor progress, cervical examination, infection, maternal hypotension, and maternal fever all can affect the fetal heart rate pattern. Attention to such factors will optimize clinical decision making regarding the management of abnormal or indeterminate fetal heart rate patterns and the need for cesarean delivery.

Specifically, amnioinfusion for repetitive variable fetal heart rate decelerations may safely reduce the rate of cesarean delivery. Scalp stimulation can be used as a means of assessing fetal acid-base status when abnormal or indeterminate (formerly, nonreassuring) fetal heart patterns (eg, minimal variability) are present and is a safe alternative to cesarean delivery in this setting (**44**).

Safety bundle

Contemporary rates of cesarean delivery in the United States are a cause of concern. Compared with vaginal deliveries, cesarean deliveries are associated with increased risks for maternal morbidity and mortality(**61, 62**) .

Women with a prior cesarean delivery are at risk for severe complications such as uterine rupture, abnormal placentation, and unplanned hysterectomy in a subsequent pregnancy(**63, 64**).

Thus, the increase in cesarean delivery rates, from 20.7% in 1996 to a relative plateau around 32% from 2009 to 2017,4 likely has contributed to overall increases in maternal mortality and morbidity documented during the past two decades(**65, 66**).

Reducing cesarean delivery rates, particularly for first-time mothers with low-risk pregnancies, is a stated goal for key professional organizations and federal agencies(**64,67**).

In a 2014 consensus statement, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine recommended adoption of evidence-based practices for improving clinical care and changing practice culture to reduce cesarean delivery rates among nulliparous, term, singleton, vertex pregnancies.8 Selected practice guidelines have been packaged by the Council on Patient Safety in Women's Health Care into the Safe Reduction of Primary Cesarean Births patient safety bundle (hereafter cesarean bundle), which is now being implemented in several states with technical assistance from the Alliance for Innovation in Maternal Health and support from the Health Resources and Services Administration.9 Several other patient safety bundles developed to address key contributors to maternal mortality and morbidity in the United States are increasingly implemented through the Alliance for Innovation in Maternal Health program across the country. Of note, the Alliance for Innovation in Maternal Health promotes widespread adoption of obstetric patient safety bundles through state-based perinatal quality collaborative networks, currently functional in more than 40 states (**67**).

All patient safety bundles implemented through the Alliance for Innovation in Maternal Health program include a list of evidence-based or evidence informed clinical practice and institutional policy recommendations organized under four domains—Readiness, Recognition and Prevention, Response, and Reporting and Systems Learning (the 4 "Rs"). They are designed to be adaptable, allowing each hospital to choose which bundle components to implement and in what order, given local context**.** Each hospital's overall implementation design and specific implementation strategies may influence its success with the Alliance for Innovation in Maternal Health bundles. Implementation strategies are commonly defined as "methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice." A wide variety of strategies are employed for quality improvement (QI) in clinical practice—some are more common (eg, consensus building, monitoring progress), whereas others are infrequent (eg, creating financial incentives). With a limited number of studies having tested strategies for implementing evidence-based practice in obstetric care, further exploratory research is needed to identify the most promising implementation strategies that may lead to desired changes in clinicalpractice and inform clinicians of these strategies. This study presents results from an assessment of the implementation of the Alliance for Innovation in Maternal Health cesarean bundle through the Maryland Perinatal Quality Improvement Collaborative. The primary objective of this study is to describe the status of implementation of practices recommended in the cesarean bundle at 1 year. The secondary objective is to assess whether hospital characteristics and implementation strategies employed are associated with bundle implementation**(64**).

Operational Design :

Patient safety bundle will be implemented on all cases who met in the study as following:

1- Readiness

1-Build a provider and maternity unit culture that values, promotes, and supports spontaneous onset and progress of labor and vaginal birth and understands the risks for current and future pregnancies of cesarean birth without medical indication.

2-Optimize patient and family engagement in education written consent, and shared decision making about normal healthy labor and birth throughout the maternity care cycle.

3-Adopt provider education and training techniques that develop knowledge and skills on approaches which maximize the likelihood of vaginal birth, including assessment of labor, methods to promote labor progress, labor support, pain management (both pharmacologic and non-pharmacologic), and shared decision making.

2- Recognition and Prevention

1-Implement standardized admission criteria, triage management, education, and support for women presenting in spontaneous labor.

2-Offer standardized techniques of pain management and comfort measures that promote labor progress and prevent dysfunctional labor.

3-Use standardized methods in the assessment of the fetal heart rate status, and encourage methods that promote freedom of movement.

4-Adopt protocols for timely identification of specific problems, such as breech presentation, for patients who can benefit from proactive intervention before labor to reduce the risk for cesarean birth.

3- Response

1-Have available an in-house maternity care provider or alternative coverage which guarantees timely and effective responses to labor problems.

2-Uphold standardized induction scheduling to ensure proper selection and preparation of women undergoing induction.

3-Utilize standardized evidence-based labor algorithms, policies, and techniques, which allow for prompt recognition and treatment of dystocia.

4-Adopt policies that outline standard responses to abnormal fetal heart rate patterns and uterine activity.

5-Make available special expertise and techniques to lessen the need for abdominal delivery, such as breech version, instrumented delivery, and twin delivery protocols

4- Reporting/Systems Learning

1- Track and report labor and cesarean measures in sufficient detail to: compare to similar institutions, conduct case review and system analysis to drive care improvement, and assess individual provider performance.

2- Track appropriate metrics and balancing measures, which assess maternal and newborn outcomes resulting from changes in labor management strategies to ensure safety.

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