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Unexpected complications of low-risk pregnancies in the United States

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Abstract

OBJECTIVE—Determining appropriate sites of care for any type of medical issue assumes successful matching of patient risks to facility capabilities and resources. In obstetrics, predicting patients who will have a need for additional resources beyond routine obstetric and neonatal care is difficult. Women without prenatal risk factors and their newborns may experience unexpected complications during delivery or postpartum. In this study, we report the risk of unexpected maternal and newborn complications among pregnancies without identified prenatal risk factors.

STUDY DESIGN—We conducted a cross-sectional investigation utilizing US natality data to analyze 10 million birth certificate records from 2011 through 2013. We categorized pregnancies as low risk (no prenatal risk factors) or high risk (at least 1 prenatal risk factor) according to 19 demographic, medical, and pregnancy characteristics. We evaluated 21 individual unexpected or adverse intrapartum and postpartum outcomes in addition to a composite indicator of any adverse outcome.

RESULTS—Among 10,458,616 pregnancies, 38% were identified as low risk and 62% were identified as high risk for unexpected complications. At least 1 unexpected complication was indicated on the birth certificate for 46% of all pregnancies, 29% of low-risk pregnancies, and 57% of high-risk pregnancies. While the risk for unexpected or adverse outcomes was greatly reduced for the low-risk group compared to the high-risk group overall and for several of the individual outcomes, low-risk pregnancies had higher risks of vacuum delivery, forceps delivery, meconium staining, and chorioamnionitis compared to high-risk pregnancies.

CONCLUSION—Of births, 29% identified to be low risk had an unexpected complication that would require nonroutine obstetric or neonatal care. Additionally, for select outcomes, risks were higher in the low-risk group compared to the group with identified risk factors. This information is important for planning location of birth and evaluating birthing centers and hospitals for necessary resources to ensure quality care and patient safety.

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Keywords

labor and delivery; labor complications; obstetric delivery; pregnancy; pregnancy outcomes

Women and their providers are presented with a range of choices with respect to the types of facilities providing obstetric care for labor and delivery. Within the hospital setting, facilities range from regional care settings offering advanced care for maternal and neonatal complications, to midwifery-attended birthing centers offering supportive care for uncomplicated pregnancies.^{1,2} After decades of decreasing frequency of home births, recent trends have shown increases in out-of-hospital births, both in the home and at freestanding birthing centers.³ The role of different birth settings in the care of pregnant women considered to be at low risk for unexpected or adverse outcomes continues to be a subject of controversy, particularly among supporters and opponents of home birth.⁴⁻¹⁴

The decision to deliver in any location other than a specialty-care hospital assumes that labor and delivery complications can be predicted with some degree of certainty and truly “low-risk” pregnancies can be identified.² In practice, this has yet to be realized and unexpected labor and delivery complications remain a concern.¹⁵⁻¹⁷ Additionally, transfer rates to a hospital during labor or soon after delivery for planned births at home or in a birthing center have ranged from 15–34% in observational studies,¹⁸⁻²² and 13–77% in a review of randomized or quasi-randomized controlled trials.²³ While these and other studies have compared outcomes among planned or actual nonhospital vs hospital births,^{4,11,18-30} such comparisons are potentially biased by women’s self-selection of location of delivery. Only a few studies have examined outcomes among women identified as low risk for adverse outcomes regardless of birth setting.^{31,32} We expand on these studies by evaluating risk of unexpected complications in a large, population-based data set of recent births.

In this study, we assessed the risk of medical complications of labor and delivery or use of clinical resources beyond routine obstetric and neonatal care among deliveries expected to be at low risk for such outcomes based on pre-pregnancy and pregnancy risk factors. We quantified the absolute risk of unexpected intrapartum or postpartum complications among all pregnancies and by risk status, and compared the risk of these outcomes between low-risk and high-risk pregnancies.

Materials and Methods

We analyzed data from the 2011 through 2013 US natality files, which consists of select vital statistics information compiled from birth certificates of every birth in the United States. During 2011 through 2013, states utilized either the 1989 or 2003 revision of the US birth certificate. To be consistent and informative of current practice, we restricted the sample to records with the 2003 revision format.

The following characteristics were used to identify pregnancies as low risk: maternal age 20–39 years, gestational age at delivery 37–42 weeks as defined by the obstetric/clinical estimate of gestation, prepregnancy body mass index <30, prenatal care initiated by the sixth month of pregnancy, singleton pregnancy, and cephalic presentation.^{25,33,34} Additionally,

we required low-risk mothers to have no evidence of any of the following conditions: prepregnancy diabetes, gestational diabetes, prepregnancy hypertension, history of preterm birth, history of poor pregnancy outcome, history of cesarean delivery, cervical cerclage, premature rupture of membranes, receipt of tocolytics, congenital anomalies (including anencephaly, meningomyelocele/spina bifida, congenital diaphragmatic hernia, omphalocele, gastroschisis, limb reduction defect, cleft lip with or without cleft palate, cleft palate alone, and Down syndrome), syphilis, hepatitis B, and hepatitis C.³⁵ Pregnancies meeting all of the aforementioned definitions were classified as low risk, and all remaining pregnancies were classified as high risk, having at least 1 prenatal risk factor. For each variable examined, responses of “unknown/not stated” resulted in assignment to the high-risk group, to maintain a strict definition of low risk.

Adverse medical outcomes and additional clinical resource use beyond routine care included the following: eclampsia, chorioamnionitis, meconium staining, uterine rupture, forceps delivery, vacuum delivery, cesarean delivery, maternal transfusion, unplanned hysterectomy, unplanned other maternal operation, admission to adult intensive care unit, mother transfer, birthweight <2500 g, 5-minute Apgar score 0–3, assisted ventilation for the newborn, admission to neonatal intensive care unit, newborn surfactant use, newborn antibiotic use, newborn seizures, birth injury, and infant transfer. A composite indicator of at least 1 unexpected or adverse outcome divided births with any of the individual outcomes and births with none of the individual outcomes. For each outcome variable, responses of “unknown/not stated” were assumed not to have the outcome.

Analyses were performed using software (SAS 9.3; SAS Institute Inc, Cary, NC). We tabulated frequencies of each low-risk characteristic, overall low-risk designation, each unexpected complication, and the composite outcome indicator. We determined the frequency of unexpected complications among low-risk and high-risk pregnancies. We calculated the relative risk and 95% confidence interval (CI) for the relationship between low-risk vs high-risk pregnancy and unexpected or adverse outcomes. We repeated the analysis stratifying by parity: no prior live births (primipara) vs at least 1 prior live birth (multipara). Finally, we conducted a sensitivity analysis to assess the impact of missing data by excluding observations with missing or unknown responses for any of the risk or outcome variables and repeating the analysis. The study was exempt from review by the Women and Infants Hospital of Rhode Island Institutional Review Board (#12-0040).

Results

Among the 11,862,780 births in the United States from 2011 through 2013, 10,458,616 (88%) submitted vital records data using the 2003 revision of the birth certificate and were included in our analysis. For each of the 19 risk characteristics, between 73–100% of women were classified as low risk, and for 12 of the 19 characteristics, at least 95% of women were classified as low risk (Table 1). However, only 38% of pregnancies met the low-risk criteria for each of the 19 characteristics and were classified overall as low risk based on prenatal risk factors (Table 1).

We examined 21 individual unexpected complications in addition to the composite outcome indicator. Among all births, the most common outcomes were cesarean delivery (33%), low birthweight (8%), admission to the neonatal intensive care unit (8%), and meconium staining (5%) (Table 2). The remaining unexpected complications each occurred in <5% of births. Of births, 46% had at least 1 unexpected complication reflected in the composite outcome measure.

Among the 4,011,139 low-risk pregnancies, 29% had at least 1 of the 21 unexpected complications studied (Table 2). The most common outcomes in the low-risk group were cesarean delivery (15%), meconium staining (5%), and vacuum delivery (4%). Among the 6,447,477 births with at least 1 risk factor identified during pregnancy, 57% had at least 1 of the 21 unexpected complications. As expected, low-risk pregnancies had a lower risk of unexpected complications than high-risk pregnancies; however, there were 4 individual outcomes where the risk was actually higher for the low-risk group than the high-risk group: vacuum delivery (risk ratio [RR], 1.60; 95% CI, 1.59–1.61), forceps delivery (RR, 1.50; 95% CI, 1.48–1.53), positive meconium staining (RR, 1.16; 95% CI, 1.15–1.16), and chorioamnionitis (RR, 1.10; 95% CI, 1.09–1.11) (Table 2).

Of mothers, 40% had no prior live births (primipara), and 60% had at least 1 prior live birth (multipara). A higher proportion of primipara pregnancies were low risk (43%) compared to multipara pregnancies (35% low risk). The risks of unexpected complications were similar for high-risk primipara pregnancies (56% with at least 1 complication) and multipara high-risk pregnancies (58% with at least 1 complication). However, unexpected complications were much less common for low-risk multipara pregnancies (19% with at least 1 complication) than low-risk primipara pregnancies (41% with at least 1 complication).

To determine the impact of missing data, a sensitivity analysis was performed. Among the 19 risk variables and 21 outcome variables, the proportion of observations with missing or unknown responses for each variable ranged from 0.0–4.4%. Overall, 1,076,009 observations (10.3%) had at least 1 risk or outcome variable that was missing or unknown and were excluded as part of the sensitivity analysis. In the restricted sample, 43% of observations were low risk and 46% had an unexpected complication (compared to 38% and 46%, respectively, in the unrestricted sample). Among low-risk pregnancies, 29% had an unexpected complication, compared to 29% in the unrestricted sample. Among high-risk pregnancies, 59% had an unexpected complication, compared to 57% in the unrestricted sample.

Comment

In this study, we used a population-based data set to identify low-risk pregnancies and assess unexpected complications among US births. Using strict criteria to identify low-risk pregnancies that included 19 different qualifying characteristics, we classified 38% of pregnancies as low risk. Among low-risk pregnancies, we found that 29% had at least 1 unexpected complication. This nontrivial risk for unexpected or adverse outcomes should be considered when planning where labor and delivery will occur because women planning a

delivery in a low-level facility can unexpectedly require advanced levels of care, even when the pregnancy is seemingly low risk.

The main strength of our study is the use of a large, population-based data set of recent births with universally abstracted data components. The use of these nationwide data reduces the potential for selection bias and improves the generalizability of our findings. There are a few limitations that warrant discussion. First, birth certificate data are subject to issues with data validity and completeness. Authors of studies that examined the 1989 revision of the US certificate of birth raised concerns over the use of birth certificate data for surveillance or research purposes because of low levels of reporting or agreement for certain variables.^{36–40} While authors of more recent studies evaluating the 2003 revision of the US certificate of birth continue to identify wide ranges in validity across variables, they also note improvements in the validity of birth certificate data over time.^{41–46} In general, it has been found that information on demographics, parity, gestational age, birthweight, Apgar scores, and delivery method are more accurate than information on maternal comorbidities, pregnancy complications, complications of labor and delivery, and congenital anomalies, with conflicting reports of accuracy for prenatal care and obstetric history.^{36,38–41,43,44,46} For most items, there is high specificity but concern for underreporting of conditions and procedures.^{42–45} If there is low sensitivity for the risk variables in our study, a portion of high-risk persons may have been misclassified as low risk due to lack of evidence of a risk condition. However, high specificity and suboptimal sensitivity would also suggest that persons identified with an unexpected or adverse outcome actually have that outcome, and so the true frequencies of adverse outcomes are at least as high as those observed.

Second, for the low-risk characteristics, responses of “unknown” or “not stated” were assigned to the high-risk group. This likely resulted in misclassification, because the probability of being high risk for any individual characteristic was low. Therefore, we prioritized the low-risk group to be truly low risk at the expense of possibly including some low-risk women in the high-risk group. However, we do not expect that the extent of the misclassification of “unknown” or “not stated” responses into the high-risk group would differ by adverse outcome status. Notably, <0.1% of the high-risk group was without at least 1 known risk factor and thus classified as high risk based on “unknown” or “not stated” responses alone. Also, there was little difference in the proportion of observations with “unknown” or “not stated” responses among the groups with and without adverse outcomes. The same type of misclassification is present when assuming that “unknown” or “not stated” responses for the outcome measures do not have the outcome, but the extent of misclassification is expected to be less extreme because assignment to the group with no unexpected complications has a higher probability of being correct due to the low incidence of nearly all outcomes studied. In addition, the sensitivity analysis restricted to observations without missing data for any risk or outcome variables found similar proportions of low-risk births with unexpected or adverse outcomes and a similar RR compared to the main analysis in the unrestricted sample.

Third, the US natality data are compiled from US live birth certificates, so stillbirths are not included in the data, and we could not include mortality as an adverse outcome. Finally, the US natality data represent a cross-sectional source of information with the potential for

detection bias. In particular, patients experiencing unexpected complications may be more likely to have a corresponding risk factor noted on the birth certificate. Presence of this bias would bias the results toward the null.

Prior studies of obstetrical risk level and medical outcomes often focused on actual or planned birth location. These studies have found births at home and at birthing centers to have lower obstetrical resource use with associated decreases in maternal complications of interventions such as operative vaginal delivery, cesarean delivery, episiotomy, and epidural use.^{4,18,20–25,29} Several studies have found that home births increase the risk of adverse neonatal outcomes,^{4,11,19,24,28–30} although some have concluded there are no increased risks of adverse perinatal or maternal outcomes.^{18,20,26,27} Studies of planned home births compared to planned hospital births involve a mixing of the level of care available at home and the characteristics of women who self-select for home births that make results difficult to interpret.⁴⁷ As expected, planned home births tend to be among low-risk mothers, and have been shown to have fewer obstetric risk factors than planned hospital births.^{4,19,29} However, a common finding in studies of birth location is the large proportion of women with a planned birthing center or home birth that are ultimately transferred to a hospital during labor or soon after delivery,^{18–23} supporting the notion that low-risk births that will not require increased obstetrical or newborn intervention are difficult to identify. Our study can be added to a growing literature suggesting that history of a low-risk pregnancy does not ensure a low-risk delivery, as the absolute risk of unexpected or adverse outcomes among low-risk women was 29%.¹¹

Our findings have implications for both individual care and hospital administration decisions. Expectant mothers and their obstetrical providers should be aware of the risk of adverse outcomes even among births expected to be of low risk. Health care systems should ensure that birthing centers and hospitals possess necessary resources to ensure quality care and patient safety. There are differences in outcomes not only between home births and hospital births, but also between hospitals with differing levels of obstetric and neonatal care.⁴⁸

While our study reveals notable risks of complications and outcomes requiring increased clinical resources among low-risk pregnancies, we do not attempt to characterize the appropriate location for a birth of a given risk status. Rather, our results question general recommendations for birth location for a low-risk pregnancy when “low risk” cannot be well defined. Further study is needed to attempt to identify the small proportion of pregnancies that can be considered low risk and to assess costs and health outcomes among comparable women and neonates delivering in different level of care environments.

In summary, among pregnancies deemed to be of low-risk based on maternal and prenatal characteristics, 29% had an unexpected complication in labor, delivery, or the neonatal period. It is difficult to identify a subset of pregnancies for which there is an acceptable level of risk of unexpected complications. This study offers obstetrical providers information to counsel women about the risks for unexpected and adverse obstetric and neonatal outcomes, even among low-risk pregnancies. This information is also important to consider when

evaluating delivery units and birthing centers, and determining the necessary resources to ensure quality care and patient safety.

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TABLE 1

Frequencies of individual and overall low risk characteristics, N = 10,458,616

Low-risk characteristic	%
Maternal age 20–39 y	89.3
Gestational age at delivery 37–42 wk	90.1
Prenatal care began by sixth month of pregnancy	90.5
No prepregnancy diabetes	98.9
No gestational diabetes	94.6
No prepregnancy hypertension	98.2
No previous preterm birth	97.3
No prior poor pregnancy outcome	97.5
No previous cesarean delivery	85.4
No cervical cerclage	99.3
No PROM	96.2
No tocolysis	98.6
Cephalic presentation	91.5
Singleton pregnancies	96.6
No congenital anomalies ^a	99.3
No syphilis	99.5
No hepatitis B	98.3
No hepatitis C	99.3
Prepregnancy BMI <30	72.9
Overall low risk: satisfies all above definitions	4,011,139 (38.4%)

BMI, body mass index; PROM, premature rupture of membranes.

^aIncludes anencephaly, meningomyelocele/spina bifida, congenital diaphragmatic hernia, omphalocele, gastroschisis, limb reduction defect, cleft lip with or without cleft palate, cleft palate alone, Down syndrome.

TABLE 2

Frequencies of individual outcomes and composite indicator of unexpected or adverse outcomes

Outcome	Among all births [10,458,616] n (%)	Among births to low- risk pregnancies [4,011,139] n (%)	Among births to high-risk pregnancies [6,447,477] n (%)	Risk ratio (95% CI) for low- vs high-risk births and unexpected or adverse outcome
Birthweight <2500 g	835,161 (8.0)	84,350 (2.1)	750,811 (11.7)	0.18 (0.18–0.18)
5-min Apgar 0–3	66,084 (0.6)	8914 (0.2)	57,170 (0.9)	0.25 (0.25–0.26)
Eclampsia	22,574 (0.2)	3230 (0.1)	19,344 (0.3)	0.27 (0.26–0.28)
Chorioamnionitis	134,413 (1.3)	54,673 (1.4)	79,740 (1.2)	1.10 (1.09–1.11)
Meconium staining	530,416 (5.1)	222,009 (5.5)	308,407 (4.8)	1.16 (1.15–1.16)
Uterine rupture	2858 (0.03)	350 (0.01)	2508 (0.04)	0.22 (0.20–0.25)
Forceps delivery	65,460 (0.6)	31,641 (0.8)	33,819 (0.5)	1.50 (1.48–1.53)
Vacuum delivery	293,973 (2.8)	146,752 (3.7)	147,221 (2.3)	1.60 (1.59–1.61)
Cesarean delivery	3,411,318 (32.6)	616,238 (15.4)	2,795,080 (43.4)	0.35 (0.35–0.36)
Maternal transfusion	28,709 (0.3)	6877 (0.2)	21,832 (0.3)	0.51 (0.49–0.52)
Unplanned hysterectomy	4166 (0.04)	662 (0.02)	3504 (0.1)	0.30 (0.28–0.33)
Unplanned operation	27,842 (0.3)	8079 (0.2)	19,763 (0.3)	0.66 (0.64–0.67)
Admission to adult intensive care unit	15,751 (0.2)	2498 (0.1)	13,253 (0.2)	0.30 (0.29–0.32)
Mother transferred	53,222 (0.5)	4404 (0.1)	48,818 (0.8)	0.15 (0.14–0.15)
Assisted ventilation for newborn	356,665 (3.4)	69,929 (1.7)	286,736 (4.5)	0.39 (0.39–0.40)
Admission to neonatal intensive care unit	810,350 (7.8)	117,441 (2.9)	692,909 (10.8)	0.27 (0.27–0.27)
Newborn surfactant	42,277 (0.4)	1700 (0.04)	40,577 (0.6)	0.07 (0.06–0.07)
Newborn antibiotics	217,081 (2.1)	42,608 (1.1)	174,473 (2.7)	0.39 (0.39–0.40)
Newborn seizures	3229 (0.03)	889 (0.02)	2340 (0.04)	0.61 (0.56–0.66)
Birth injury	6160 (0.1)	2148 (0.1)	4012 (0.1)	0.86 (0.82–0.91)
Infant transferred	115,496 (1.1)	18,964 (0.5)	96,532 (1.5)	0.32 (0.31–0.32)
Composite indicator of unexpected or adverse outcomes: observation had at least 1 of above outcomes	4,841,011 (46.3)	1,149,872 (28.7)	3,691,139 (57.3)	0.50 (0.50–0.50)

CI, confidence interval.