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**A Risk Calculator to Predict the Need for Maternal or Neonatal Hospital-Based
Peripartum Intervention: Modelling National Surveillance Data**

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ABSTRACT

Objective: Given growing interest in alternatives to hospital birth, particularly given the COVID-19 pandemic, we developed a peripartum intervention risk calculator (PIRC) to estimate maternal and neonatal risk of requiring hospital-based peripartum intervention.

Design: National cohort study.

Setting: United States.

Sample: Hospital births captured by the Pregnancy Risk Assessment Monitoring System from 2009-2018.

Methods: The cohort was stratified by receipt of hospital-based interventions, defined as: 1) operative vaginal delivery (forceps or vacuum), 2) cesarean delivery, or 3) requiring neonatal intensive care unit admission. Gravidas with prior cesarean delivery or fetal malformation were excluded.

Main Outcome Measures: Risk of requiring hospital-based intervention.

Results: A total of 63,234 births were evaluated (72.6% full-term, 48.5% nulliparous) including 37.9% who received one or more hospital-based interventions. Gestational age was the most predictive factor of requiring hospital-based intervention, with lowest odds at 40^{0/7}-40^{6/7} weeks. Previous live births (Ref: none; 1, OR 0.41; 2, OR 0.35; ≥3, OR 0.29; p<0.05 for all) were protective. Other predictors included advanced maternal age, high pre-pregnancy body mass index, maternal diabetes, maternal hypertension, and not exercising during pregnancy. The resulting seven-factor model demonstrated strong discrimination (optimism corrected C-statistic=0.776) and calibration (mean absolute error=0.009).

Conclusions: We developed and validated the PIRC for predicting individualized risk for hospital-based intervention among gravidas based on seven readily accessible prenatal factors. This calculator can support personalized counseling regarding planned birth setting, helping to close a critical gap in current clinical guidance and providing an evidence-based risk assessment for those contemplating alternatives to hospital birth.

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Keywords: Maternal and neonatal morbidity, Obstetrics, Planned birth setting, Prenatal Counseling, Risk calculator.

Tweetable Abstract: A calculator to estimate maternal and neonatal risk of requiring hospital-based peripartum intervention.

78 INTRODUCTION

79 Over 98% of U.S. births occur in hospitals (1,2), reflecting current safety standards and
80 cultural norms surrounding childbirth. Though still a small fraction of total births, out-of-hospital
81 birth has increased in recent years, with home births increasing by 77% and birth center births by
82 226% between 2004-2017 (1,3). During the COVID-19 pandemic, concerns about hospital
83 birth's infection risks and the impact of COVID-19-related infection control policies on birth
84 experience have further amplified interest in alternatives to hospital birth (4,5).

85 The American College of Obstetricians and Gynecologists (ACOG) and American
86 Academy of Pediatrics (AAP) view hospital birth as the standard of care, caution against out-of-
87 hospital births, and assert that prior cesarean delivery, multiple gestation, and malpresentation
88 are absolute contraindications (6,7). Meanwhile, clinical guidelines and counseling remain
89 limited for uncomplicated gravidas with singleton, vertex presenting fetuses who may be
90 considering alternative delivery settings. This is in part due to the wide variability of birth
91 outcomes in the general population and lack of tools for assessing personalized risk of birth
92 complications for which hospital-based interventions are necessary (8,9). Reducing harms related
93 to increasing out-of-hospital birth requires tools to improve birth setting counseling for those
94 most likely to require hospital-based interventions (i.e., operative delivery or neonatal intensive
95 care unit [NICU] care). Currently, clinical risk calculators are widely used to inform counseling
96 regarding mode of birth (e.g. the vaginal birth after cesarean [VBAC] calculator and Bishop's
97 Score) (10,11); however, none have assessed the likelihood of need for hospital-based maternal
98 or neonatal interventions.

Here, we aimed to examine a large cohort of hospital births to 1) identify predictors of maternal and neonatal need for hospital-based peripartum interventions and 2) develop the peripartum intervention risk calculator (PIRC) to evaluate an individual's risk of requiring hospital birth^a. We propose that this calculator will help identify parturients for whom out-of-hospital birth is especially high-risk and will be a critical tool for individualized counseling.

METHODS

Considering hospital birth as the standard-of-care for all parturients, we hypothesized that national birth outcomes data could inform a probability model by identifying those who delivered in hospitals and ultimately required hospital-based interventions.

Data Source

This study was a retrospective cohort analysis of the Pregnancy Risk Assessment Monitoring System (PRAMS) dataset from 2009-2018. PRAMS is a state-specific, population-based surveillance study jointly sponsored by the Centers for Disease Control and Prevention (CDC) and state health departments. Through linked birth certificate data and questionnaire surveys, PRAMS collects individual-level data on maternal experiences and outcomes before, during, and shortly after pregnancy (12–14). Currently, PRAMS surveillance covers approximately 83% of all U.S. births, and the cohort consists of a representative sample of all births within its purview (12). This study was reviewed and deemed exempt by the Institutional Review Board of the Johns Hopkins University School of Medicine, as all data has been deidentified.

^a An interactive online tool allowing providers to utilize and evaluate PIRC is currently under development.

121 *Patient Factors*

122 All live births from U.S. states and territories participating in PRAMS from parturients
123 who had no prior cesarean deliveries were included in the study. Births in which the infant
124 expired, had a congenital defect, took place in a non-hospital setting, (e.g. birthing center or
125 home), or were reported to occur outside of a clinically feasible gestational window (22-44
126 weeks) were excluded from consideration. Births in which data on key outcomes or predictor
127 variables was missing were also excluded.

128 To address maternal risks, we considered any operative vaginal or cesarean delivery as an
129 inherently hospital-based intervention. For neonatal risks, we sought evidence of requiring NICU
130 admission among otherwise normal infants. Thus, need for hospital-based intervention was
131 defined as having experienced one or more of the following: 1) operative vaginal delivery
132 (forceps or vacuum), 2) cesarean delivery, or 3) requiring NICU admission. The cohort was
133 subsequently stratified by whether or not there was a need for hospital-based intervention.

134 To generate an optimized predictive model, we considered several pre-specified potential
135 predictors that expert physicians deemed important, practical variables which would be both
136 available during prenatal care and relevant to need for hospital-based intervention. Demographic
137 factors included maternal age (in years: ≤ 17 , 18-19, 20-24, 25-29, 30-34, 35-39, ≥ 40) and pre-
138 pregnancy body mass index (underweight [$< 18.5 \text{ kg/m}^2$], normal [$18.5\text{-}25$], overweight [$25\text{-}30$],
139 obese [$30\text{-}40 \text{ kg/m}^2$], morbidly obese [≥ 40]). Obstetric factors included maternal diabetes,
140 maternal hypertension, and number of previous live births (none, 1, 2, ≥ 3). Other considerations
141 included whether the parturient exercised three or more times per week during pregnancy.
142 Finally, we included gestational week at birth (in weeks: < 35 , $35^{0/7}\text{-}35^{6/7}$, $36^{0/7}\text{-}36^{6/7}$, $37^{0/7}\text{-}37^{6/7}$,

38^{0/7}-38^{6/7}, 39^{0/7}-39^{6/7}, 40^{0/7}-40^{6/7}, 41^{0/7}-41^{6/7}, 42^{0/7}-42^{6/7}, 43^{0/7}-44) as a non-linear factor, producing a spectrum of risk for each parturient varying by the gestational week of birth.

Statistical Analysis

Predictive factors were compared between individuals with and without hospital-based intervention. All categorical variables were compared using Pearson's chi-square tests. Using multivariable logistic regression, we evaluated the performance of eight model selection methods: 1) backwards selection, 2) forward selection, and 3) bi-directional selection using Akaike information criterion (AIC), best subset using each 4) adjusted R², 5) bias-corrected AIC, 6) Mallows' C_p, 7) Bayesian information criterion (BIC), and 8) the full model consisting of all considered predictors. Each was applied to a subset of the dataset to develop candidate models. The strength of each candidate model was evaluated by AIC along with discrimination and calibration capability using optimism-corrected C-statistics and Brier scores from 150-replication bootstrap resampling. After selecting the set of predictors with the best fit and performance, the final model was fit on the full dataset using multivariable logistic regression. Discrimination was assessed using a receiver operating characteristic (ROC) curve, and calibration was estimated by using 40-replication resampled bootstrap to calculate optimism-corrected mean absolute errors by comparing predicted versus actual probability of requiring hospital-based intervention.

In secondary analysis, the value of potential interaction terms was assessed using both *a priori* interactions pre-specified by experts as well as candidate interactions identified through rank correlation assessments using Spearman's ρ^2 . Log-rank tests were used to determine whether interaction and non-linear terms added significantly to the final model. A nomogram of the final model was generated to depict how the predictors could be used to estimate risk of

requiring hospital-based intervention. Additionally, using this final model, eight sample patient cases were presented as examples of how this risk calculator may be used to estimate risk of needing hospital-based intervention by gestational week. Two-sided p-values of less than 0.05 were used for all definitions of statistical significance. All analyses were performed using Stata version 14.2 (StataCorp LP, College Station, Texas) and R version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Study Cohort

A total of 63,234 births between 2009-2018 were identified for this study (**Table 1**). Among them, 39,257 (62.1%) were classified as without hospital-based peripartum intervention and 23,977 (37.9%) were classified as with. When compared to those without, parturients with hospital-based intervention tended to be older and have a larger BMI ($p>0.05$ for both). Additionally, those with hospital-based intervention were more likely to have short gestational time, been diagnosed with diabetes or hypertension, and had no previous live births ($p<0.05$ for all).

Model Selection

During model selection, the backwards and bi-direction selection methods converged to the same selection of variables. Additionally, the bias-corrected AIC and Mallows' C_p best subset models also converged to the same set of predictors, different from those of the backwards and bi-direction selection models. The forward selection and adjusted R^2 best subset methods also yielded the same set of variables as the full model. Thus, from the eight model selection

methods, we generated a total of four models for consideration. The model generated from the backwards and bi-direction selection yielded the strongest AIC, calibration, and discrimination (Table S1).

The final model consisted of seven predictors: maternal age, pre-pregnancy BMI, gestational week at birth, maternal diabetes, maternal hypertension, number of previous live births, and whether mother exercised during pregnancy (Table 2). After modeling the final set of predictors in the dataset, the model also yielded strong discrimination (C-statistic = 0.773, Figure 1A). The calibration (optimism-corrected mean absolute error = 0.003) was also strong, demonstrating no apparent bias and strong agreement between actual observed and predicted probabilities of requiring hospital-based intervention (Figure 1B). Secondary analyses evaluating interaction terms did not demonstrate significant improvement over the final model.

Predictors of need for hospital-based intervention

Gestation age less than 35 weeks had the strongest independent effect on hospital-based intervention (Ref: 40^{0/7}-40^{6/7} weeks; OR 23.75, 95% CI [21.95-25.71]) (Table 2). Maternal age ≤ 17 years, 18-19 years, and 20-24 years were protective (Ref: 25-29 years; ≤ 17 years: 0.61 [0.54-0.70]; 18-19 years: 0.74, [0.68-0.80]; 20-24 years: 0.87, [0.83-0.92]), whereas age between 30-34, 35-39, and ≥ 40 years conferred an increased odds of requiring hospital-based intervention (Ref: 25-29 years; 30-34 years: 1.22, [1.16-1.28]; 35-39 years: 1.84, [1.63-2.07]; ≥ 40 years, 1.63 [1.52-1.75]). Other factors associated with increased odds of requiring hospital-based intervention included BMI classification of overweight, obese, or morbidly obese, diabetes, as well as hypertension (p<0.05 for all).

The odds of needing hospital-based intervention decreased with increasing number of previous live births (Ref: none; 1: OR 0.41, 95% CI [0.39-0.43]; 2: OR 0.35, [0.33-0.37]; ≥ 3 : OR 0.29, [0.27-0.31]) (**Table 2**). The adjusted probability of hospital-based intervention decreased significantly by gestational week, leveling around gestational week 38^{0/7}-38^{6/7} (**Figure 2**). Predicted probability of requiring hospital-based intervention in the study population demonstrated a bimodal distribution with a group of individuals at markedly higher risk and a different group at lower risk (**Figure 3**). The predictors in this final model were used to generate a nomogram to visualize how the predictors' weights can be converted into percent risk of needing a hospital-based intervention (**Figure 4**). Eight example patient cases are presented of predicted risk by gestational week (**Table 3**).

In secondary analyses, we included need for blood transfusions in the composite outcome. However, this did not significantly affect the calibration (mean absolute error = 0.01) or discrimination (AUC = 0.772) of the model. Due to high levels of missingness (46.5%), the outcome of need for blood transfusions was not included in the main analysis.

DISCUSSION

Main Findings

To our knowledge, the PIRC is the first risk-scoring system to assess both maternal and neonatal risk of needing hospital-based peripartum interventions which incorporates specific prenatally available demographic and obstetric factors reflecting a U.S. population-based sample of hospital births. After adjustment, the strongest predictors for needing one or more hospital-based interventions were preterm delivery and nulliparity. Other predictors included advanced maternal age, high BMI, diabetes, hypertension, and not exercising during pregnancy. As

gestational week increased, particularly beyond 35 weeks, the probability of birth complications decreased accordingly, with lowest odds between 39 and 42 weeks. This optimized set of predictors demonstrated strong discrimination and calibration to accurately report personalized risk. Given potential use during prenatal counseling and significance of gestational week, we constructed our model to provide a breakdown of risk as a function of gestational age at delivery (**Table 3**).

Strengths and Limitations

In the U.S., hospital birth is the standard-of-care given irreducible risk of requiring immediate access to hospital-based maternal or neonatal interventions (6). Existing literature regarding out-of-hospital birth is complicated by differences between neonatal outcomes for U.S. populations and those from other high-income countries where out-of-hospital birth may be integrated into maternity care systems (15–17). To avoid potential confounders, we did not incorporate non-hospital birth data, but instead focused on identifying prenatal factors associated with various outcomes of hospital birth, thus providing immediate access to hospital-based interventions. Therefore, our model can help individuals better understand their risk related to deviating from the standard of care by illustrating the chance they or their neonates will require interventions only available in hospital settings.

Further, PRAMS data included cases in which offspring did not survive, however whether deaths occurred antepartum, intrapartum or postpartum was not specified, and thus we excluded all such cases from our analysis. Another limitation is that PRAMS does not indicate planned birth setting, and thus a small subset of hospital births may include intrapartum transfers of those planning out-of-hospital birth. We note that all out-of-hospital birth plans should

incorporate a plan for hospital transfer, should probability of needing hospital-based intervention were to increase. Likewise, ultimately requiring hospital-based intervention is not tantamount to the relatively smaller risk of requiring acute intervention. Therefore, the calculator can inform those contemplating out-of-hospital birth on the likelihood that they will either require intrapartum transfer or potentially suffer harm from delayed access to hospital-based interventions.

Though PRAMS did not capture some critical hospital-based interventions, such as acute antihypertensive or magnesium treatment, it allowed for development of a model covering the most significant and common of them: operative delivery and neonatal intensive care. Similarly, the severity of diabetes and hypertension was not accounted for. We stipulate that the PIRC should not be used for gravidas whose comorbidities require inpatient monitoring and management—including, but not limited to, insulin-dependent diabetes and severe hypertension. While we exclude highest risk individuals from using the calculator given their clear indication for hospital delivery, their inclusion in the underlying model suggests that risk is likely overestimated for the majority of gravidas who have more mild disease.

Sensitivity analysis demonstrated that including blood transfusion as a hospital-based outcome measure did not significantly impact results, likely due to relative rarity of blood transfusion compared to operative delivery and NICU admission as well as substantial overlap in the affected populations. Additionally, our model intentionally omitted race, payer, and history of sexually transmitted infections to avoid reifying race-based inequities, as we hypothesize that any plausible physiological linkage between these factors and hospital-based interventions are overshadowed by historic impact of provider biases on adverse outcomes. For example, black women are known to have higher rates of both primary and repeat cesarean delivery (18), a

disparity substantially attributed to the role of implicit bias in obstetrics. This marks a departure from traditional approaches to medical risk modeling which have incorporated race on the basis of assumed biological differences (10,19), which have since been appropriately challenged (20,21).

Interpretation

ACOG asserts that gravidas have the right to make medically informed decisions about birth setting (6). However, hospital birth is the norm and assumed de facto plan, whereas counseling regarding birth setting typically arises as recommendations against home birth when interest in alternatives is disclosed (6,7). By providing personalized risk stratification regarding need for hospital-based intervention, our calculator could facilitate birth setting counseling and promote informed decisions at a time when alternatives to hospital birth are increasingly popular.

Notably, planned out-of-hospital births may occur at birth centers or individual homes. ACOG supports accredited birth centers for low risk parturients (6), however this option may be geographically unavailable and does not address all potential concerns regarding hospital birth, including those related to social distancing during COVID-19. Meanwhile, ACOG recommends against home birth given evidence of increased neonatal risks in U.S. settings (6,15). The pandemic has nevertheless amplified already growing interest in home birth (4,5), and although quality and safety of this alternative may vary widely, there is heightened necessity for evidence-based counseling tools.

Prior vaginal birth is protective against operative delivery and related maternal or neonatal morbidity and mortality (22–24). Likewise, increasing parity is inversely associated with hospital-based intervention in our model which demonstrates large differences in risk as a

function of prior birth experience. The PIRC's personalized risk scores are more informative than existing population averages and may facilitate targeted counseling for primiparous gravidas and others for whom hospital birth has the greatest likelihood of being medically necessary.

Our model validates the importance of hospital birth among those who deliver preterm, including late preterm, due to dramatically higher risk of requiring hospital-based interventions (25,26). Of note, some hospitals may routinely observe all preterm neonates in the NICU as a precaution, potentially overestimating medical necessity of NICU admission among near-term infants. Though not available in PRAMS, further studies incorporating Apgar scores could help delineate late-preterm risk.

Importantly, PRAMS does not specify the indication or circumstances surrounding operative deliveries, and therefore we cannot account for those which may have been elective or the byproduct of "defensive medicine" in U.S. obstetrics wherein operative interventions are often overused (27–29). In contrast, we assume that all operative deliveries and NICU admissions that occurred during hospital births were medically necessary. This suggests that the resulting model overestimates risk of requiring hospital-based interventions, generating a relatively conservative, but overall safe counseling tool.

Notably, PRAMS also does not distinguish medically indicated or elective inductions from spontaneous labor, likely contributing to greater risk of interventions among late preterm and early term deliveries (**Table 2**), particularly given comorbid hypertension or diabetes. Comparison of the model with more detailed clinical data will be helpful for further elucidating differences in risk.

Ultimately, PRAMS is a comprehensive and well-validated dataset (13,30–32), supporting our proposal that the resulting model is a safe and precise tool for assessing individualized risk and informing counseling for those who may be considering alternative birth settings. A number of considerations greatly impact how the calculated risk scores may influence individual decision-making. Availability and feasibility of safe out-of-hospital alternatives varies considerably based on individual health, values, and resources, and geography. Subsequent work is underway to validate the PIRC’s use in prenatal counseling, especially in high-risk populations, and to develop a decision aid supporting comprehensive consideration of risks related to out-of-hospital birth.

CONCLUSION

The PIRC can help individuals understand their risk of requiring hospital-based interventions for maternal or neonatal wellbeing, and therefore the chance of requiring hospital transfer, should they pursue an out-of-hospital birth plan. This unique tool will be critical for individualizing birth setting counseling for gravidas with singleton, vertex presenting fetuses and may be especially helpful for targeted counseling of those who should be most strongly urged to plan for a hospital birth. As home birth continues to increase in popularity and access to birth centers remains limited, this calculator and forthcoming complementary decision aid will be key components of harm reduction.

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DISCLOSURE OF INTERESTS

The authors report no conflicts of interest.

CONTRIBUTION TO AUTHORSHIP

Study concept and design: GQZ, FMW, HN, JLB, MSG. Analysis and interpretation of data: GQZ, FMW. Drafting of the manuscript: GQZ, FMW, MSG. Critical revision of the manuscript for important intellectual content: GQZ, FMW, HN, JLB, MSG. Final approval of the version to be published: GQZ, FMW, HN, JLB, MSG.

DETAILS OF ETHICS APPROVAL

This study was reviewed and deemed exempt by the Institutional Review Board of the Johns Hopkins University School of Medicine.

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