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Safe Prevention of the Primary Cesarean Delivery

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Abstract: In 2011, one in three women who gave birth in the United States did so by cesarean delivery. Cesarean birth can be life-saving for the fetus, the mother, or both in certain cases. However, the rapid increase in cesarean birth rates from 1996 to 2011 without clear evidence of concomitant decreases in maternal or neonatal morbidity or mortality raises significant concern that cesarean delivery is overused. Variation in the rates of nulliparous, term, singleton, vertex cesarean births also indicates that clinical practice patterns affect the number of cesarean births performed. The most common indications for primary cesarean delivery include, in order of frequency, labor dystocia, abnormal or indeterminate (formerly, nonreassuring) fetal heart rate tracing, fetal malpresentation, multiple gestation, and suspected fetal macrosomia. Safe reduction of the rate of primary cesarean deliveries will require different approaches for each of these, as well as other, 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 was historically taught. Additionally, improved and standardized fetal heart rate interpretation and management may have an effect. Increasing women's access to nonmedical interventions during labor, such as continuous labor and delivery 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 are other of several examples of interventions that can contribute to the safe lowering of the primary cesarean delivery rate.

Background

In 2011, one in three women who gave birth in the United States did so by cesarean delivery (1). Even though the rates of primary and total cesarean delivery have plateaued recently, there was a rapid increase in cesarean rates from 1996 to 2011 (Fig. 1). Although cesarean delivery can be life-saving 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 (2). 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.

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 (3) (Table 1). For certain clinical conditions—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

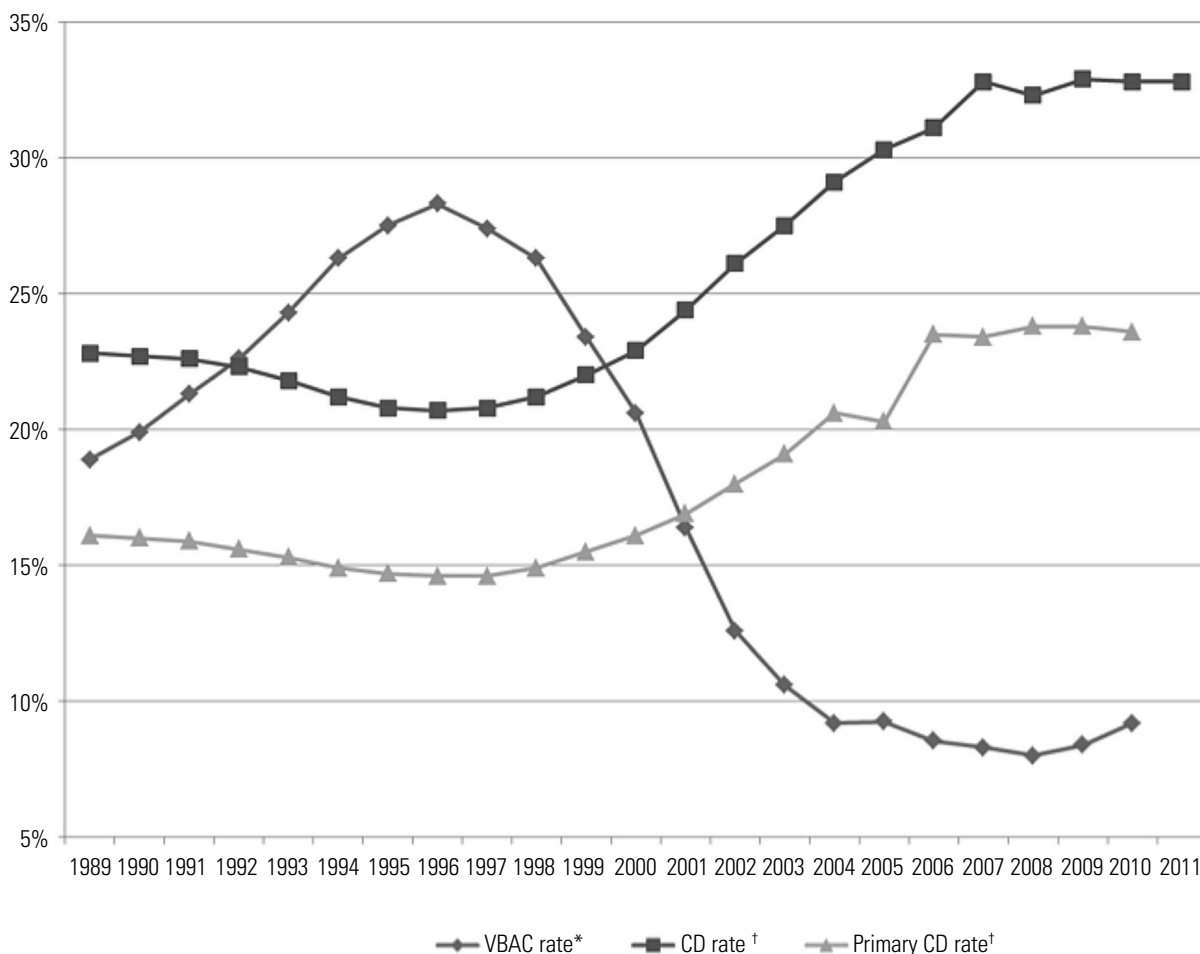


Fig. 1. U.S. delivery rates, 1989–2011. Data from National Vital Statistics. Abbreviations: CD, cesarean delivery; VBAC, vaginal birth after cesarean delivery. *Percent of women who have a vaginal birth after prior cesarean delivery. †Rate based on total number of deliveries. (Data from Martin JA, Hamilton BE, Ventura SJ, Osterman MJ, Mathews TJ. Births: final data for 2011. Natl Vital Stat Rep 2013;62(2):1–90.) ↩

delivery appears to pose greater risk of maternal morbidity and mortality than vaginal delivery (4) (Table 1).

It is difficult to isolate the morbidity caused specifically by route of delivery. 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 (5). 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 (6). Because of the size of this randomized trial, it was not powered to look at other measures of maternal morbidity.

A large population-based study from Canada found that the risk of *severe maternal morbidities*—defined as hemorrhage that requires hysterectomy or transfu-

sion, 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 threefold for cesarean delivery as compared with vaginal delivery (2.7% versus 0.9%, respectively) (7). There also are concerns regarding the long-term risks associated with cesarean delivery, particularly those associated with subsequent pregnancies. The incidence of placental abnormalities, such as placenta previa, in future pregnancies increases with each subsequent cesarean delivery, from 1% with one prior cesarean delivery to almost 3% with three or more prior cesarean deliveries. In addition, an increasing number of prior cesareans is associated with the morbidity of placental previa: after three cesarean deliveries, the risk that a placenta previa will be complicated by placenta accreta is nearly 40% (8). This combination of complications not only significantly increases

Table 1. Risk of Adverse Maternal and Neonatal Outcomes by Mode of Delivery ↵

Outcome	Risk	
	Vaginal Delivery	Cesarean Delivery
<i>Maternal</i>		
Overall severe morbidity and mortality*†	8.6%	9.2%*
	0.9%	2.7%†
Maternal mortality‡	3.6:100,000	13.3:100,000
Amniotic fluid embolism§	3.3–7.7:100,000	15.8:100,000
Third-degree or fourth-degree perineal laceration	1.0–3.0%	NA (scheduled delivery)
Placental abnormalities¶	Increased with prior cesarean delivery versus vaginal delivery, and risk continues to increase with each subsequent cesarean delivery.	
Urinary incontinence#	No difference between cesarean delivery and vaginal delivery at 2 years.	
Postpartum depression	No difference between cesarean delivery and vaginal delivery.	
<i>Neonatal</i>		
Laceration**	NA	1.0–2.0%
Respiratory morbidity**	< 1.0%	1.0–4.0% (without labor)
Shoulder dystocia	1.0–2.0%	0%

Abbreviations: CI, confidence interval; NA, not available; NICU, neonatal intensive care unit; OR, odds ratio; RR, relative risk.

*Overall severe morbidity and mortality defined as one or more of the following: death, postpartum bleeding, genital tract injury; wound disruption, wound infection, or both; systemic infection. Data from Hofmeyr GJ, Barrett JF, Crowther CA. Planned caesarean section for women with a twin pregnancy. *Cochrane Database of Systematic Reviews* 2011, Issue 12. Art. No.: CD006553. DOI: [10.1002/14651858.CD006553.pub2](https://doi.org/10.1002/14651858.CD006553.pub2).

†Overall severe morbidity and mortality defined as any one of the following: death, hemorrhage requiring hysterectomy or transfusion; uterine rupture; anesthetic complications; shock; cardiac arrest; acute renal failure; assisted ventilation venous thromboembolic event; major infection; in-hospital wound disruption, wound hematoma, or both. Data from Liu S, Liston RM, Joseph KS, Heaman M, Sauve R, Kramer MS. Maternal mortality and severe morbidity associated with low-risk planned cesarean delivery versus planned vaginal delivery at term. *Maternal Health Study Group of the Canadian Perinatal Surveillance System. CMAJ* 2007;176:455–60.

‡Data from Deneux-Tharoux C, Carmona E, Bouvier-Colle MH, Breart G. Postpartum maternal mortality and cesarean delivery. *Obstet Gynecol* 2006;108:541–8.

§Data from Abenham HA, Azoulay L, Kramer MS, Leduc L. Incidence and risk factors of amniotic fluid embolisms: a population-based study on 3 million births in the United States. *Am J Obstet Gynecol* 2008;199:49.e1–49.e8.

||Data from Hofmeyr GJ, Barrett JF, Crowther CA. Planned caesarean section for women with a twin pregnancy. *Cochrane Database of Systematic Reviews* 2011, Issue 12. Art. No.: CD006553. DOI: [10.1002/14651858.CD006553.pub2](https://doi.org/10.1002/14651858.CD006553.pub2).

¶Silver RM, Landon MB, Rouse DJ, Leveno KJ, Spong CY, Thom EA, et al. Maternal morbidity associated with multiple repeat cesarean deliveries. *National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Obstet Gynecol* 2006;107:1226–32.

#Data from Hannah ME, Whyte H, Hannah WJ, Hewson S, Amankwah K, Cheng M, et al. Maternal outcomes at 2 years after planned cesarean section versus planned vaginal birth for breech presentation at term: the international randomized Term Breech Trial. *Term Breech Trial Collaborative Group. Am J Obstet Gynecol* 2004;191:917–27.

**Data from Gregory KD, Jackson S, Korst L, Fridman M. Cesarean versus vaginal delivery: whose risks? Whose benefits? *Am J Perinatol* 2012;29:7–18.

maternal morbidity but also increases the risk of adverse neonatal outcomes, such as neonatal intensive care unit admission and perinatal death (3, 9, 10). 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 (11).

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% (Fig. 2). 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% to 69.9%, and a 15-fold variation among low-risk women, from 2.4% to 36.5% (12). 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 (13–15). 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.

In order 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

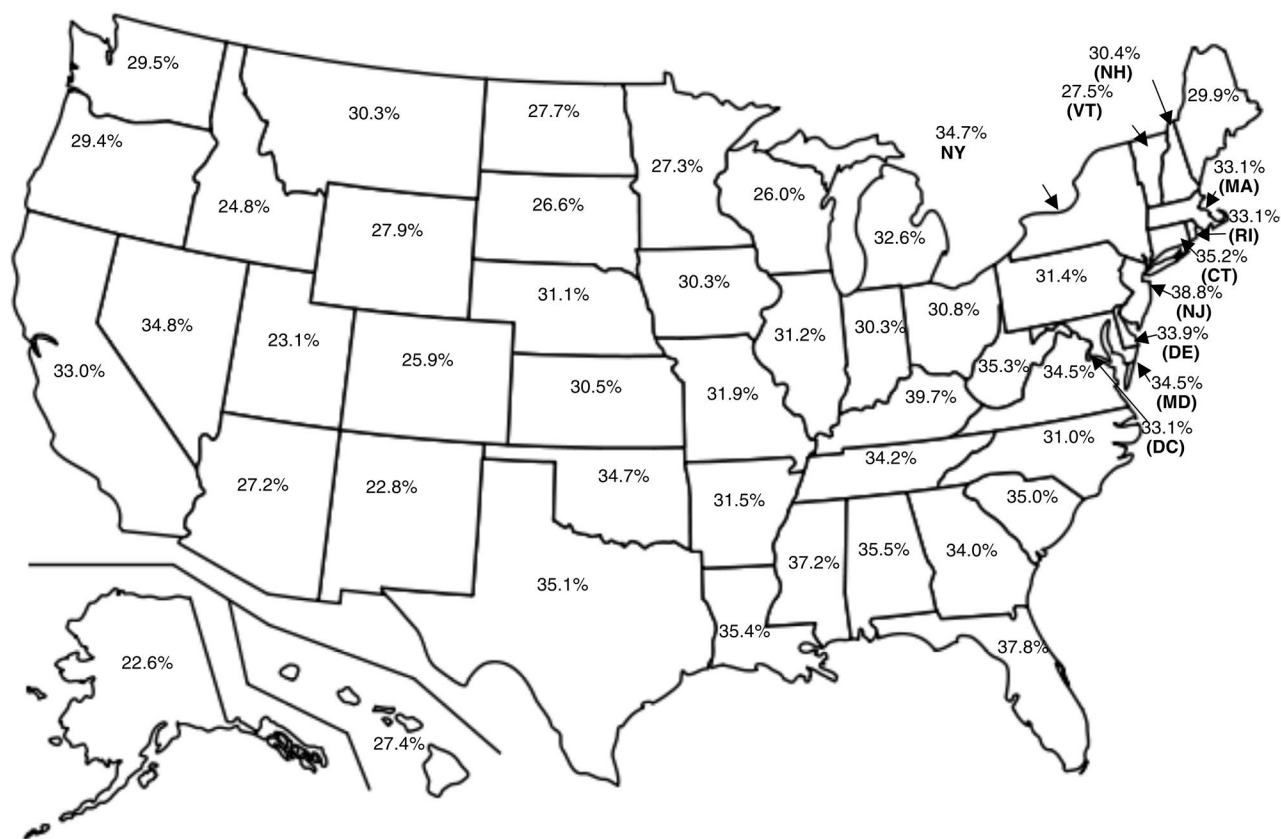


Fig. 2. U.S. total cesarean delivery rates by state, 2010. (Data from Martin JA, Hamilton BE, Ventura SJ, Osterman MJ, Mathews TJ. Births: final data for 2011. Natl Vital Stat Rep 2013;62(2):1–90.) ←

cesarean delivery included, in order of frequency, labor dystocia, abnormal or indeterminate (formerly, non-reassuring) fetal heart rate tracing, fetal malpresentation, multiple gestation, and suspected fetal macrosomia (Fig. 3) (16). Arrest of labor and abnormal or indeterminate fetal heart rate tracing accounted for more than one 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.

Clinical Management Questions and Answers

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

Definition of Abnormal 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 (17). On the basis of the 95th percentile threshold, historically, the latent phase has been defined as prolonged when it exceeds 20 hours in nulliparous women and 14 hours in multiparous women (18). 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

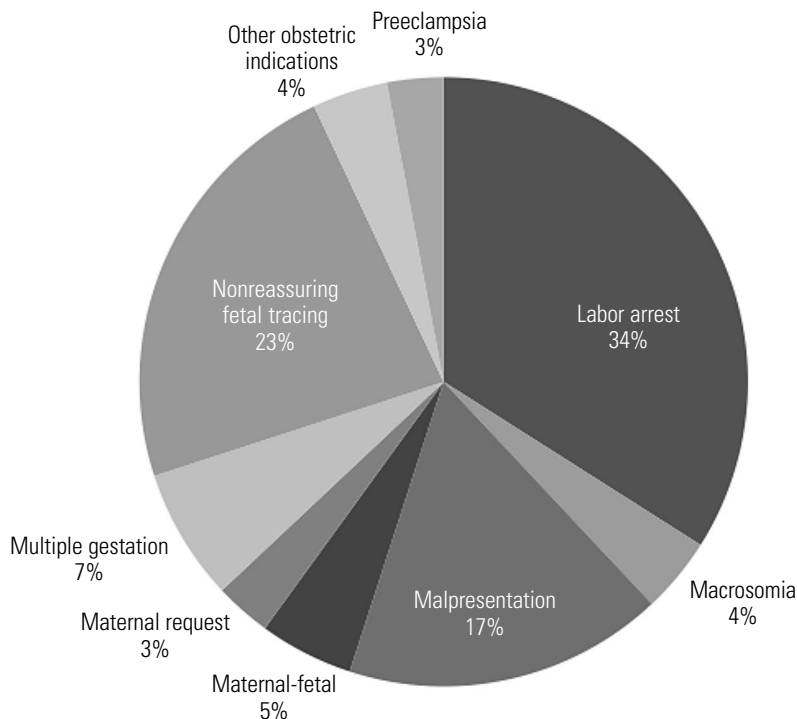


Fig. 3. Indications for primary cesarean delivery. (Data from Barber EL, Lundsberg LS, Belanger K, Pettker CM, Funai EF, Illuzzi JL. Indications contributing to the increasing cesarean delivery rate. *Obstet Gynecol* 2011;118:29–38.) ↵

a protracted active phase (based on the 95th percentile) has been cervical dilatation in the active phase of less than 1.2 cm/h for nulliparous women and less than 1.5 cm/h for multiparous women (19). *Active phase arrest* traditionally has been defined as the absence of cervical change for 2 hours or more in the presence of adequate uterine contractions and cervical dilation of at least 4 cm.

However, more recent data from the Consortium on Safe Labor have been used to revise the definition of contemporary normal labor progress (20). In this retrospective study conducted at 19 U.S. 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 0.5 cm/h to 0.7 cm/h for nulliparous women and from 0.5 cm/h to 1.3 cm/h for multiparous women (the ranges reflect that at more advanced dilation, labor proceeded more quickly) (Table 2).

The Consortium on Safe Labor data highlight two important features of contemporary labor progress (Fig. 4). First, from 4–6 cm, nulliparous and multiparous women dilated at essentially the same rate, and more slowly than historically described. Beyond 6 cm, multiparous women dilated more rapidly. 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 before 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.

► *How should abnormally progressing first-stage labor be managed?*

Management of Abnormal First-Stage Labor

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 (18). Thus, a prolonged latent

Table 2. Spontaneous Labor Progress Stratified by Cervical Dilation and Parity ↵

Cervical Dilation (cm)	Median Elapsed Time (h)		
	Parity 0 (95th percentile)	Parity 1 (95th percentile)	Parity 2 or Greater (95th percentile)
3–4	1.8 (8.1)	—	—
4–5	1.3 (6.4)	1.4 (7.3)	1.4 (7.0)
5–6	0.8 (3.2)	0.8 (3.4)	0.8 (3.4)
6–7	0.6 (2.2)	0.5 (1.9)	0.5 (1.8)
7–8	0.5 (1.6)	0.4 (1.3)	0.4 (1.2)
8–9	0.5 (1.4)	0.3 (1.0)	0.3 (0.9)
9–10	0.5 (1.8)	0.3 (0.9)	0.3 (0.8)

Modified from Zhang J, Landy HJ, Branch DW, Burkman R, Haberman S, Gregory KD, et al. Contemporary patterns of spontaneous labor with normal neonatal outcomes. Consortium on Safe Labor. *Obstet Gynecol* 2010;116:1281–7.

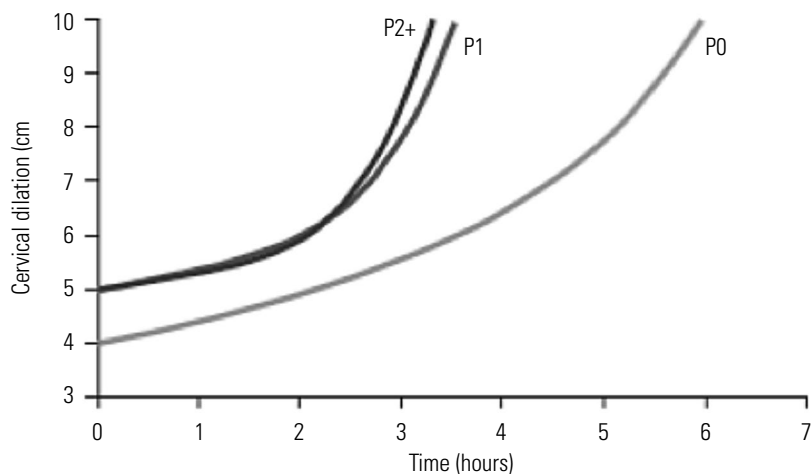


Fig. 4. Average labor curves by parity in singleton term pregnancies with spontaneous onset of labor, vaginal delivery, and normal neonatal outcomes. Abbreviations: P0, nulliparous women; P1, women of parity 1; P2+, women of parity 2 or higher. (Modified from Zhang J, Landy HJ, Branch DW, Burkman R, Haberman S, Gregory KD, et al. Contemporary patterns of spontaneous labor with normal neonatal outcomes. Consortium on Safe Labor. *Obstet Gynecol* 2010;116:1281–7.) ↵

phase (eg, greater than 20 hours in nulliparous women and greater than 14 hours in multiparous women) should not be an indication for cesarean delivery (Table 3).

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 (21).

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 less than 6. In nulliparous women, a period of 8 hours of augmentation resulted in an 18% cesarean delivery rate and no cases of birth injury or asphyxia, whereas if the period of augmentation had been limited to 4 hours, the cesarean delivery rate would have been twice as high given the number of women who had not made significant progress at 4 hours. Thus, slow but progressive labor in the first stage of labor should not be an indication for cesarean delivery (Table 3).

A study of more than 500 women found that extending the minimum period of oxytocin augmentation for

Table 3. Recommendations for the Safe Prevention of the Primary Cesarean Delivery ←

Recommendations	Grade of Recommendations
<i>First stage of labor</i>	
A prolonged latent phase (eg, greater than 20 hours in nulliparous women and greater than 14 hours in multiparous women) should not be an indication for cesarean delivery.	1B Strong recommendation, moderate quality evidence
Slow but progressive labor in the first stage of labor should not be an indication for cesarean delivery.	1B Strong recommendation, moderate quality evidence
Cervical dilation of 6 cm should be considered the threshold for the active phase of most women in labor. Thus, before 6 cm of dilation is achieved, standards of active phase progress should not be applied.	1B Strong recommendation, moderate quality evidence
Cesarean delivery for active phase arrest in the first stage of labor should be reserved for women at or beyond 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.	1B Strong recommendation, moderate quality evidence
<i>Second stage of labor</i>	
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.	1C Strong recommendation, low quality evidence
Before diagnosing arrest of labor in the second stage, if the maternal and fetal conditions permit, allow for the following: <ul style="list-style-type: none"> • At least 2 hours of pushing in multiparous women (1B) • At least 3 hours of pushing in nulliparous women (1B) 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. (1B)	1B Strong recommendation, moderate quality evidence
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.	1B Strong recommendation, moderate quality evidence
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. In order 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.	1B Strong recommendation, moderate quality evidence
<i>Fetal heart rate monitoring</i>	
Amnioinfusion for repetitive variable fetal heart rate decelerations may safely reduce the rate of cesarean delivery.	1A Strong recommendation, high quality evidence
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.	1C Strong recommendation, low quality evidence
<i>Induction of labor</i>	
Before 41 0/7 weeks of gestation, induction of labor generally should be performed based on maternal and fetal medical indications. Inductions at 41 0/7 weeks of gestation and beyond should be performed to reduce the risk of cesarean delivery and the risk of perinatal morbidity and mortality.	1A Strong recommendation, high quality evidence
Cervical ripening methods should be used when labor is induced in women with an unfavorable cervix.	1B Strong recommendation, moderate quality evidence
If the maternal and fetal status allow, cesarean deliveries for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (up to 24 hours or longer) and requiring that oxytocin be administered for at least 12–18 hours after membrane rupture before deeming the induction a failure.	1B Strong recommendation, moderate quality evidence

(continued)

Table 3. Recommendations for the Safe Prevention of the Primary Cesarean Delivery (*continued*)

Recommendations	Grade of Recommendations
<i>Fetal malpresentation</i>	
Fetal presentation should be assessed and documented beginning at 36 0/7 weeks of gestation to allow for external cephalic version to be offered.	1C Strong recommendation, low quality evidence
<i>Suspected fetal macrosomia</i>	
Cesarean delivery to avoid potential birth trauma should be limited to estimated fetal weights of at least 5,000 g in women without diabetes and at least 4,500 g in women with diabetes. The prevalence of birth weight of 5,000 g or more is rare, and patients should be counseled that estimates of fetal weight, particularly late in gestation, are imprecise.	2C Weak recommendation, low quality evidence
<i>Excessive maternal weight gain</i>	
Women should be counseled about the IOM maternal weight guidelines in an attempt to avoid excessive weight gain.	1B Strong recommendation, moderate quality evidence
<i>Twin gestations</i>	
Perinatal outcomes for twin gestations in which the first twin is in cephalic presentation are not improved by cesarean delivery. Thus, women with either cephalic/cephalic-presenting twins or cephalic/noncephalic presenting twins should be counseled to attempt vaginal delivery.	1B Strong recommendation, moderate quality evidence
<i>Other</i>	
Individuals, organizations, and governing bodies should work to ensure that research is conducted to provide a better knowledge base to guide decisions regarding cesarean delivery and to encourage policy changes that safely lower the rate of primary cesarean delivery.	1C Strong recommendation, low quality evidence

Abbreviation: IOM, Institute of Medicine.

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 (22). The researchers defined active phase labor arrest as 1 cm or less 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 managed women (23). An additional study of 1,014 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 (24). 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 relationship needs further elucidation, neither chorioamnionitis nor its duration should be an indication for cesarean delivery (25).

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 1). Thus, before 6 cm of dilation is achieved, standards of active phase progress should not be applied (Table 3). Further, cesarean delivery for active phase arrest in the first stage of labor should be reserved for women at or beyond 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

Box 1. Definition of Arrest of Labor in the First Stage ←

Spontaneous labor: More than or equal to 6 cm dilation with membrane rupture and one of the following:

- 4 hours or more of adequate contractions (eg, more than 200 Montevideo units)
- 6 hours or more of inadequate contractions and no cervical change

administration with inadequate uterine activity and no cervical change (Table 3) (22).

► **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 (26). 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 (20).

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 4,126 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 or more: 5-minute Apgar score of less than 4, umbilical artery pH less than 7.0, intubation in the delivery room, need for admission to the neonatal intensive care unit, or neonatal sepsis (27). Similarly, in a secondary analysis of 1,862 women enrolled in an early versus delayed pushing trial, a longer duration of active pushing was not associated with adverse neonatal outcomes, even in women who pushed for more than 3 hours (28). 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 beyond 4 hours (29).

The duration of the second stage of labor and its relationship to neonatal outcomes has been less extensively studied in multiparous women. In one retrospective study of 5,158 multiparous women, when the duration of the second stage of labor exceeded 3 hours, the risk of a 5-minute Apgar score of less than 7, admission to the neonatal intensive care unit, and a composite of neonatal morbidity were all significantly increased (30).

A population-based study of 58,113 multiparous women yielded similar results when the duration of the second stage was greater than 2 hours (31).

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 (27). Moreover, for each hour of the second stage, the chance for spontaneous vaginal delivery decreases progressively. Researchers have found that after a 3-hour or more second stage of labor, only one in four nulliparous women (27) and one in three 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 (30).

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) (32). 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 less than 7 and birth depression was increased when the second stage of labor lasted longer than 2 hours, the absolute risk of these outcomes was low (less than 1.5%) with durations less than 2 hours and was not doubled even with durations greater than 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 (Table 3). 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.

► **How should abnormally progressing second-stage labor be managed?**

Given the 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 (Table 3). 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 (Table 3). For example, the recent *Eunice Kennedy Shriver* National

Institute of Child Health and Human Development document suggested allowing one 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 (33).

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

In addition to greater expectant management of the second stage, two 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.

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 (34). 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], 0.7–2.2) or cesarean delivery (OR, 0.9; 95% CI, 0.6–1.4) (35). 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, 0.40–0.90) or cesarean delivery (OR, 0.68; 95% CI, 0.48–0.97), with no significant difference between vacuum delivery or cesarean delivery (36).

Fewer than 3% of women in whom an operative vaginal delivery has been attempted go on to deliver by cesarean (37). Although attempts at operative vaginal delivery from a mid-pelvic station (0 and +1 on the -5 to +5 scale) or from an occiput transverse or occiput posterior position with rotation are reasonable in selected cases (38), these procedures require a higher level of skill and are more likely to fail than low (+2 or greater) 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 (39). 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 (40). 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 (Table 3).

Manual Rotation of the Fetal Occiput

Occiput posterior and occiput transverse positions are associated with an increase in cesarean delivery and neonatal complications (41, 42). 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 (43–45). 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 managed without manual rotation (23%, $P=.001$) (46). A large, retrospective cohort study found a similar large reduction in cesarean delivery (9% versus 41%, $P<.001$) associated with the use of manual rotation (43). 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 acidemia between neonates who had experienced an attempt at manual rotation versus those who had not (43). In order 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 (47).

Given these data, which is 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. In order 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 (Table 3).

► **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 (Fig. 3). 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 (48). The elements of Category III patterns—which include either absent fetal heart rate variability with recurrent late decelerations, recurrent variable decelerations, or bradycardia; or a sinusoidal rhythm—have been associated with abnormal neonatal arterial umbilical cord pH, encephalopathy, and cerebral palsy (49–52). 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. The American College of Obstetricians and Gynecologists recommends preparations for imminent delivery in the event that intrauterine resuscitative measures do not improve the fetal heart rate pattern (48).

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 or greater) (53, 54).

Most intrapartum fetal heart rate tracings are Category II (50, 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 re-evaluation (48). Based on the high rate of first cesarean deliveries performed for the indication of “nonreassuring 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 nonreassuring fetal status (16). Thus, one important consideration for health care providers who are making the diagnosis of nonreassuring 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 a 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 or greater) (54, 56). 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 acidemia over time. Conservative measures, such as position change, may improve this pattern. Amnioinfusion with normal saline also has been demon-

strated to resolve variable fetal heart rate decelerations (57–59) and reduce the incidence of cesarean delivery for a nonreassuring fetal heart rate pattern (59–61). Similarly, other elements of Category II fetal heart rate tracings that may indicate fetal acidemia, such as minimal variability or recurrent late decelerations, should be approached with in utero resuscitation (48).

Prolonged fetal heart rate decelerations (which last more than 2 minutes but less than 10 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 (62–64). *Uterine tachysystole*, defined as more than five 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 (65). In contrast, there are no current data to support interventions specifically for decelerations with “atypical features” (such as shoulders, slow return to baseline, or variability only within the deceleration) because they have not been associated with fetal acidemia (66, 49).

There is not consistent evidence that ST-segment analysis and fetal pulse oximetry either improve outcomes or reduce cesarean delivery rates (67, 68). Despite the evidence that fetal scalp sampling reduces the risk of cesarean delivery (69, 70) and 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. Currently, this testing is not performed in most U.S. centers and a fetal blood sampling “kit” that is approved by the U.S. 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, 71). Supplemental oxygen (72), intravenous fluid bolus (73), and tocolytic agents (74) are routine components of intrauterine resuscitation (75) 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 (48). 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 (Table 3). 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 (Table 3).

► **What is the effect of induction of labor on cesarean delivery?**

The use of induction of labor has increased in the United States concurrently with the increase in the cesarean delivery rate, from 9.5% of births in 1990 to 23.1% of births in 2008 (76, 77). Because women who undergo induction of labor have higher rates of cesarean delivery than those who experience spontaneous labor, it has been widely assumed that induction of labor itself increases the risk of cesarean delivery. However, this assumption is predicated on a faulty comparison of women who are induced versus women in spontaneous labor (78). Studies that compare induction of labor to its actual alternative, expectant management awaiting spontaneous labor, have found either no difference or a decreased risk of cesarean delivery among women who are induced (79–82). This appears to be true even for women with an unfavorable cervix (83).

Available randomized trial data comparing induction of labor versus expectant management reinforce the more recent observational data. For example, a meta-analysis of prospective randomized controlled trials conducted at less than 42 0/7 weeks of gestation, found that women who underwent induction of labor had a lower rate of cesarean delivery compared with those who received expectant management (84). In addition, a meta-analysis of three older, small studies of induction of labor before 41 0/7 weeks of gestation also demonstrated a statistically significant reduction in the rate of cesarean delivery (85). Additionally, increases in stillbirth, neonatal, and infant death have been associated with gestations at 41 0/7 weeks and beyond (86, 87). In a 2012 Cochrane meta-analysis, induction of labor at 41 0/7 weeks of gestation and beyond was associated with a reduction in perinatal mortality when compared with expectant management (85). Therefore, before 41 0/7 weeks of gestation, induction of labor generally should be performed based on maternal and fetal medical indications. Inductions at 41 0/7 weeks of gestation and beyond should be performed to reduce the risk of cesarean delivery and the risk of perinatal morbidity and mortality (Table 3).

Once a decision has been made to proceed with a labor induction, variations in the management of labor induction likely affect rates of cesarean delivery, particu-

larly the use of cervical ripening agents for the unfavorable cervix and the lack of a standard definition of what constitutes prolonged duration of the latent phase (a failed induction). Numerous studies have found that the use of cervical ripening methods—such as misoprostol, dinoprostone, prostaglandin E₂ gel, Foley bulbs, and laminaria tents—lead to lower rates of cesarean delivery than induction of labor without cervical ripening (69, 88). The benefit is so widely accepted that recent studies do not include a placebo or nonintervention group, but rather compare one cervical ripening method with another (89). There also are data to support the use of more than one of these methods sequentially or in combination, such as misoprostol and a Foley bulb, to facilitate cervical ripening (90). Thus, cervical ripening methods should be used when labor is induced in women with an unfavorable cervix (Table 3).

In the setting of induction of labor, nonintervention in the latent phase when the fetal heart tracing is reassuring and maternal and fetal statuses are stable seems to reduce the risk of cesarean delivery. Recent data indicate that the latent phase of labor is longer in induced labor compared with spontaneous labor (91). Furthermore, at least three studies support that a substantial proportion of women undergoing induction who remain in the latent phase of labor for 12–18 hours with oxytocin administration and ruptured membranes will give birth vaginally if induction is continued (92–94). In one study, 17% of women were still in the latent phase of labor after 12 hours, and 5% remained in the latent phase beyond 18 hours (93). In another study, of those women who were in the latent phase for longer than 12 hours and achieved active phase of labor, the majority (60%) gave birth vaginally (94). Membrane rupture and oxytocin administration, except in rare circumstances, should be considered prerequisites to any definition of failed labor induction, and experts have proposed waiting at least 24 hours in the setting of oxytocin and ruptured membranes before declaring an induction failed (33).

Therefore, if the maternal and fetal status allow, cesarean deliveries for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (up to 24 hours or longer) and requiring that oxytocin be administered for at least 12–18 hours after membrane rupture before deeming the induction a failure (Table 3).

► **What are the other indications for primary cesarean delivery? What alternative management strategies can be used for the safe prevention of cesarean delivery in these cases?**

Although labor arrest and abnormal or indeterminate fetal heart rate tracing are the most common indications for primary cesarean delivery, less common indications—such as fetal malpresentation, suspected macrosomia, multiple gestation, and maternal infection (eg, herpes simplex virus)—account for tens of thousands of cesar-

ean deliveries in the United States annually. Safe prevention of primary cesarean deliveries will require different approaches for each of these indications.

Fetal Malpresentation

Breech presentation at 37 weeks of gestation and beyond is estimated to complicate 3.8% of pregnancies, and more than 85% of pregnant women with a persistent breech presentation are delivered by cesarean (95). In one recent study, the rate of attempted external cephalic version was 46% and decreased during the study period (96). Thus, external cephalic version for fetal malpresentation is likely underutilized, especially when considering that most patients with a successful external cephalic version will give birth vaginally (96). Obstetricians should offer and perform external cephalic version whenever possible (97). Furthermore, when an external cephalic version is planned, there is evidence that success may be enhanced by regional analgesia (98). Fetal presentation should be assessed and documented beginning at 36 0/7 weeks of gestation to allow for external cephalic version to be offered (Table 3). Before a vaginal breech delivery is planned, women should be informed that the risk of perinatal or neonatal mortality or short-term serious neonatal morbidity may be higher than if a cesarean delivery is planned, and the patient's informed consent should be documented.

Suspected Fetal Macrosomia

Suspected fetal macrosomia is not an indication for delivery and rarely is an indication for cesarean delivery. To avoid potential birth trauma, the College recommends that cesarean delivery be limited to estimated fetal weights of at least 5,000 g in women without diabetes and at least 4,500 g in women with diabetes (Table 3) (99). This recommendation is based on estimations of the number needed to treat from a study that modeled the potential risks and benefits from a scheduled, nonmedically indicated cesarean delivery for suspected fetal macrosomia, including shoulder dystocias and permanent brachial plexus injuries (100). The prevalence of birth weight of 5,000 g or more is rare, and patients should be counseled that estimates of fetal weight, particularly late in gestation, are imprecise (Table 3). Even when these thresholds are not reached, screening ultrasonography performed late in pregnancy has been associated with the unintended consequence of increased cesarean delivery with no evidence of neonatal benefit (101). Thus, ultrasonography for estimated fetal weight in the third trimester should be used sparingly and with clear indications.

Excessive Maternal Weight Gain

A large proportion of women in the United States gain more weight during pregnancy than is recommended by the Institute of Medicine (IOM). Observational evidence suggests that women who gain more weight than recommended by the IOM guidelines have an increased risk of cesarean delivery and other adverse outcomes (15, 102, 103). In a recent Committee Opinion, the College recom-

mends that it is “important to discuss appropriate weight gain, diet, and exercise at the initial visit and periodically throughout the pregnancy” (104). Although pregnancy weight-management interventions continue to be developed and have yet to translate into reduced rates of cesarean delivery or morbidity, the available observational data support that women should be counseled about the IOM maternal weight guidelines in an attempt to avoid excessive weight gain (Table 3).

Twin Gestation

The rate of cesarean deliveries among women with twin gestations increased from 53% in 1995 to 75% in 2008 (105). Even among vertex-presenting twins, there was an increase from 45% to 68% (105). Perinatal outcomes for twin gestations in which the first twin is in cephalic presentation are not improved by cesarean delivery. Thus, women with either cephalic/cephalic-presenting twins or cephalic/noncephalic-presenting twins should be counseled to attempt vaginal delivery (Table 3) (106). In order to ensure safe vaginal delivery of twins, it is important to train residents to perform twin deliveries and to maintain experience with twin vaginal deliveries among practicing obstetric care providers.

Herpes Simplex Virus

In women with a history of herpes simplex virus, the administration of acyclovir for viral suppression is an important strategy to prevent genital herpetic outbreaks requiring cesarean delivery and asymptomatic viral shedding (107, 108). Given the favorable benefit-risk profile for the administration of maternal acyclovir, efforts should be made to ensure that women with a history of genital herpes, even in the absence of an outbreak in the current pregnancy, are offered oral suppressive therapy within 3–4 weeks of anticipated delivery (109) and at the latest, at or beyond 36 weeks of gestation (110). Cesarean delivery is not recommended for women with a history of herpes simplex virus infection but no active genital disease during labor (110).

Continuous Labor and Delivery Support

Published data indicate that one of the most effective tools to improve labor and delivery outcomes is the continuous presence of support personnel, such as a doula. A Cochrane meta-analysis of 12 trials and more than 15,000 women demonstrated that the presence of continuous one-on-one support during labor and delivery was associated with improved patient satisfaction and a statistically significant reduction in the rate of cesarean delivery (111). Given that there are no associated measurable harms, this resource is probably underutilized.

What organizational actions are necessary for the primary cesarean delivery rate to safely decline?

A number of approaches are needed to reduce the primary cesarean delivery rate, which in turn would lower the repeat cesarean delivery rate. Although national and

regional organizations can take the lead in setting the agenda regarding the safe prevention of primary cesarean delivery, such an agenda will need to be prioritized at the level of practices, hospitals, health care systems, and, of course, patients.

Changing the local culture and attitudes of obstetric care providers regarding the issues involved in cesarean delivery reduction also will be challenging. Several studies have demonstrated the feasibility of using systemic interventions to reduce the rate of cesarean delivery across indications and across community and academic settings. A 2007 review found that the cesarean delivery rate was reduced by 13% when audit and feedback were used exclusively but decreased by 27% when audit and feedback were used as part of a multifaceted intervention, which involved second opinions and culture change (112). Systemic interventions, therefore, provide an important strategic opportunity for reducing cesarean delivery rates. However, the specific interventional approaches have not been studied in large, prospective trials, thus specific recommendations cannot be made.

A necessary component of culture change will be tort reform because the practice environment is extremely vulnerable to external medico-legal pressures. Studies have demonstrated associations between cesarean delivery rates and malpractice premiums and state-level tort regulations, such as caps on damages (113, 114). A broad range of evidence-based approaches will be necessary—including changes in individual clinician practice patterns, development of clinical management guidelines from a broad range of organizations, implementation of systemic approaches at the organizational level and regional level, and tort reform—to ensure that unnecessary cesarean deliveries are reduced. In addition, individuals, organizations, and governing bodies should work to ensure that research is conducted to provide a better knowledge base to guide decisions regarding cesarean delivery and to encourage policy changes that safely lower the rate of primary cesarean delivery (Table 3).

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Society for Maternal-Fetal Medicine Grading System: Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Recommendations

Obstetric Care Consensus documents will use Society for Maternal-Fetal Medicine's grading approach: <http://www.ajog.org/article/S0002-9378%2813%2900744-8/fulltext>. Recommendations are classified as either strong (Grade 1) or weak (Grade 2), and quality of evidence is classified as high (Grade A), moderate (Grade B), and low (Grade C)*. Thus, the recommendations can be 1 of the following 6 possibilities: 1A, 1B, 1C, 2A, 2B, 2C.

Grade of Recommendation	Clarity of Risk and Benefit	Quality of Supporting Evidence	Implications
1A. Strong recommendation, high quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk.	Strong recommendations, can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.	Strong recommendation, and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1C. Strong recommendation, low quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.	Strong recommendation, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.
2A. Weak recommendation, high quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well-performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk.	Weak recommendation, best action may differ depending on circumstances or patients or societal values.
2B. Weak recommendation, moderate quality evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an effect on confidence in the estimate of benefit and risk and may change the estimate.	Weak recommendation, alternative approaches likely to be better for some patients under some circumstances.
2C. Weak recommendation, low quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.	Very weak recommendation, other alternatives may be equally reasonable
Best practice	Recommendation in which either (i) there is enormous amount of indirect evidence that clearly justifies strong recommendation (direct evidence would be challenging, and inefficient use of time and resources, to bring together and carefully summarize), or (ii) recommendation to contrary would be unethical.		

Modified from Grading guide. In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2013. Available at: <http://www.uptodate.com/home/grading-guide>. Retrieved October 9, 2013.

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