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Validation of obstetric estimate of gestational age on US birth certificates

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Abstract

OBJECTIVE—The birth certificate variable obstetric estimate of gestational age (GA) has not been previously validated against GA based on estimated date of delivery from medical records.

STUDY DESIGN—We estimated sensitivity, specificity, positive predictive value, negative predictive value and the corresponding 95% confidence intervals (CIs) for preterm delivery (<37 weeks' gestation) based on obstetric estimate using estimated date of delivery-based GA as the gold standard. Trained abstractors obtained the estimated date of delivery from the prenatal record (64.8% in New York City, and 94.6% in Vermont), or, when not available, from the hospital delivery record for 2 population-based samples: 586 live births delivered in New York City and 649 live births delivered in Vermont during 2009. Weights were applied to account for nonresponse and sampling design.

RESULTS—In New York City, the preterm delivery rate based on estimated date of delivery was 9.7% (95% CI, 7.6–12.4) and 8.2% (95% CI, 6.3–10.6) based on obstetric estimate; in Vermont, it was 6.8% (95% CI, 5.4–8.4) based on estimated date of delivery and 6.3% (95% CI, 5.1–7.8) based on obstetric estimate. In New York City, sensitivity of obstetric estimate-based preterm delivery was 82.5% (95% CI, 69.4–90.8), specificity 98.1% (95% CI, 96.4–99.1), positive predictive value 98.0% (95% CI, 95.2–99.2), and negative predictive value 98.8% (95% CI, 99.6–99.9). In Vermont, sensitivity of obstetric estimate-based preterm delivery was 93.8% (95% CI, 81.8–98.1), specificity 99.6% (95% CI, 98.5–99.9), positive predictive value 100%, and negative predictive value 100%.

CONCLUSION—Obstetric estimate-based preterm delivery had excellent specificity, positive predictive value and negative predictive value. Sensitivity was moderate in New York City and

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excellent in Vermont. These results suggest obstetric estimate-based preterm delivery from the birth certificate is useful for the surveillance of preterm delivery.

Keywords

birth certificates; gestational age; preterm; validation

Gestational age (GA) recorded in the birth certificate is the cornerstone of several important maternal and child health indicators including percent of US infants born preterm (<37 weeks' gestation), small for GA and large for GA. In 2003, the National Centers for Health Statistics (NCHS) released a revised US Standard Certificate of Live Birth that included a new measure for GA, obstetric estimate (OE). OE replaced clinical estimate (CE) of GA from the 1989 version of the birth certificate. The most significant differences between these 2 measures is that the instructions for birth clerks or clinicians recording the OE were more detailed and explicitly state that the estimate should be determined by all perinatal factors and assessments but not the neonatal examination.¹ In addition, the instructions note that OE should not be completed solely on the infant date of birth and the mother's last menstrual period (LMP). Whereas instructions for the previously used CE simply noted to enter the length of gestation estimated by the attendant, and to not compute the item based on the infant date of birth and mother's LMP.

Two previous validations of the OE on the birth certificate have used different gold standards and study populations, and found varying results. The first study compared the distributions of birthweight for GA using the OE and a gold standard. The sample was 2005 US births and the gold standard was LMP-based GA if it agreed within 1 week to the OE. It found that the median, 10th, and 90th percentile birthweight distributions were virtually identical for the gold standard and the OE but that they differed for LMP-based GA.² Another study used early ultrasound (<20 weeks) as its gold standard and the population was a subsample of California births. It found OE-based preterm delivery (<37 weeks' gestation) had moderate sensitivity (74.9%) and positive predictive value (PPV) (85.1%).³ Neither of these studies used what clinicians would consider to be their gold standard, the best obstetric date of delivery (BO-EDD).

During prenatal care, clinicians estimate a BO-EDD based on all available information, including ultrasound, LMP, and physical examination. In the first trimester, the American College of Obstetrics and Gynecology (ACOG) recommends that the BO-EDD be based on the following hierarchy: (1) LMP if confirmed by ultrasound and dates are within 7 days, or (2) by ultrasound if the LMP is unknown or differs >7 days from the ultrasound estimate, or (3) by the date of conception if resulting from assisted reproductive technology.⁴ For women entering prenatal care in the second trimester, the same criteria are recommended, with the exception of basing EDD on ultrasound if it differs with the LMP >10 days. In the third trimester, ultrasound is not recommended for dating purposes. Once the BO-EDD is determined during the initial prenatal care visits, clinicians use it to estimate GA during the pregnancy and at delivery. Thus, for clinicians, BO-EDD is the gold standard for determining an infant's GA at delivery. We sought to validate the OE reported on the birth

certificate using the BO-EDD as the gold standard. A secondary purpose of this analysis was to assess the frequency with which EDD is based on LMP or ultrasound-based dates.

Materials and Methods

This study is part of a special validation project funded by the Centers for Disease Control and Prevention. Two Pregnancy Risk Assessment Monitory System (PRAMS) sites, NYC and Vermont, were funded to validate self-reported information from mothers in the PRAMS⁵ and from the 2003 birth certificate. PRAMS is a population-based surveillance system that uses state vital records as its sampling frame, and which links birth certificate data to mother's responses on a questionnaire filled out 4 months on average after delivery. The sample from NYC included all PRAMS respondents who delivered in any of the city's 41 birthing hospitals from Jan. 1 to June 4, 2009 (n = 603); Vermont's sample included all PRAMS respondents who delivered in any of the state's 12 hospitals or in 1 New Hampshire Hospital close to Vermont's border from Jan. 1 through Aug. 31, 2009 (n = 664). The PRAMS response rates were 67.3% for NYC and 82.8% for Vermont during the study period. Our inclusion criteria for this analysis required complete OE information on the birth certificate, complete EDD information on the prenatal or hospital record, and GA estimates between 20 and 44 weeks. For Vermont, 15 of 664 did not meet inclusion criteria resulting in a final sample size of 649. For NYC, 17 of 603 did not meet inclusion criteria resulting in a final sample size of 586.

Medical record abstraction was done manually with physical records, except in the few hospitals where the records were electronic. In those circumstances, the information was abstracted manually from the computerized record. The data abstractors were trained by 2 authors (P.D. and J.B.) and 4 additional staff members to abstract information in a standardized manner. To evaluate reliability of record abstraction, approximately 25 medical records in both NYC and Vermont were re-abstracted by authors PD, JB, and 4 additional project staff and compared. Errors in abstractions (estimated to be <3% for all variables) were noted and then reviewed with the abstractors. The final EDD, which we refer to as the BO-EDD in this paper, recorded in the prenatal or hospital record was abstracted from paper or electronic records at each birthing hospital. The prenatal record was the first place abstractors looked for the BO-EDD, and if the prenatal record was missing, it was abstracted from the hospital delivery record. In NYC, 64.8% of the BO-EDD was abstracted from the prenatal record and 33.2% from the hospital record; in Vermont 94.6% of the BO-EDD was abstracted from the prenatal record and 5.4% from the hospital delivery record. Prenatal medical forms have several fields for recording the initial EDD, the LMP-based EDD, the ultrasound-based EDD and the final-EDD. Some hospital records also noted ultrasoundbased EDD. All of these EDDs were abstracted if available. We considered the final EDD recorded in the prenatal record to be the BO-EDD. The EDD recorded in the delivery record was used as the BO-EDD in the absence of a prenatal record. Date of birth was also abstracted from the hospital delivery record. EDD-based GA was calculated using this formula: [280 days - (EDDDOB)]/7, then rounded down to nearest whole number for completed weeks of gestation. The OE was taken from the birth certificate and was based on completed weeks of gestation.

To describe the characteristics of the NYC and Vermont samples, we examined age, race/ ethnicity, marital status, education, and trimester entering prenatal care using data from the birth certificate, and mothers' participation in the Special Supplemental Nutrition Program for Women, Infants and Children Program (WIC) using self-reported data on the PRAMS questionnaire. To explore the validity of the OE, we estimated sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% confidence intervals (CIs) for early/moderate (20-33 weeks), late (34-36 weeks), and all (<37 weeks) preterm groups. The BO-EDD was the gold standard. Estimates were considered excellent if >90% and moderate if 70-90%.⁶ The source of the BO-EDD was determined by comparing it with the EDD based on LMP and the EDD based on ultrasound abstracted from prenatal records. If the BO-EDD matched the EDD based on LMP then we concluded that LMP was the source of BO-EDD. If the BO-EDD matched the EDD based on ultrasound then we concluded that ultrasound was the source. All analyses weighted data to account for sample design, nonresponse, and noncoverage; the data represent all live births among NYC or Vermont residents during the study period. Analyses were run with SAS version 9.2 (SAS Institute, Cary, NC) and SUDAAN version 10.1 (RTI International).

Results

The women included in the NYC and Vermont samples had similar age distributions but differed by all other demographic characteristics (Table 1). Women from NYC were more likely than women from Vermont to be black, Hispanic or of another nonwhite race, to have been enrolled in WIC, to be unmarried, to have had less than a high school education, and to have entered prenatal care later.

Percent preterm

For NYC births, the mean (37.1 weeks based on OE, 37.0 based on EDD) and median (38.0 weeks on both) GA were consistent between the 2 sources (data not shown). The percent preterm was lower using OE (8.2%; 95% CI, 6.3–10.6) than using EDD (9.7%; 95% CI, 7.6–12.4); however, 95% CI overlapped. For Vermont births, the mean (38.0 weeks) and median (39.0 weeks) were consistent between the 2 sources. The percent preterm was lower using OE (6.3%; 95% CI 5.1–7.8%) than using EDD (6.8%; 95% CI, 5.4–8.4%), however, 95% CI overlapped.

Source of the BO-EDD

In NYC, the BO-EDD matched the LMP-based EDD for 35.0% of births, the BO-EDD matched the ultrasound-based EDD for 31.4% of the births, and the BO-EDD, matched both the LMP- and ultrasound-based EDDs for 22.3% of births (data not shown). For 11.3% of births the BO-EDD matched neither the LMP-based nor ultrasound-based EDD. When we stratified by source of BO-EDD, the results were similar. For example, when the hospital record was the source of the BO-EDD, BO-EDD matched the LMP-based EDD for 31.0% of births, the BO-EDD matched the ultrasound-based EDD for 32.9% of the births, and the BO-EDD matched both the LMP- and ultrasound-based EDDs for 26.5% of births. In Vermont, for 39.8% of births the BO-EDD matched the LMP-based EDD, for 39.3% the BO-EDD matched the ultrasound-based EDD and for 13.5% of births the BO-EDD matched

both the LMP- and ultrasound-based EDDs. For 7.4% of births, the EDD matched neither the LMP-based nor ultrasound-based EDD.

Sensitivity, specificity, PPV, NPV

For NYC, the overall sensitivity of preterm delivery based on OE was 82.5%; 95% CI, 69.4-90.8 (Table 2). Sensitivity was higher for infants at 20-33 weeks' GA (96.7%; 95% CI, 90.5-98.9) than for infants born between 34-36 weeks' gestation (75.6%; 95% CI, 59.6-86.6). Specificity and PPV were all above 90%. For Vermont, the overall sensitivity for preterm delivery based on OE was 93.8%; 95% CI, 81.8-98.1 (Table 2). Sensitivity was higher for infants at 34-36 weeks' GA than for infants born between 20-33 weeks' gestation, however, 95% CI overlapped for the 2 estimates. Specificity, PPV, and NPV were all above 90%. The results did not differ when stratifying by source of BO-EDD. In New York City, when the hospital record was the source of the BO-EDD (n = 239), sensitivity was 83.7%, specificity was 99.8%, PPV was 97.6%, and NPV was 98.3%. When the prenatal record was the source of the BO-EDD (n = 347), sensitivity was 81.8%, specificity was 98.7%, PPV was 98.1%.

Comment

This study compared the OE on the birth certificate to the BO-EDD as the gold standard and found the sensitivity for preterm delivery to be moderate in NYC and excellent in Vermont, and specificity, PPV, and NPV to be excellent for both NYC and Vermont. The results of this study differ from the study of births in California that used early ultrasound-based GA as the gold standard and found a lower sensitivity for OE.³ This difference may be explained by our finding that the BO-EDD is not based solely on early ultrasound. We found that the BO-EDD matched ultrasound dating for approximately one-third of the births, and both LMP-based and ultrasound dating for approximately another 20% of births. For one-third of the records, only a LMP-based EDD and a final EDD were recorded in the prenatal record and the 2 EDDs were the same; we suspect many of these LMP-based EDDs had an early ultrasound to confirm the LMP but that the ultrasound-EDD was not recorded. Although we do not have the data in this study, it is widely accepted that nearly all women who receive prenatal care receive at least 1 ultrasound.⁵ ACOG recommends that if the ultrasound-based EDD is within 7 days of the LMP-based EDD in the first trimester or within 10 days in the second trimester, the LMP-based EDD should be used. Hence, differences in LMP-based EDD and ultrasound-based EDD could be 1 to 2 weeks depending on which trimester the final dating is completed. The BO-EDD may be a better gold standard than the ultrasoundbased EDD for this reason.

This study has several strengths worthy of mention. The gold standard used in this study, the BO-EDD, is a synthesis of all available GA information including LMP and ultrasound dating when available. In clinical practice, once the EDD is established it serves as the basis for the best obstetric estimate of GA at each point in pregnancy, including at the time of presentation for labor and delivery. In addition, this study analyzed data from 2 population-based samples of births with geographically and demographically diverse populations. NYC had a lower sensitivity for OE than Vermont, which may reflect its different health care system and larger volume of deliveries. NYC also had a lower response rate and fewer

available prenatal records available for records abstraction that may have contributed to the lower sensitivity. Women in New York City who did respond compared with those in the entire sample were less likely to be <25 years of age and black, and more likely to be enrolled in WIC and more educated (data not shown). Although the nonresponse weights did adjust for these differences, the weights assume that responders and nonresponders with common characteristics are the same.

Sensitivity, specificity, PPV, and NPV are generalizable to all women who delivered live infants in the 2 jurisdictions during the time period. Two important limitations are worthy of mention as well, possible medical record abstraction errors and the inability to assess validity by hospital due to small sample sizes.

This study has several important findings and potential implications. The preterm delivery rate using OE-based GA was similar to preterm delivery rate using BO-EDD, and sensitivity, specificity, PPV, and NPV were excellent for OE-based preterm using EDD as the gold standard in Vermont and in New York City with the exception of sensitivity (moderate). These results, along with the results from the other 2 validity studies reaffirm that OE is a valid source of GA.^{2,3} Currently, national preterm delivery rates are calculated using a LMP-based GA; LMP-based GA has lower validity than OE.^{2,7} In the future, NCHS will transition to calculating preterm delivery rates using OE for GA. In addition, NCHS plans to modify the instructions for recording obstetric estimate to be consistent with ACOG recommendations. These changes are likely to lead to improvements in the quality of OE on the birth certificate.

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The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention, the New York City Department of Health and Mental Hygiene, or the Vermont Department of Health.

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TABLE 1

Demographic characteristics of mothers from NYC and Vermont

	NYC	<u>Vermont</u> Weighted % (unweighted n = 649)	
Demographic	Weighted % (unweighted n = 586)		
Maternal age, y			
<24	28.8	29.8	
25-34	53.4	55.2	
35	17.9	15.0	
Race/ethnicity ^a			
NonHispanic white	23.4	92.7	
NonHispanic black	21.2	0.6	
Hispanic	40.0	1.3	
Other	15.3	5.4	
WIC recipient during pregnancy ^a			
Yes	57.5	45.6	
No	42.5	55.4	
Marital status ^a			
Married	55.3	62.6	
Not married	44.7	37.4	
Mother's education ^a			
<high graduate<="" school="" td=""><td>24.1</td><td>9.2</td></high>	24.1	9.2	
High school graduate	26.4	27.7	
Some college	20.4	25.3	
College graduate	29.0	37.8	
Trimester entered into prenatal care ^a			
First	84.9	90.3	
Second	8.9	6.5	
Third/no prenatal care	2.3	0.8	
Unknown	3.9	2.4	

NYC included births Jan. 1 through June 4, 2009; Vermont included births Jan. 1 through Aug. 31, 2009. Percentages weighted to adjust for survey design, sampling, and nonresponse.

WIC, Special Supplemental Nutrition Program for Women, Infants and Children.

 $a_{\chi^2}, P < .01$

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TABLE 2

Sensitivity, specificity, PPV, and NPV for OE-based gestational age

Variable	Sensitivity 95% CI	Specificity 95% CI	PPV 95% CI	NPV 95% CI
NYC				
OE 20-33 wks	96.7 (90.5–98.9)	99.9 (99.8–100)	92.4 (83.2–96.7)	99.8 (99.6–99.9)
OE 34-36 wks	75.6 (59.6–86.6)	99.8 (99.6–99.9)	96.8 (93.1–98.6)	98.1 (96.4–99.0)
OE 36 wks	82.5 (69.4–90.8)	99.8 (99.6–99.9)	98.0 (95.2–99.2)	98.1 (96.4–99.1)
Vermont				
OE 20-33 wks	88.6 (61.9–97.4)	99.8 (98.8–99.9)	98.2 (95.8–99.3)	100
OE 34-36 wks	94.7 (81.9–98.6)	99.7 (99.0–99.9)	99.2 (98.0–99.7)	100
OE 36 wks	93.8 (81.8–98.1)	100	100	99.6 (98.5–99.9)

CI, confidence interval; EDD, estimated date of delivery; NPV, negative predictive value; OE, obstetric estimate; PPV, positive predictive value