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Effect of Early Prenatal Care Entry on Trial of Labor Rate and Vaginal Birth After Cesarean Section Rate Among Women with a Prior Cesarean Delivery: Georgia, United States (1999-2006)

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An abstract of
A thesis submitted to the Faculty of the
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Abstract

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Modes of delivery for women with a history of cesarean section include elective repeat cesarean delivery, successful trial of labor (TOL) leading to vaginal birth after cesarean section (VBAC), and unsuccessful trial of labor leading to repeat cesarean delivery. Maternal and perinatal outcomes differ for each delivery method, and likelihood of TOL success differs for each woman. Early access to prenatal care (PNC) provides time for in-depth counseling on these matters and is associated with improved overall pregnancy outcomes, but no data exist on the relationship between timing of PNC entry and rates of TOL and VBAC. Thus, we utilized Georgia's linked birth and hospital discharge records (1999 through 2006) to model the association between early initiation of PNC and rates of TOL and VBAC among singleton, second-order, live births at ≥20 weeks gestational age to women with a history of a primary cesarean section (n=48,048). Overall, TOL was documented for fewer than one-third of these women (32 percent) and only 8 percent delivered via VBAC. Women who accessed PNC early (prior to the fifth month of pregnancy) were only slightly more likely to have a documented TOL than women who accessed PNC late or not at all (crude RR 1.06 [95 percent confidence interval 1.00, 1.12]), and they were no more likely to deliver via VBAC (crude RR 0.92 [95 percent confidence interval 0.81, 1.04]). While early PNC may offer obstetric providers the opportunity to assess risk and advise patients about TOL, current counseling could be improved. Moreover, late entry into PNC should not be a barrier to engaging in discussion about TOL and VBAC.

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Chapter I: Literature Review

DELIVERY METHOD: Pregnant Women with a Prior Cesarean Section

Cesarean Delivery in the United States: Population trends and contributing factors

Between 1970 and 2009, the cesarean delivery rate (cesarean sections per 100 births) in the United States rose dramatically from 5 percent to nearly 33 percent.[1-3] Prior to 2009, a twelve-year stretch of consecutive annual rate increases led to a climb in the cesarean delivery rate of more than 50 percent (21 percent in 1996).[2, 3] The record-high 2009 U.S. rate of 32.9 percent made cesarean section the most common medical procedure performed on American women.[4] Delivery trends throughout the developed world parallel those in the U.S, but the U.S. consistently has one of the highest national cesarean section rates.[5, 6]

Experts agree that the main driving force behind the overall rise in U.S. cesarean deliveries is the increase in primary, or first-time, cesarean deliveries.[6, 7] Studies chiefly ascribe the primary rate increase over past few decades to obstetrical practice environment changes, including the introduction of electronic fetal monitoring,[8] the preference for cesarean instead of vaginal delivery of breech infants,[9] and the decline in forceps deliveries.[10] Changes in the medicolegal environment, sociocultural propensities, and maternal medical risk profiles may also play a role.[6, 10, 11]

However, as U.S. primary cesarean section rates continue to climb, a related upsurge of repeat cesarean deliveries (among women with one or more prior cesarean deliveries) increasingly contributes to the overall rise in cesarean sections.[6, 7] For most of

the twentieth century, most American obstetric care providers practiced according to the dictum, "once a cesarean, always a cesarean."[1, 7] Studies performed in the 1970s, however, led to a reassessment of this paradigm.[1] In 1980, a National Institutes of Health (NIH) Consensus Development Conference Panel questioned the necessity of habitual repeat cesarean sections and outlined situations in which a vaginal birth after a previous cesarean section (VBAC) could be considered.[7]

Subsequent research and dialogue resulted in the 1995 American College of Obstetricians and Gynecologists (ACOG) Committee Opinion stating, "In the absence of contraindications, a woman with one previous cesarean delivery with a lower transverse uterine incision is a candidate for VBAC and should be counseled and encouraged to undergo a trial of labor."[12] As a result, American women with a prior cesarean delivery were more routinely offered a trial of labor (TOL) from 1980 to 1996. The U.S. VBAC rate (VBACs per 100 women with one or more prior cesarean deliveries) increased from 5 percent in 1985 to a record 28 percent in 1996.[1] Repeat cesarean delivery rates reflexively decreased during that time, resulting in a reduction in the overall cesarean delivery rate from its peak of 25 percent in 1989 to a valley of 20 percent in 1996.[13]

As the number of American women attempting a TOL increased, however, so did the number of reports of TOL complications.[1] In 1996, McMahon[14] published a landmark paper that reignited the U.S. tendency toward cesarean section.[6] His study described similar overall rates of maternal and neonatal morbidity among women choosing a TOL and women choosing an elective repeat cesarean delivery (ERCD), but emphasized that major maternal complications were nearly twice as likely among women undergoing a TOL. McMahon's combined odds ratio for hysterectomy, uterine rupture,

and operative injury was 1.8 [95 percent confidence interval (95% CI): 1.1, 3.0].[14] ACOG subsequently released a Practice Bulletin in 1999 specifying, "VBAC should be attempted in institutions equipped to respond to emergencies with physicians immediately available to provide emergency care."[15] In 2001, another landmark paper by Lydon-Rochelle underscored the risk of uterine rupture with a TOL. In her study, uterine rupture occurred at a rate of 1.6 per 1000 among women with ERCD, 5.2 among women with spontaneous TOL, and 7.7 to 24.5 among women with induced TOL (depending on the type of induction).[16]

These landmark studies on the risks of TOL – compounded by maternal concern about safety and recovery,[17] physician fear of liability and litigation,[18] differential reimbursement by insurance,[19-21] and institutional pressure to restrict access to TOL[15] – led to a dramatic decrease in the U.S. TOL rate (TOLs per 100 pregnant women with one or more prior cesarean deliveries). A pooled analysis of 35 observational studies calculated that the TOL rate before 1996 (63 percent [95% CI: 55, 72 percent]) was significantly higher than the TOL rate after 1996 (47 percent [95% CI: 37, 58 percent]). While the pre- and post-1996 rate difference is likely a true difference (p=0.009), the effect estimates may overestimate the actual U.S. TOL rate.[6] The majority of the studies included in the analysis took place at large tertiary teaching hospitals, and delivery site characteristics are an independent predictor of TOL rate; sites with higher volumes of deliveries, tertiary care centers, and teaching hospitals have higher TOL rates.[6] Of note, other predictors of a TOL include prior vaginal delivery and non-white race.[6]

The authors of the pooled analysis on TOL rate performed a parallel pooled analysis on TOL success rate (VBACs per 100 women attempting a TOL), including 67

observational studies. They calculated that the TOL success rate has remained steady over time at 74 percent [95% CI: 72, 75 percent]; their analysis showed no significant difference in success rates before or after 1996.[6] Though the overall TOL success rate has not changed nationwide, it is important to recognize that there are several independent predictors of VBAC, including delivery site characteristics, demographic traits, obstetric and medical history, and factors related to the prior and current pregnancy. Similar to trends seen in TOL rates, women at rural and private hospitals that provide obstetric care for lower risk deliveries have a decreased likelihood of a VBAC. In contrast, even though non-white women are more likely to attempt a TOL, Hispanic women and African American women are less likely to have a successful TOL (compared to non-Hispanic and white women, respectively). Not surprisingly, and again paralleling the TOL rate predictive patterns, women with a prior vaginal delivery (either before or after their prior cesarean section) have a greater likelihood of a VBAC. While the associations are not consistent across studies, it appears that pre-existing maternal factors (height, BMI, smoking, and substance use) and pre-existing medical conditions (hypertension, diabetes, asthma, seizures, renal disease, thyroid disease, and collagen vascular disease) may affect the TOL success rate.[6] Also, elements of the current pregnancy (maternal age, gestational age, labor spontaneity, dilation, effacement, station, Bishop score,[22] cervix position, and baby position) consistently predict the likelihood of having a successful TOL.[1, 6] Finally, factors related to both the prior cesarean delivery and the current pregnancy play a role; short interpregnancy interval and increased birthweight portend a decreased probability of VBAC.[1]

In spite of a variety of independent predictors for TOL success, the U.S. TOL success rate has remained steady over time. Therefore, the drop in the U.S. TOL rate after 1996 caused the U.S. VBAC rate (VBACs per 100 women with one or more prior cesarean deliveries) to fall from a record-high 28 percent in 1996 to a record-low 9 percent in 2006.[1, 7] This decline in VBACs was accompanied by a reflexive rise in repeat cesarean deliveries and, therefore, an increase in the overall cesarean delivery rate to a record 32.9 percent in 2009.[1, 3, 6] However, following publication of the 2010 NIH Consensus Development Conference Statement[7] and the 2010 ACOG Practice Bulletin[1] (discussed in detail below), the cesarean rate declined for the first time in over a decade to 32.8 percent in 2010.[3] While the change is only modest, it may be the first evidence of yet another paradigm shift in U.S. obstetric practice.

Delivery Method Terminology in Women with a Previous Cesarean Section

Oftentimes, conflicting and confusing terminology is used to describe the delivery method options for women with a history of a cesarean delivery. The following adaptations of the definitions from the 2010 NIH Consensus Development Conference Statement are used throughout this document for clarity and consistency:[7]

- *Trial of labor (TOL):* Planned attempt to labor by a woman who has had one or more prior cesarean deliveries and desires a VBAC.
- *Vaginal birth after cesarean delivery (VBAC):* Vaginal delivery after a TOL; that is, a successful TOL.
- *Unsuccessful TOL:* Cesarean delivery in a woman who has had a trial of labor with the intention of delivering via VBAC.

- *Elective repeat cesarean delivery (ERCD):* Planned cesarean delivery by a woman who has had one or more prior cesarean deliveries; the delivery may or may not be scheduled.
- *Labor followed by an ERCD:* Of note, some obstetricians will labor a pregnant patient with a prior cesarean delivery, even if she desires an ERCD, as several studies indicate that infants born by repeat cesarean delivery following the onset of labor have improved respiratory outcomes compared to infants born by repeat cesarean delivery prior to the onset of labor.[23-25] Discussion of this concept, however, is beyond the scope of this paper.

When evaluating the TOL, VBAC, and ERCD literature, the reader must take note of varying definitions and analytic methods. The most important distinction to discern is whether the author stratified by intended or actual mode of delivery.

Some experts argue that the appropriate statistical comparison is by intended delivery method, or TOL versus ERCD.[1] Obstetric providers that counsel their patients about desired delivery method may directly cite research on the differential outcomes of study groups stratified by intended delivery method. In contrast, the results of a study examining the differential outcomes of actual delivery method may not apply to patient discussion. For instance, perhaps a patient decides to pursue a TOL. The provider cannot guarantee that patient will have a successful TOL (a VBAC), and certain benefits and harms may be disproportionately associated with an unsuccessful TOL and subsequent cesarean delivery. Therefore, presenting the patient with information on the differential outcomes by actual delivery method may be inappropriate.

Nevertheless, research stratified by actual delivery method – VBAC versus cesarean section (both unsuccessful TOL and ERCD) – does play an important role in the literature. As discussed below, most of the poor outcomes that occur during a TOL occur when a repeat cesarean delivery becomes necessary.[26] That is, compared to an ERCD, a VBAC is associated with fewer complications, and an unsuccessful TOL is associated with more complications. Therefore, obstetric providers should consider the differential outcomes by actual delivery method, especially if a woman's probability of success with a TOL is higher or lower than an average patient; the decision about introducing this type of research to the patient, however, should be made at the provider's discretion and on a case-by-case basis.

Whether the obstetric provider presents information based on intended or actual delivery method, an implicit part of any patient counseling must be the woman's probability of achieving a VBAC with a TOL. The importance of that probability in determining risk for maternal and neonatal morbidity is also discussed below.

Health Outcomes of Trial of Labor and Elective Repeat Cesarean Delivery

The collective literature on maternal and neonatal outcomes of TOL, VBAC, and ERCD is vast. Fortunately, the evidence report prepared by Guise et al.[6] for the 2010 NIH Consensus Statement Development Conference on Vaginal Birth after Cesarean[7] provides a thorough review of the studies on each outcome in women attempting a TOL versus women having an ERCD, and typically includes a pooled analysis of results. Occasionally, the report also includes investigations that compare women based on actual

delivery method, in addition to intended delivery method. The highlights of this report, with respect to both maternal and neonatal outcomes, are summarized below.

Maternal Outcomes of TOL and ERCD

Maternal mortality among women with a prior cesarean delivery is rare, with a rate of 10.1 per 100,000 across twelve studies. In these investigations, the mortality rate among women attempting a TOL (3.8 per 100,000 [95% CI: 0.9, 15.5 per 100,000]) was significantly lower than the mortality rate among women having an ERCD (13.4 per 100,000 [95% CI: 4.3, 41.6 per 100,000]) (p=0.027). The risk ratio for TOL compared to ERCD was 0.33 [95% CI: 0.13, 0.88].[6]

Uterine rupture has been directly attributed to TOL and VBAC and is strongly associated with maternal and perinatal morbidity and mortality.[6] The literature is plagued with variable definitions and diagnostic methodologies for uterine rupture, as well as statistical comparisons of its risk by both intended and actual delivery mode. Nevertheless, Guise et al. successfully identified four studies that were stratified on intended delivery method and consistently defined uterine rupture as a complete separation through the entire thickness of the uterine wall (including the serosa). They calculated that the overall risk of rupture for all women with a prior cesarean delivery was quite low, at 0.3 percent [95% CI: 0.23, 0.40 percent]. However, women attempting a TOL had a significantly higher risk of uterine rupture (0.47 percent [95% CI: 0.28, 0.77 percent]) than women having an ERCD (0.026 percent [95% CI: 0.009, 0.082 percent]) (p<0.0010). The risk ratio for TOL compared to ERCD was 20.74 [95% CI: 9.77, 44.02]).[6]

To date, there have been no reported maternal deaths attributed to uterine rupture. Among eight studies exploring the risks associated with rupture in both TOL and ERCD groups or in a TOL cohort only, the pooled risk of perinatal death in the event of uterine rupture was 6.2 percent; mortality was higher in the TOL group than in the ERCD group. Among four studies reporting the risk of hysterectomy given uterine rupture, the range of occurrence was 14 to 33 percent. Thus far, no research has explored the association between length of labor and uterine rupture to determine whether there is a dose-response relationship.[6]

Hysterectomy is another rare but serious complication of TOL and ERCD, occurring in less than 3 percent of deliveries of women with a prior cesarean delivery. Based on results from eight studies, Guise et al. calculated that the risk of hysterectomy was lower among women attempting a TOL (0.17 percent [95% CI: 0.12, 0.26 percent]) than among those having an ERCD (0.28 percent [95% CI: 0.12, 0.67 percent]), but the difference was not statistically significant.[6]

Among six studies that examined the risk of hemorrhage associated with TOL and ERCD, the overall risk among women with a previous cesarean delivery ranged from 0.3 percent to 29 percent. Though varying definitions of hemorrhage preclude meaningful interpretation of effect estimates, the studies did report a trend toward a lower risk of hemorrhage with TOL (0.9 percent) than with ERCD (1.2 percent), as well as a trend toward less blood loss with TOL than with ERCD. However, neither difference achieved statistical significance.[6]

Twenty-two studies evaluated infectious morbidity (fever, wound infection, endometritis, chorioamnionitis) in TOL compared to ERCD; overall, there was no

significant difference in risk. Seven investigations comparing surgical injuries between TOL and ERCD found an increased risk with TOL, but the studies lacked uniform definitions and statistical significance. As expected, women attempting a TOL have a significantly shorter average length of hospital stay than women having an ERCD. A pooled analysis of eight investigations calculated a mean length of stay for TOL of 2.55 days [95% CI: 2.34, 2.76 days] and a mean for ERCD of 3.92 days [95% CI: 3.56, 4.29 days].[6]

Neonatal Outcomes of TOL and ERCD

To begin the examination of neonatal outcomes among women with a prior cesarean delivery, Guise et al. evaluated five studies of mortality among the term infants of women attempting a TOL or having an ERCD.[6] They calculated that the perinatal mortality rate (fetal and neonatal deaths up to 28 days of life) associated with maternal attempt of a TOL (0.13 percent [95% CI: 0.06, 0.3 percent]) was significantly higher than the perinatal mortality rate associated with maternal choice of an ERCD (0.05 percent [95% CI: 0.007, 0.38 percent]) (p=0.041). The risk ratio for TOL compared to ERCD was 1.82 [95% CI 1.24, 2.67]. Two studies focusing on fetal mortality reported that intrapartum fetal demise occurred in 0.01 to 0.04 percent of deliveries to women attempting a TOL, and 0 to 0.004 percent of deliveries to women having an ERCD. A pooled analysis of six neonatal mortality studies demonstrated that the risk of neonatal death was significantly higher with a TOL (0.11 percent [95% CI: 0.06, 0.2 percent]) than with an ERCD or indicated repeat cesarean delivery (0.6 percent [95% CI: 0.02, 0.15 percent]).[6]

Because of the relationship between gestational age and neonatal outcomes, Guise et al. limited their analysis of infant morbidity to eleven studies of term neonates. For instance, respiratory distress syndrome was not included in their literature review, as it is primarily a disease of prematurity. They instead focused on three respiratory outcomes: transient tachypnea of the newborn (TTN), need for bag-and-mask ventilation, and meconium-related respiratory care. A pooled analysis of three studies showed no significant difference in TTN risk by intended delivery method. The TTN risk was 3.6 percent [95% CI: 0.9, 8.0 percent] for TOL and 4.2 percent [95% CI: 1.9, 7.3 percent] for ERCD. Summary estimates from three bag-mask-ventilation studies demonstrated that infants in the TOL group were significantly more likely to receive this intervention (5.4 percent [95% CI: 3.5, 7.6 percent]) than infants in the ERCD group (2.5 percent [95% CI: 0.72, 5.0 percent]). Only two studies evaluated meconium-related respiratory care, and both found higher risks among infants of women attempting a TOL than among infants of women having an ERCD. One investigation examined neonatal respiratory morbidity by stratifying on both intended and actual delivery method. Infants born by ERCD (with or without labor) required the most oxygen therapy (blow-by oxygen and continuous positive airway pressure), while infants born by cesarean delivery after an unsuccessful TOL required the most bag-and-mask ventilation and intubation.[6]

Guise et al. reviewed three studies on the relationship between perinatal hypoxic ischemic encephalopathy (HIE) and delivery method among women with a prior cesarean section. All investigations reported a higher risk of perinatal HIE with TOL than with ERCD, but the evaluators deemed it impossible to know the true association due to the low number of studies and the lack of consistency in measurement. A similar absence of

precision and uniformity in definitions plagued the three studies on infant sepsis. While the investigations suggested there was no significant difference in the risk of infection among delivery methods, study limitations prevent an understanding of the true relationship. There is also a low volume of research on birth trauma, TOL, and ERCD. Two studies suggested an insignificant increase in neonatal injury during delivery for women attempting a TOL compared to women having an ERCD, but lacking studies made it difficult to estimate the true association.[6]

While Apgar scores suffer from subjectivity and have little long-term predictive value, they are an established and accepted part of the neonatal assessment, and have thus been somewhat well-studied in association with TOL and ERCD. Four investigations found no significant differences in five-minute Apgar scores of less than six and seven in infants of women attempting a TOL and those of women having an ERCD. Moreover, two of the three studies of women attempting a TOL described no significant differences in Apgar scores of infants born by VBAC versus repeat cesarean delivery.[6]

Newborn admission to the neonatal intensive care unit (NICU) is a commonly measured neonatal outcome and is often used as a proxy for serious morbidity. However, admission significance may vary by hospital protocols and setting (particularly, the level of care available), as well as provider availability and experience. Six of the seven studies identified by Guise et al. reported no significant difference in the frequency of NICU admissions among infants born to women attempting a TOL and those born to women having an ERCD. Two of the investigations analyzed the results according to both intended and actual delivery method. One study found that, among neonates born following a TOL, those born by repeat cesarean delivery were significantly more likely to

be admitted to the NICU than those born by VBAC (7 percent versus 2 percent) ($p<0.007$). The other investigation also demonstrated that neonates born by repeat cesarean deliveries after a TOL had moderately increased risk of NICU admission (odds ratio 2.26 [95% CI: 0.85, 6.0]; its main significant finding, however, was that neonates born by ERCD without a TOL were the most likely to be admitted to the NICU (odds ratio 2.93 [95% CI: 1.28, 6.72]).[6]

Guise et al. found no studies that measured the impact of a TOL versus an ERCD on neonatal neurological development or on breastfeeding initiation and continuation.[6]

Trial of Labor: Probability of success (VBAC)

As discussed previously, the U.S. TOL success rate (VBACs per 100 women attempting a TOL) has remained steady over time at 74 percent [95% CI: 72, 75 percent].[6] Though there are several independent predictors of VBAC (delivery site characteristics, demographic traits, obstetric and medical history, and factors related to the current pregnancy),[6] obstetric providers typically advise average women that their likelihood of a successful TOL and VBAC is 60 to 80 percent.[27] Screening tools aide physicians in identifying women who have a VBAC likelihood estimate outside of this range, so that they may encourage or discourage a TOL. The literature review by Guise et al. identified fourteen studies of five screening tools designed to assess a patient and predict the likelihood of a VBAC or a repeat cesarean delivery when certain thresholds were reached. All the screening tools successfully recognized women who were good candidates for VBAC, but none had the discriminating ability to identify women who were at risk for a repeat cesarean delivery.[6]

Two screening tools were developed for use in the prenatal setting; specifically, their objectives were to create predictive models based on factors ascertainable at the first or second prenatal visit.[28, 29] Both tools targeted providers counseling pregnant women with one prior cesarean delivery, whose current pregnancy was ultimately delivered at term. The prenatal scoring tool by Hashima and Guise incorporated three evenly-weighted patient factors: indication for prior cesarean delivery (recurrent=0, non-recurrent=1), prior macrosomic infant (yes=0, no=1), and current anemia (yes=0, no=1).[28] Among the validation group, scores of 0, 1, 2, and 3 translated into TOL success rates of 25, 48.5, 52.9, and 66.9 percent respectively. The predictive model by Grobman et al. was based on a multivariable logistic regression and included the following factors: maternal age, body mass index, ethnicity, prior vaginal delivery, prior VBAC, and potentially recurrent indication for cesarean delivery. Their corresponding receiver operating characteristics curve had an area under the curve of 0.75 in both the original and cross-validation datasets.[29]

As mentioned previously, and as demonstrated in the evidence report by Guise et al., the majority of literature on TOL and VBAC performs statistical comparisons based on intended delivery method. Given that all predictive models are imperfect (including Hashima and Grobman's screening tools for TOL success rate), it seems logical to present patients with data about TOL versus ERCD, rather than VBAC versus repeat cesarean delivery (unsuccessful TOL or ERCD). However, obstetric providers should still consider statistical comparisons by actual delivery mode, especially in women seriously contemplating a TOL and in women whose estimated likelihood of TOL success is higher or lower than the usual 60 to 80 percent. Understanding the differential

risk profile by both intended and actual delivery method may add value to the counseling conversation.

Three recent investigations compared maternal and neonatal outcomes among women with successful and unsuccessful TOL. Two studies examined morbidity among both women and their infants, and treated successful TOL (VBAC) as the referent;[30, 31] the third study examined only maternal outcomes, but also utilized women having an ERCD as an additional referent group.[26] Oboro et al. found that, compared to women with a successful TOL culminating in a VBAC, women with an unsuccessful TOL leading to a repeat cesarean delivery had significantly higher risk for uterine rupture, hysterectomy, hemorrhage, transfusion, and chorioamnionitis. Their infants also had a significantly higher risk of neonatal sepsis, neonatal jaundice, five-minute Apgar scores less than seven, and neonatal intensive care unit admission for greater than 24 hours.[30] Similarly, El-Sayed et al. demonstrated a significantly increased risk of hysterectomy, chorioamnionitis, hemorrhage, neonatal sepsis, neonatal jaundice, and neonatal pneumonia in the unsuccessful TOL group compared to the VBAC group.[31] The study by Hibbard et al. was unique in that it compared women who had an unsuccessful TOL to both women with a successful TOL and women having an ERCD. The investigation showed that women with an unsuccessful TOL had a significantly higher risk of uterine rupture, hemorrhage, transfusion, chorioamnionitis, and endometritis than women with a successful TOL; these same women also had a significantly higher risk of uterine disruption (dehiscence or rupture), chorioamnionitis, and endometritis than women having an ERCD.[26]

Given that Guise et al. demonstrated significant differences in the risk profiles for TOL and ERCD – and these three studies found significant differences in the risk profiles for unsuccessful TOL, VBAC, and ERCD – it is clear that both intended and actual delivery method play a role in maternal and neonatal morbidity and mortality among women with a prior cesarean delivery. From the perspective of intention, some outcomes are more favorable for TOL, and others for ERCD.[6] Yet, among the TOL group, most of the poor maternal outcomes occur more often when the TOL fails and the actual delivery mode becomes repeat cesarean delivery.[26, 30, 31] Moreover, having an unsuccessful TOL is riskier than having an ERCD.[26] Therefore, VBAC is associated with fewer complications, and unsuccessful TOL is associated with more complications than ERCD. Consequently, the risk of maternal and neonatal morbidity and mortality is integrally related to a woman's probability of having a successful TOL and achieving a VBAC.[1]

Current Clinical Guidelines for Delivery Method after a Previous Cesarean Section

In 2010, the NIH hosted a Consensus Development Conference on the issues of TOL, VBAC, and ERCD, which were last explored by the NIH in 1980. Following the conference, the 2010 NIH Consensus Development Panel released a statement that summarized and evaluated current research on rates, patterns of utilization, predictive factors, short- and long-term benefits and harms to both the mother and baby, and critical gaps in the evidence. While the panel did not commit to definitive recommendations regarding a woman's likelihood of TOL or the overall superiority of VBAC or ERCD, they did provide a comprehensive and quality-driven summary of available data.

Following the release of the NIH Statement, ACOG published updated practice guidelines for the management of pregnant women with a history of a cesarean section.[1] Prior to discussion of their key points, the authors highlighted the complete lack of randomized trials comparing maternal and neonatal outcomes between TOL and ERCD in order to ensure the reader understood the recommendations were based on observational data alone, which may be subject to misclassification and bias.

In their guidelines, ACOG underscored the importance of finding both a balance of risks (as low as possible) and a chance of success (as high as possible) that are acceptable to the patient and the obstetric provider. The practice bulletin emphasized that, although there is no universally agreed on discriminatory point, evidence suggests that women with at least a 60 to 70 percent chance of VBAC have equal or less maternal morbidity when they attempt a TOL than when they have an ERCD.[32, 33] Conversely, women with less than a 60 percent chance of VBAC have greater maternal morbidity. Moreover, women with higher chances of VBAC have less neonatal morbidity.

Therefore, ACOG recommends discussing VBAC with, and offering a TOL to, most women with one previous cesarean delivery with a low transverse incision.[1] They also offer additional guidelines for women with unique medical and obstetrical factors and give advice about patient counseling. According to the practice bulletin, patient-provider discussion should include potential benefits and risks of TOL and ERCD, as well as individual characteristics that affect the chances of TOL success and delivery method morbidity. ACOG recommends beginning the counseling process early in a woman's prenatal care (PNC) course to allow the most time for her to consider her options. They emphasize that most factors related to chance of VBAC and complications

are known early in pregnancy, especially given the increasing reliability of predictive models.

Ultimately, ACOG recognizes that global mandates for TOL are inappropriate because they ignore individual variables. They recommend that the final decision about delivery method be made by the patient in consultation with her provider. However, they also uphold their prior recommendation (which is in agreement with other international guidelines) that TOL should only be attempted at facilities that have "immediately available" resources for emergency deliveries. ACOG cites this policy as another reason that discussions and decisions about TOL should occur during PNC visits; ideally, early counseling will avoid relocation after the onset of labor to facilitate TOL.[1]

PRENATAL CARE: Content, Schedule, Utilization, and Outcomes

Past and Present U.S. Guidelines on Prenatal Care Content and Schedule

In 1999, Gregory and Davidson published a valuable review of PNC in the United States, called "Prenatal Care: Who needs it and why?" The opening line of their article was "The simplest answer to the title question is: everybody needs it, but it is unclear why." They went on to emphasize the consistently-reported relationship between absence of PNC and increased risk of preterm birth, low birthweight, and perinatal mortality. They also pointed out, however, that the solely observational research on PNC may be subject to several types of bias that overestimate its benefits. Thus, given the questionable ethics of a trial randomizing women to PNC or no PNC, Gregory and

Davidson challenged future observational investigations to identify the specific content and schedules of PNC that are vital to its association with optimal birth outcomes.

The title question and proposed "next steps" from Gregory and Davidson's 1999 review were by no means new, and have in fact been the impetus behind multiple evidence reports, collaborative studies, and consensus panels over the past several decades.[34] In 1989, the U.S. Public Health Service (USPHS) published *Caring for Our Future: The Content of Prenatal Care*, a landmark evidence report and collection of recommendations on the practice, outcomes, and research of American PNC.[35] Overarching themes espoused by the panel may be summarized as follows:[36, 37]

- The objectives of PNC are to promote not only the health and well-being of the pregnant woman, fetus, and newborn, but also the health of the family up to one year after the birth of the infant.
- Health promotion should be an integral part of care for any woman and her current and future pregnancies. Thus, it is apposite to introduce the concept of the "preconception visit" as the true initial PNC visit (which may be operationalized as almost any health care interaction involving a woman of reproductive age).
- Risk assessment should be early, continuous, and patient-specific, with the frequency of clinical visits adjusted accordingly. For example, more visits are needed for nulliparous and high-risk women than for multiparous and low-risk women, respectively (Figure 1).

- PNC should emphasize both medical and psychosocial concerns, interventions, and follow-up.
- Standardized and comprehensive documentation of prenatal visits is essential to provide for communication and continuity of care between providers and to allow comparable analyses of quality of care and patient outcomes over time and across different clinical settings.
- Additional research on the specific content of PNC is needed in order to continue to improve efficiency and effectiveness.

"The Content of Prenatal Care: Update 2005" by Gregory et al. recounted that research performed since the 1989 report has identified important content for the USPHS-defined preconception visit and has supported the USPHS' recommendation on reduced prenatal visit frequency for low-risk women.[37] However, the authors emphasized that – despite repetitive summits emphasizing agreement and extending the content and schedule recommendations advocated by the expert panel in 1989 – few of the USPHS' suggested changes have been implemented into practice. Based on their own literature review and panel discussion, Gregory et al. also recommended new PNC initiatives, including augmentation of the electronic medical record, multidisciplinary approaches to patient education, improvement of patient literacy, and an extended maternal life span approach (including post-gestation visits that transform the single postpartum visit into interconception and well-woman care).

The most recent PNC content and schedule guidelines from the American Academy of Pediatrics (AAP) and ACOG were published in 2007.[38] They resulted from

thorough review of the literature (including reports like those from the USPHS and Gregory et al.) and panel discussion of the best available evidence on PNC. The collaborative report provides a summary of the important content of preconception and antepartum care and counseling, and generally parallels the recommendations of the 1989 report and the 2005 update.[35, 37] Unfortunately, it does not comment on the specific impact of each of the care components on perinatal outcomes.

With regard to PNC schedule, AAP and ACOG maintain that PNC technically begins at the preconception visit, but that "early" (without further definition) diagnosis of pregnancy and initiation of PNC is also important. Then, the frequency of PNC visits is subsequently determined by individual needs of the woman and an assessment of her risk. They do emphasize that, regardless of the patient risk profile, the visit schedule should be sufficient to enable coverage of the AAP/ACOG screening and education recommendations. Generally, "sufficient" care translates into the following appointment schedule for a low-risk woman: every 4 weeks for the first 28 weeks of gestation, every 2-3 weeks until 36 weeks of gestation, and weekly thereafter (Figure 1).[38] Thus, depending on when PNC is initiated, a generic AAP/ACOG visit schedule involves 9 to 14 visits for an uncomplicated pregnancy; i.e., assuming no extra appointments for genetic counseling/procedures, antepartum fetal surveillance, or postdates management.

Though both the USPHS and AAP/ACOG label the preconception visit as a women's true point of access into PNC, the *Healthy People* Objectives from the U.S. Department of Health and Human Services (USDHHS) alternatively define initiation of PNC.[39] In order to monitor progress toward their goal of increasing the "proportion of pregnant women who receive early and adequate PNC," the USDHHS measures the

percent of females delivering a live birth that received PNC beginning in the first trimester. Though they also have objectives regarding an increase in preconception care, they clearly differentiate between preconception care and PNC. The USDHHS distinction provides the reader with a more lucid and logical definition of "early" PNC than that offered by the USPHS and AAP/ACOG.

Though there are differences between the 2007 AAP/ACOG recommendations and the 1989 USPHS Expert Panel recommendations (Figure 1), two randomized controlled trials in the U.S. have demonstrated similar perinatal outcomes and patient satisfaction with both visit schedules.[40, 41] It also seems that the USPHS and AAP/ACOG guidelines essentially agree on the vital content of PNC, even if their suggested strategies do not have significant or specific supportive evidence and have not yet been fully implemented in the U.S.[37] Furthermore, the USDHHS *Healthy People* Objectives have stepped in to provide a concrete alternative to the ideology of the preconception care visit as the first PNC visit, while still supporting the preconception care initiative.[39] Thus, with a united front on PNC content, two viable care schedules with comparable outcomes, and a tangible recommendation for timing of PNC initiation, the U.S. has the framework to launch into both research and practice. As Gregory et al. wrote, "The time has come for us to stop talking and planning, and start doing."[37]

Prenatal Care Utilization in the U.S.

Given the persistent inability of prominent public health and medical organizations to agree on what precisely constitutes an adequate PNC schedule (timing of initiation and visit frequency), precisely determining the adequacy of PNC utilization in

the United States has been a difficult task. Moreover, multiple PNC utilization indices have been published in the scientific literature (Figure 2).[42] They are based on varying standards, classify women based on distinct measures, and assign patients to a range of utilization categories that include two to five of the following: intensive, adequate, intermediate, inadequate, and no care. Not surprisingly, a review by Alexander et al. showed that the proportion of patients assigned to utilization categories varied by each index, ranging from 9.2 to 20.3 percent for inadequate care, 33.6 to 58.1 percent for adequate care, and 7.4 to 22.6 percent for intensive utilization.[42] Therefore, the report stressed that selection of a PNC utilization index for research purposes requires careful consideration.

The existence of multiple standards for the measurement of PNC utilization is not ideal, particularly when each index classifies a moderately different proportion of women into a given category. However, a recent application of multiple indices to U.S. PNC trends from 1981 to 1995 suggests that the variability may not be as severe as suggested by Alexander et al., or that it at least may be consistent over time.[43] Kogan et al. found that three indices and the generic "trimester care began" categorization employed by U.S. vital statistics all reported significant improvement in PNC utilization over a fifteen-year period. The proportion of women in the R-GINDEX adequate/intensive categories rose from 32.7 to 47.1 percent, the proportion in the APNCU adequate/intensive categories rose from 63.5 to 72.7 percent, the proportion in the IOM adequate category rose from 67.0 to 74.3, and the proportion beginning care in the first trimester rose from 76.9 to 81.6.

In another study of PNC utilization trends from 1980 to 1994, Lewis et al. relied solely on the "trimester care began" index from U.S. vital statistics.[44] However, they dichotomized the measure into early care (initiated in first trimester) and late or no care (initiated in second or third trimester or not at all), and extended its application to subgroups of the American population. They found that the proportion of women receiving early care remained at 76 percent from 1980 to 1991 and then increased each year thereafter to 80 percent in 1994. That year, 83 percent of white women had early PNC, along with 68 percent of black women, 89 percent of Asian women, and 76 to 86 percent of other Asian and Pacific Islander subgroups; moreover, 69 percent of Hispanic women began PNC early. In general, older women were more likely to start care in the first trimester in 1994; 64 percent of teenage women accessed early care, while 85 to 88 percent of women aged 25 to 35 years visited a provider in the first trimester. More educated pregnant women were also more likely to receive early care; 60 to 65 percent of women with 0 to 11 years of education attained early care, compared to 79 to 94 percent of women with 12 or more years in school. Eighty-seven percent of married women had a PNC visit in the first trimester, versus only 66 percent of unmarried women. Women pregnant with their first or second child accessed early PNC 82 to 83 percent of the time, while utilization fell for later children, dropping to 65 percent for the fifth child and 55 percent for the sixth child and more. Of note, a 2011 literature review of determinants of PNC adequacy in high-income countries (including the U.S.) had similar findings to the Lewis et al. U.S. birth record review.[45] Their analysis of eight studies identified the following as individual determinants of adequate PNC use: older maternal age, high

education level, married status, non-ethnic minority, insured status, low parity, previous premature birth, and early recognition of pregnancy.

U.S. PNC utilization rates in the general population continued to rise from the time of the Lewis et al. publication through 2004. Data released with the USDHHS' *Healthy People 2010* Objectives reported that overall, 83 percent of woman received early PNC in 1998.[46] Their analysis of utilization by subgroup (race, ethnicity, age, and education) revealed nearly identical trends to those observed by Lewis et al in 1994. A subsequent *Healthy People 2010* Progress Review reported that 84 percent had care in the first trimester in 2004.[47] However, the most current data, released with the *Healthy People 2020* Objectives, suggest that U.S. PNC progress has not only slowed, but actually regressed. The USDHHS reported that only 70.8 percent of females delivering a live birth in 2007 received PNC beginning in the first trimester.[39]

Outcomes Associated with Inadequate Prenatal Care

The recent decline in PNC utilization by pregnant American women is concerning, as the absence of PNC has been tied to increased risk for preterm birth, low birthweight, and perinatal mortality.[34] Though no major randomized controlled trials of PNC versus no care have been performed due to ethical reasons, countless studies have utilized less direct methods to evaluate outcomes. Some experts argue that the lack of a conventional PNC utilization index and the difficulty in controlling for confounding factors hinders the ability of researchers and policy makers to draw categorical conclusions from the chiefly observational PNC literature.[42, 48] Others suggest that poor conceptualization and implementation of PNC in the U.S have led to an attenuation of the

positive outcomes associations.[49, 50] However, in spite of the research challenges, several major studies have reported an association between inadequate PNC and poor outcomes, both in the U.S. and abroad; thus, support remains for the continued practice, research, and funding of PNC.

Three reviews of U.S. vital statistics from the 1990s by Vintzileos et al. demonstrated a link between absent PNC and preterm birth, neonatal death, and postneonatal death, even after adjusting for multiple confounders and stratifying based on race and obstetrical and medical risk factors.[51-53] Their first study found that women who did not access PNC had a 2.9-fold increase in the risk of preterm delivery, compared to women who did (adjusted risk ratio (ARR) 2.9 [95% CI: 2.8, 3.0]).[52] There was a clear inverse dose-response relationship between the number of prenatal visits and the gestational age at delivery. Moreover, the association between absent PNC and preterm delivery was consistent for both white and black women, and for women with and without high-risk antenatal conditions. The second review by Vintzileos et al. demonstrated that neonatal death rates (deaths during the first 27 days of life per 1,000 live births) were also higher among women that did not access PNC (ARR 1.4 [95% CI 1.3, 1.5]).[53] The risk ratio for absent PNC and neonatal death was consistent for white and black women, and was higher for infants born at 36 weeks or later (ARR 2.1 [95% CI 1.7, 2.6]). Moreover, the association between absent PNC and neonatal death was consistent in women with and without placenta previa, fetal growth restriction, and preterm premature rupture of membranes. The third investigation by Vintzileos et al. found that absent PNC was also associated with an increased rate of postneonatal death (deaths between 28 and 365 days of life per 1,000 neonatal survivors) (ARR 1.7 [95% CI:

1.7-1.9]).[51] The risk ratio for lack of PNC and postneonatal death was again consistent for white and black women, and was higher for small-for-gestational-age and postterm infants, and women with pregnancy-induced hypertension and intrapartum fever.

A review of records from 1987 to 1993 at a tertiary care center in Cleveland, Ohio demonstrated similar results to the Vintzileos series.[54] Amini et al. found that, compared to women with three or more PNC visits, women with two or fewer visits had a significantly increased risk of admission at gestational age less than 37 weeks ($p<0.001$), antepartum and intrapartum stillborn ($p<0.001$), thick meconium in the amniotic fluid ($p=0.001$), one-minute Apgar scores less than six ($p<0.001$), five-minute Apgar scores less than seven ($p<0.001$), NICU admission ($p<0.001$), birthweight less than 1500g and birthweight less than 2500g ($p<0.001$), and length of infant hospital stay greater than seven days ($p<0.001$). Moreover, women with two or fewer PNC visits had a mean gestational age at admission that was 1.3 weeks younger ($p<0.001$), a mean birthweight that was 393g lower ($p<0.001$), and a mean length of infant hospital stay that was 3.5 days longer ($p<0.001$) than women with three or more visits.

An investigation by VanderWeele et al. examined similar outcomes to Vintzileos and Amini, but employed more sophisticated PNC adequacy indices (the Kessner index, GINDEX, APNCU, and two modifications of APNCU) to U.S. birth records.[55] They applied each index to outcome models for small-for-gestational-age, preterm birth, and infant mortality. The odds ratios for the small-for-gestational-age model were comparable across all PNC utilization indices, and suggested an association between less PNC and higher risk of a small-for-gestational-age infant. Four of five indices gave similar odds ratio estimates for the preterm birth and infant mortality models, but the

GINDEX index results varied markedly from the others. While most of the indices suggested an association between less PNC and an increased risk of preterm birth and infant mortality, GINDEX paradoxically showed that outcomes were better in the inadequate, intermediate, and intensive PNC categories than in the adequate category. This investigation thus indicated that the associations between PNC utilization and small-for-gestational-age, preterm birth, and infant mortality are relatively robust, in the sense that they are moderately consistent across indices. Care must be taken, however, in choosing indices for research, especially if an investigator is considering the use of GINDEX to analyze preterm birth and infant mortality models.

Chen et al. also performed an analysis of U.S. vital statistics from 1995 to 2000.[56] They reported that inadequate PNC (measured by the APNCU index) was associated with increased neonatal mortality in the presence and absence of high-risk antenatal conditions (anemia, cardiac disease, lung disease, chronic hypertension, diabetes, renal disease, pregnancy-induced hypertension, and previous preterm/small-for-gestational-age birth). They also proposed that the association between inadequate PNC and neonatal death may be mediated by the increased risk of preterm delivery and low birthweight in these pregnancies, as adjustment for gestational age at delivery and birthweight led to a disappearance of the observed association in pregnancies with high-risk conditions.

While the content and schedule of PNC in the U.S. may vary somewhat from that in other nations, it is important to recognize that international PNC outcomes research has demonstrated similar findings to that performed in the U.S. Several investigations have identified an association between PNC and decreased risk of preterm delivery,[57-59] low birthweight/small-for-gestational-age,[57-61] and perinatal mortality.[57, 59, 61]

Given that these U.S. and international investigations support an association between PNC and improved birth outcomes, ideological and financial support of American PNC seems not only logical, but necessary. However, as mentioned previously, many experts emphasize that the inconsistent definitions of PNC adequacy, the lack of control for critical confounders, and the existence of strictly observational studies preclude the ability to draw categorical conclusions.[42, 48] For instance, after thoroughly reviewing the literature on PNC outcomes and cost-effectiveness, Fiscella concluded that current evidence did not satisfy the necessary criteria to establish that PNC (a) definitively improves birth outcomes or (b) saves the U.S. money; however, he also made it clear that the evidence did not (c) provide sufficient basis for the defunding of PNC practice or research.[48] Fiscella emphasized that cost-effectivenesss research on PNC has based its calculations only on short-term outcomes, and not the potential for lifelong effects. He estimated that the studies therefore underestimated the cost-effectiveness of PNC, and also argued that the only health interventions actually proven to be cost-effective are immunizations. Moreover, Fiscella underscored that PNC should not be evaluated solely on its ability to improve birth outcomes. Rather, it should be assessed as an integral component of the holistic care of the health and well-being of American women, the impact of which has been extensively documented.

LITERATURE GAP:

Prenatal Care and Delivery Method in Women with a Prior Cesarean Section

As detailed above, recent research has identified a variety of independent predictors for TOL rate and TOL success rate among women with a prior cesarean section. Similarly, multiple studies have investigated the outcomes associated with PNC timing of initiation and overall adequacy. However, minimal work has been done to examine the potential association between PNC and TOL, VBAC, and ERCD. Several investigations explore the delivery method decision-making process specifically experienced by women who enter PNC early and who visit a provider frequently enough to learn about and discuss TOL, VBAC, and ERCD. Notably absent from these investigations, however, are the voices of women who entered PNC late or not at all.

Most research on the prenatal delivery method decision-making process for women with a previous cesarean delivery has focused on the woman's reasoning and reported influences. One review by Eden et al. found that the most commonly cited reason for a woman selecting a trial of labor was ease of recovery and desire to return quickly to caring for other children (reported in 6 of 7 analyzed studies).[17] The authors also emphasized the role of safety for the woman and/or infant in the delivery method choice (reported in 4 of 11 analyzed studies). A telephone survey of fifty women with a recent VBAC or repeat cesarean delivery demonstrated that the major reason for the VBAC choice was to experience a natural vaginal delivery, while the major reason for the repeat cesarean delivery choice was to avoid an unsuccessful labor.[62] Not surprisingly, a study of patients' perspectives on VBAC found that both a history of a

vaginal delivery and negative feelings toward the previous cesarean delivery (usually due to postoperative pain and long recovery times) were significantly associated with acceptance of VBAC ($p<0.01$).[63]

Clearly, women's birth choices are complex and are driven by multiple competing factors. Women must balance perceived health risks to themselves and their infants, while also processing prior birth experiences and external influences.[6] Upon closer examination of these external influences, however, research indicates that women highly value the opinion of their healthcare provider, and to a lesser extent seek input from their partners, family, friends, or other outside sources, such as the Internet.[64] Four studies have reported on effects of providers on the delivery method decision-making process that is undertaken during PNC. First, McClain interviewed 100 women that had recently had a VBAC or repeat cesarean delivery in three VBAC "friendly" San Francisco, California hospitals, and she asserted that their choice of delivery method was "largely influenced" by their interactions with physicians.[65] The next two investigations reported a differential level of physician influence by facility type and racial/ethnic status. A questionnaire study by Kirk et al. demonstrated that physicians exerted more influence on the decisions of patients at a public hospital than at a private hospital,[66] and the review by Eden et al. found that non-white women were more likely to identify their provider as an important influence than white women (39% versus 19%).[17] The final investigation into providers' influences on pregnant women with a previous cesarean delivery involved diaries, observations, and semi-structured interviews.[64] Despite a universal desire for these women to be involved in the decision-making process regarding their subsequent delivery method, most of them did not have firm plans initially; their final decision

typically developed over the course of the pregnancy. They usually looked for targeted information and guidance from medical personnel, based on their individual circumstances. Some women even admitted to being unhappy about being responsible for the ultimate delivery method decision.

In order to grasp the essentials of the patient-provider interaction in regards to delivery method decision-making, the evidence report for the 2010 NIH Consensus Development Conference by Guise et al. summarized the limited research on the formality and timing of counseling.[6] Specifically, they identified four investigations that demonstrated an association between choice of TOL and patient involvement in decision-making, counseling, and/or educational programs. Two studies also found that early timing of delivery method education led to higher TOL rates, and two reported that a lack of education and/or patient-provider discussion led to higher ERCD rates. Interestingly, discussion of uterine rupture as a potential complication of TOL did not have undue negative influence on patient decision-making.

As mentioned previously, there is much value in this literature on the delivery method decision-making process experienced by women who entered PNC early and who visited a provider frequently enough to learn about and discuss TOL, VBAC, and ERCD. However, these studies make no remarks whatsoever about the delivery method decision-making process for women who entered PNC late or not at all. Thus, there is a need for investigations that more inclusively examine the general association between PNC adequacy and the intended and actual delivery method. For women with a prior cesarean section, does entering PNC in the first trimester of pregnancy lead to an increased or decreased likelihood of TOL and VBAC?

Findings from a study investigating this question would be of value to both the medical and public health communities. The 2010 NIH Consensus Development Conference Statement outlined Ten Critical Gaps in the evidence for decision-making in regards to delivery method for women with a prior cesarean section.[7] An examination of the potential association between PNC and TOL rate and VBAC rate would address both Critical Gap 2 and Critical Gap 6:

- Critical Gap 2: There appear to be persistent racial/ethnic, geographic, and socioeconomic differences in the rate of TOL and VBAC compared with elective repeat cesarean delivery. We recommend investigation to understand the reasons for these differences.
- Critical Gap 6: A variety of nonmedical factors affects the availability and management of trial of labor, but they have not been well studied. Access to safe trial of labor appears to be restricted by factors such as geography workforce availability and training, professional association guidelines, type of maternity care provider, liability concerns, health insurance, and institutional policy. We recommend well-designed studies to better understand these factors and to test clinical, institutional, or policy interventions to increase access to safe trial of labor.

The proposed study may elucidate whether or not PNC is a mediating factor in the persistent ties between race/ethnicity and socioeconomic status (Critical Gap 2). It may

also indicate that PNC is a nonmedical factor affecting the availability and success rates of a TOL (Critical Gap 6).

While the aforementioned research results would be exciting – finding a positive association, identifying a mediator, and implicating the importance of nonmedical factor in medical outcomes – they are not necessary for the proposed study to make an impact. Regardless of the investigation's outcomes, the work will introduce new knowledge to the medical and public health literature. For instance, if there is a direct association between early PNC and TOL, and a direct association between early PNC and VBAC, then the study may be cited as evidence for all women with a prior cesarean section to enter PNC early in order to receive proper counseling on TOL, VBAC, and ERCD. If there is a null association between early PNC and TOL and VBAC, then the study may be cited as evidence – for obstetric providers who do not meet a woman until late in her pregnancy (or even after labor has begun) – to counsel all patients, regardless of timing of PNC initiation, and offer a TOL if the patient is deemed otherwise to be low-risk. Finally, if there is an inverse association between early PNC and TOL, the study may be cited as evidence that counseling by PNC providers – in the current medicolegal environment – may be inadvertently steering women toward an ERCD.

Consequently, the evident literature gap and the important medical and public health impact (regardless of results) certify the need for an investigation of the following question: Among women with a prior cesarean delivery, does entering PNC early increase the likelihood of a TOL and/or the likelihood of a VBAC? In broader terms, does early opportunity for patient-provider discussion on the options for delivery method after cesarean and the individual patient risk profile ultimately affect intended and/or

actual mode of delivery? The study described in the subsequent manuscript seeks to answer these important questions.

Chapter II: Manuscript

Effect of Early Prenatal Care Entry on Trial of Labor Rate and Vaginal Birth After Cesarean Section Rate Among Women with a Prior Cesarean Delivery: Georgia, United States (1999-2006)

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SUMMARY

Modes of delivery for women with a history of cesarean section include elective repeat cesarean delivery, successful trial of labor (TOL) leading to vaginal birth after cesarean section (VBAC), and unsuccessful trial of labor leading to repeat cesarean delivery. Maternal and perinatal outcomes differ for each delivery method, and likelihood of TOL success differs for each woman. Early access to prenatal care (PNC) provides time for in-depth counseling on these matters and is associated with improved overall pregnancy outcomes, but no data exist on the relationship between timing of PNC entry and rates of TOL and VBAC. Thus, we utilized Georgia's linked birth and hospital discharge records (1999 through 2006) to model the association between early initiation of PNC and rates of TOL and VBAC among singleton, second-order, live births at ≥20 weeks gestational age to women with a history of a primary cesarean section (n=48,048). Overall, TOL was documented for fewer than one-third of these women (32 percent) and only 8 percent delivered via VBAC. Women who accessed PNC early (prior to the fifth month of pregnancy) were only slightly more likely to have a documented TOL than women who accessed PNC late or not at all (crude RR 1.06 [95 percent confidence interval 1.00, 1.12]), and they were no more likely to deliver via VBAC (crude RR 0.92 [95 percent confidence interval 0.81, 1.04]). While early PNC may offer obstetric providers the opportunity to assess risk and advise patients about TOL, current counseling could be improved. Moreover, late entry into PNC should not be a barrier to engaging in discussion about TOL and VBAC.

INTRODUCTION

Between 1970 and 2009, the United States' cesarean delivery (CD) rate rose from 5 percent to nearly 33 percent,[1-3] making CD the most common medical procedure performed on American women.[4] The driving factor for the rising rates of CD was an increase in primary CDs,[5, 6] mainly due to obstetrical practice developments,[7-9] as well as to changes in the medicolegal environment, sociocultural propensities, and maternal medical risk profiles.[5, 9, 10]

As primary CD rates continued to climb, a related upsurge of repeat cesarean deliveries (RCD) also began contributing to the overall rise in CDs.[5, 6] The twentieth century paradigm of "once a cesarean, always a cesarean"[1, 6] waned, however, after research in the 1970s[1] and subsequent statements from the National Institutes of Health (NIH)[6] and American College of Obstetricians and Gynecologists (ACOG)[11] encouraged vaginal birth after cesarean delivery (VBAC) in low-risk women. As a result, American women with a prior CD were more routinely offered a trial of labor (TOL), and the U.S. VBAC rate increased from 5 percent in 1985 to 28 percent in 1996.[1] RCD and overall CD rates reflexively decreased during that time.[12]

Yet, as the number of American women attempting a TOL increased, so did the number of reports of TOL complications.[1] Two landmark studies on the risks of TOL[13, 14] – compounded by maternal concern about safety and recovery,[15] physician fear of liability and litigation,[16] differential reimbursement by insurance,[17-19] and institutional pressure to restrict access to TOL[20] – led to a decrease in the U.S. TOL rate after 1996. Meanwhile, the TOL success rate remained steady at 74 percent,[5] causing the U.S. VBAC rate to fall from the record-high 28 percent in 1996 to only 9 percent in 2006.[1, 6]

This decline in VBACs was accompanied by a reflexive rise in RCDs and, therefore, an increase in the overall CD rate to a record-high 32.9 percent in 2009.[1, 3, 5] In 2010, the CD rate fell for the first time in over a decade to 32.8 percent.[3]

Research on women with one prior CD typically utilizes one of two statistical methodologies: comparison by intended delivery method (TOL versus elective RCD [ERCD]) or by actual delivery method (VBAC versus any RCD).[1] Pooled analyses of studies employing comparison by intention demonstrate that maternal and perinatal mortality among women with a prior CD are rare, but maternal mortality is significantly lower and perinatal mortality is significantly higher among women attempting a TOL, compared to women having an ERCD.[5] Uterine rupture, hysterectomy, and hemorrhage occur more frequently in women attempting a TOL, but the relative risk is significant only for uterine rupture. Surgical injury and infectious morbidity are equivalent with both TOL and ERCD.[5]

Investigations of both intended and actual delivery method show that, compared to women who have a successful TOL and a VBAC, women who have an unsuccessful TOL and a RCD have a significantly increased risk of uterine rupture, hysterectomy, hemorrhage, transfusion, and infection.[21-23] They also have a significantly higher risk of uterine disruption and infection than women having an ERCD.[23] Their infants, compared to infants born by VBAC, have a significantly increased risk of sepsis, jaundice, low five-minute Apgar scores, and prolonged neonatal intensive care unit (NICU) admission.[21, 22] In fact, infants of both unsuccessful TOLs and of ERCDs are more likely to be admitted to the NICU than infants of VBACs.[5] Moreover, when considering all infants born to women with a prior CD, infants of an ERCD need the most blow-by oxygen and

continuous positive airway pressure, while those of an unsuccessful TOL (requiring RCD) demand the most bag-and-mask ventilation and intubation.[5]

Clearly, both intended and actual delivery method play a role in maternal and neonatal morbidity and mortality. VBAC is associated with fewer complications, and unsuccessful TOL is associated with more complications than ERCD.[5, 21-23] Consequently, the risk of maternal and neonatal morbidity and mortality is integrally related to a woman's probability of having a successful TOL and achieving a VBAC.[1]

Though obstetric providers typically advise women that their likelihood of a successful TOL is 60 to 80 percent,[24] there are several independent predictors of VBAC, including delivery site characteristics, race/ethnicity, prior vaginal delivery, maternal medical risk factors and diseases, and factors related to the prior CD and current pregnancy.[1, 5] Screening tools have been developed to aide providers in identifying women who have a high or low VBAC likelihood estimate, so that they may encourage or discourage a TOL.[5] In general, ACOG recommends discussing VBAC with, and offering a TOL to, most women with one previous cesarean delivery with a low transverse incision.[1] They suggest that counseling occur "early in PNC," as most factors related to the likelihood of VBAC and the risk of complications are known early in pregnancy, and early decision-making can prevent relocation after the onset of labor to a facility that provides ACOG's requisite "immediately available" resources for emergency deliveries.[1]

Unfortunately, "early in PNC" is poorly defined. The 1989 U.S. Public Health Service (USPHS) landmark recommendations on the content and schedule of American prenatal care (PNC)[25] – as well as subsequent guidelines from the American Academy of

Pediatrics (AAP) and ACOG[26] – emphasize the concept of the preconception visit as a women's true point of access into PNC. They also state, however, that "early" (again, poorly defined) diagnosis of pregnancy and initiation of PNC is important. The *Healthy People* Objectives from the U.S. Department of Health and Human Services (USDHHS) alternatively identify the appropriate time for initiation of PNC as the first trimester.[27]

Under this USDHHS definition, the proportion of American women accessing early PNC (care initiated in the first trimester) remained at 76 percent from 1980 to 1991 and then increased to 80 percent in 1994[28] and 84 percent in 2004.[29] However, current data show that only 71 percent received early care in 2007.[27] PNC utilization rates vary by maternal race/ethnicity, age, education, marital status, parity, prior pregnancy outcomes, insurance status, and timing of pregnancy diagnosis.[28, 30]

Though the chiefly observational literature on PNC is plagued by methodological issues,[31-34] several major studies have reported an association between inadequate PNC and poor outcomes.[35] Reviews of U.S. vital statistics demonstrate a link between inadequate PNC and preterm birth, low birthweight, and perinatal death, even with stratification by race/ethnicity and obstetrical and medical risk factors.[36-39] Several international investigations corroborate these associations.[40-44]

Recent research has examined the poor outcomes of inadequate PNC or has investigated the variety of independent predictors for TOL rate and TOL success among women with a prior cesarean section. However, minimal work has been done to examine the potential association between PNC and TOL, VBAC, and ERCD. Several investigations explore the delivery method decision-making process experienced by women who enter PNC early and who visit a provider frequently enough to learn about

and discuss TOL, VBAC, and ERCD.[5, 15, 45-49] Notably absent from these investigations, however, are the voices of women who enter PNC late or not at all. Thus, there is a need to examine the question of whether early PNC initiation among women with a prior CD is associated with intended and/or actual delivery method.

METHODS

Study Design and Data Sources

We conducted a retrospective analysis of a cohort created through the linkage of Georgia birth records and hospital discharge records from 1999 through 2006. Utilizing unique maternal identifiers, we were able to explore the linked vital statistics and administrative data for each mother-infant pair, as well as longitudinal records for consecutive births to the same woman (if they occurred within the identified timeframe). This technique both broadened our list of potential covariates for analysis, and validated those variables which appeared in both datasets.

Inclusion and Exclusion Criteria

We limited the population to second-order, live births to women who delivered their first-order, live birth via primary CD. This restriction prevented confounding by both number of prior CDs and number of prior vaginal deliveries (before or after CD).

To identify the population for analysis, we initially restricted the cohort to first- and second-order, live births. We then removed duplicate entries and excluded non-singleton births, deliveries at <20 weeks gestational age, and births with missing PNC measures. Our ultimate study population included only the singleton, second-order, live births at ≥20 weeks gestational age to women whose first-order birth (if it occurred in Georgia between 1999 and 2006) was a CD, and whose birth of interest for this analysis was a VBAC or RCD.

Definitions and Covariate Selection

Based on our literature review, the ideal definition of early PNC is initiation in the first trimester, which is typically defined as the first 12 to 14 weeks of pregnancy.

However, since Georgia birth certificates record month of care entry instead of trimester, we divided the upper limit of weeks defining the first trimester (14 weeks) by the number of weeks per month (4.3 weeks) to compute the number of months in the first trimester (3.3 months). According to these calculations, women who enter care in the first two weeks of the fourth month enter care in the first trimester; thus, we included the entire fourth month as part of the first trimester. We defined early PNC as initiation of care prior to the fifth month of pregnancy according to the birth certificate, and a total number of visits of ≥1. We labeled those with initiation of care in the fifth month or later, or no documented visits at all, as late/no PNC. We excluded records that were missing PNC measures.

Our outcomes of interest were documentation of a TOL and an ultimate delivery method of VBAC. We defined documented TOL as birth certificate record of induced, stimulated, precipitous, prolonged, or dysfunctional labor or hospital discharge record of at least one of 10 Current Procedural Terminology (CPT) codes, 126 International Classification of Diseases Ninth Edition (ICD-9) Diagnosis codes, or 32 ICD-9 Procedure codes indicative of labor (Box 1). Each maternal hospital discharge record documented up to four CPT, ten ICD-9 Diagnosis, and six ICD-9 Procedure codes. We characterized delivery method based on birth certificate listing of VBAC or RCD (with or without use of additional techniques, including forceps, vacuum, and version and extraction). No births were missing data for all the TOL indicators, likely due to the abundance of potential sites for documentation. We excluded records that were missing delivery method.

Based on a review of the literature, we considered fifteen categorical variables as covariates in the initial analysis (Table 2). We narrowed this list based on preliminary analyses, and ultimately considered only twelve variables in our final models.

Analysis

We initially examined potential covariates among all eligible births and among births stratified by PNC and by both outcomes, testing for differences with chi-square and Fisher's exact tests, as appropriate. We defined candidate confounders for subsequent model exploration as covariates statistically associated with the exposure and at least one outcome. These criteria identified twelve covariates for inclusion in our models, including two (paternal age, missing/unknown paternal demographics) which were only significant for one outcome. Although we identified interpregnancy interval as an a priori potential confounder, it barely met our inclusion criteria for only the VBAC outcome, and the VBAC model with interaction terms did not converge with the addition of a thirteenth covariate. Thus, we left it out of our twelve-covariate models and later performed a simple check for confounding.

Because both TOL and VBAC were not statistically rare (each with prevalence >8%), odds ratios (ORs) would exaggerate RRs. Therefore, we chose statistical modeling approaches that calculated RRs instead of ORs. We employed log-binomial regression and – when a log-binomial model did not converge – log-Poisson regression with robust standard errors.[50]

Utilizing these techniques, we performed backward elimination on multivariable models with interaction terms to identify potential effect modification (at significance level $p<0.05$). We subsequently investigated for confounding by dropping single and

grouped covariates from our full multivariable model. We used a data-based criterion to define confounding as a ≥10 percent change in the effect estimate from the full model.

Following creation of our final TOL and VBAC models, we performed a sensitivity analysis for the effects of missing PNC data. We alternately assigned all births with missing data to "early" and then to "late/no" PNC. Then we applied both the bivariable and full multivariable models for both outcomes to these formulated datasets to describe effects under the extreme assumptions that the missing were all one PNC value or the other.

The Institutional Review Board at Emory University reviewed and approved our study. All data analyses were performed using SAS 9.2 (Carey, NC).

RESULTS

The study population consisted of 48,048 singleton, second-order, live births at ≥20 weeks gestational age delivered to Georgia women whose first-order, live birth was a primary CD (6.8 percent of Georgia's 728,130 total live births from 1999 through 2006). Women accessed PNC before the fifth month of pregnancy in 94 percent of these births (Table 1). TOL was attempted in 32 percent, and 8 percent were ultimately delivered via VBAC, representing a TOL success rate of 25 percent.

Early PNC entry was significantly more common among women that were ≥25 years, white or Asian, more educated, married, aware of all paternal data, and privately insured (Tables 1 and 2). Early PNC was also associated with healthier birthweight and gestational ages at delivery, interpregnancy interval >18 months, and fewer behavioral risk factors. The likelihood of having a documented TOL was significantly higher among women who were in the mid-range of their reproductive years (25-39), a racial/ethnic minority, more educated, married, aware of all paternal data, and privately insured, as well as among women who drank alcohol but did not smoke during pregnancy. A TOL was also associated with delivery of postdates and anomalous infants. The chances of VBAC were significantly higher among women who were <35 years old, Asian or Hispanic, and privately insured, and among women who had an interpregnancy interval ≤18 months and drank alcohol during pregnancy. VBAC was associated with delivery of <500-gram infants, as well as postdates and anomalous infants.

Evaluation of the covariates that met our criteria for modeling inclusion (with exceptions noted above) demonstrated no interaction within the TOL model (data not shown). The only potential effect modifier for the PNC and VBAC relationship was

paternal race/ethnicity (interaction term p=0.0018). However, small numbers in a significant proportion of the stratified paternal race/ethnicity categories cast doubt on the true significance of the interaction term (data not shown). Thus, we ultimately excluded all interaction terms from our final models.

Women with early PNC were significantly more likely to have a documented TOL than women with late or no PNC (crude RR 1.06 [95 percent confidence interval (95% CI) 1.002, 1.124]) (Table 3). This relationship attenuated to null with full adjustment for all covariates, although none of the covariates confounded the relationship according to the data-based criterion. The largest changes in the effect estimate were with interpregnancy interval (-2.08%), primary payor (0.82%), maternal education (0.78%), and gestational age (-0.68%). Moreover, intermediate models presented no evidence for joint confounding upon ordered exclusion of related groups of variables.

There was no relationship between early PNC and the likelihood of VBAC (crude RR 0.92 [95% CI 0.81, 1.04]) (Table 3). Full adjustment for single and grouped covariates did not significantly change the effect estimate. The largest changes in the adjusted RR were with interpregnancy interval (2.93%), maternal age (-1.93%), gestational age (-1.61%), and maternal education (1.04%).

Sensitivity analysis showed that both the TOL and VBAC effect estimates were robust to missing data (Table 4). Adding the births with at least one missing PNC measure (n=1,724) to the births with known late/no PNC (n=2,876 for crude model and n=1,910 for full model) increased those counts by 60 to 90 percent. However, when these births were reintroduced to the dataset as “early” and subsequently as “late/no”

PNC, the point estimates and confidence intervals changed neither their direction of association, nor their significance.

DISCUSSION

This study provides some evidence that women who initiate PNC prior to the fifth month of their pregnancy are slightly more likely to attempt a TOL than women who initiate PNC in the fifth month or later or not at all, yet both groups of women have the same likelihood of VBAC. The most remarkable findings, however, are the study population's strikingly low rates of TOL and VBAC in the presence of its remarkably high rates of early PNC. Even when Georgia women with a prior cesarean section access early PNC, they may not be receiving adequate counseling about their delivery method options.

The association between early PNC and TOL may be related to an early PNC recipient obtaining an individualized risk assessment from her obstetric provider, as well as counseling regarding the success rate and the benefits and harms of VBAC versus ERCD. In the appropriate situation, these discussions may help the woman and/or her provider to feel more comfortable and confident in the decision to pursue a TOL. The null association between early PNC and VBAC, however, downplays the importance of early counseling. If women who access PNC early do not have a higher VBAC rate than women who access PNC late or not at all, there is no reason to restrict TOL attempts among the latter. As long as the provider discusses the issues surrounding TOL, VBAC, and ERCD and deems a patient to be otherwise low-risk – whether in the last couple PNC visits before delivery, or when the patient arrives at the hospital in early labor – he or she should feel comfortable with the patient attempting a TOL. Of note, VBAC rate (modeled in our study) is not identical to TOL success rate (a more ideal measure in exploring this issue), but it can serve as a proxy when TOL rate is similar amongst the

groups being compared (e.g., in this investigation: 32 percent for early PNC and 30 percent for late/no PNC).

Only 32 percent of women in our study had a documented TOL, which is considerably lower than the 47 percent reported in the literature.[5] The majority of prior TOL rate studies took place at large tertiary teaching hospitals—which may slightly overestimate the true rate in the general population—but it is unlikely that practice setting accounts for the entire difference. Rather, it is probable that Georgia women with a prior cesarean section do not receive adequate counseling on their delivery method options and/or that Georgia obstetric providers and birthing facilities do not feel comfortable offering TOLs.

Our study group's VBAC rate of 8 percent is also lower than the U.S. VBAC rate, which was at a record-high just prior to our study (28 percent in 1996) and fell to its record-low upon the conclusion of our study (9 percent in 2006).[1, 6] The TOL success rate of 25 percent in our study population, which is markedly lower than the 74 percent reported in the literature,[5] suggests that this low VBAC rate is not only due to a low TOL rate, but also to a low probability of success with each TOL.

It is possible that the TOL success rate is falsely decreased due to misclassification of two groups of women: those presenting to the hospital with signs of labor and then requesting their previously decided upon RCD, and those being purposefully labored in order to "prime" the infant for safe delivery via ERCD. However, these women are unlikely to account for the entire difference in rates. Perhaps Georgia obstetric providers are too quick to jump to RCD at any sign of maternal or fetal distress during TOL. Alternatively, they may need more education on the selection of

appropriate candidates for TOL. Of note, 2.2 percent of women that delivered via VBAC lacked TOL documentation, indicating the presence of at least some outcome misclassification; it is unclear whether or not the misclassification is differential.

A limitation of our study – and of all studies investigating PNC, TOL, and VBAC, alone or in concert – is the observational design; the well-established positive outcomes of PNC, and the pregnant woman's autonomy to ultimately choose her own intended delivery method, preclude a randomized controlled trial on this topic. Weaknesses inherent to observational studies include the unequal distribution of covariates within the exposed and unexposed groups, as well as the inability to control for unmeasured confounders. Fortunately, none of our measured covariates modified the effect of PNC on TOL or VBAC, and none met the data-based criterion for confounding.

While there are some disadvantages to population-based datasets, we consider our chosen data sources to be a strength of our study. Birth certificates document a wealth of information on more than 99 percent of all births in the U.S.,[51] suggesting that our analyses of Georgia natality records may be generalizable to the Georgia population. Yet, while birth records certainly provide a virtually complete dataset on an expansive population, the validity of their measures is imperfect.[51, 52] Our study gleaned several variables from vital statistics data, including our exposure (PNC) and one of our outcomes (delivery method). Recent validation studies of these birth certificate measures (in comparison to a "gold standard," often medical records) typically demonstrated a 90 to 100 percent sensitivity and specificity for delivery method[53-57] and a 70 to 80 percent concordance for PNC,[53-59] although a study at a public health department prenatal clinic in northeast Georgia reported a trimester concordance of only 51 percent.[58] These

concordance rates are tolerable, but they provide evidence that misclassification (which may or may not be differential) may afflict our analyses.

Hospital discharge records, which utilize codes to identify diagnoses and procedures, were the main resource for our second outcome (documented TOL). The accuracy of these diagnostic and procedural codes is influenced by both the validity of the diagnosis or procedure (which is related to the provider's diagnostic/therapeutic decision-making and documentation), and the association of the code with the documented diagnosis or procedure (which is related to the health records abstractor's interpretation of the documentation and code assignment).[60] Provider capacity may play a role in the validity aspect of code accuracy, but incentives are likely the main influence. Limited studies have investigated this topic,[11, 12] but we hypothesized that lacking reimbursement incentives for both attempt and documentation of TOL may lead to potential underreporting.

The association between codes and actual diagnoses and procedures must be measured in order to quantify misclassification and estimate resulting bias.[61] We did not conduct a validation study, but we estimated that a TOL was likely to be documented for a given woman by at least one of the 168 coding options in at least one of the 20 coded variables we included in our TOL definition (Box 1), even if incentives were lacking. A review of the literature also revealed that our supplementation of hospital discharge codes with data from vital statistics likely increased the validity of our TOL measure.[62-64] Thus, based on our own analyses and a literature review of the advantages and disadvantages of birth and hospital discharge records, our utilization of a linked population-based dataset

allowed us to maximize our population size and generalizeability, without sacrificing the validity of our exposure and outcome measures.

While our study demonstrated novel findings, it is only the first of many steps in understanding the complex interactions between the elements of PNC (entry, visit frequency, risk assessment, and delivery method counseling), the patient-provider decision regarding pursuit of a TOL, and the ultimate mode of delivery. Moving forward, we recommend investigations that incorporate potential confounders we could not include in our study, and we suggest the examination of TOL success rate as an outcome (in addition to TOL rate and VBAC rate). Furthermore, in addition to evaluating the relationship between PNC and TOL and between PNC and VBAC, subsequent studies should examine whether PNC modifies the effect of TOL attempt on delivery method. Future research might also involve multilevel regression modeling and geospatial analysis of potential clustering of women by exposure and/or outcome status.

Our study has potential public health and medical implications. The small but direct association between early PNC and TOL provides evidence that public health proponents may use to emphasize the importance of preconception care and PNC, yet the null association between early PNC and VBAC also allows obstetric providers to feel more comfortable offering a TOL to all low-risk women, regardless of the timing of their entry into PNC. In addition, Georgia's low TOL, VBAC, and TOL success rates suggest the need for broad improvement in patient-provider counseling. Nevertheless, much more research is needed prior to institutionalized changes. We have generated hypotheses and described trends, and now we must validate these relationships to ultimately alter clinical practice and improve maternal and child health.

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Box 1. United States standard birth certificate (1989 revision) indicators, Current Procedural Terminology (CPT) codes, International Classification of Diseases Ninth Edition (ICD-9) Diagnosis codes, and ICD-9 Procedure codes indicative of labor, among live, second-order, singleton births to Georgia women with a history of primary cesarean section.[a]

Classification	Code	Description
Birth certificate	39-03	Induction of labor
	39-04	Stimulation of labor
	40-08	Precipitous labor (<3 hours)
	40-09	Prolonged labor (>20 hours)
	40-10	Dysfunctional labor
CPT	01960	Anesthesia for vaginal delivery only
	59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and pospartum care
	59409	Vaginal delivery only (with or without episiotomy and/or forceps)
	59410	Vaginal delivery only (with or without episiotomy and/or forceps), including postpartum care
	59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps), and pospartum care, after previous cesarean delivery
	59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps)
	59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps), including postpartum care
	59618	Routine obstetric care including antepartum care, cesarean delivery, and pospartum care, following attempted vaginal delivery after previous cesarean delivery
	59620	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery
	59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery, including postpartum care
ICD-9 Diagnosis	65900	Failed mechanical induction of labor, unspecified as to episode of care or not applicable
	65901	Failed mechanical induction of labor, delivered, with or without mention of antepartum condition
	65903	Failed mechanical induction of labor, antepartum condition or complication

65910 Failed medical or unspecified induction of labor, unspecified as to episode of care or not applicable

65911 Failed medical or unspecified induction of labor, delivered, with or without mention of antepartum condition

65913 Failed medical or unspecified induction of labor, antepartum condition or complication

66000 Obstruction caused by malposition of fetus at onset of labor, unspecified as to episode of care or not applicable

66001 Obstruction caused by malposition of fetus at onset of labor, delivered, with or without mention of antepartum condition

66003 Obstruction caused by malposition of fetus at onset of labor, antepartum condition or complication

66010 Obstruction by bony pelvis during labor, unspecified as to episode of care or not applicable

66011 Obstruction by bony pelvis during labor, delivered, with or without mention of antepartum condition

66013 Obstruction by bony pelvis during labor, antepartum condition or complication

66020 Obstruction by abnormal pelvic soft tissues during labor, unspecified as to episode of care or not applicable

66021 Obstruction by abnormal pelvic soft tissues during labor, delivered, with or without mention of antepartum condition

66023 Obstruction by abnormal pelvic soft tissues during labor, antepartum condition or complication

66030 Deep transverse arrest and persistent occipitoposterior position, unspecified as to episode of care or not applicable

66031 Deep transverse arrest and persistent occipitoposterior position, delivered, with or without mention of antepartum condition

66033 Deep transverse arrest and persistent occipitoposterior position, antepartum condition or complication

66040 Shoulder (girdle) dystocia, unspecified as to episode of care or not applicable

66041 Shoulder (girdle) dystocia, delivered, with or without mention of antepartum condition

66043 Shoulder (girdle) dystocia, antepartum condition or complication

66050 Locked twins, unspecified as to episode of care or not applicable

66051 Locked twins, delivered, with or without mention of antepartum condition

66053 Locked twins, antepartum condition or complication

66060 Unspecified failed trial of labor, unspecified as to episode of care or not applicable

66061 Unspecified failed trial of labor, delivered, with or without mention of antepartum condition

66063 Unspecified failed trial of labor, antepartum condition or complication

66070 Failed forceps or vacuum extractor, unspecified, unspecified as to episode of care or not applicable

66071 Failed forceps or vacuum extractor, unspecified, delivered, with or without mention of antepartum condition

66073 Failed forceps or vacuum extractor, unspecified, antepartum condition or complication

66080 Other causes of obstructed labor, unspecified as to episode of care or not applicable

66081 Other causes of obstructed labor, delivered, with or without mention of antepartum condition

66083 Other causes of obstructed labor, antepartum condition or complication

66090 Unspecified obstructed labor, unspecified as to episode of care or not applicable

66091 Unspecified obstructed labor, delivered, with or without mention of antepartum condition

66093 Unspecified obstructed labor, antepartum condition or complication

66100 Primary uterine inertia, unspecified as to episode of care or not applicable

66101 Primary uterine inertia, delivered, with or without mention of antepartum condition

66103 Primary uterine inertia, antepartum condition or complication

66110 Secondary uterine inertia, unspecified as to episode of care or not applicable

66111 Secondary uterine inertia, delivered, with or without mention of antepartum condition

66113 Secondary uterine inertia, antepartum condition or complication

66120 Other and unspecified uterine inertia, unspecified as to episode of care or not applicable

66121 Other and unspecified uterine inertia, delivered, with or without mention of antepartum condition

66123 Other and unspecified uterine inertia, antepartum condition or complication

66130 Precipitate labor, unspecified as to episode of care or not applicable

66131 Precipitate labor, delivered, with or without mention of antepartum condition

66133 Precipitate labor, antepartum condition or complication

66140 Hypertonic, incoordinate, or prolonged uterine contractions, unspecified as to episode of care or not applicable

66141 Hypertonic, incoordinate, or prolonged uterine contractions, delivered, with or without mention of antepartum condition

66143 Hypertonic, incoordinate, or prolonged uterine contractions, antepartum condition or complication

66190 Unspecified abnormality of labor, unspecified as to episode of care or not applicable

66191 Unspecified abnormality of labor, delivered, with or without mention of antepartum condition

66193 Unspecified abnormality of labor, antepartum condition or complication

66200 Prolonged first stage of labor, unspecified as to episode of care or not applicable

66201 Prolonged first stage of labor, delivered, with or without mention of antepartum condition

66203 Prolonged first stage of labor, antepartum condition or complication

66210 Unspecified prolonged labor, unspecified as to episode of care or not applicable

66211 Unspecified prolonged labor, delivered, with or without mention of antepartum condition

66213 Unspecified prolonged labor, antepartum condition or complication

66220 Prolonged second stage of labor, unspecified as to episode of care or not applicable

66221 Prolonged second stage of labor, delivered, with or without mention of antepartum condition

66223 Prolonged second stage of labor, antepartum condition or complication

66230 Delayed delivery of second twin, triplet, etc., unspecified as to episode of care or not applicable

66231 Delayed delivery of second twin, triplet, etc., delivered, with or without mention of antepartum condition

66233 Delayed delivery of second twin, triplet, etc., antepartum condition or complication

66300 Prolapse of cord complicating labor and delivery, unspecified as to episode of care or not applicable

66301 Prolapse of cord complicating labor and delivery, delivered, with or without mention of antepartum condition

66303 Prolapse of cord complicating labor and delivery, antepartum condition or complication

66310 Cord around neck with compression, complicating labor and delivery, unspecified as to episode of care or not applicable

66311 Cord around neck, with compression, complicating labor and delivery, delivered, with or without mention of antepartum condition

66313 Cord around neck, with compression, complicating labor and delivery, antepartum condition or complication

66320 Other and unspecified cord entanglement, with compression, complicating labor and delivery, unspecified as to episode of care or not applicable

66321 Other and unspecified cord entanglement, with compression, complicating labor and delivery, delivered, with or without mention of antepartum condition

66323 Other and unspecified cord entanglement, with compression, complicating labor and delivery, antepartum condition or complication

66330 Other and unspecified cord entanglement, without mention of compression, complicating labor and delivery, unspecified as to episode of care or not applicable

66331 Other and unspecified cord entanglement, without mention of compression, complicating labor and delivery, delivered, with or without mention of antepartum condition

66333 Other and unspecified cord entanglement, without mention of compression, complicating labor and delivery, antepartum condition or complication

66340 Short cord complicating labor and delivery, unspecified as to episode of care or not applicable

66341 Short cord complicating labor and delivery, delivered, with or without mention of antepartum condition

66343 Short cord complicating labor and delivery, antepartum condition or complication

66350 Vasa previa complicating labor and delivery, unspecified as to episode of care or not applicable

66351 Vasa previa complicating labor and delivery, delivered, with or without mention of antepartum condition

66353 Vasa previa complicating labor and delivery, antepartum condition or complication

66360 Vascular lesions of cord complicating labor and delivery, unspecified as to episode of care or not applicable

66361 Vascular lesions of cord complicating labor and delivery, delivered, with or without mention of antepartum condition

66363 Vascular lesions of cord complicating labor and delivery, antepartum condition or complication

66380 Other umbilical cord complications complicating labor and delivery, unspecified as to episode of care or not applicable

66381 Other umbilical cord complications complicating labor and delivery, delivered, with or without mention of antepartum condition

66383 Other umbilical cord complications complicating labor and delivery, antepartum condition or complication

66390 Unspecified umbilical cord complication complicating labor and delivery, unspecified as to episode of care or not applicable

66391 Unspecified umbilical cord complication complicating labor and delivery, delivered, with or without mention of antepartum condition

66393 Unspecified umbilical cord complication complicating labor and delivery, antepartum condition or complication

66400 First-degree perineal laceration, unspecified as to episode of care or not applicable

66401 First-degree perineal laceration,delivered, with or without mention of antepartum condition

66404 First-degree perineal laceration, postpartum condition or complication

66410 Second-degree perineal laceration, unspecified as to episode of care or not applicable

66411 Second-degree perineal laceration, delivered, with or without mention of antepartum condition

66414 Second-degree perineal laceration, postpartum condition or complication

66420 Third-degree perineal laceration, unspecified as to episode of care or not applicable

66421 Third-degree perineal laceration, delivered, with or without mention of antepartum condition

66424 Third-degree perineal laceration, postpartum condition or complication

66430 Fourth-degree perineal laceration, unspecified as to episode of care or not applicable

66431 Fourth-degree perineal laceration, delivered, with or without mention of antepartum condition

66434 Fourth-degree perineal laceration, postpartum condition or complication

66440 Unspecified perineal laceration, unspecified as to episode of care or not applicable

66441 Unspecified perineal laceration, delivered, with or without mention of antepartum condition

66444 Unspecified perineal laceration, postpartum condition or complication

66510 Rupture of uterus during labor, unspecified as to episode of care or not applicable

66511 Rupture of uterus during labor, delivered, with or without mention of antepartum condition

66520 Inversion of uterus, unspecified as to episode of care or not applicable

66522 Inversion of uterus, delivered, with mention of postpartum complication

66524 Inversion of uterus, postpartum condition or complication

66530 Laceration of cervix, unspecified as to episode of care or not applicable

66531 Laceration of cervix, delivered, with or without mention of antepartum condition

66534 Laceration of cervix, postpartum condition or complication

66540 High vaginal laceration, unspecified as to episode of care or not applicable

	66541	High vaginal laceration, delivered, with or without mention of antepartum condition
	66544	High vaginal laceration, postpartum condition or complication
	66950	Forceps or vacuum extractor delivery without mention of indication, unspecified as to episode of care or not applicable
	66951	Forceps or vacuum extractor delivery without mention of indication, delivered, with or without mention of antepartum condition
	66960	Breech extraction, without mention of indication, unspecified as to episode of care or not applicable
	66961	Breech extraction, without mention of indication, delivered, with or without mention of antepartum condition
	67420	Disruption of perineal wound, unspecified as to episode of care or not applicable
	67422	Disruption of perineal wound, delivered, with mention of postpartum complication
	67424	Disruption of perineal wound, postpartum condition or complication
ICD-9 Procedure	720	Low forceps operation
	721	Low forceps operation with episiotomy
	7221	Mid forceps operation with episiotomy
	7229	Other mid forceps operation
	7231	High forceps operation with episiotomy
	7239	Other high forceps operation
	724	Forceps rotation of fetal head
	7251	Partial breech extraction with forceps to aftercoming head
	7252	Other partial breech extraction
	7253	Total breech extraction with forceps to aftercoming head
	7254	Other total breech extraction
	726	Forceps application to aftercoming head
	7271	Vacuum extraction with episiotomy
	7279	Other vacuum extraction
	728	Other specified instrumental delivery
	729	Unspecified instrumental delivery
	7301	Induction of labor by artificial rupture of membranes
	7309	Other artificial rupture of membranes
	731	Other surgical induction of labor
	7321	Internal and combined version without extraction

7322	Internal and combined version with extraction
733	Failed forceps
734	Medical induction of labor
7351	Manual rotation of fetal head
7359	Other manually assisted delivery
736	Episiotomy
738	Operations on fetus to facilitate delivery
7391	External version assisting delivery
7392	Replacement of prolapsed umbilical cord
7393	Incision of cervix to assist delivery
7394	Pubiotomy to assist delivery
7399	Other operations assisting delivery

[a]Based on Georgia birth certificate and hospital discharge data, 1999-2006.

Table 1. Characteristics of live, second-order, singleton births to Georgia women with a history of primary cesarean section.[a]

	Eligible Births (n=48,048)		Early PNC[b] (n=45,172)		Doc. TOL[c] (n=15,181)		VBAC[d] (n=3,872)	
	No.	%	%	p-value[e]	%	p-value	%	p-value
Prenatal care (PNC) before 5th month								
Yes	45,172	94.01			94.34	0.0398 *	93.52	0.1742
No	2,876	5.99			5.66		6.48	
Documented trial of labor (TOL)								
Yes	15,181	31.60	31.71	0.0398 *			97.83	< 0.0001 *
No	32,867	68.40	68.29				2.17	
Delivery method								
VBAC	3,872	8.06	8.02	0.1742	24.95	< 0.0001 *		
Repeat c-section	44,176	91.94	91.98		75.05			
Maternal age (years)								
14-19	1,625	3.38	2.85	< 0.0001 *	3.32	0.0011 *	4.08	< 0.0001 *
20-24	9,999	20.81	19.69		20.26		22.26	
25-29	12,997	27.05	27.23		27.59		29.31	
30-34	14,363	29.89	30.78		30.71		29.52	
35-39	7,565	15.74	16.24		15.31		12.63	
≥40	1,499	3.12	3.20		2.81		2.20	
Maternal race/ethnicity								
Non-Hispanic white	27,600	57.44	58.80	< 0.0001 *	54.57	< 0.0001 *	56.02	< 0.0001 *
Non-Hispanic black	13,507	28.11	27.39		29.00		25.54	
Non-Hispanic Asian	1,473	3.07	3.13		3.99		4.42	
Hispanic	5,310	11.05	10.36		12.06		13.61	
Non-Hispanic other	158	0.33	0.32		0.38		0.41	
Maternal education (highest achieved)								
Some college or higher	25,552	54.08	55.67	< 0.0001 *	56.08	< 0.0001 *	56.81	0.0003 *
High school diploma or GED	14,678	31.07	30.66		29.51		28.14	
9th through 11th grade	5,404	11.44	10.72		10.75		11.27	
Less than 9th grade	1,615	3.42	2.95		3.66		3.78	
Unknown	799							
Maternal marital status								
Married	35,026	72.90	74.82	< 0.0001 *	73.83	0.0018 *	73.92	0.1375
Unmarried	13,022	27.10	25.18		26.17		26.08	
Paternal age (years)								
14-24	5,416	12.73	11.98	< 0.0001 *	12.27	0.0536	14.29	0.0040 *
≥25	37,132	87.27	88.02		87.73		85.71	
Unknown	5,500							

Paternal race/ethnicity								
Non-Hispanic white	26,431	62.22	63.33	< 0.0001 *	59.05	< 0.0001 *	59.82	< 0.0001 *
Non-Hispanic black	10,778	25.37	24.97		26.24		23.35	
Non-Hispanic Asian	1,288	3.03	3.06		4.01		4.58	
Hispanic	3,839	9.04	8.31		10.25		11.47	
Non-Hispanic other	144	0.34	0.34		0.45		0.78	
Unknown	5,568							
Missing/unknown paternal demographics								
None	41,840	87.08	88.31	< 0.0001 *	87.64	0.0135 *	87.78	0.1729
≥1	6,208	12.92	11.69		12.36		12.22	
Primary payor								
Private insurance	27,413	58.21	60.53	< 0.0001 *	59.81	< 0.0001 *	60.71	< 0.0001 *
Public insurance	18,585	39.47	37.36		37.39		36.24	
No insurance/Self-pay	1,092	2.32	2.12		2.80		3.06	
Unknown	958							
Infant birthweight (grams)								
<500	26	0.05	0.05	< 0.0001 *	0.07	0.0090 *	0.23	< 0.0001 *
500-1499	421	0.88	0.86		0.72		0.88	
1500-2499	2,233	4.65	4.50		4.38		4.83	
2500-3999	40,314	83.90	83.90		83.93		85.77	
≥4000	5,054	10.52	10.69		10.91		8.29	
Gestational age (weeks)								
<34	986	2.05	1.99	< 0.0001 *	1.71	< 0.0001 *	2.20	< 0.0001 *
34-36	3,927	8.17	8.04		7.58		7.10	
37-40	39,818	82.87	83.18		80.93		77.89	
≥41	3,317	6.90	6.78		9.78		12.81	
Interpregnancy interval ≤18 months								
Yes	4,153	9.70	9.04	< 0.0001 *	9.63	0.7683	10.63	0.0506
No	38,678	90.30	90.96		90.37		89.37	
Unknown	5,217							
Mother drank alcohol during pregnancy								
Yes	290	0.60	0.59	0.0317 *	0.71	0.0377 *	1.06	0.0001 *
No	47,666	99.40	99.41		99.29		98.94	
Unknown	92							
Mother used tobacco during pregnancy								
Yes	3,807	7.94	7.53	< 0.0001 *	6.93	< 0.0001 *	7.14	0.0537
No	44,143	92.06	92.47		93.07		92.86	
Unknown	98							
Maternal medical risk factors								
None	41,075	85.49	85.46	0.5708	85.55	0.7773	86.21	0.1839
≥1	6,973	14.51	14.54		14.45		13.79	

Congenital anomalies								
None	47,676	99.23	99.25	0.0327 *	99.10	0.0293 *	98.86	0.0073 *
≥1	372	0.77	0.75		0.90		1.14	
Maternal complications								
None	42,394	88.23	88.34	0.0054 *	82.64	< 0.0001 *	81.79	< 0.0001 *
≥1	5,654	11.77	11.66		17.36		18.21	
Neonatal complications								
None	46,869	97.55	97.62	< 0.0001 *	97.38	0.1203	97.24	0.1940
≥1	1,179	2.45	2.38		2.62		2.76	

[a]Based on Georgia birth certificate and hospital discharge data, 1999-2006.
[b]Birth certificate documentation of prenatal care initiation prior to the fifth month of pregnancy and at least one prenatal visit.
[c]Birth certificate documentation of induced, stimulated, precipitous, prolonged, or dysfunctional labor, or hospital discharge documentation of trial of labor (TOL) by CPT, ICD9-Procedure, or ICD9-Diagnosis code(s).
[d]Birth certificate documentation of delivery method as vaginal birth after cesarean section (VBAC), as opposed to repeat cesarean-section.
[e]P-value for chi-square or Fisher's exact test comparing proportions of covariates among women with the exposure/outcome to proportions among women without. * p-value = <0.05.

Table 2. Unadjusted risk ratios (RR) and 95 percent confidence intervals (CI) for early prenatal care (PNC),[a] documentation of trial of labor (TOL),[b] and vaginal birth after cesarean section (VBAC)[c] among live, second-order, singleton births to Georgia women with a history of primary cesarean section.[d]

	Early PNC			Documented TOL			VBAC		
	RR	95% CI[e]		RR	95% CI		RR	95% CI	
Maternal age (years)									
14-19	0.89	0.87	0.91	1.01	0.93	1.09	1.13	0.96	1.33
20-24[f]	1.00			1.00			1.00		
25-29	1.06	1.06	1.07	1.05	1.01	1.09	1.01	0.93	1.10
30-34	1.09	1.08	1.10	1.06	1.02	1.10	0.92	0.85	1.00
35-39	1.09	1.08	1.10	1.00	0.96	1.04	0.75	0.67	0.83
≥40	1.08	1.07	1.10	0.93	0.85	1.01	0.66	0.53	0.82
Maternal race/ethnicity									
Non-Hispanic white[f]	1.00			1.00			1.00		
Non-Hispanic black	0.95	0.95	0.96	1.09	1.05	1.12	0.93	0.87	1.00
Non-Hispanic Asian	1.00	0.99	1.01	1.37	1.28	1.46	1.48	1.28	1.71
Hispanic	0.92	0.91	0.93	1.15	1.10	1.20	1.26	1.15	1.38
Non-Hispanic other	0.94	0.89	0.99	1.20	0.98	1.48	1.29	0.81	2.05
Maternal education (highest achieved)									
Some college or higher[f]	1.00			1.00			1.00		
High school diploma or GED	0.96	0.95	0.96	0.92	0.89	0.94	0.86	0.80	0.93
9th through 11th grade	0.91	0.90	0.92	0.91	0.87	0.95	0.94	0.85	1.04
Less than 9th grade	0.84	0.82	0.86	1.03	0.96	1.11	1.05	0.90	1.24
Maternal marital status									
Married[f]	1.00			1.00			1.00		
Unmarried	0.91	0.90	0.91	0.95	0.93	0.98	0.95	0.89	1.02
Paternal age (years)									
14-24	0.93	0.93	0.94	0.96	0.92	1.00	1.14	1.04	1.25
≥25[f]	1.00			1.00			1.00		
Paternal race/ethnicity									
Non-Hispanic white[f]	1.00			1.00			1.00		
Non-Hispanic black	0.97	0.96	0.97	1.09	1.05	1.13	0.96	0.89	1.04
Non-Hispanic Asian	0.99	0.98	1.00	1.39	1.30	1.49	1.57	1.35	1.83
Hispanic	0.90	0.89	0.91	1.19	1.14	1.25	1.32	1.19	1.46
Non-Hispanic other	0.99	0.95	1.02	1.40	1.16	1.70	2.39	1.70	3.36
Missing/unknown paternal demographics									
None[f]	1.00			1.00			1.00		
≥1	0.89	0.88	0.90	0.95	0.91	0.99	0.94	0.86	1.03

Primary payor									
Private insurance[f]	1.00			1.00			1.00		
Public insurance	0.91	0.91	0.92	0.92	0.90	0.95	0.88	0.83	0.94
No insurance/Self-pay	0.88	0.86	0.90	1.17	1.09	1.27	1.26	1.06	1.51
Infant birthweight (grams)									
<500	0.94	0.82	1.08	1.22	0.75	1.98	4.20	2.48	7.13
500-1499	0.98	0.96	1.01	0.82	0.70	0.96	0.98	0.71	1.36
1500-2499	0.97	0.95	0.98	0.94	0.88	1.01	1.02	0.88	1.17
2500-3999[f]	1.00			1.00			1.00		
≥4000	1.02	1.01	1.02	1.04	0.99	1.08	0.77	0.69	0.86
Gestational age (weeks)									
<34	0.97	0.95	0.99	0.85	0.77	0.95	1.14	0.93	1.40
34-36	0.98	0.97	0.99	0.95	0.90	1.00	0.92	0.82	1.04
37-40[f]	1.00			1.00			1.00		
≥41	0.98	0.97	0.99	1.45	1.39	1.51	1.97	1.81	2.16
Interpregnancy interval ≤18 months									
Yes	0.93	0.92	0.94	0.99	0.95	1.04	1.11	1.00	1.23
No[f]	1.00			1.00			1.00		
Mother drank alcohol during pregnancy									
Yes	0.97	0.93	1.00	1.18	1.02	1.37	1.76	1.32	2.34
No[f]	1.00			1.00			1.00		
Mother used tobacco during pregnancy									
Yes	0.94	0.93	0.95	0.86	0.82	0.91	0.89	0.79	1.00
No[f]	1.00			1.00			1.00		
Maternal medical risk factors									
None[f]	1.00			1.00			1.00		
≥1	1.00	1.00	1.01	0.99	0.96	1.03	0.94	0.86	1.03
Congenital anomalies									
None[f]	1.00			1.00			1.00		
≥1	0.97	0.94	1.00	1.17	1.02	1.33	1.47	1.11	1.95

[a]Birth certificate documentation of prenatal care initiation prior to the fifth month of pregnancy and at least one prenatal visit.

[b]Birth certificate documentation of induced, stimulated, precipitous, prolonged, or dysfunctional labor, or hospital discharge documentation of trial of labor (TOL) by CPT, ICD9-Procedure, or ICD9-Diagnosis code(s).

[c]Birth certificate documentation of delivery method as vaginal birth after cesarean section (VBAC), as opposed to repeat cesarean-section.

[d]Based on Georgia birth certificate and hospital discharge data, 1999-2006.

[e]95 percent confidence interval.

[f]Reference group.

Table 3. Evaluation for confounding of the relationships between early prenatal care (PNC)[a] and documentation of trial of labor (TOL),[b] and between early PNC and vaginal birth after cesarean section (VBAC)[c] among live, second-order, singleton births to Georgia women with a history of primary cesarean section.[d]

	Documented TOL				VBAC			
Main Models	**Risk Ratio**	**95% Confidence Interval**		**Change from full model (%)**	**Risk Ratio**	**95% Confidence Interval**		**Change from full model (%)**
Crude Model	1.06	1.00	1.12	0.36	0.92	0.81	1.04	-2.31
Partially Adjusted Model[e]	1.06	1.00	1.13	0.29	0.95	0.84	1.07	0.79
Partially Adjusted Model[f]	1.05	0.99	1.12	-0.37	0.95	0.83	1.08	0.77
Full Model[g]	1.06	0.99	1.13		0.94	0.81	1.09	
Covariate Excluded from Full Model								
Maternal age (years)	1.05	0.98	1.13	-0.29	0.92	0.79	1.07	-1.93
Maternal race/ethnicity	1.06	0.99	1.13	-0.09	0.94	0.81	1.09	-0.16
Maternal education (highest achieved)	1.07	0.99	1.14	0.78	0.95	0.82	1.10	1.04
Maternal marital status	1.06	0.99	1.14	0.13	0.94	0.81	1.09	-0.03
Paternal age (years)	1.06	0.99	1.13	-0.03	0.94	0.81	1.09	-0.53
Paternal race/ethnicity	1.05	0.98	1.13	-0.26	0.94	0.81	1.09	-0.42
Missing/unknown paternal demographics	1.06	0.99	1.13	0.02	0.94	0.81	1.09	0.12
Primary payor	1.07	0.99	1.14	0.82	0.95	0.82	1.09	0.54
Infant birthweight (grams)	1.06	0.99	1.13	-0.01	0.94	0.81	1.09	-0.32
Gestational age (weeks)	1.05	0.98	1.13	-0.68	0.93	0.80	1.07	-1.61
Mother drank alcohol during pregnancy	1.06	0.98	1.13	-0.13	0.94	0.81	1.09	-0.05
Mother used tobacco during pregnancy	1.06	0.99	1.14	0.13	0.94	0.81	1.09	0.19
Covariate Added to Full Model								
Interpregnancy interval ≤18 months[h]	1.04	0.96	1.11	-2.08	0.97	0.83	1.13	2.93

[a]Birth certificate documentation of prenatal care initiation prior to the fifth month of pregnancy and at least one prenatal visit.

[b]Birth certificate documentation of induced, stimulated, precipitous, prolonged, or dysfunctional labor, or hospital discharge documentation of trial of labor (TOL) by CPT, ICD9-Procedure, or ICD9-Diagnosis code(s).

[c]Birth certificate documentation of delivery method as vaginal birth after cesarean section (VBAC), as opposed to repeat cesarean section.

[d]Based on Georgia birth certificate and hospital discharge data, 1999-2006.

[e]Adjusted for maternal age, maternal race/ethnicity, and maternal education.

[f]Adjusted for maternal age, maternal race/ethnicity, maternal education, marital status, primary payor, infant birthweight, and gestational age.

[g]Adjusted for maternal age, maternal race/ethnicity, maternal education, marital status, paternal age, paternal race/ethnicity, missing/unknown paternal demographics, primary payor, infant birthweight, gestational age, alcohol consumption during pregnancy, and tobacco use during pregnancy.
[h]Interpregnancy interval barely met inclusion criteria for evaluation as a potential confounder, and addition of this thirteenth variable to the models evaluating for effect modification precluded convergence. Therefore, we excluded it from the full model, but verified there was no significant confounding via post-hoc analysis.

Table 4. Sensitivity analysis of the potential effect of missing prenatal care (PNC) data on the associations between early PNC[a] and documentation of trial of labor (TOL),[b] and between early PNC and vaginal birth after cesarean section (VBAC)[c] among live, second-order, singleton births to Georgia women with a history of primary cesarean section.[d]

	No.				Documented TOL				VBAC			
	Total	Early PNC	TOL	VBAC	Risk Ratio	95% CI[e]		% Diff.[f]	Risk Ratio	95% CI		% Diff.
Final Dataset[g]												
Crude Model	48,048	45,172	15,181	3,872	1.06	1.00	1.12		0.92	0.81	1.04	
Full Model	40,808	38,898	12,937	3,341	1.06	0.99	1.13		0.94	0.81	1.09	
Set All Missing to Early PNC												
Crude Model	49,772	46,896	15,735	4,000	1.06	1.00	1.12	0.05	0.92	0.81	1.03	-0.27
Full Model	42,064	40,154	13,344	3,429	1.06	0.99	1.14	0.12	0.94	0.81	1.09	-0.24
Set All Missing to Late/No PNC												
Crude Model	49,772	45,172	15,735	4,000	1.03	0.99	1.08	-2.77	0.97	0.88	1.08	5.93
Full Model	42,064	38,898	13,344	3,429	1.03	0.97	1.08	-3.06	1.03	0.91	1.16	9.29

[a]Birth certificate documentation of prenatal care initiation prior to the fifth month of pregnancy and at least one prenatal visit.

[b]Birth certificate documentation of induced, stimulated, precipitous, prolonged, or dysfunctional labor, or hospital discharge documentation of trial of labor (TOL) by CPT, ICD9-Procedure, or ICD9-Diagnosis code(s).

[c]Birth certificate documentation of delivery method as vaginal birth after cesarean section (VBAC), as opposed to repeat cesarean section.

[d]Based on Georgia birth certificate and hospital discharge data, 1999-2006.

[e]95 percent confidence interval.

[f]Percent change from respective risk ratio in final dataset.

[g]No births missing PNC data.

Chapter III: Summary

CONCLUSIONS: Implications for Public Health and Medicine

While this study demonstrated a significant association between early PNC and attempted TOL among Georgia women with a history of one prior cesarean section that delivered a singleton, second-order infant at ≥20 weeks gestation between 1999 and 2006 (crude RR 1.06 [95% CI 1.00, 1.12]), only 32 percent of all women in this group had a documented TOL. There was no evidence of confounding in the fully adjusted TOL model (RR remained identical at 1.06), but there was a slight loss of statistical precision [95% CI 0.99, 1.13]. Furthermore, only 8 percent of women in the study population had a VBAC, and there was no significant relationship between early PNC and VBAC (crude RR 0.92 [95% CI 0.81, 1.04]). This association was unchanged with full covariate adjustment (RR 0.94 [95% CI 0.81, 1.09]), and no variables confounded the relationship, again endorsing use of the crude RR.

These findings provide some evidence that women who initiate PNC prior to the fifth month of their pregnancy (and who attend at least one visit) are slightly more likely to attempt a TOL than women who initiate PNC in the fifth month or later, or not at all; yet, women who access early PNC have the same low likelihood of VBAC as women who access late PNC or do not access care at all. These relationships could have important medical and public health implications for women, children, and their healthcare providers, in both Georgia and the United States. However, the most remarkable findings were not the associations within this population of Georgia women, but the proportions. Although 93.5 percent accessed early PNC, only 31.6 percent had a

documented TOL, and only 8.1 percent ultimately delivered via VBAC, equating to a 25.0 percent TOL success rate. These strikingly low rates of TOL and VBAC and strikingly high rates of early PNC indicate that, even when Georgia women do access early PNC, they may not be receiving adequate counseling about their delivery method options.

The association between early PNC and TOL may result from two separate, but related, phenomena. First, women who enter PNC early may receive an individualized risk assessment and personal counseling from their obstetric provider regarding the success rate, benefits, and harms of VBAC versus ERCD. In the appropriate situation, these discussions may help both the woman and her provider to feel more comfortable and more confident in the decision to pursue a TOL. Thus, early PNC alone may result in more TOL. Second, women who enter PNC late or not at all may be unlikely to receive adequate risk assessment and counseling. Therefore, both the patient and the provider may be less likely to feel comfortable or confident in attempting a TOL and more likely to turn to ERCD. Thus, late or no PNC may also result in less TOL. Consequently, it is possible that the direct association between PNC and TOL is due to both increased TOL among women with early PNC, and decreased TOL among women with late or no PNC.

The null association between early PNC and VBAC, however, may serve as evidence for both women and their providers to abandon this prospective pattern for determining pursuit of TOL. If women who access PNC early do not have a higher TOL success rate (and thus VBAC rate) than women who access PNC late or not at all, there is no reason to restrict TOL attempts to women who have received individualized risk

assessment and personal counseling over several visits. As long as the provider discusses the issues surrounding TOL, VBAC, and ERCD and deems a patient to be otherwise low-risk – whether in the last few PNC visits before delivery, or when the patient arrives at the hospital in early labor – he or she should feel comfortable with the patient attempting a TOL. Of note, VBAC rate (modeled in our study) is not identical to TOL success rate (a more ideal measure in exploring this issue), but it may serve as a proxy when TOL rate is similar amongst the groups being compared. In this investigation, 31.7 percent of women with early PNC had a TOL and 29.9 percent of women with late or no PNC had a TOL, so they are sufficiently similar to justify the substitution of VBAC rate for TOL success rate.

This application of our results to public health and medical practice is important, but perhaps more significant are the conclusions we can draw from the differences between our study population's TOL, VBAC, and TOL success rates and those reported in previous studies. Only 31.6 percent of women in our study had a documented TOL, which is considerably less than the 47 percent reported in the literature.[6] The majority of prior TOL rate studies took place at large tertiary teaching hospitals—which may slightly overestimate the true rate in the general population—but it is unlikely that practice setting accounts for the entirety of Georgia's 33 percent reduction in TOL attempts. Rather, it is probable that Georgia women with a prior cesarean section do not receive adequate counseling on their delivery method options, in spite of the 93.5 percent early PNC initiation rate. It is also possible that Georgia obstetric providers and birthing facilities do not feel comfortable offering TOLs. Clearly, more education on TOL, VBAC, and ERCD is needed for both patients and healthcare professionals.

The VBAC rate of 8.1 percent within our study group is also lower than that reported in the literature; national vital statistics indicate that the U.S. VBAC rate was at a record-high just prior to our study (28 percent in 1996) and fell to its record-low upon the conclusion of our study (9 percent in 2006).[1, 7] State-specific vital statistics support our study's finding of low VBAC rates in Georgia from 1999 to 2006, as they report that only 4.7 percent of Georgia women with a prior cesarean delivery had a VBAC in 2006 (compared to 9 percent nationally).[67]

A TOL rate of 31.6 percent and a VBAC rate of 8.1 percent equate to a TOL success rate of 25.0 percent in our study population, which is two-thirds lower than the 74 percent reported in the literature.[6] This striking difference indicates that our study population's low VBAC rate is not only due to a low TOL rate, but also to a low probability of success with each TOL. It is possible that our TOL success rate is falsely decreased due to misclassification of two groups of women: those presenting to the hospital with signs of labor and then requesting their previously decided upon RCD, and those being purposefully labored in order to "prime" the infant for safe delivery via ERCD. However, these women are unlikely to account for the entire difference in rates, so it is likely that Georgia's TOL success rate is at least somewhat lower than that reported in the literature. Perhaps obstetric providers that are overseeing a woman's TOL are too quick to jump to RCD at any sign of maternal or fetal distress. Alternatively, patients and healthcare professionals may need more education on risk assessment and selection of appropriate candidates for TOL. Of note, 2.2 percent of the women in our study that delivered via VBAC lacked TOL documentation, indicating the presence of at

least some outcome misclassification; it is unclear whether or not the misclassification was differential.

Based on these study results and justifications, it is apparent that Georgia's obstetric providers have much room for improvement in their delivery method counseling of women with a prior cesarean section. The slight association between early PNC and TOL (intended delivery method) also provides us with some evidence that public health proponents may use to continue to emphasize the importance of preconception and PNC. Yet, the null association between early PNC and VBAC rate (actual delivery method) – which we assume parallels TOL success rate – is actually more important, as it allows obstetric providers to feel more comfortable offering a TOL to all low-risk women, regardless of the timing of their entry into PNC.

These findings contribute to two of the Ten Critical Gaps in the evidence for delivery method decision-making for women with a prior cesarean section, as outlined by the 2010 NIH Consensus Development Conference Statement.[7] In reference to Critical Gap 6, our investigation indicates that the institution of PNC is one of a variety of nonmedical factors that may affect the TOL rate. Moreover, in reference to Critical Gap 2, it seems that PNC may be a mediating factor in the persistent ties between race/ethnicity, socioeconomic status, and TOL rate. Both timing of PNC entry and TOL rate were significantly different between categories of maternal race/ethnicity, maternal education, maternal marital status, paternal race/ethnicity, missing/unknown paternal demographics, and primary payor (Table 1). Though none of the TOL model's interaction terms were statistically significant, these consistent relationships and the

direct association between early PNC and TOL suggest that PNC may at least partially mediate the relationship between race/ethnicity, socioeconomic status, and TOL.

This study of a novel relationship between PNC and TOL among Georgia women that delivered from 1999 through 2006 should be replicated to determine whether it pertains to more recent obstetric practices and to other locations. In the meantime, the weak relationship that we noted between PNC and TOL should encourage all women to access early PNC and the lack of a relationship between early PNC and both VBAC and TOL success rates should help providers to feel comfortable with counseling all women, even if they did not enter PNC early. Georgia's overall TOL rate of 32 percent and VBAC rate of 8 percent strongly suggest that many pregnant women with a prior cesarean section are not receiving adequate counseling on their delivery method options for their current pregnancy (regardless of their timing of PNC initiation), thereby signifying a crucial need for statewide improvement.

STRENGTHS and LIMITATIONS

Observational Design: An Unmodifiable Limitation

A limitation of our study – and of all studies investigating PNC, TOL, and VBAC, alone or in concert – is the observational design. The gold standard for public health and medical research alike is the randomized controlled trial (RCT), but the well-established positive outcomes of PNC and the pregnant woman's autonomy to ultimately choose her own intended delivery method preclude this type of investigation. Research

ethics and the rights of American citizens far outweigh the desire to definitively answer the questions surrounding the associations of PNC, TOL, and VBAC with a RCT.

Weaknesses inherent to observational studies include the unequal distribution of covariates within the exposed and unexposed groups, as well as the inability to control for unmeasured confounders. Table 1, for instance, demonstrates a statistically significant difference in the distribution of almost all measured characteristics between women that accessed PNC early and women that accessed PNC late or not at all. Fortunately, none of these variables modified the effect of PNC on TOL or VBAC, and none met the data-based criterion for confounding, so models with covariate adjustment were not necessary. Nevertheless, several other unmeasured potential confounders were excluded from our investigation, including: birthing facility characteristics, indication for prior cesarean section, history of maternal or neonatal complications with prior cesarean section, spontaneity of index pregnancy's labor, maternal height and weight, first infant's gestational age and birthweight, and intended family size.

Dataset Selection: Both a Limitation and a Strength

There are both advantages and disadvantages to using data from birth certificates, hospital discharge documents, and medical records. Population-based data provide information on much larger groups of women than medical records. However, vital statistics and administrative databases also have less detail, accuracy, and reliability, and more missing and misclassified information. We viewed these population-based disadvantages to be less important than the associated advantages, and thus selected a birth and hospital discharge record dataset for our investigation.

Birth certificates have been used to track maternal and child health in the U.S. since the early twentieth century.[68] The most obvious advantage of using birth records for obstetric and perinatal research is their comprehensive nature. Birth certificates document a wealth of information – including parental demographics, maternal reproductive and obstetric history, infant birthweight, gestational age at delivery, maternal and infant health problems, and medical procedures – on more than 99 percent of all births in the U.S.[68] The virtual completeness of this database assures that analyses are generalizable to, at a minimum, the American population. In other words, there is minimal risk of selection bias, especially in comparison to a study population defined by the medical record database of a single clinical setting. Moreover, the large number of observations in vital statistics provides for stratified analyses of sub-populations, defined by any number of characteristics. For instance, even though we restricted our dataset based on year, state of delivery, birth order, plurality, gestational age, and obstetric history, we still had almost 50,000 observations to analyze.

Though vital statistics data are well-known for comprehensiveness, experts continue to raise questions about their validity.[69] A number of studies have examined the accuracy and reliability of birth certificate documentation in comparison to the "gold standards" of medical records and maternal report. Investigative reviews of published literature have concluded that most of the maternal demographics and infant characteristics are adequately recorded, but that birth certificates may underreport maternal and neonatal conditions, labor and delivery complications, and procedures.[68, 69] Moreover, they suggest that this underreporting may not be random.

Seven studies have evaluated birth certificate concordance with "gold standards," specifically in regards to timing of entry into PNC and/or delivery method (our study exposure and outcome, which were garnered from Georgia birth records). Five studies compared vital statistics data to clinic and/or hospital records, the first three of which reported very similar results. In New York, Roohan et al. found that birth certificate documentation of date of PNC initiation was correct for the exact date in 70 percent of births and was correct within one week in 76 percent; moreover, all birth certificate delivery method documentation had a sensitivity and specificity of greater than 98 percent.[70] In Ohio, DiGiuseppe et al. demonstrated that the birth record's documented trimester of entry into PNC agreed with the medical record's trimester for 80 percent of women, and that delivery method had a concordance of 99 percent (equating to a birth certificate delivery method documentation sensitivity of 96 percent and specificity of 100 percent).[71] In North Carolina, Buescher et al. reported an agreement rate of 79 percent for month of PNC initiation and 92 percent for delivery method.[72]

In northeast Georgia, Clark et al. examined records at a single public health department prenatal clinic and published substantially different results. They found that birth certificates and clinic records agreed on month and trimester of PNC initiation for only 31 and 51 percent of births, respectively.[73] In Tennessee, Piper et al. demonstrated a similarly low concordance rate of 32 percent for month of PNC entry and 65 percent for trimester.[74] Piper et al. also examined the sensitivity of birth certificate report of delivery method and highlighted the differential rates among women with and without adverse pregnancy outcomes. In women with adverse outcomes, the sensitivity of vaginal birth report was 98 percent, VBAC was 39 percent, primary cesarean section was 93 percent,

and RCD was 79 percent. In contrast, in women without adverse outcomes, the birth record sensitivities were 96, 53, 91, and 97 percent, respectively.

The two remaining investigations of vital statistics validity in regards to PNC and delivery method utilized alternative "gold standards" for comparison. Schoendorf et al. compared the 1988 national birth records to results of the 1988 National Maternal and Infant Health Survey (a questionnaire completed by women).[75] They found that trimester of PNC initiation agreed in 85 percent of whites and 67 percent of blacks. Among women whose birth records reported first trimester PNC entry, concordance was 95 percent for whites and 87 percent of blacks. However, among women whose birth records reported later PNC entry, concordance was less than 40 percent. Thus, the survey results likely suffered from reporting bias, probably due to the stigma associated with lacking PNC. Finally, in New Jersey, Reichman et al. compared vital statistics to *HealthStart* documentation (a program of enriched PNC for pregnant women on Medicaid).[76] They demonstrated that birth certificate report of PNC initiation in the first trimester had a sensitivity of 82 percent and a specificity of 64 percent. Delivery method sensitivities and specificities were as follows: 91 and 82 percent for vaginal birth, 47 and 99 percent for VBAC, 81 and 98 percent for primary cesarean section, and 80 and 99 percent for RCD.

In summary, all five investigations of the sensitivity and specificity of birth certificate delivery method report typically found both to be greater than 90 percent. Both of the PNC concordance studies that used alternatives to medical records as the "gold standard" reported a concordance of 70 to 85 percent, and three of the five studies that used medical records also reported 70 to 85 percent; the other two reported 50 to 65

percent. The Georgia study had the lowest PNC concordance overall, indicating that utilization of Georgia birth records may be more likely to result in misclassification bias than utilization of records from other states.

According to the seven identified studies, U.S. vital statistics natality files are an adequate source for timing of PNC initiation (our exposure) and a good source for delivery method (one of our two outcomes). Georgia's birth records may be less accurate than expected, but we still felt comfortable utilizing the vital statistics dataset in order to maximize our population size, while also maintaining adequate measures of exposure and outcome.

As mentioned previously, Georgia birth records are linked in a deterministic fashion via unique maternal longitudinal identification numbers to another population-based database: Georgia hospital discharge records. We garnered our second outcome (documented TOL) from these records, in combination with Georgia vital statistics. Van Walraven et al. would define this hospital discharge database as an administrative database.[77, 78] They describe the phenomenon simply: "When health care is administered, data are created, which can be used for secondary purposes."[77] Hospitalization databases – which record diagnoses, procedures, laboratory tests, radiological studies, and simple outcomes of emergency department visits and hospital admissions – leave a "trail of digital information that describes (to varying degrees of detail) a patient's course through a health care system," which can then be used for research.[78]

Most administrative databases, including Georgia's hospital discharge records, utilize codes to identify diagnoses and procedures. Van Walraven et al. describe four steps that are required to get this clinical information into the administrative database: 1)

the healthcare provider recognizes the diagnosis or the need for a procedure, 2) the provider legibly documents the diagnosis or the executed procedure in the chart, 3) the health records abstractor (HRA) recognizes and correctly interprets the provider's documentation, and 4) the HRA identifies the proper code for the diagnosis or procedure. Therefore, the accuracy of the administrative database's codes is influenced by two issues: the validity of the diagnosis or procedure (related to steps 1 and 2), and the association of the code with the documented diagnosis or procedure (related to steps 3 and 4).[78]

Van Walraven's first issue of valid documentation of diagnoses and procedures is infrequently discussed in relation to research performed with administrative databases,[78] though it remains an important issue. A related topic is that of incentives for physician diagnostic and procedural decision-making and documentation. In general, administrative databases are significantly more complete when those responsible for supplying the information benefit in some way from providing the data.[78] For instance, healthcare providers that do research with administrative databases will likely fully document all diagnoses, procedures, laboratory tests, and radiological studies. Similarly, physicians paid on a "fee-for-service" basis will likely record all completed procedures, and physicians paid according to "diagnosis-related-group" will likely record all patient diagnoses. Investigations by Grant[19] and Gruber et al.[21] demonstrated a direct association between reimbursement rates and cesarean section utilization, but no other studies have analyzed differential incentives within the realm of PNC, TOL, VBAC, and ERCD. We hypothesized that there may be lacking incentives for documentation of TOL, and

therefore recognized that a potential limitation of using Georgia's hospital discharge records may be an underreporting of TOL.

Van Walraven's second issue in regard to the accuracy of codes within administrative databases (association of the code with the documented diagnosis or procedure) is more commonly considered in the literature.[78] Database variables defined by diagnostic or procedural codes are, in essence, surrogate measures of the disease or procedure they represent. Therefore, according to van Walraven, any analysis using codes should measure the association between the code variable and the true variable in order to quantify misclassification and estimate resulting bias. However, in a random sample of investigations utilizing administrative databases, only 77 percent measured or referenced the association of the code with the entity it was meant to represent.[77]

While we could not conduct a validation study, even amidst potentially lacking incentives, we estimated that a TOL was likely to be documented for a given woman by at least one of the 168 coding options in at least one of the 20 coded variables we included in the TOL definition. Moreover, a review of the literature revealed that supplementing our administrative database codes with variables from our vital statistics database would increase the validity of our TOL measure. In Washington state, Lydon-Rochelle et al. found that, when comparing to the "gold standard" of medical records, birth certificate and hospital discharge data combined had substantially higher true positive fractions (TPF, proportion of women with a positive medical record assessment who were positive using the administrative database) than did birth certificate or hospital discharge data alone.[79, 80] Their findings held true for all examined pre-existing maternal medical conditions, maternal in-hospital diagnoses, intrapartum procedures, and

complications of pregnancy. Though Lydon-Rochelle et al. did not specifically examine measures of TOL, they did investigate induction of labor, which falls under the definition of a TOL.[80] They found that the TPF for labor induction was 52 percent on in the birth records, 73 percent in the hospital discharge documents, and 86 percent when both databases were examined.

Roberts et al. performed a similar study utilizing birth records and hospital discharge documents in New South Wales, Australia.[81] They found that, overall, sensitivities increased with use of combined databases, but specificities were unchanged. For instance, the sensitivity and specificity for labor induction were 93 and 99 percent in the birth records, 78 and 99 percent in the hospital discharge documents, and 95 and 98 percent when both databases were examined. Similarly, the sensitivity and specificity for labor augmentation in each database were 55 and 97 percent, 58 and 95 percent, and 76 and 93 percent, respectively.

The studies described above increased confidence in our investigative approach to our population selection, variable definition, and research questions. Nevertheless, given the limitations of observational and population-based research, we consider our work to be hypothesis-generating. As Cahill and Macones stated in their review on the use of birth and hospital discharge records in obstetric and perinatal research, "[W]e view research using administrative or vital statistics data as hypothesis generating rather than hypothesis testing. Though these large data sets can be helpful in exploring trends and generating hypotheses, the findings are best validated in well-designed observational or interventional studies before altering clinical practice."[82]

External Validity: An Uncertain Strength

As mentioned above, the most significant advantage of using birth records (and any associated datasets) for obstetric and perinatal research is their comprehensive nature. Vital statistics document a wealth of information on more than 99 percent of all U.S. births,[68] and the Georgia rate is expected to be similar. Moreover, of all live births in the U.S. from 1999 through 2006, an average of 96.7 percent were singleton, 21.4 percent were second-order, and 26.7 percent were delivered via cesarean section[67] (specific data on proportion of births at ≥20 weeks gestational age not available). When we extrapolate these proportions to our Georgia-specific dataset, we can calculate that our study population should comprise approximately 5.5 percent of all Georgia's live births from 1999 through 2006 (n=728,130). It comprises 6.8 percent, indicating both an adequate dataset selection process, and the potential for our results to be generalizeable to the Georgian population as a whole.

Nevertheless, the investigation by Clark et al. – which reported a 51 percent birth certificate and medical record concordance for trimester of PNC initiation among pregnant patients attending a public health department prenatal clinic northeast Georgia – does cast some doubt on the validity of Georgia's birth certificate PNC measures.[73] Furthermore, the proportion of women in our dataset that accessed PNC within the first four months of pregnancy (94.0 percent) was significantly higher than the reported 83.3 percent of all pregnant Georgia women that accessed PNC in the first trimester in 2006.[67] This difference may reflect a true difference, suggesting that women with a prior cesarean section that are in their second pregnancy are more likely to access PNC than other pregnant women. Alternatively, the 10 percent discrepancy may result from the

differences in the definition of "early;" we defined early PNC as entry prior to the fifth month, whereas the comparison study only included those who began care in the first, second, or third month of pregnancy. Finally, it is possible that the majority of the 1,724 births excluded for missing PNC data did not ever enter PNC; perhaps the healthcare worker filling out the birth certificate left the PNC section blank, believing that was the appropriate way to indicate no PNC. If this differential misclassification were corrected, however, our early PNC proportion would only drop to 90.7 percent, which is still moderately different from 83.3. For this reason, we performed a sensitivity analysis with our final models, which did not result in any significant differences in our effect measures.

FUTURE RESEARCH

Among women in their second pregnancy with a history of a cesarean section, our study identified a small but direct relationship between early PNC and intended delivery method (TOL versus ERCD), and a null association between early PNC and actual delivery method (VBAC versus RCD). While these are novel findings with significant implications for public health and medicine, they represent only the first of many steps in understanding the complex interactions between the elements of PNC (timing of entry, number of appointments, individualized risk assessment, discussion of predicted TOL success rate, and counseling on the benefits and harms of VBAC and ERCD), the patient-provider decision regarding pursuit of a TOL, and the ultimate mode of delivery. Our study's other important findings were the remarkably low rates of TOL and VBAC among all Georgia women with a prior cesarean section, regardless of their timing of

PNC initiation. These results suggest the need for broad changes in patient-provider counseling and decision-making about delivery method options in Georgia, but they require validation.

Moving forward, we recommend continued investigation of questions involving PNC, TOL, and VBAC via utilization of maternally-linked vital statistics and administrative records, but we propose three minor alterations in design. First, we suggest an increased emphasis on improved maternal linkage to prior pregnancies. By exerting additional effort to create a dataset with clean linkages between all birth records and hospital discharge records, the investigators can more adequately control for potential confounders for which we did not adjust in our study, including indication for prior cesarean section, history of maternal or neonatal complications with prior cesarean section, and prior infant's gestational age and birthweight. Second, we recommend expansion of the source population via the inclusion of data from other years and/or additional states. Our dataset of almost 50,000 births seemed adequate, but we still had fairly small numbers when we stratified the data by more than two variables. For instance, only 2,876 women had late or no PNC, and only 251 of those had a VBAC; thus, almost all the covariate categories in this subpopulation had less than 100 observations. A larger population would also improve the implementation of our third and final suggestion; in addition to evaluating the outcomes of TOL rate and VBAC rate, we propose evaluation of TOL success rate. Quantifying this measure will more adequately answer the question of whether early PNC (along with evaluation of patient risk profile and in-depth patient-provider discussion) leads to better selection of TOL candidates and therefore a higher TOL success rate.

Future investigations should also consider framing our study questions in an alternative manner. In addition to evaluating the relationship between PNC and TOL, and between PNC and VBAC, subsequent studies should examine the relationship between TOL and VBAC among women with and without early PNC. Preliminary analyses in our dataset demonstrated that PNC (early versus late/no) may modify the effect of TOL (yes versus no) on delivery method (VBAC versus RCD). However, our numbers were too small to move beyond a contingency table examination to a modeling of this potential interaction.

Subsequent research might also involve multilevel regression modeling and geospatial analysis of potential clustering of women by exposure and/or outcome status. Conventional regression models, like those utilized in our study, assume that subjects are independent of one another; however, investigations involving administrative databases are frequently subject to clustering, where outcomes for patients within the same cluster are more similar than those of subjects in a different cluster.[78] In regards to geospatial clustering, one can imagine that women from certain areas in rural Georgia will have limited access to obstetric providers and thus PNC. Similarly, women clustered around a given obstetric provider or a given birthing facility will be subject to that provider's practice tendencies and that institution's policies regarding TOL. In addition to geospatial investigation of these potential clusters, researchers might also pursue multilevel regression modeling of clustering according to interpregnancy interval, primary payor, or annual delivery volume of birthing facility. Identification of clusters within the research databases would not only be an interesting standalone finding, but it

would also dictate the statistical methods that should be utilized when evaluating relationships between exposure and outcome across the entire study population.

Clearly, our findings are only the first step of a long journey toward a full understanding of the effect that PNC has on pregnant women with a prior cesarean who are trying to decide a) whether or not to pursue a TOL, and b) what their ultimate chances of a VBAC might be. Our demonstration of a direct relationship between PNC and TOL indicates a connection, but the null association between PNC and VBAC suggests it is more complicated than one might expect. Thus, based on our investigation, we may promote PNC as a public health endeavor, and we may encourage obstetric providers to assess all women for a TOL, regardless of timing of PNC entry. However, much more research is needed prior to institutionalized changes. We have generated hypotheses and described trends, and now we must validate these relationships to ultimately alter clinical practice.

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Figure 1. Comparison of prenatal care schedules, adapted from Gregory and Davidson's review.[34]

Gestational Age (weeks)	USPHS[a] Recommendations (1989): Nulliparous Women	Multiparous Women	AAP/ACOG[b] Guidelines (2007)	Test or Intervention
1-4	X	X		Dating
5-8	X	X	X	
9-12	X		X	
13-16	X	X	X	
17-20			X	AFP/Triple screen
21-24			X	
25-28	X	X	X	Glucose tolerance
29-30				
31-32	X	X	X	Childbirth education
33-34				Risk assessment
35-36	X	X	X	Growth
37	X		X	
38	X		X	Risk assessment
39			X	
40	X		X	
41	X	X	X	Postdates

[a] United States Public Health Service
[b] American Academy of Pediatrics / American Congress of Obstetricians and Gynecologists

Figure 2. Comparison of prenatal care adequacy indices, adapted from Alexander et al.[42]

	Indices					
Attributes	M-IOM[a]	ACOG-REC[b]	USPHS-REC[c]	GINDEX[d]	GINDEX-R[e]	APNCU[f]
Basis for standard	ACOG	ACOG	USPHS	ACOG	ACOG	ACOG
Adequate start of care	1-3 months	1-3 months	1-2 months	1-3 months	1-3 months	1-4 months
Adequate number of visits at 40 weeks	9	13	7 (multiparous) 9 (nulliparous)	9	13	11
Intensive visit category	No	No	No	Yes	Yes	Yes
Missing category	No	No	No	Yes	Yes	Yes
No care category	No	No	No	Yes	Yes	No
Standard computer program	No	No	No	Yes	Yes	Yes
Risk modified	No	No	Yes (parity)	No	No	No

[a] Modified Institute of Medicine (Kessner)
[b] Variation of the Institute of Medicine Index, using the American Congress of Obstetricians and Gynecologists' visit recommendations
[c] Index derived from the United States Public Health Service 1989 Report
[d] Graduated Index (Alexander and Cornley)
[e] Revised Graduated Index
[f] Adequacy of Prenatal Care Utilization (Kotelchuck)

Appendix A:
Collaborative Institutional Training Initiative Certification

CITI Collaborative Institutional Training Initiative

Social & Behavioral Research - Basic/Refresher
Curriculum Completion Report
Printed on 8/24/2010

Learner: Adrienne DeMarais (username: ademara)
Institution: Emory University
Contact Information Department: Rollins School of Public Health, Epidemiology
Phone: 6126184806
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Social & Behavioral Research - Basic/Refresher:

Stage 1. Basic Course Passed on 08/24/10 (Ref # 4798673)

Required Modules	***Date Completed***	
Belmont Report and CITI Course Introduction	08/23/10	3/3 (100%)
Students in Research - SBR	08/23/10	8/10 (80%)
History and Ethical Principles - SBR	08/24/10	4/4 (100%)
Defining Research with Human Subjects - SBR	08/24/10	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	08/24/10	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	08/24/10	5/5 (100%)
Informed Consent - SBR	08/24/10	5/5 (100%)
Privacy and Confidentiality - SBR	08/24/10	3/3 (100%)
Research with Prisoners - SBR	08/24/10	4/4 (100%)
Research with Children - SBR	08/24/10	4/4 (100%)
Research in Public Elementary and Secondary Schools - SBR	08/24/10	4/4 (100%)

International Research - SBR	08/24/10	3/3 (100%)
Internet Research - SBR	08/24/10	4/4 (100%)
HIPAA and Human Subjects Research	08/24/10	2/2 (100%)
Workers as Research Subjects-A Vulnerable Population	08/24/10	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	08/24/10	1/2 (50%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Appendix B: Institutional Review Board Approval

TO: Anne Dunlop, MD MPH
Principal Investigator
SOM: F&P PREV MED

DATE: September 22, 2011

RE: **Notification of Amendment Approval**
AM1_IRB00046780
IRB00046780
Severe and Near-miss Maternal Morbidity

Thank you for submitting an amendment request. The Emory IRB reviewed and approved this amendment under the expedited review process on **9/22/2011**. This amendment includes the following:

Personnel Change only: Adding Adrianne DeMarais as Non-Emory study staff.

In future correspondence with the IRB about this study, please include the IRB file ID, the name of the Principal Investigator and the study title. Thank you.

Sincerely,

Donna Thomas
Administrative Assistant
This letter has been digitally signed

CC

Kramer	Michael	Epidemiology
Raynor	B	GYN & OB

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