# Validity of Maternal and Perinatal Risk Factors Reported on Fetal Death Certificates

Mona T. Lydon-Rochelle, PhD, CNM, Vicky Cárdenas, PhD, MPH, Jennifer L. Nelson, PhD, Kay M. Tomashek, MD, MPH, Beth A. Mueller, DrPh, and Thomas R. Easterling, MD

We sought to estimate the accuracy, relative to maternal medical records, of perinatal risk factors recorded on fetal death certificates. We conducted a validation study of fetal death certificates among women who experienced fetal deaths between 1996 and 2001. The number of previous births, established diabetes, chronic hypertension, maternal fever, performance of autopsy, anencephaly, and Down syndrome had very high accuracy, while placental cord conditions and other chromosomal abnormalities were reported inaccurately. Additional population-based studies are needed to identify strategies to improve fetal death certificate data. (Am J Public Health. 2005;95:1948-1951. doi:10.2105/AJPH.2004.044305)

Rates of fetal mortality declined dramatically in the United States in the decades preceding 1990.<sup>1</sup> However, since 1990, US fetal mortality rates have remained steady at between 6.7 and 7.5 per 1000 births. These trends in fetal mortality rates and the limited understanding of the etiology of fetal death are so compelling that the Centers for Disease Control and Prevention, as well as the National Institutes of Health, have identified this as a high priority area for epidemiological research.<sup>2,3</sup>

One national research goal is to improve the quality and completeness of fetal death certificates, which are currently the major source of data on stillbirths.<sup>2,3</sup> No studies have assessed the accuracy of the information on perinatal risk factors in fetal death certificates compared with medical records. Thus, we examined the validity of fetal death certificates for identifying risk factors among women experiencing stillbirths in a tertiary care center in Washington State.

# **METHODS**

In Washington State, fetal death reporting is required by law for all spontaneous pregnancy losses occurring at 20 weeks or more. We identified 211 fetal death records between January 1, 1996, and December 31, 2001, using electronic vital records files. The following factors, considered etiologies of stillbirth in previous perinatal epidemiological studies,<sup>4–14</sup> were assessed: reproductive history, pregnancy risk factors, labor and delivery complications, and fetal conditions and characteristics.

A trained medical record abstractor reviewed each woman's medical record, including physician and nurses' notes, autopsy and pathology reports, medical and surgical consultations, and prenatal records. Using standard protocol definitions, perinatal risk factors were coded as either present or absent. To assess the reliability, one of the authors reabstracted 15 randomly selected medical records, with no disagreements.

Using the medical record as the gold standard, we estimated the accuracy of dichotomous variables recorded on the fetal death by calculating the true positive rate (TPR), false positive rate (FPR), positive predictive value (PPV), and negative predictive value (NPV). The accuracy parameters were defined as follows: TPR is the proportion of women with a positive assessment on the fetal death certificate among those with a positive medical record assessment; FPR is the proportion of women with a positive assessment on the fetal death certificate among those with a negative medical record assessment; PPV is the proportion of women with a positive medical record assessment among those with a positive fetal death certificate assessment; and NPV is the proportion of women with a negative medical record assessment among those with a negative fetal death certificate assessment.

# **RESEARCH AND PRACTICE**

We assessed the agreement of nondichotomous factors using weighted  $\kappa$  statistics (for ordinal measures and count data), intraclass correlation coefficients (for continuous measures), and the absolute difference between the values on the fetal death certificate versus the medical record.

Women with missing fetal death certificate data on the item of interest were dropped from the analyses. Overall, data was missing for 1.4% to 25.1% of maternal and perinatal conditions in the fetal death certificate. All of the analyses were performed using Stata version 8.0 (Stata Corporation, College Station, TX).

# RESULTS

Our study sample was comparable to the statewide fetal death cohort (data not shown). The fetal death certificate was most accurate in reporting the presence of 1 or more prior pregnancies (TPR=95%), established diabetes (TPR=100%), chronic hypertension (TPR=81%), incompetent cervix (TPR=71%), maternal smoking (TPR= 79%), maternal fever more than 100°F (83%), autopsy performed (96%), more than 1 plurality (85%), anencephaly (100%), and Down syndrome (88%; Table 1). How-

# TABLE 1—Validation Measures for Maternal and Perinatal Conditions on Fetal Death Certificates Compared With Medical Records in a Tertiary Care Center: Washington State, 1996–2001 (n=211)

	Frequency <sup>a</sup>	TPR (95% CI)	FPR (95% CI)	PPV (95% CI)	NPV (95% CI)
Reproductive history					
$\geq 1$ prior pregnancies	153	95.0 (90, 98)	1.9 (0.05, 10)	99.3 (96, 100)	88.3 (77, 95)
$\geq$ 1 prior live births	171	64.4 (52, 75)	7.1 (0.2, 34)	97.9 (89, 100)	33.3 (19, 50)
$\geq$ 1 spontaneous terminations < 20 wks	49	67.4 (51, 81)	4.6 (2, 10)	78.4 (62, 90)	91.1 (86, 95)
$\geq$ 1 spontaneous terminations $\geq$ 20 wks	15	53.3 (27, 79)	6.1 (4, 12)	42.1 (20, 67)	96.0 (92, 98)
$\geq 1$ induced terminations	36	66.7 (48, 92)	2.5 (0.7, 6)	84.6 (65, 96)	93.5 (89, 97)
Pregnancy risk factors					
Anemia	3	66.7 (9, 99)	1.7 (.4, 5)	40.0 (5, 85)	99.4 (97, 100)
Established diabetes	5	100.0 (48, 100)	0.6 (0.01, 3)	83.3 (36, 100)	100.0 (98, 100)
Gestational diabetes	3	50.0 (1, 99)	0.0 (0, 2)	100.0 (3, 100)	99.4 (97, 100)
Chronic hypertension	22	81.0 (58, 95)	2.5 (0.7, 6)	81.0 (58, 95)	97.5 (94, 99)
Preeclampsia	23	63.6 (41, 83)	1.9 (0.4, 5)	82.4 (57, 96)	95.2 (91, 98)
Incompetent cervix	14	71.4 (42, 92)	3.0 (1, 7)	66.7 (38, 88)	97.6 (94, 99)
Uterine bleeding	16	33.3 (12, 62)	4.8 (2, 9)	38.5 (14, 68)	94.1 (89, 97)
Maternal smoking	42	78.6 (59, 92)	1.6 (0.2, 5)	91.7 (73, 99)	95.6 (91, 98)
Amniocentesis	58	55.2 (42, 68)	9.3 (5, 15)	69.6 (54, 82)	84.0 (77, 89)
Labor and delivery complications					
Febrile	8	83.3 (36, 100)	10.5 (6, 16)	21.7 (8, 44)	99.4 (96, 100)
Abruptio placenta	17	68.8 (41, 89)	3.7 (1, 8)	64.7 (38, 86)	96.9 ( 93, 99)
Placenta previa	3	0.0 (0, 71)	0.6 (0.02, 3)	0.0 (0, 97)	98.3 (95, 100)
Cord prolapse	8	57.1 (18, 90)	2.9 (1, 7)	44.4 (14, 79)	98.2 (95, 100)
Fetal conditions and characteristics					
Autopsy performed	87	96.3 (90, 99)	0.0 (0, 3)	100.0 (95, 100)	97.3 (92, 99)
>1 Plurality	38	85.2 (66, 96)	0.0 (0, 3)	100.0 (85, 100)	97.1 (93, 99)
Placental cord conditions	96	19.7 (11, 30)	15.9 (9, 25)	51.7 (33, 71)	54.8 (46, 63)
Anencephalus	3	100.0 (16, 100)	0.0 (0, 2)	100.0 (16, 100)	100.0 (98, 100)
Other chromosomal abnormalities	35	28.1 (14, 47)	1.6 (0.2, 6)	81.8 (48, 98)	84.4 (77, 90)
Down syndrome	8	87.5 (47, 100)	1.3 (0.2, 5)	77.8 (40, 97)	99.3 (96, 100)

Note. TPR = true positive rate; CI = confidence interval; FPR = false positive rate; PPV = positive predictive value; NPV = negative predictive value. Estimates were based on women with nonmissing data.

<sup>a</sup>Data source was a medical record.

ever, estimates of TPR were low for spontaneous terminations at 20 weeks or more (53%), gestational diabetes (50%), amniocentesis (55%), uterine bleeding (33%), placental cord conditions (20%), cord prolapse (57%), and other chromosomal abnormalities (28%). Except for fever more than 100°F and placental cord conditions, FPRs were consistently low. Similarly, NPVs were consistently high, with 2 exceptions: 1 or more prior live births and placental cord conditions. The PPVs for spontaneous abortion (42%), anemia (40%), and uterine bleeding (39%) were also low, indicating that the medical records often did not indicate the presence of these conditions when they were coded on the fetal death certificates.

Agreement was quite high for 10 of the 11 nondichotomous perinatal factors (Table 2). Intraclass correlations ranged from 0.87 for the clinical estimate of gestation to 0.99 for the date of last menstrual period. The observed agreement was high for most ordinal measures and count data, ranging from 81% for total prior pregnancies to 98% for plurality. The agreement was poor for the average number of cigarettes per day (weighted  $\kappa$ = 0.43), although the absolute mean difference in the recorded number of cigarettes per day was small.

#### DISCUSSION

This is the first study to compare fetal death certificate data to medical records for the detection of maternal and perinatal risk factors. We found that fetal death certificates had very good validity for reporting of the number of prior births, established diabetes, chronic hypertension, maternal fever, performance of autopsy, plurality, anencephaly, and Down syndrome. However, some reporting was markedly inaccurate, such as that for placental cord conditions and chromosomal abnormalities other than Down syndrome. The low accuracy of these two variables may be explained by the lack of specific diagnostic criteria for these conditions. We suspect that ambiguous terms such as "condition" or "other" are used loosely and that conditions that fall under these broad categories often go unreported.

### TABLE 2—Agreement of Maternal and Perinatal Factors on Fetal Death Certificate Compared With Medical Record in a Tertiary Care Center, 1996-2001 (n=211)

	% Agreement	ICC (95% CI)	Weighted $\kappa$ Statistic (95% CI)	Absolute Mean Difference
	Ordinal and	count data		
Total prior pregnancies	80.60	.96 (.94, .97)	.87 (.77, .98)	.24
No. prior live births now living	91.35	.98 (.97, .99)	.93 (.80, 1.06)	.09
Plurality	97.50	.95 (.93, .96)	.92 (.79, 1.05)	.03
Timing of fetal death	86.47	.73 (.66, .81)	.63 (.48, .78)	.14
Trimester of amniocentesis $(n = 27)^{a}$	92.59	.66 (.45, .87)	.64 (.34, .94)	.07
Average no. of cigarettes per day (n = 19) <sup>b</sup>	47.37	.55 (.23, .87)	.43 (.16, .70)	3.05
	Continuo	us data		
Date of LMP		.99 (.99,.99)		26.05
Weight before pregnancy, lbs		.97 (.95, 1)		2.14
Weight gained during pregnancy, lbs		.88 (.75, 1)		4.38
Clinical estimate of gestation, days		.87 (.83, .92)		10.65
Birth weight, g		.97 (.96, .98)		45.92

Note. ICC = intraclass correlation coefficient; CI = confidence interval. Estimates were based on women with nonmissing data. <sup>a</sup>Based only on women who had an amniocentesis.

<sup>b</sup>Based only on women who smoked.

Generally, reporting of continuous variables, such as weight gained during pregnancy, was accurate. The agreement of ordinal and count data was less consistent. Reporting of the number of prior pregnancies, number of prior live births now living, and plurality was very accurate, whereas the accuracy of the average number of cigarettes smoked per day was quite low.

We know of no research on the accuracy of fetal death certificate reporting of maternal and fetal risk factors with which to compare our findings. The generalizability of our findings is limited, given that our study population is from a single tertiary care center in Washington State. In a study that evaluated the accuracy of live birth certificates among a population of women giving birth in 19 Washington State hospitals, however, the reported accuracies of this tertiary care hospital were similar to other statewide hospitals.<sup>15</sup>

We found that fetal death certificates had substantial missing data compared with the medical records. A Massachusetts study of 574 fetal cause-of-deaths reported that many fields of the Massachusetts fetal death certificate were incomplete as well.<sup>16</sup> Missing fetal death certificate data result in the underreporting of national surveillance-based vital statistics. The 2003 revised US Standard Report of Fetal Death Certificate includes a greater number of measurements that require advanced judgment on the part of the recorder. Consequently, quality assurance will become increasingly important.<sup>17</sup>

Improvements are needed in the quality of reporting in fetal death certificates. Until then, variables with poor accuracy should be used with caution. Additional population-based studies are needed to identify strategies to improve fetal death certificate data.

#### **About the Authors**

Mona T. Ludon-Rochelle is with the Department of Family and Child Nursing, School of Nursing, and the Department of Health Services, School of Public Health and Community Medicine, University of Washington, Seattle. Jennifer Nelson is with the Center for Health Studies, Group Health Cooperative, and the Department of Biostatistics, School of Public Health and Community Medicine, University of Washington. Vicky Cárdenas is with the Department of Epidemiology, School of Public Health and Community Medicine, University of Washington. Kay Tomashek is with the Maternal and Infant Health Branch, Division of Reproductive Health, Centers for Disease Control and Prevention, Atlanta, Ga. Beth Mueller is with the Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, and the Program in Epidemiology, Division of Public Health Sciences. Fred Hutchinson Cancer Research Center, Seattle. Thomas Easterling is with the Department of Obstetrics and Gynecology, School of Medicine, University of Washington.

Requests for reprints should be sent to Mona T. Lydon-Rochelle, Mail Stop 357262, University of Washington, Seattle, WA 98195–7262 (e-mail: minot@u.washington. edu).

This brief was accepted January 25, 2005.

### **Contributors**

M. T. Lydon-Rochelle led the study design, implementation, and interpretation and supervised all aspects of the study completion and writing of the paper. All authors were involved in design of the study, development of the study protocol, interpretation of the results, and preparation of the paper. V. Cardenas was also responsible for programming and analyses, and J. Nelson was also responsible for the biostatistical design.

#### **Acknowledgments**

This study was funded by a grant from the Council of State and Territorial Epidemiologists.

The authors thank Helen Harte for her medical record abstraction expertise and William O'Brien for his data linkage expertise.

#### **Human Participant Protection**

Prior to conducting this study, approvals were obtained from the human subjects institutional review boards of the University of Washington, Washington State Department of Health, and the Centers for Disease Control and Prevention.

#### References

1. National Center for Health Statistics. Infant mortality rates, fetal mortality rates, and perinatal mortality rates, according to race: United States, selected years, 1950–99 (Table 22). In: *Data Highlights, Infant, Fetal and Perinatal Mortality Rates.* US Department of Health and Human Services, Centers for Disease Control and Prevention, 2001. Available at: http://www.cdc.gov/nchs/ about/major/fetaldth/abfetal.htm. Accessed January 30, 2005.

2. Bruce FC. Highlights from the National Summit on Safe Motherhood: investing in the health of women. *Matern Child Health J.* 2002;6:67–69.

3. Setting a research agenda for stillbirth. National Institutes of Health, National Institute of Child Health and Human Development, 2001. Available at: http:// www.nichd.nih.gov/about/cdbpm/pp/PastMeetings/ stillbirth\_research\_agenda.htm. Accessed January 30, 2005.

4. Gibson E, Culhane J, Saunders T, Webb D, Greenspan J. Effect of nonviable infants on the infant mortality rate in Philadelphia, 1992. *Am J Public Health.* 2000;90:1303–1306.

5. Hoyert DL, Martin JA. Vital statistics as a data source. *Semin Perinatol.* 2002;26:12–16.

6. Cnattingius S, Stephansson O. The epidemiology of stillbirth. *Semin Perinatol.* 2002;26:25–30.

 Barfield WD, Tomashek KM, Flowers LM, Iyasu S. Contribution of late fetal deaths to US perinatal mortality rates, 1995–1998. *Semin Perinatol.* 2002;26: 17–24.

8. Martin JA, Hoyert DL. The national fetal death file. *Semin Perinatol.* 2002;26:3–11.

9. Mathews TJ, Menacker F, MacDorman MF. Infant

# **RESEARCH AND PRACTICE**

mortality statistics from the 2000 period linked birth/ infant death data set. *Natl Vital Stat Rep.* 2002;50: 1–28.

10. Smulian JC, Ananth CV, Vintzileos AM, Scorza WE, Knuppel RA. Fetal deaths in the United States. Influence of high-risk conditions and implications for management. *Obstet Gynecol.* 2002;100:1183–1189.

11. Kramer MS, Liu S, Luo Z, Yuan H, Platt RW, Joseph KS. Analysis of perinatal mortality and its components: time for a change? *Am J Epidemiol.* 2002; 156:493–497.

12. Divon MY, Haglund B, Nisell H, Otterblad PO, Westgren M. Fetal and neonatal mortality in the post-term pregnancy: the impact of gestational age and fetal growth restriction. *Am J Obstet Gynecol.* 1998;178: 726–731.

13. Fretts RC, Boyd ME, Usher RH, Usher HA. The changing pattern of fetal death, 1961–1988. *Obstet Gynecol.* 1992;79:35–39.

14. Alexander GR, Kogan MD, Himes JH, Mor JM, Goldenberg R. Racial differences in birthweight for gestational age and infant mortality in extremely-low-risk US populations. *Paediatr Perinat Epidemiol.* 1999;13: 205–217.

15. Lydon-Rochelle M, Holt VL. Health Insurance Portability and Accountability Act (HIPAA) transition: challenges of a multisite medical records validation study of maternally linked birth records. *Matern Child Health J.* 2004;8:35–38.

16. Lammer EJ, Brown LE, Anderka MT, Guyer B. Classification and analysis of fetal deaths in Massachusetts. *JAM*. 1989;261:1757–1762.

17. US standard report of fetal death. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 2003. Available at: http://www.cdc.gov/nchs/data/dvs/FDEATH11–03finalACC.pdf. Accessed January 30, 2005.