

Provider Adherence to Syphilis Testing Guidelines Among Stillbirth Cases

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Short Summary

A study on prenatal syphilis screening adherence found that majority of women with a stillbirth delivery do not receive syphilis testing in accordance with CDC-recommended screening guidelines.

ABSTRACT

Background: The Centers for Disease Control and Prevention (CDC) recommends that all women with a stillbirth have a syphilis test after delivery. Our study seeks to evaluate adherence to CDC guidelines for syphilis screening among women with a stillbirth delivery.

Methods: We utilized data recorded in electronic health records for women who gave birth between January 1, 2014 and December 31, 2016. Patients were included if they were 18-44 years old and possessed an ICD-9-CM or ICD-10-CM diagnosis of stillbirth. Stillbirth diagnoses were confirmed through a random sample of medical chart reviews. To evaluate syphilis screening, we estimated the proportion of women who received syphilis testing within 300 days before stillbirth, within 30 days after a stillbirth delivery, and women who received syphilis testing both before and after stillbirth delivery.

Results: We identified 1,111 stillbirths among a population of 865,429 unique women with encounter data available from electronic health records. Among a sample of 127 chart reviewed cases, only 35 (27.6%) were confirmed stillbirth cases, 45 (35.4%) possible stillbirth cases, 39 (30.7%) cases of miscarriage, and 8 (6.3%) cases of live births. Among confirmed stillbirth cases, 51.4% had any syphilis testing conducted, 31.4% had testing before their stillbirth delivery, 42.9% had testing after the delivery, and only 22.9% had testing before and after delivery.

Conclusions: A majority of women with a stillbirth delivery do not receive syphilis screening adherent to CDC guidelines. Stillbirth ICD codes do not accurately identify cases of stillbirth.

Keywords: syphilis; Stillbirth; Testing Adherence; Prenatal; pregnancy; Treponema pallidum

INTRODUCTION

A stillbirth is defined as a delivery of fetus born at 20 weeks or greater of gestation with no signs of life¹. Stillbirths have numerous potential causes such as restriction of fetal growth²⁻⁴, chromosomal and genetic abnormalities⁵⁻⁷, and infections⁸, including syphilis⁹. In the United States, the rate of stillbirth slowly declined from 6.05 cases per 1,000 births between 2006 and 2012¹⁰ to 5.89 per 1,000 births in 2017¹¹. Moreover, there are significant disparities in stillbirth rates among racial and ethnic minority groups, suggesting more progress is needed to achieve equity as well as the U.S. Health People 2020 target of 5.6 per 1,000 births¹².

Rates of primary and secondary (P & S) syphilis increased in recent years, with a 72.7% increase from 2013 to 2017 (from 5.5 per 100,000 population to 9.5 per 100,000 population) in the United States¹³. Despite the increase in P & S syphilis being most prominent among men who have sex with men, rates of congenital syphilis have more than doubled during the same time period (9.2 per 100,000 live births to 23.3 per 100,000 live births, respectively)¹³. During this time in Indiana, the rate of P & S syphilis doubled, increasing by 60% among females¹⁴. Congenital syphilis rates rose from 0 to 9.5 cases per 100,000¹⁵. This rise in congenital syphilis rates might indicate a possible increase in syphilitic stillbirth rates during this time period.

The Centers for Disease Control and Prevention (CDC), U.S. Preventive Services Task Force (USPSTF), and the state of Indiana all recommend screening at the time of diagnosis of pregnancy and in the third trimester if a woman is considered “high” risk¹⁶. The USPSTF and CDC also recommend testing at the time of delivery and in the case of stillbirth¹⁷. Despite these recommendations, several studies¹⁸⁻²¹ have shown gaps in screening at the first prenatal visit and failure to rescreen during the third trimester among congenital syphilis cases. Further, a study²² using Truven MarketScan, a claims database which contains approximately 40-50 million

insured patients per year, found that approximately one-third of stillbirth cases did not receive syphilis testing either prenatally or after the stillbirth delivery. The study²² utilized International Classification of Diseases, Ninth Revision, (ICD-9) codes to identify cases of stillbirth. However, the use of ICD-9 codes to identify cases of stillbirth has only been validated once in the U.S., using patients in California from 1992-1993 and therefore may not currently be valid²³. There is little evidence available regarding provider adherence to the CDC syphilis testing guidelines among women with stillbirth. The objective of the study was to utilize electronic health records (EHRs) to evaluate prenatal syphilis screening and syphilis testing after delivery, among women with a stillbirth delivery.

MATERIALS AND METHODS

Study Design and Setting

We employed a retrospective cohort study design using data from the Indiana Network for Patient Care (INPC). The INPC is a health information exchange (HIE) network that connects and aggregates EHRs for more than 100 hospitals representing 38 health systems²⁴. The INPC utilizes a master person index to uniquely link medical records for the same individual across medical encounters, laboratory test results, and clinical procedures. With respect to the state's population, the INPC represents two-thirds of Indiana residents. The INPC is frequently used to study both health services and population health outcomes²⁵.

To assess syphilis testing compliance with CDC guidelines, we compared syphilis laboratory testing dates to the date of stillbirth delivery recorded for women who gave birth between January 1, 2014 and December 31, 2016. This study was approved by Indiana University's Institutional Review Board.

Cohort Assembly and Data Extraction

Women were included if they were aged 18-44 years old and possessed an ICD-9-CM or ICD-10-CM diagnosis of stillbirth delivery documented in the INPC. The ICD-9-CM codes utilized to identify stillbirth delivery were V27.1, V27.3, V27.4, V27.6, V27.7, V32.X, V35.X, V36.X, 656.4, and 779.9. For ICD-10-CM, codes utilized were Z37.1, Z37.3, Z37.4, Z37.6, Z37.7, O36.4, P95, and P96.9. A case of stillbirth delivery was defined based on the presence of at least one of the aforementioned diagnostic codes documented in the INPC aggregated medical record during the study period. The date of the first diagnosis with stillbirth was defined as the date of stillbirth. If a patient received multiple stillbirth diagnostic codes ≥ 20 weeks apart within the study period, that next diagnosis was considered a new case of stillbirth.

Cases of stillbirth were separated into three categories based on the presence of syphilis testing and syphilis test results documented in the INPC during the time interval of 300 days before and 30 days after the date of stillbirth. The categories included cases in which 1) the woman had any positive or reactive syphilis laboratory test; 2) the woman had all syphilis laboratory tests that were negative, non-reactive, or indeterminate; and 3) the woman had no evidence of syphilis laboratory testing. All patient data, including medical record numbers, prenatal encounters (ICD-9-CM: V22.X, V23.X, V28.9, and V72.42; ICD-10-CM: Z34.X, Z36.X, Z3A.X and O09.X), names of institutions that documented the stillbirth delivery, encounter settings, and laboratory test results, during the time interval of 300 days before and 30 days after the date of stillbirth were linked and extracted for each case from the INPC.

Chart Reviews

Data quality checks were performed using medical chart reviews among a sample of stillbirth cases to examine: 1) the diagnosis of stillbirth delivery was correct by reviewing

clinician notes up to 35 days after diagnosis; 2) the syphilis laboratory testing and treatment information might be missing from designated fields in the structured medical record but might be present in clinician notes; or 3) the stillbirth was potentially caused by other underlying conditions which may have been documented in clinician notes, ultrasound results, genetic screening results, placental examinations, and fetal autopsies. A confirmed case of stillbirth was defined as that in which a fetus had no sign of life at the time of delivery and gestational age was 20 weeks or later. A possible case of stillbirth was defined as a case with 1) no sign of life and missing gestational age; or 2) missing information on signs of life at the time of delivery and missing gestational age. A false case of stillbirth was defined as a case in which the fetus was documented to be born alive or gestational age was <20 weeks, which should have been classified as a miscarriage¹.

The sample for medical chart reviews was stratified by category. All positive or reactive syphilis cases were reviewed to verify the clinical diagnosis. For the other two categories, we randomly sampled roughly 10% of remaining cases for data quality purposes to confirm the stillbirth diagnosis and the syphilis laboratory testing result of negative, non-reactive, indeterminate, or lack thereof. Sample size was determined based on our goal of performing a data quality check; generally, a 10% sample of cases is sufficient to identify quality issues. A trained medical chart reviewer (K.A.) conducted all chart reviews. No additional syphilis laboratory testing or treatment information were found in the detailed medical charts, suggesting the dataset contained all of the available information from the INPC. Additionally, no other potential causes of stillbirths were found.

Assessment of Provider Adherence

In order to assess provider adherence to guidelines, we examined whether and the number of times a woman was tested for syphilis during the pregnancy and after the stillbirth delivery for each case. Laboratory tests were included up to 300 days before and 30 days after the date of stillbirth to allow for potential delays in clinical documentation. A case was determined to have received prenatal testing of syphilis if testing occurred within 1 to 300 days before the stillbirth diagnosis. A case was determined to have received post-delivery testing of syphilis if testing occurred on the same day of the stillbirth diagnosis or up to 30 days after the date of stillbirth. For a confirmed or possible stillbirth case to be considered adherent to guidelines, the case had to possess both prenatal testing and post-delivery testing of syphilis. Among positive syphilis cases, we did not require cases to have the presence of syphilis testing among the 1st trimester and 3rd trimester due to the possibility of the stillbirth delivery occurring before the 3rd trimester, and some cases did not document the gestational age of fetus at the time of delivery.

Statistical Analyses

Prevalence of provider adherence to guidelines was estimated and stratified by stillbirth case status. We further examined adherence based on whether the medical record contained documentation of prenatal visits. All analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Overall Cohort Description and Category Classifications

Over the 2-year study period, a total of 865,429 unique women, between the ages of 18 and 44 years old, had at least one encounter in the INPC. Of these, 1,111 (0.1%) women received a stillbirth ICD-9-CM or ICD-10-CM diagnosis.

When categorized, there were 2 (0.2%) syphilis positive stillbirth cases, 527 (47.4%) stillbirth cases in which syphilis laboratory testing occurred with a negative/indeterminate result, and 582 (52.4%) stillbirth cases that possessed no documentation of syphilis laboratory testing. A total 127 chart reviews from 18 different institutions were conducted: 2 syphilis positive cases; 53 (10.1%) cases with a negative/indeterminate laboratory result; and 72 (12.4%) cases with no syphilis laboratory testing.

Assessment of ICD-based Stillbirth Diagnosis

No cases with multiple deliveries were found from chart review. The 2 syphilis positive cases had reactive nontreponemal, rapid plasma regain (RPR) testing, but no confirmatory treponemal test was conducted.

Chart reviews of 127 cases revealed only 35 (27.6%) confirmed stillbirth cases, 45 (35.4%) possible stillbirth cases, 39 (30.7%) cases of miscarriage, and 8 (6.3%) cases with live births (Table 1). Of the possible stillbirth cases, 13.3% (6/45) had missing information on signs of life at time of delivery and 86.7% (39/45) had missing information on both gestational age and signs of life. Demographic information for the total cases and those charts reviewed are provided in Table 1. Among the miscarriage cases, gestational age ranged from 6 weeks to 19 weeks plus 6 days and the average length of gestation was 12.6 weeks.

Assessment of Provider Adherence

Only 22.9% (8/35) of confirmed stillbirth cases and 2.2% (1/45) possible stillbirth cases had both prenatal syphilis testing and post-delivery syphilis testing to adhere to guidelines. When looking at the entire cohort, only 10.7% (119/1111) cases had both prenatal syphilis testing and post-delivery syphilis testing. Syphilis testing in general was low as only 37.8% (48/127) among the chart review sample and 47.6% (529/1111) among the total cohort had any syphilis testing

before or after delivery. When only assessing if cases were tested after stillbirth, 42.9% (15/35) confirmed stillbirth cases, 8.9% (4/45) possible stillbirth cases, and 29.8% (331/1111) among the total cohort were tested for syphilis after the stillbirth diagnosis. Of the two cases which tested positive for syphilis during the pregnancy period, neither case was tested for syphilis at the time of or following the stillbirth diagnosis. Assessment of syphilis testing after the stillbirth delivery found no positive syphilis laboratory test results for any cases. However, one case was found to be treated for syphilis (identified in provider notes) following a confirmed stillbirth. The case had no syphilis laboratory testing before or after the stillbirth delivery. Syphilis testing information is presented in Table 3.

Assessment of Prenatal Visits

In the subset of chart reviewed cases, assessment of prenatal visits found that 100% (2/2) of syphilis positive cases, 66.0% (35/53) of cases which received syphilis testing, and 29.2% (21/72) of cases with no syphilis testing had at least one prenatal visit. When stratified by stillbirth case status, 48.6% (17/35) of confirmed stillbirth cases, 35.6% (16/45) of possible stillbirth cases, 75% (6/8) of live birth cases, and 48.7% (19/39) of miscarriage cases had at least one prenatal visit. Of the 58 cases with a prenatal visit, 37 (63.8%) cases were tested for syphilis before the date of stillbirth.

DISCUSSION

Using a population-based cohort, we examined provider adherence to CDC recommended laboratory testing guidelines for stillbirth deliveries. First, we discovered that ICD codes for stillbirth do not accurately identify cases of stillbirth. Second, we found that few cases

of stillbirth delivery are compliant with laboratory testing recommendations. Without compliant syphilis screening, congenital syphilis cases, including syphilitic stillbirths, are unlikely to be identified and reported to the national STD surveillance system. The study provides both methodological guidance for secondary analysis of administrative health data and identifies further areas for study as well as intervention to improve syphilis screening in stillbirth delivery cases.

Due to the rate of confirmed stillbirth cases observed in this study for ICD-based stillbirth delivery codes, we do not recommend the use of ICD codes alone to identify cases of stillbirth delivery for secondary analyses. To better identify stillbirth cases, our study suggests that gestational ages and additional information about status of delivery are needed to confirm case status. Unfortunately, many cases identified as possible stillbirth cases lacked sufficient structured data in the patient's medical record to confirm case status. Although documentation of delivery details does exist in free-text clinical notes from obstetrics and gynecology (OB/GYN) providers, such data may not be readily available in HIE networks for use by quality improvement, public health, or research teams. While the INPC receives laboratory test results ordered by OBGYN providers, not all EHR systems used in OB/GYN clinics submit medical records to the HIE data network.

Another key finding is that the majority of women with a stillbirth delivery do not receive syphilis testing adherent to CDC guidelines as only 22.9% (8/35) of confirmed stillbirth cases and 2.2% (1/45) possible stillbirth cases were found to be adherent. Our results indicate provider knowledge of guidelines may be low based on the number of confirmed stillbirth cases, 42.9% (15/35), which were tested for syphilis following a stillbirth delivery. Results also show that most pregnant women with a stillbirth diagnosis in Indiana are not receiving syphilis testing at

any time during their pregnancy or after a stillbirth or miscarriage, as only 37.8% of chart reviewed cases and 47.6% of the total stillbirth population had any syphilis testing. These findings suggest that more public health interventions are required to ensure that all pregnant women are screened for syphilis and that additional provider education may be required to ensure syphilis screening occurs after a stillbirth delivery. Finally, these findings may have implications for public health surveillance and indicate that cases of congenital syphilis may be underdiagnosed and underreported.

Based on the assessment of prenatal visits, if a patient had a prenatal visit, they tended to be tested for syphilis during their pregnancy. However, 54.3% of cases had no prenatal visits, suggesting further public health interventions are needed to ensure pregnant women in Indiana receive prenatal care. This result is significant as one case, without prenatal syphilis testing, was found to be treated for syphilis immediately following a confirmed stillbirth. However, no autopsy was performed on the fetus and placental examination results were missing from the patient record to determine if syphilis was a cause of fetal demise. Lack of documentation hinders after-action mortality review by public health professionals in coordination with health system providers.

This study has several limitations. The INPC may not capture all prenatal visits as the HITECH Act²⁶ did not require specialty care, such as OB/GYN clinics, to participate in health information exchange. Because of this, patient visit data may only be available within a specialty EHR system. Thus, cases might have had prenatal visits, but the visit information, including gestational age, last menstrual period, expected date of delivery, and potential causes of stillbirth, was not present in the INPC. Therefore, we could not assess when prenatal care began during a pregnancy. However, laboratory testing information from all settings, including OB/GYN

clinics, should be captured in the INPC as laboratory results are sent to the INPC directly from public, hospital, and commercial laboratories. An additional limitation was that we may have included syphilis testing not associated with a pregnancy as we included all syphilis testing up to 300 days before a stillbirth diagnosis. We chose this cutoff because we believed that the conception date could not accurately be determined, and a more restrictive cutoff may exclude some prenatal syphilis testing. Our results may therefore overstate syphilis testing during pregnancy. Another limitation was that the low rate of syphilis testing following delivery may have been due to providers forgoing testing because the cause of the stillbirth was known prior to delivery. However, this theory could not be confirmed despite our chart review. Additionally, the rates of provider adherence and misclassification of stillbirth may have differed between providers, facilities, or health systems. However, we could not assess these differences due to data agreements between the INPC and health systems which prohibit these comparisons. Finally, the findings of this study may not be generalizable outside of the state of Indiana, however patients were from multiple health systems of various sizes.

In conclusion, ICD codes for stillbirth should be utilized cautiously when identifying case of stillbirth in administrative data, and provider adherence to CDC guidelines for syphilis testing is low. The results in this study may provide helpful information for public health's efforts in addressing stillbirths and congenital syphilis.

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ACCEPTED

Table 1. Demographic information stratified by case status.

	Chart Reviewed					All ICD Cases	
	Confirmed Stillbirth (n=35)	Possible Stillbirth (n=45)	Live Birth (n=8)	Miscarriage (n=39)	Total (N=127)	Count (N=1,111)	Percentage (%)
Maternal Age at Delivery (Years)							
<20	5	4	0	3	12	92	8.28
20-34	24	32	8	22	86	844	75.97
35-39	0	5	0	9	14	131	11.79
40+	6	4	0	5	15	44	3.96
Maternal race/ethnicity							
White (Non-Hispanic)	26	22	5	26	79	663	59.68
Black (Non-Hispanic)	5	3	1	6	15	121	10.89
Hispanic or Latino	0	1	0	1	2	11	0.99
American Indian or Alaska Native	0	0	1	0	1	3	0.27
Asian	0	0	0	0	0	1	0.09
Other	3	5	1	4	13	110	9.90
Unknown	1	14	0	2	17	202	18.18
Stillbirth ICD Diagnosing Setting							
Emergency Department	2	7	0	17	26	131	11.79
Inpatient	23	8	4	14	49	65	5.85
Obstetrics	0	2	0	2	4	1	0.09
Outpatient	3	6	3	5	17	237	21.33
Unknown	7	22	1	1	31	677	60.94

Location of ICD diagnosing setting was determined by the location in which the stillbirth ICD diagnosis was recorded.

Table 2. Chart reviewed stillbirth case status stratified by category.

	Case Status				Total
	Confirmed Stillbirth	Possible Stillbirth	Live Birth	Miscarriage	
Syphilis Positive	0	1	0	1	2
Received Syphilis Laboratory Testing with Negative or Indeterminate Result	21	10	4	18	53
No Syphilis Laboratory Testing	14	34	4	20	72
Total Case Statuses	35	45	8	39	127

Cases represent a pregnancy episode which possessed at least one stillbirth diagnostic code and do not reflect the number of deliveries.

Table 3. Syphilis testing adherence stratified by case group and case status

		Any Testing*			Testing Before Delivery			Testing After Delivery**			Testing Before and After Delivery**		
		Yes	No	% Tested	Yes	No	% Tested	Yes	No	% Tested	Yes	No	% Tested
Chart Reviewed	Confirmed Stillbirth (n=35)	18	17	51.4%	11	24	31.4%	15	20	42.9%	8	27	22.9%
	Possible Stillbirth (n=45)	8	37	17.8%	5	40	11.1%	4	41	8.9%	1	44	2.2%
	Live Birth (n=8)	4	4	50.0%	4	4	50.0%	2	6	25.0%	2	6	25.0%
	Miscarriage (n=39)	18	21	46.2%	17	22	43.6%	8	31	20.5%	8	31	20.5%
	Total	48	79	37.8%	37	90	29.1%	29	98	22.8%	19	108	15.0%
All Cases	Total Cases (N=1,111)	529	582	47.6%	317	794	28.5%	331	780	29.8%	119	992	10.7%

*Any testing was defined as any testing within 300 days before or 30 days after delivery.

**Testing after delivery was defined as syphilis testing on the same day or 30 days after the stillbirth diagnosis.