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Improving Surveillance for the Hidden Half of Fetal-Infant Mortality

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Doctor of Philosophy

Epidemiology

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Abstract

Improving Surveillance for the Hidden Half of Fetal-Infant Mortality

By Lauren Christiansen-Lindquist

Stillbirths, defined as the death of a fetus of at least 20 weeks' gestation, devastate and forever change the lives of the 26,000 families who endure them annually in the United States. Despite a similar annual prevalence as infant mortality, far fewer resources are allocated to understanding and preventing stillbirths. Vital statistics, the only source of national stillbirth data, are limited due to underreporting and poor data quality. To date, there have been no multi-site population-based estimates of stillbirth incidence in the US, and it is unknown whether fetal death certificate (FDC) data quality varies by maternal and delivery characteristics. Additionally, it is unclear whether FDC reporting of gestational age represents age at death or delivery. We addressed these gaps using the Stillbirth Collaborative Research Network's (SCRN) multi-site, population-based, case-control study of stillbirth. SCRN stillbirths enrolled in DeKalb County, GA and Salt Lake County, UT were linked to FDCs.

To estimate the incidence of stillbirth among residents of DeKalb and Salt Lake Counties, we compared SCRN- and FDC-identified stillbirths using capture-recapture methods. Estimates using SCRN and FDC data were higher than those obtained by FDCs alone for both counties; this difference was more striking for DeKalb than for Salt Lake County.

The second study described the completeness and accuracy of the FDC among SCRN enrollees in DeKalb and Salt Lake Counties with a linked FDC, using SCRN as the gold standard. Data quality varied by FDC item and county of residence, and, with few exceptions, was not associated with maternal and delivery characteristics.

The final study compared gestational age reported on the FDC to SCRN's estimate of gestational age at death. The FDC did not provide a good estimate of the gestational age at death for most stillbirths. The difference between these values was not associated with the timing of the stillbirth relative to labor initiation or county of residence, which suggests that dating of all stillbirths needs improvement.

Taken together, these studies demonstrate the need for improvement of stillbirth surveillance and provide a better description of the limitations of these data than was previously available.

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And finally, to my own little family: Matt, Ethan, Reid, and Celeste. Without you, none of this would have been possible.

> To Ethan and Reid: Mommy loves you "to the moon and the sandbox"—always follow your dreams, no matter how crazy they might seem. I will support you and stand beside you, cheering you on—*always*.
>
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>
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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

Stillbirths, defined as the death of a fetus of at least 20 weeks' gestation, devastate and forever change the lives of the 26,000 families who endure them annually in the United States. Despite an annual prevalence and emotional burden similar to that of infant mortality, far fewer resources are allocated to understanding and preventing stillbirths. Vital statistics, the only source of national stillbirth data, are limited due to underreporting and poor data quality. To date, there have been no multi-site population-based estimates of stillbirth incidence in the US, and it is unknown whether fetal death certificate (FDC) data quality varies by maternal and delivery characteristics. Additionally, it is unclear whether FDC reporting of gestational age represents the fetus's age at death or delivery. We addressed these gaps using the Stillbirth Collaborative Research Network's (SCRN) multi-site, population-based, case-control study of stillbirth. SCRN stillbirths enrolled in DeKalb County, GA and Salt Lake County, UT were linked to FDCs.

CHAPTER 2: STILLBIRTH IN THE UNITED STATES

Definitions: Fetal Death and Stillbirth in the United States

The Centers for Disease Control and Prevention (CDC) defines fetal death, as follows:

> "…death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps" [1] (pg. 2).

There is no standard definition for the reporting of fetal deaths because each reporting area (the 50 states, New York City, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam) creates its own reporting requirements stating which fetal deaths must be reported. To assist in determining when a fetal death should be reported, the CDC provides the following guidance:

> "Each fetal death of 350 grams or more, or if weight is unknown, of 20 completed weeks gestation or more, calculated from the date last normal menstrual period began to the date of delivery, which occurs in this state shall be reported within 5 days after delivery to the (Office of Vital Statistics) or as otherwise directed by the State Registrar" [1] (pg. 8).

Since national estimates of stillbirth are typically reported for fetal deaths occurring among fetuses of at least 20 weeks' gestation,[2] this is the definition that we will consider for this dissertation. Although a fetal death describes a loss at any time during pregnancy, the terms stillbirth and fetal death are often used interchangeably. For the purposes of this dissertation, we will use the term stillbirth to refer to fetal deaths of at least 20 weeks' gestation. The exception to this is when discussing data obtained from vital records, as these data come from '*fetal death* certificates.'

Prevalence of Stillbirth

In 2006 (the most recent year for which published data are available), nearly 26,000 stillbirths (or 6.05 stillbirths per 1,000 live births and stillbirths) were reported in the United States.[2] Despite an annual prevalence similar to that of infant deaths (death of a child before age 1),[3] which receives great attention in both advocacy and research, much less has been done to describe, understand, and improve stillbirth rates.

Stillbirth rates declined steadily and significantly between 1990 and 2003, declined only slightly (but not statistically significantly) from 2003-2005, and declined by 3% from 2005-2006.[2] Nearly all of the improvement in the stillbirth rates between 1990 and 2003 can be attributed to a drop in the rates among fetuses at 28 weeks' gestation or more. The rates of stillbirth between 20 and 27 weeks' gestation changed very little during the same period. This difference is likely due to improvements in health care in the third trimester of pregnancy and delivery, which only influence stillbirth rates at later gestations. Contrary to earlier trends, the decline in the stillbirth rates between 2005 and 2006 was only among stillbirths from 20-27 weeks' gestation.[2]

Stillbirth rates vary by maternal demographic characteristics.[2] The stillbirth rate for Non-Hispanic Black women is 2.2 times that of Non-Hispanic White women. Non-Hispanic Black women are also more likely than Non-Hispanic White women to have a stillbirth at earlier gestations. Women aged 25-29 years have the lowest stillbirth rates—compared to this group, teenagers younger than 15 years and women aged 45 years and older have at least twice the rates of stillbirth. Stillbirth rates are also higher among unmarried women, male fetuses, and multiple gestations, compared to married women, female fetuses, and singleton pregnancies, respectively. Stillbirth rates also vary by period of gestation: in 2006, 51% of all stillbirths occurred between 20 and 27 weeks' gestation (with just over one-third of stillbirths occurring between 20 and 23 weeks' gestation), 49% of stillbirths occurred at 28 weeks' gestation or later.[2]

These estimates all reflect the known prevalence of stillbirth, as they rely on vital records for reporting. As we will discuss later, stillbirths are known to be underreported in the United States.[4-8] To date, there have been no multi-site studies of the incidence of stillbirth in the US. An estimate of the incidence of stillbirth is needed to better describe the burden of stillbirth in the United States.

Factors Associated with Stillbirth

Two recent reviews identified major risk factors for stillbirth in developed countries, many of which could potentially be reduced through intervention, and some have a behavioral or socio-cultural component.[9,10] These factors are as follows: maternal overweight and obesity, smoking during pregnancy, advanced maternal age, Non-Hispanic Black race, lower maternal educational attainment, nulliparity, previous stillbirth, interpregnancy interval less than 18 months, small for gestational age (SGA), and placental abruption.

Causes of Stillbirth

The main causes of stillbirth in the United States are as follows: placental abruption (10-20% of stillbirths),[11] congenital anomalies (25%),[12] infection (10-25%),[13-15] cord accidents (15%),[16] fetal-maternal hemorrhage (5-14%),[17] and maternal medical conditions (e.g. hypertension, diabetes, lupus, chronic renal disease, thyroid disorders, and cholestasis in pregnancy) (10%).[18] Stillbirths occurring before 24 weeks' gestation are often associated with infection and obstetric complications, whereas those occurring after 24 weeks' gestation are associated with placental disorders.[19] Unfortunately, even with complete postmortem examination, the cause of death remains unknown in approximately 25% of cases.[19,20]

CHAPTER 3: VITAL STATISTICS FOR STILLBIRTH – FETAL DEATH CERTIFICATE DATA QUALITY

Vital statistics are the only nationally available data for stillbirths, and are plagued by five different issues affecting the data quality. These areas of concern are: inconsistent definitions of fetal death, incomplete registration, data completeness, data accuracy, and data availability.

Fetal Death Definitions by Reporting Area

In the United States, data collection for vital events is part of a decentralized system, with the responsibility for registering events given to each reporting area (e.g. state or territory). The CDC recommends that pregnancy losses of fetuses weighing at least 350 grams, or 20 weeks' gestation be reported. Despite this guidance, not all reporting areas apply the same definition when considering whether a pregnancy loss should be reported.[21] The majority of reporting areas apply one or both of the criteria set forth by CDC, with some starting reporting at earlier gestations. Ten reporting areas require reporting for losses at all periods of gestation. Three states require reporting of stillbirths having a birth weight of at least 500 grams, which roughly corresponds to 22 weeks' gestation. Different definitions of stillbirth pose serious challenges to surveillance, particularly when it comes to making comparisons across states.

Incomplete Registration of Fetal Deaths

Even if a pregnancy loss meets the requirements for reporting, a fetal death certificate may not always be issued; additionally, the degree of non-reporting is not random. One study of stillbirths in the state of Wisconsin found that 17.8% of stillbirths identified through the Wisconsin Stillbirth Service Project (WiSSP) did not have a fetal death certificate on file.[6] Stillbirths with low birth weights and those with lower estimated gestational ages were more likely to be unreported than their larger and older counterparts, despite meeting the criteria for reporting in Wisconsin. Another study in Washington State found that 7.5% of stillbirths occurring in sixteen hospitals did not have a corresponding fetal death certificate.[7] Again, those stillbirths that were unreported had both lower fetal weights and occurred earlier in gestation. Two other studies, one in an HMO population in California[5] and the other among Atlanta-area stillbirths with birth defects,[4] reported similar findings. In the study of stillbirths with birth defects, Duke and colleagues also found that reporting was associated with race/ethnicity and autopsy status, such that fetuses of Non-Hispanic Black and Hispanic mothers and those who had an autopsy were significantly more likely to have been issued a fetal death certificate. These associations remained significant after adjustment for gestational age. County of residence and the class of birth defect were not associated with having a fetal death certificate on file.

It is believed that the completeness of reporting is influenced by the lower limit for reporting set by each state, such that deaths occurring at gestations towards the beginning of the reporting period are less likely to be reported than those occurring later in pregnancy.[7,8] The different limits for reporting of pregnancy losses in the United States are shown in Table 2.1 below.

Table 2.1. Fetal death reporting requirements in the United States

Reporting Requirements	Number of Reporting Areas (50 states, New York City, District of Columbia)
All periods of gestation	8
16 weeks	1
20 weeks	25
20 weeks or 350 grams	12
350 grams	1
20 weeks or 400 grams	1
20 weeks or 500 grams	1
500 grams	3

The wide range of definitions of stillbirth shown in Table 2.1 is problematic, especially when comparing stillbirth rates across the country. The National Center for Health Statistics (NCHS) reports the proportion of stillbirths (losses occurring at 20 weeks' gestation or later) occurring between 20 and 27 weeks' gestation by state reporting requirements. States that report all pregnancy losses, irrespective of the period of gestation, and those that begin reporting at 16 weeks' gestation have comparable rates of these "early" stillbirths (58% and 57%, respectively). The proportion of "early" stillbirths in states that begin reporting at 20 weeks' gestation or 350 grams is slightly lower at 50%. For states that require reporting of fetuses weighing at least 500 grams (corresponding to approximately 22 weeks' gestation), the proportion of "early" stillbirths is only 28%. These figures demonstrate that reporting areas that don't require reporting until later in gestation are missing a substantial number of pregnancy losses that would meet the definition of a stillbirth, but do not meet the reporting requirements for their area.

Completeness of the Fetal Death Certificate

In addition to differences in the definition of fetal death, states have varying levels of completeness of data elements on the fetal death certificate.[8,22] In 2005, 11.9% of fetal death records were missing the delivery weight of the fetus (range of states: 0% - 78.5%),[22] while only 0.1% of birth certificates were missing the delivery weight for live born babies (range: <0.05% - 0.4%).[23] Other key variables are frequently missing including: mother's educational attainment, information about prenatal care, maternal tobacco use, complications of labor and delivery, and congenital anomalies of the fetus. A study of 2,226 stillbirths occurring in the state of Georgia between 1989-1990 found that 15% of the records were missing data on birth weight or gestational age.[24]

In an effort to improve stillbirth surveillance, Duke and colleagues sought to expand a population-based surveillance system for birth defects to include all stillbirths occurring in metropolitan Atlanta.[25] To do this, they selected a random sample of stillbirths (both with and without birth defects) and linked the fetal death certificates to data collected by the Metropolitan Atlanta Congenital Defects Program (MACDP). They found high levels of missing data for several fetal death certificate items, including paternal age (73.5% missing), fetal sex (8.8%), date of last menstrual period (4.9%), birth weight (10.8%), weight gain during pregnancy (69.6%), number of previous pregnancies

(10.8%), alcohol use during pregnancy (17.6%), tobacco use during pregnancy (17.6%), and cause of death or potentially associated condition (42.2%).

While it is known that fetal death certificates suffer from frequently missing data, it is unknown whether data are more likely to be missing by certain maternal and delivery characteristics. If fetal death certificate data are more likely to be missing by these characteristics, the information that we obtain from these vital statistics will systematically underrepresent certain groups. Additionally, if we lack information on key variables, we are unable to accurately identify and target areas for reducing stillbirth rates.

Accuracy of Data Reported on the Fetal Death Certificate

Even with completed fields on the fetal death certificate, there is great concern about the accuracy of the data reported.[4,24,26-30] Little can be done with the available data if they are of poor quality.

When comparing fetal death certificates to stillbirths identified through the Wisconsin Stillbirth Service Project (WiSSP), Greb et al. found sex, birth weight, and gestational age to be mostly accurately reported on the fetal death certificate.[6] Fetal abnormalities, however, were less likely to be correctly reported: 40% of stillbirths with fetal anomalies had no such indication on the fetal death certificate, and 9% of stillbirths without fetal abnormalities were documented as having an abnormality on the fetal death certificate. Discrepancies were also noted between the fetal death certificate and WiSSP records for the cause of fetal death.

A study in the state of Georgia sought to improve fetal death data from 1989-1990 by identifying cases with missing and implausible values of birth weight and gestational age.[24] Researchers queried the reporting hospitals to obtain the correct information from medical records. Birth weight was determined to be implausible if it fell outside of the upper or lower limits of gestational age-specific birth weight distributions. Any stillbirths with a gestation of 43 weeks or more were also considered improbable and were queried for hospital record review. Values were either missing or improbable for 817 (36.7%) of stillbirths in the study; of these, 88% had data available for review. Of the 460 records that had questionable values for birth weight, 27% were found to have had an incorrect birth weight recorded on the fetal death certificate.

Similarly, of the 704 records with implausible gestational age values, 23.3% were found to have been incorrectly reported on the fetal death certificate.

Lydon-Rochelle and colleagues sought to assess the validity of maternal and perinatal risk factors reported on the fetal death certificate by comparing specific elements to data from medical record abstraction.[29] Data were missing from the fetal death certificate for 1.4%-25.1% of these factors, which resulted in dropping a significant number of records from the analysis. They found that the validity of the following data items on the fetal death certificate was generally good: number of prior births, established diabetes, chronic hypertension, maternal fever, whether an autopsy was performed, plurality, anencephaly, and Down syndrome. Reporting was less accurate for the following variables: previous miscarriages, gestational diabetes, anemia, amniocentesis, uterine bleeding, placental cord conditions, cord prolapse, and other chromosomal abnormalities.

Another study linked fetal death certificates to the Metropolitan Atlanta Congenital Defects Program (MACDP), a birth defects surveillance program, to collect data on stillbirths with birth defects.[4] The authors found that the fetal death certificates had good or very good agreement with data collected through the surveillance system on maternal age, gestational age, and fetal weight. In this population of stillbirths with congenital defects, only 50% of the fetal death certificates reported these defects. Additionally, the fetal death certificate erroneously identified certain cases as having specific congenital defects which, according to MACDP's review, they did not have. Using the same dataset, but for the purposes of improving stillbirth surveillance, Duke and colleagues found excellent agreement or strong correlation between the fetal death certificate and data collected on: county of residence, maternal race or ethnicity, fetal sex, reported alcohol and tobacco use, plurality, gestational age, fetal weight, maternal and paternal age, date of delivery, last menstrual period, weight gain during pregnancy, and number of previous pregnancies.[25] Any information pointing to the cause of fetal death was lacking in 42.2% of stillbirth cases.

A study in Utah compared fetal death certificates to medical records from eight Salt Lake City hospitals from 1998-2002 to determine the accuracy of reporting of stated cause of death, maternal demographics, and obstetric details.[27] To be eligible for review, each stillbirth had to have both a fetal death certificate on file as well as a medical record available for review. Gestational age and birth weight were generally accurately reported on the fetal death certificate. The authors used two different classification systems for determining the cause of death to determine the accuracy of reporting of this variable on the fetal death certificate. Under both classification systems, just under half of the stillbirths were assigned an incorrect cause of death on the fetal death certificate.

While misreporting of information on the fetal death certificate has been documented, it is unclear whether data are more likely to be misreported by maternal and delivery characteristics. Again, if data are more likely to be misreported for one group compared to another, the resulting data are likely to provide a skewed portrait of the true distribution of stillbirth in the United States, which limits our ability to focus appropriate interventions to reduce stillbirth rates.

Fetal Death Data Availability

A final concern regarding the available data for fetal deaths is the frequency with which fetal death statistics are released. The most recent published reports for stillbirths in the US from the National Center for Health Statistics (NCHS) are from 2006, compared to 2013 for live births.[2,31] Without up-to-date data, it is difficult for public health professionals and policy makers to make decisions on policies and programs aimed at improving fetal and maternal health.

CHAPTER 4: STILLBIRTH COLLABORATIVE RESEARCH NETWORK

In 2001, a workshop of experts was convened by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) to set a national agenda for stillbirth research.[32] A product of this workshop was the Stillbirth Collaborative Research Network (SCRN), which was established in 2003. The purpose of SCRN was to:

> "(i) determine the causes of stillbirth using a standardized stillbirth postmortem protocol, to include review of clinical history, protocols for post-mortem and pathological examinations of the fetus and placenta, as well as other post-mortem tests to illuminate genetic, maternal and other environmental influences; (ii) obtain a geographical population-based determination of the incidence of stillbirth, defined as fetal death at $\geq$20 weeks' gestation; and (iii) elucidate risk factors for stillbirth"[33] (pg. 426).

The Stillbirth Collaborative Research Network (SCRN) conducted a multisite, population-based case-control study that enrolled mothers of both stillbirths and a sample of live births at the time of delivery. This study has been described in detail elsewhere.[33] The study took place in five clinical sites, each with corresponding catchment areas: Brown University (State of Rhode Island, and Bristol County, MA), Emory University (DeKalb County, GA), University of Texas Medical Branch—Galveston (Galveston and Brazoria Counties, TX), University of Texas Health Science Center—San

Antonio (Bexar County, TX), and the University of Utah (Salt Lake County, UT). Hospitals were selected for participation such that at least 90% of all pregnancies of catchment area residents ending in a stillbirth (gestation $\geq$ 20 weeks) or a live birth would be identified and potentially approached to consent in the study. Eligible residents were at least 13 years of age and identified for potential participation prior to hospital discharge. An effort was made to enroll mothers of all eligible stillbirths. The following data were collected for both consenting mothers of stillbirth cases and live birth controls:

1) Maternal interview: social information, demographics, reproductive history, complications of the index pregnancy, early indications of problems with the pregnancy, psychosocial data, and medical history;
2) Abstraction of prenatal care records; and
3) Biological specimens: maternal blood, umbilical cord section, placental sections, and cord blood from infants and fetuses.

For stillbirth cases, additional biological specimens were collected from the fetus, including: fetal tissue, heart blood, and meconium.

All of the analyses for this dissertation used data collected by SCRN. These data were linked with fetal death certificates to:

1) Estimate the incidence of stillbirth among residents of DeKalb and Salt Lake Counties from January 1, 2007 – June 15, 2009, overall and by maternal race/ethnicity *(Chapter 5)*
2) Evaluate the completeness and accuracy of fetal death certificate data among SCRN stillbirths enrolled in DeKalb and Salt Lake Counties *(Chapter 6)*
3) Determine whether gestational age as reported on the fetal death certificate provides an estimate of the gestational age at death *(Chapter 7)*

CHAPTER 5:

USING CAPTURE-RECAPTURE METHODS TO OBTAIN A GEOGRAPHICAL POPULATION-BASED ESTIMATE OF THE INCIDNCE OF STILLBIRTH IN TWO US COUNTIES

Using capture-recapture methods to obtain geographical population-based estimates of the incidence of stillbirth in two US counties

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Objectives: To obtain geographical population-based estimates of the incidence of stillbirth (death of a fetus $\geq$ 20 weeks' gestation) in DeKalb County, Georgia and Salt Lake County, Utah from January 1, 2007 – June 15, 2009, overall and by maternal race/ethnicity.

Methods: Stillbirths prospectively identified by the Stillbirth Collaborative Research Network's (SCRN) case-control study of stillbirth in DeKalb and Salt Lake Counties were compared to fetal death certificates (FDCs) for residents of these counties during the study period. Through linkage and data checks, we identified FDCs that did not meet eligibility criteria (duplicates, induced terminations of pregnancy, out-of-county residents, gestational age < 20 weeks, or neonatal deaths). The total number of stillbirths that occurred among residents of DeKalb and Salt Lake Counties during the study period were estimated using capture-recapture methods. These estimates were used to calculate stillbirth rates, overall and by maternal race/ethnicity, which were compared to the rates obtained using vital records alone.

Results: Thirty-seven of the 318 DeKalb County FDCs (11.6%) and 10 of the 267 Salt Lake County FDCs (3.7%) did not meet eligibility criteria for inclusion. The proportions of SCRN-identified stillbirths in DeKalb and Salt Lake Counties with a linked FDC were 85% and 95%, respectively. Among FDCs without a known ineligibility, SCRN identified 49% in DeKalb County and 91% in Salt Lake County. The overall estimated stillbirth rates for DeKalb (13.42 per 1,000 live births plus stillbirths) and Salt Lake (5.77 per 1,000)

Counties were higher than the rates obtained using vital records alone (Dekalb – 10.92 per 1,000; Salt Lake – 5.58 per 1,000).

Conclusions: Stillbirths are underreported to vital records, and the degree of underreporting is associated with reporting area. Researchers and clinicians should consider stillbirth rates obtained by vital records to be the lower limit of the true rates. Delivery attendants need training in the public health importance of reporting stillbirths, and efforts to improve stillbirth reporting will likely need to happen at the level of the reporting area.

Keywords: stillbirth, incidence, fetal death certificate, vital records, capture-recapture

Introduction

Stillbirths, defined as the death of a fetus of at least 20 weeks' gestation, account for approximately half of all fetal-infant mortality in the United States.[2] Despite a similar annual prevalence as infant mortality, far fewer resources have been allocated to preventing stillbirths. Further, the stillbirth rate, defined as the number of stillbirths per 1,000 live births and stillbirths, declined much more slowly during 1990-2006 than did the infant mortality rate.[2] These rates are calculated using vital statistics data, which rely on complete and accurate reporting of stillbirths. Previous research has shown that not all stillbirths are registered,[4-8,34] which results in an underestimate of the true stillbirth rate. These studies showed that non-registration of stillbirths is not random; fetuses of younger gestational age and lower birth weights were less likely to be registered than their older and bigger counterparts. Duke and colleagues also found that fetuses of non-Hispanic Black and Hispanic mothers and those who had had an autopsy were more likely to have been issued a fetal death certificate than babies born to non-Hispanic White mothers and those who did not have an autopsy.[4] Completeness of stillbirth reporting is also associated with the reporting requirements of the reporting area, such that losses occurring near the lower limit of the reporting area are more likely to be unreported.[2] Reporting areas that require registration of all fetal deaths (irrespective of length of gestation), or areas that require reporting starting at 16 weeks' gestation tend to have more complete reporting than those that start reporting at 20 weeks' gestation or for fetal deaths with birth weights of at least 500 grams.

Like any public health concern, we cannot appropriately target prevention strategies for stillbirths if we cannot accurately describe the magnitude of the problem. In an effort to obtain an estimate of the incidence of stillbirth, we combined data from the Stillbirth Collaborative Research Network's (SCRN) case-control study of stillbirth with vital statistics data. We estimated the incidence of stillbirth among residents of DeKalb County, GA and Salt Lake County, UT from January 1, 2007 – June 15, 2009 using a capture-recapture method. Stillbirths identified by SCRN were compared to fetal death certificates (FDCs) for pregnancy losses occurring at 20 weeks' gestation or later among residents of these counties.

Methods

The Stillbirth Collaborative Research Network (SCRN) conducted a multisite, population-based case-control study that enrolled mothers of both stillbirths and a sample of live births at the time of delivery. This study has been described in detail elsewhere.[33] The study took place in five clinical sites, each with corresponding catchment areas: Brown University (State of Rhode Island, and Bristol County, MA), Emory University (DeKalb County, GA), University of Texas Medical Branch—Galveston (Galveston and Brazoria Counties, TX), University of Texas Health Science Center—San Antonio (Bexar County, TX), and the University of Utah (Salt Lake County, UT). Hospitals were selected for participation such that at least 90% of all pregnancies of catchment area residents ending in a stillbirth (gestation $\geq$ 20 weeks) or a live birth would be identified and potentially approached to consent in the study. Eligible residents were at least 13 years of age and identified for potential participation prior to hospital discharge. An effort was made to enroll mothers of all eligible stillbirths. Data collection included maternal interview, prenatal care medical chart abstraction, and biological specimens.

For this analysis, records for SCRN stillbirths identified in DeKalb and Salt Lake Counties were linked to fetal death certificates (FDCs). We were unable to obtain FDCs for Texas, Massachusetts, and Rhode Island enrollees. Recruitment of stillbirths began on March 18, 2006 in Utah, and on May 19, 2006 in Georgia. All participating hospitals had begun enrollment in both states by January 1, 2007. Active surveillance continued through September 2, 2008 in Utah, and through September 12, 2008 in Georgia. Descriptive information on all stillbirths occurring to catchment area residents continued to be collected in both states during a "continued surveillance" period, which ended on June 15, 2009.

We requested select FDC data elements for all fetal deaths that were reported in Georgia and Utah from 2006 – 2009. Georgia requires reporting of all fetal deaths, irrespective of the period of gestation, while Utah requires reporting of fetal deaths occurring at 20 weeks' gestation or later. Stillbirths identified by SCRN were linked deterministically to FDCs using one of four different identifiers constructed using portions of the mother's first and last names, mother's date of birth, and the date of delivery. The identifiers were constructed as follows: 1) first letter of mother's first name, first two letters of mother's last name, last two letters of mother's last name, mother's date of birth; 2) first letter of mother's first name, first letter of mother's last name, mother's date of birth; 3) first letter of mother's first name, first letter of mother's last name, last letter of mother's last name, date of delivery; 4) mother's date of birth, date of delivery. A manual search of mother's date of birth, the first and last two letters of her last name, and a review of all FDCs reported within a 5 day span of the SCRN date of delivery was conducted for SCRN stillbirths that did not link to an FDC using the above identifiers. We used this same process to link SCRN stillbirths with live birth certificates to determine whether stillbirths were erroneously reported as live births.

We report descriptive statistics of maternal and delivery characteristics of SCRN- and FDC-identified stillbirths. Chi-square and t-tests were used to determine whether there were any statistically significant differences between SCRN stillbirths with and without a linked FDC, as well as whether there were any statistically significant differences in SCRN identification among FDC-identified stillbirths.

Correcting the Vital Records Files

To avoid overestimating the incidence of stillbirth, we examined the FDCs to ensure that they did not contain any records that did not meet SCRN eligibility criteria.

As part of the screening process for study inclusion, SCRN staff identified many pregnancies originally identified in hospital records as potentially eligible stillbirths, but were subsequently found to not meet the SCRN eligibility criteria. These included induced terminations of pregnancy, pregnancy losses occurring before 20 weeks' gestation, and stillbirths occurring to residents outside of the catchment areas. We linked these records to FDCs to determine whether they were erroneously included as stillbirths occurring to catchment area residents (e.g. terminations registered as stillbirths, or losses actually occurring before 20 weeks' gestation with FDCs reporting gestational ages of 20 weeks or more). Any FDCs that did not meet our eligibility criteria were excluded from the adjusted vital records files.

During the linkage process, we identified duplicate FDCs for the same loss. To determine if there were duplicate reports among SCRN-missed stillbirths, we reviewed the frequencies of the maternal identifiers. If a maternal identifier appeared more than once, the corresponding records were compared using the date of delivery, plurality, gestational age, fetal sex, and birth weight to distinguish true duplicates from multiple gestation losses, or multiple losses during the study period. Any duplicate FDCs that were identified during this process were removed from the adjusted vital records files.

Finally, there was an unexpected number of FDCs for pregnancy losses occurring at 20 weeks' gestation or later among DeKalb County residents that were not captured by SCRN. Due to concerns of over-reporting in vital records, we compared this list to records that were identified by the Metropolitan Atlanta Congenital Defects Program (MACDP), which conducted a similar surveillance during 2006 and 2008.[34] FDCs identified by MACDP that did not meet our eligibility criteria were also excluded from the adjusted vital records files.

Capture-Recapture

Capture-recapture methods were used to estimate the total population of stillbirths (*N*) that occurred to catchment area residents during the study period. These methods were developed for use in ecology, and have been applied in epidemiology to estimate the completeness of two (or more) disease registries.[35-39] Let S denote the total number of stillbirths identified by SCRN, V_{adj} denote the number of stillbirths reported to vital records (adjusted to exclude duplicates and those with known ineligibility), and a denote the number of stillbirths identified independently by both sources. We estimated N using the Chapman estimator[37] which provides approximately unbiased estimates at smaller sample sizes, and is calculated as follows:

$$N \approx \frac{(S+1)(V_{adj}+1)}{(a+1)} - 1$$

We estimated the variance of the estimated total number of stillbirths using the following formula described by Seber:[40]

$$Var(N) = \frac{(S+1)(V_{adj}+1)(S-a)(V_{adj}-a)}{(a+1)^2(a+2)}$$

The number of stillbirths that occurred among residents of the catchment areas during the study period must be at least as large as the unique number of stillbirths that were observed between SCRN and vital records. Wald-type 95% confidence intervals for the estimated total number of stillbirths, and corresponding rates, were not appropriate for these data as they yielded lower limits that were less than the number of unique stillbirths identified between the two data sources. To help circumvent this problem, we used a log transformation as has been previously suggested.[41] We used the delta method to approximate the variance of the natural log of Chapman's estimator, yielding the following estimated variance:

$$V\hat{a}r(\ln(Var(N)) \doteq \frac{V\hat{a}r(N)}{N^2} = \frac{\dfrac{(S+1)(V_{adj}+1)(S-a)(V_{adj}-a)}{(a+1)^2(a+2)}}{\left(\dfrac{(S+1)(V_{adj}+1)}{(a+1)}-1\right)^2}$$

This transformation resulted in confidence intervals for N that were shifted to the right, with lower limits guaranteed to exceed 0. However, the lower limits still did not always exceed the number of stillbirths that we observed. In these cases, we truncated the lower limit of the approximate 95% confidence intervals to equal the number of observed stillbirths during the study period.

Estimates of stillbirth rates were calculated as *N* per 1,000 live births plus stillbirths reported to vital records among catchment area residents. For each county, we estimated stillbirth incidence overall and by maternal race and ethnicity.

Sensitivity Analyses

Since the SCRN surveillance period was longer than that of MACDP, we were unable to compare the SCRN sample to MACDP records for 2007 and 2009. Due to concerns of over-reporting of DeKalb County stillbirths during these years, we sought to estimate the proportion of stillbirths erroneously reported during 2007 and 2009. To do this, we conducted sensitivity analyses by examining the proportion of SCRN-unidentified FDCs that were found to have been ineligible by MACDP in 2006 and 2008. We applied these exclusions to the SCRN-unidentified FDCs of DeKalb County residents from 2007 and 2009 in three ways: 1) eliminating the same proportion of FDCs as was eliminated from 2006 FDCs using MACDP, 2) eliminating the same proportion of FDCs as was eliminated from 2008 FDCs using MACDP, and 3) eliminating the same proportion of FDCs as was eliminated from 2006 and 2008 FDCs using MACDP.

Results

There were 318 fetal death certificates (FDCs) for fetal deaths occurring at 20 weeks' gestation or later to residents of DeKalb County between January 1, 2007 and June 15, 2009 (Figure 5.1). Of these, we determined that 2 occurred to residents of other counties, 7 were terminations of pregnancy reported as stillbirths, 16 were losses that actually occurred prior to 20 weeks' gestation, 9 were duplicate reports, and 3 were neonatal deaths reported as stillbirths. Excluding these records yields an adjusted FDC population size for DeKalb County of 281. There were 267 FDCs for fetal deaths occurring at 20 weeks' gestation or later to residents of Salt Lake County during the study period (Figure 5.2). Of these, we determined that 9 were terminations of pregnancy reported as stillbirths, and 1 was a duplicate report. Excluding these records yields an adjusted FDC population size for Salt Lake County of 257.

Between January 1, 2007 and June 15, 2009, there were 191 and 252 fetal deaths identified by SCRN as having occurred at 20 weeks' gestation or later to residents of DeKalb and Salt Lake Counties, respectively (Table 5.1). Of these, 85% of DeKalb County residents and 95% of Salt Lake County residents had a linked FDC. Three Salt Lake County stillbirths were registered as live births; we did not identify any DeKalb County stillbirths registered as live births (data not shown). In DeKalb County, there were no statistically significant differences between SCRN-identified stillbirths with and without a linked FDC. In Salt Lake County, the only statistically significant difference between SCRN-identified stillbirths with and without a linked FDC was gestational age, with unlinked stillbirths having occurred at earlier gestations.

During the study period, there were 281 and 257 FDCs with no known ineligibility reported as having occurred at 20 weeks' gestation or later to residents of DeKalb and Salt Lake Counties, respectively (Table 5.2). Forty-nine percent of DeKalb County FDCs were identified by SCRN, compared to 91% of FDCs among Salt Lake County residents. DeKalb County stillbirths missed by SCRN were more likely to be non-Hispanic White, and to have occurred earlier in pregnancy than those that were identified by SCRN. There were no statistically significant differences between SCRN-identified and SCRN-missed stillbirths in Salt Lake County.

SCRN identified 191 stillbirths among DeKalb County residents, while FDCs identified 281 (Table 5.3). Of these, 137 were identified independently by both sources. We estimated that 56 stillbirths were missed by both sources, for an estimated total number of stillbirths of 391 (range: 367 – 416). Together, FDCs and SCRN captured 85.7% of the stillbirths estimated to have occurred among DeKalb County residents during the study period. Among Salt Lake County residents, SCRN identified 252 stillbirths, while FDCs identified 257. Of these, 234 were independently identified by both sources. We estimated that only one stillbirth was missed by both sources, for an estimated total number of stillbirths of 276 (range: 275 – 278). Together, FDCs and

SCRN captured 99.6% of the stillbirths estimated to have occurred among Salt Lake County residents during the study period.

Due to incomplete stillbirth ascertainment by both SCRN and vital records in DeKalb County, the estimated rates for each source independently are much lower than the rate obtained by the capture-recapture method, which considered both data sources (Table 5.4). The stillbirth rate estimated using the capture-recapture method for residents of DeKalb County during our study period is 13.42 per 1,000 live births plus stillbirths reported to vital records (95% CI: (12.60, 14.30)). Despite including records that do not meet the criteria for reporting, the stillbirth rate using the unadjusted vital records file is 19% lower than our estimate at 10.92 per 1,000. The stillbirth rate estimated using the capture-recapture method for residents of Salt Lake County during our study period is 5.77 per 1,000 live births plus stillbirths reported to vital records (95% CI: (5.75, 5.83)). This is only slightly higher than the stillbirth rate obtained using the unadjusted vital file of 5.58 per 1,000. Stillbirth rates were highest among Non-Hispanic Black residents of DeKalb County, with an estimated rate of 20.13 per 1,000 live births plus stillbirths reported to vital records. Stillbirth rates were lowest among Non-Hispanic White residents of Salt Lake County, with an estimated rate of 5.47 per 1,000 live births plus stillbirths reported to vital records.

Sensitivity Analysis

Among the 110 SCRN-missed FDCs sent for comparison with MACDP records, 3 of 41 (7.3%) that occurred in 2006 and 9 of 69 (13.0%) that occurred in 2008 were found to have been ineligible for inclusion, for an overall exclusion rate of 10.9% (data not shown). During 2007 and 2009, there were a total of 84 SCRN-unidentified FDCs. Applying the 2006, 2008, and average exclusion rates to these SCRN-unidentified FDCs yields adjusted stillbirth rates of 13.15, 12.94, and 12.98 per 1,000 live births and stillbirths reported to vital records among DeKalb County residents, respectively.

Since a majority (75%) of the FDCs found to have been ineligible for inclusion after the comparison with MACDP were among Non-Hispanic Black women, we also conducted sensitivity analyses for this group (data not shown). Among the 70 SCRN-unidentified FDCs for Non-Hispanic Black women sent for comparison with MACDP records, 1 of 27 (3.7%) that occurred in 2006 and 7 of 43 (16.3%) that occurred in 2008 were found to have been ineligible for inclusion, for an overall exclusion rate of 11.4%. During 2007 and 2009, there were a total of 46 SCRN-unidentified FDCs among Non-Hispanic Black women. Applying the 2006, 2008, and average exclusion rates to these SCRN-unidentified FDCs yields adjusted stillbirth rates of 20.00, 19.23, and 19.51 per 1,000 live births and stillbirths reported to vital records among Non-Hispanic Black residents of DeKalb County, respectively.

Discussion

We estimated the stillbirth rates among DeKalb and Salt Lake County residents from January 1, 2007 – June 15, 2009 to be 13.42 and 5.77 per 1,000 live births plus stillbirths reported to vital records, respectively. The estimated rates are higher for both counties compared to rates obtained using vital records alone; this difference is most striking for DeKalb County, with a vital records rate of 10.92 per 1,000 live births plus stillbirths reported to vital records. The stillbirth rate among Non-Hispanic Black residents of DeKalb County using vital records was 31% less than our most conservative estimate of the stillbirth rate for this group.

These findings highlight the need for improvement of stillbirth registration. In DeKalb County, stillbirth rates obtained using vital records underestimate the true rates, despite including records for pregnancy terminations, fetal deaths actually occurring before 20 weeks' gestation, neonatal deaths, and duplicate reports. We found an association between FDC-linkage status and period of gestation only among Salt Lake County stillbirths, which is consistent with what would be expected given the different reporting requirements for Georgia and Utah, and that earlier losses are more likely to be unreported when the lower limit for reporting occurs later in gestation.[2]

Our study is not without limitations. While SCRN intended to capture at least 90% of all pregnancies of catchment area residents resulting in a stillbirth or live birth, only 49% of fetal death certificates for DeKalb County residents were identified by SCRN. This may largely be explained by errors in determining a woman's county of residence during the screening process. Additionally, SCRN may have missed stillbirths occurring to incarcerated women. SCRN's records indicate that there were no stillbirths that occurred among incarcerated residents of DeKalb County during the study period. Although they were not eligible for enrollment, limited information about these women should have been recorded in the screening process. Given the high risk population that is served by some of the hospitals that enrolled DeKalb County residents, we would have expected to see some stillbirths among incarcerated women. We suspect that these women were mistakenly ignored in the screening process since they would not have been eligible for enrollment. Although the SCRN-identification rate was lower than anticipated in DeKalb County, the capture-recapture methods remain valid for estimating the total number of stillbirths that occurred during the study period, as these methods were designed to estimate a total population using two incomplete samples.[37]

Our study also has several strengths. To our knowledge, this is the first multi-site population-based estimate of the incidence of stillbirth in the United States. Stillbirths were identified prospectively, which allowed us to estimate the incidence of stillbirth in DeKalb and Salt Lake Counties. Additionally, we were able to identify and exclude fetal death certificates that did not meet eligibility criteria for inclusion, which prevented overestimation of the true stillbirth rates.

In order to improve stillbirth reporting, delivery attendants need adequate training on the public health importance of accurately reporting these events. If they see the effort as something that could improve the health outcomes of their patient population and not as an administrative burden, they may be more motivated to correctly report these losses. Delivery attendants must be able to distinguish between a fetal death and a live birth followed by an infant death. Given that we did not identify many stillbirths erroneously reported as live births, this problem may only explain a small proportion of the underreporting of stillbirths. Efforts to improve dating of pregnancies in general, and stillbirths in particular, will also improve the completeness of stillbirth reporting as the definition often relies on an estimate of the gestational age of the fetus.

Since reporting of vital events is part of a decentralized system, efforts to improve stillbirth reporting will likely have to occur at the level of the reporting area. Advocacy groups may play a key role in advancing these improvement efforts. A recent example that may serve as a model for efforts to improve stillbirth surveillance in other states is the Autumn Joy Stillbirth Research and Dignity Act, which was introduced in the New Jersey State Senate in 2013, and signed into law in 2014.[42] Drafted by a bereaved mother who was frustrated by the lack of resources and attention given to stillbirth, this law requires dignified and sensitive management of stillbirths, as well as the establishment of a fetal death evaluation protocol, and a stillbirth research database in New Jersey. Progress in reporting, and ultimately preventing stillbirths can be made as advocacy groups help shine the spotlight on the importance of this issue.

These data demonstrate that the incidence of stillbirth is higher than what is suggested by vital records. Given that vital records are our only source of national data for stillbirths, researchers, clinicians, and policy makers should consider these estimates to be the lower bound for the number of stillbirths occurring annually in the United States. Stillbirths are no less devastating to the families who endure them than infant deaths, and deserve to be a priority area for surveillance and prevention.

Figure 5.1. Adjustments made to the vital records file for DeKalb County, Georgia

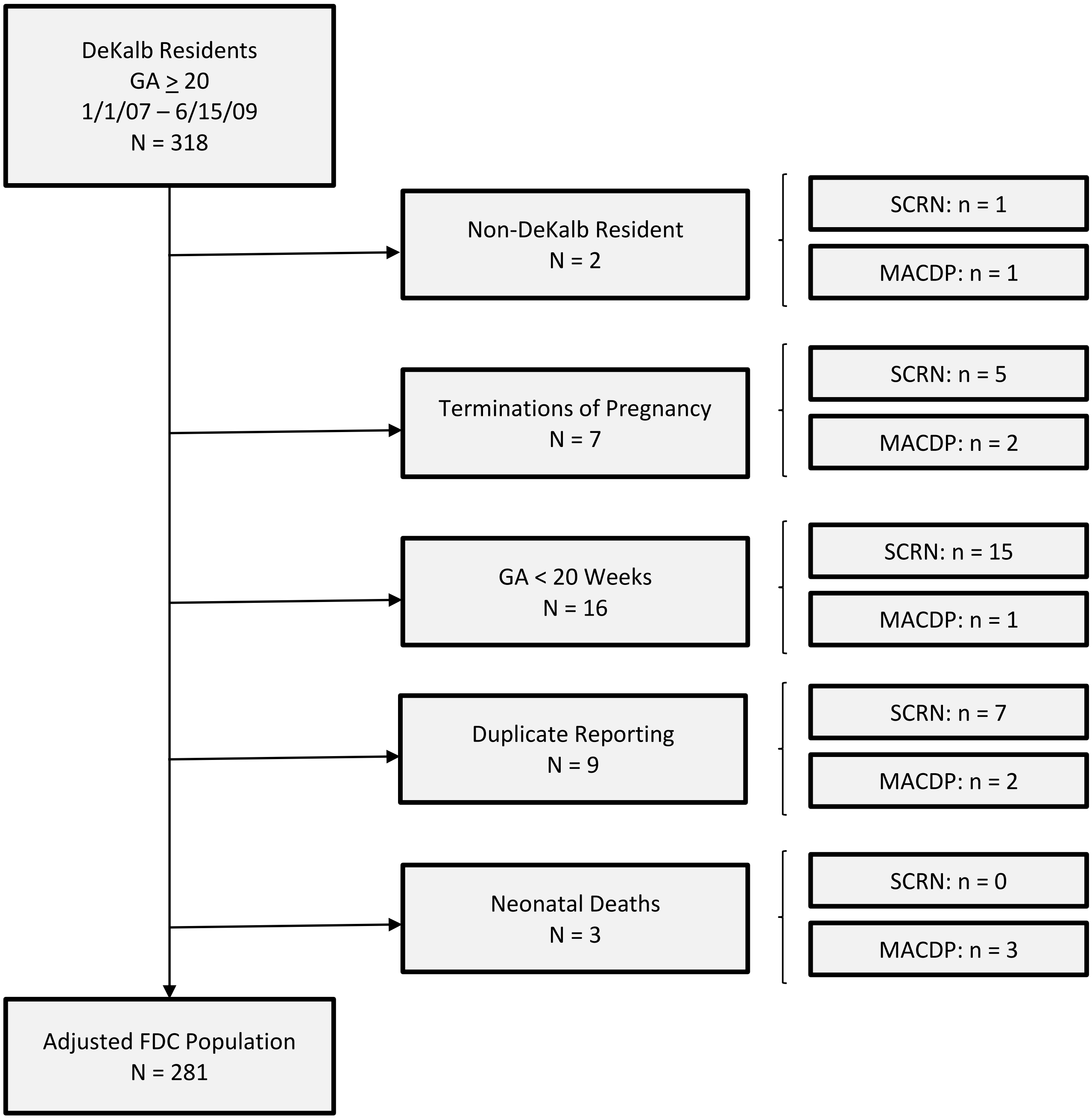

Figure 5.2. Adjustments made to the vital records file for Salt Lake County, Utah

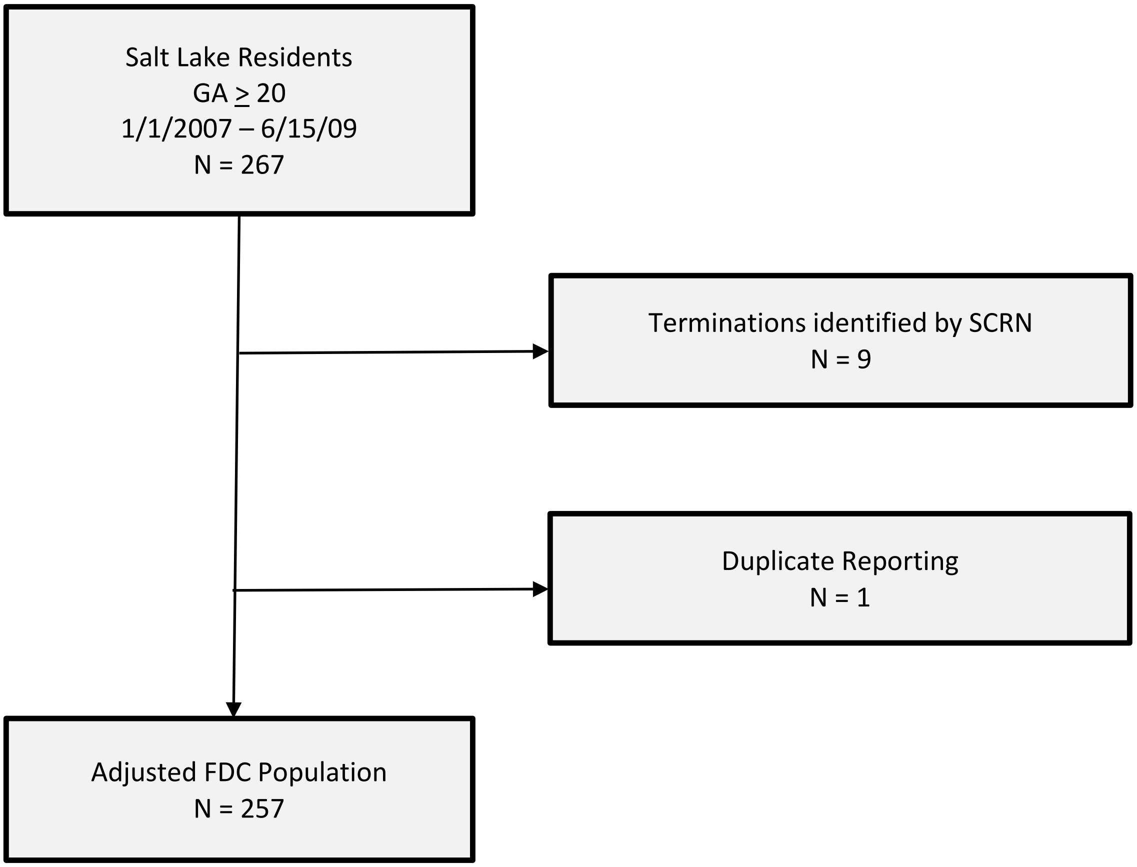

Table 5.1. Characteristics of 443 stillbirths among residents of DeKalb and Salt Lake Counties identified by the Stillbirth Collaborative Research Network study, by county of residence and Fetal Death Certificate (FDC) linkage status, January 1, 2007 – June 15, 2009*

Characteristic †	DeKalb County (N = 191)		Salt Lake County (N = 252)	
	Linked FDC	No Linked FDC ‡	Linked FDC	No Linked FDC §
Participants	162 (84.8)	29 (15.2)	239 (94.8)	13 (5.2)
Maternal Characteristics				
Age º	27.3 (6.4)	28.1 (7.0)	28.7 (6.5)	29.8 (6.4)
Race/Ethnicity				
Non-Hispanic White	7 (4.3)	1 (3.5)	150 (62.8)	7 (53.9)
Non-Hispanic Black	126 (77.8)	21 (72.4)	5 (2.1)	0 (0)
Hispanic	17 (10.5)	3 (10.3)	67 (28.0)	5 (38.5)
Other	12 (7.4)	4 (13.8)	17 (7.1)	1 (7.7)
Delivery Characteristics				
Delivery Period				
Period 1: 1/1/2007 – 9/30/2008	111 (68.5)	23 (79.3)	170 (71.1)	11 (84.6)
Period 2: 10/1/2008 – 6/15/2009	51 (31.5)	6 (20.7)	69 (28.9)	2 (15.4)
Active Surveillance ‖	106 (65.4)	23 (79.3)	161 (67.4)	10 (76.9)
Continued Surveillance ⁞	56 (34.6)	6 (20.7)	78 (32.6)	3 (23.1)
Gestational Age º	27.5 (6.8)	27.2 (6.2)	28.9 (6.9)	24.4 (5.3)
Period of Gestation				
20 – 27 weeks	92 (56.8)	15 (51.7)	124 (51.9)	10 (76.9)
28 weeks or more	70 (43.2)	14 (48.3)	115 (48.1)	3 (23.1)

* Values are n (%) unless otherwise stated
† As reported by SCRN
‡ All p-values for differences between DeKalb County residents with and without a linked FDC > 0.05
§ All p-values for differences between Salt Lake County residents with and without a linked FDC > 0.05, except for gestational age (p = 0.02)
º Mean (SD)
‖ DeKalb: 1/1/2007 – 9/12/2008; Salt Lake: 1/1/2007 – 9/2/2008
⁞ DeKalb: 9/13/2008 – 6/15/2009; Salt Lake: 9/3/2008 – 6/15/2009

Table 5.2. Characteristics of 538 Fetal Death Certificates (FDCs)* among DeKalb and Salt Lake County residents, by county of residence and Stillbirth Collaborative Research Network (SCRN) identification status, January 1, 2007 – June 15, 2009†

Characteristic ‡	DeKalb County (N = 281)		Salt Lake County (N = 257)	
	Identified by SCRN	Missed by SCRN§	Identified by SCRN	Missed by SCRN°
Fetal Death Certificates	137 (48.8)	144 (51.3)	234 (91.1)	23 (9.0)
Maternal Characteristics				
Age ‖	27.7 (6.2)	28.5 (6.4)	28.8 (6.5)	27.5 (5.7)
Race/Ethnicity				
Non-Hispanic White	6 (4.4)	21 (14.6)	142 (60.7)	14 (60.9)
Non-Hispanic Black	88 (64.2)	82 (56.9)	5 (2.1)	0 (0)
Hispanic	13 (9.5)	18 (12.5)	63 (26.9)	3 (13.0)
Other	7 (5.1)	4 (2.8)	20 (8.6)	4 (17.4)
Missing	23 (16.8)	19 (13.2)	4 (1.7)	2 (8.7)
Delivery Characteristics				
Delivery Period				
Period 1: 1/1/07 – 9/30/08	98 (71.5)	104 (72.2)	172 (70.8)	17 (70.8)
Period 2: 10/1/08 – 6/15/09	39 (28.5)	40 (27.8)	71 (29.2)	7 (29.2)
Active Surveillance ⋮	94 (68.6)	104 (72.2)	158 (67.5)	15 (65.2)
Continued Surveillance □	43 (31.4)	40 (27.8)	76 (32.5)	8 (34.8)
Gestational Age ‖	28.3 (6.8)	25.9 (6.0)	28.7 (7.0)	28.2 (7.7)
Period of Gestation				
20 – 27 weeks	74 (54.0)	98 (68.1)	125 (53.4)	12 (52.2)
28 weeks or more	63 (46.0)	46 (31.9)	109 (46.6)	11 (47.8)

* Excludes 37 DeKalb County and 10 Salt Lake County FDCs with known ineligibility
† Values are n (%) unless otherwise stated
‡ As reported on FDC
§ All p-values for the differences between DeKalb County FDC records identified by SCRN and those missed by SCRN > 0.05, except for race/ethnicity (p = 0.03) gestational age (p = 0.003) and period of gestation (p = 0.02)
° All p-values for the differences between Salt Lake County FDC records identified by SCRN and those missed by SCRN > 0.05
‖ Mean (SD)
⋮ DeKalb: 1/1/2007 – 9/12/2008; Salt Lake: 1/1/2007 – 9/2/2008
□ DeKalb: 9/13/2008 – 6/15/2009; Salt Lake: 9/3/2008 – 6/15/2009

Table 5.3. Distribution of stillbirths by source identification, estimated number of stillbirths, and vital records totals for stillbirths and live births among residents of DeKalb County, Georgia, and Salt Lake County, Utah, by county of residence and maternal race/ethnicity, January 1, 2007 – June 15, 2009

Maternal Race/Ethnicity	Identified by FDC* and SCRN	Identified by SCRN Only	Identified by FDC* Only	Estimated Number Missed by Both Sources	Estimated Total Number of Stillbirths (95% CI)	Number of FDCs Reported to Vital Records†	Live Births
DeKalb County							
All Races ‡	137	54	144	56	391 (367, 416)	318	28,807
Non-Hispanic White	3	5	21	26	55 (29, 101)	31	6,164
Non-Hispanic Black	82	65	82	64	293 (265, 323)	194	14,365
Hispanic	12	8	18	11	49 (38, 63)	32	4,256
Other	5	11	4	7	27 (20, 40)◊	12	2,637
Salt Lake County							
All Races ‡	234	18	23	1	276 (275, 278)◊	267	47,589
Non-Hispanic White	138	19	14	1	172 (171, 175)◊	160	31,312
Non-Hispanic Black	4	1	0	0	5 (5, 5)◊	6	722
Hispanic	60	12	3	0	75 (75, 76)◊	70	11,274
Other	14	4	4	1	23 (22, 25)◊	24	3,337

* Excludes 37 DeKalb County and 10 Salt Lake County FDCs with known ineligibility

† Includes all FDCs for losses reported as having occurred at 20 weeks' gestation or later among county residents

‡ Numbers for individual racial/ethnic groups do not sum to total due to missing and/or misclassified values for race/ethnicity on FDC

◊ Lower limit for the approximate 95% confidence interval truncated to reflect the stillbirth rate using the number of unique stillbirths observed between SCRN and vital records

Table 5.4. Estimated stillbirth rates* and approximate 95% confidence intervals for residents of DeKalb and Salt Lake Counties, by source of identification, and maternal race/ethnicity, January 1, 2007 – June 15, 2009

Data Source	County of Residence	
	DeKalb County	Salt Lake County
All Races		
Vital Records Alone †	10.92	5.58
SCRN Alone	6.56	5.27
Capture-Recapture Estimate ‡	13.42 (12.60, 14.30)	5.77 (5.75, 5.83)◊
Non-Hispanic White		
Vital Records Alone †	5.00	5.08
SCRN Alone	1.29	4.99
Capture-Recapture Estimate ‡	8.88 (4.81, 16.38)	5.47 (5.43, 5.56)◊
Non-Hispanic Black		
Vital Records Alone †	13.33	8.24
SCRN Alone	10.10	6.87
Capture-Recapture Estimate ‡	20.13 (18.20, 22.25)	6.87 (6.87, 6.87)◊
Hispanic		
Vital Records Alone †	7.46	6.17
SCRN Alone	4.66	6.35
Capture-Recapture Estimate ‡	11.43 (8.88, 14.70)	6.61 (6.61, 6.76)◊
Other		
Vital Records Alone †	4.53	7.14
SCRN Alone	6.04	5.36
Capture-Recapture Estimate ‡	10.19 (7.55, 15.14)◊	6.84 (6.55, 7.62)◊

* Number of stillbirths reported by each source per 1,000 live births plus stillbirths reported to vital records among county residents

† Numerator includes all FDCs for losses reported as having occurred at 20 weeks' gestation or later among county residents

‡ Numerator excludes 37 DeKalb County and 10 Salt Lake County FDCs with known ineligibility

◊ Lower limit for the approximate 95% confidence interval truncated to reflect the stillbirth rate using the number of unique stillbirths observed between SCRN and vital records

CHAPTER 6:

A DESCRIPTIVE STUDY OF THE COMPLETENSS AND ACCURACY OF THE FETAL DEATH CERTIFICATE

A descriptive study of the completeness and accuracy of fetal death certificate data in two US counties

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Objective: To describe the frequency of missing and misclassified information on the fetal death certificate (FDC) and determine whether these are associated with maternal or delivery characteristics.

Methods: FDCs were linked with stillbirths identified by the Stillbirth Collaborative Research Network's (SCRN) case-control study of stillbirth from 2006-2008 in DeKalb County, Georgia and Salt Lake County, Utah. Misclassified information on the FDC was defined as any departure from the value reported by SCRN. Chi-square and Fisher's exact tests were used to determine whether missing and misclassified FDC data were associated with state of residence, maternal race/ethnicity, gestational age, and whether the stillbirth was antepartum or intrapartum.

Results: Data quality varied significantly by FDC item and state of residence. With few exceptions, missing and misclassified data were not associated with maternal or delivery characteristics. In both states, variables with the highest levels of data quality included fetal sex, plurality, and marital status. Utah also had high levels of data quality for maternal race, ethnicity, receipt of prenatal care, smoking, and gestational diabetes. In both states, data quality was worse for birth weight, gestational age, and number of prenatal care visits. Additionally, data quality was worse for maternal ethnicity, first pregnancy, receipt of prenatal care, and smoking in Georgia.

Conclusions: FDC data quality varied by state of residence and FDC item. Efforts to improve FDC data quality should focus on reducing the frequency of missing values as well as improving the accuracy of data reported.

Key Words: stillbirth, fetal death certificate, data quality, missing data, misclassification

Introduction

In 2012, stillbirths, defined as the death of a fetus of at least 20 weeks' gestation, accounted for more than one-half of all fetal and infant mortality.[43] Despite a similar emotional burden and annual prevalence as infant mortality, much less research and attention has focused on reducing stillbirth rates and disparities.

As with all vital events in the United States, stillbirth reporting is part of a decentralized system, with the responsibility for registering the events residing not at the national level, but rather with smaller geographical areas (e.g. states, territories, and large counties). The Centers for Disease Control and Prevention (CDC) recommends reporting of the death of all fetuses weighing at least 350 grams, or occurring at 20 weeks' gestation or later. Despite this guidance, not all reporting areas apply the same definition when considering whether a pregnancy loss is reportable,[2] which may result in inappropriate comparisons when evaluating stillbirth rates across states.

Additionally, the quality of these data is hampered by high levels of missing and misclassified data. According to the 2006 data user's guides provided by the National Center for Health Statistics, 12.0% of fetal death certificates (FDCs) were missing the baby's birth weight (range of reporting areas: 0.5 – 48.4%),[44] compared to only 0.1% of live birth certificates (range of reporting areas: 0.0 – 0.8%).[45] The fetal death data user guide also indicates that other key FDC variables are missing with a high frequency; these include mother's educational attainment, information about prenatal care, and tobacco use during pregnancy. Previous research has identified high levels of missing data among other variables, including gestational age,[24] fetal sex, date of mother's last menstrual period, weight gain during pregnancy, number of previous pregnancies, alcohol and tobacco use during pregnancy, paternal age, and cause of death.[25] A recent study conducted in New York City compared fetal and neonatal death records and found that the fetal death records generally had more missing values than did the neonatal death records.[46]

Even when FDC data are available, there is concern about the accuracy of the information collected.[4,24,26-30] Greb et al. compared FDCs to records for stillbirths identified through the Wisconsin Stillbirth Service Project (WiSSP).[6] They found that sex, birth weight, and gestational age were mostly accurately reported; however there were many discrepancies between the two data sources for congenital anomalies and cause of death. A study conducted in Georgia that aimed to improve fetal death data quality by reviewing the medical records for stillbirths with implausible values of birth weight and gestational age reported on the FDC found that a large proportion of these implausible values were due to incorrect reporting.[24]

While certain FDC variables are likely to be missing or inaccurate, it is unknown whether missing and misclassified data are associated with certain maternal and delivery characteristics. Further, how the combination of missing and misclassified FDC data affects data quality is also uncertain. We linked FDCs to stillbirths enrolled in a population-based case-control study of stillbirth, and report the frequency of missing and misclassified data for select FDC data elements. We also assessed whether missing and misclassified data were associated with maternal and delivery characteristics.

Finally, we describe the joint effect of missing and misclassified data on the quality of FDC data.

Methods

The Stillbirth Collaborative Research Network (SCRN) conducted a multisite, population-based case-control study that enrolled mothers of both stillbirths and a sample of live births at the time of delivery. This study has been described in detail elsewhere.[33] The study took place in five clinical sites, each with corresponding catchment areas: Brown University (State of Rhode Island, and Bristol County, MA), Emory University (DeKalb County, GA), University of Texas Medical Branch—Galveston (Galveston and Brazoria Counties, TX), University of Texas Health Science Center—San Antonio (Bexar County, TX), and the University of Utah (Salt Lake County, UT). Hospitals were selected for participation such that at least 90% of all pregnancies of catchment area residents ending in a stillbirth (gestation $\geq$ 20 weeks) or a live birth would be identified and potentially approached to consent in the study. Eligible residents were at least 13 years of age and identified for potential participation prior to hospital discharge. An effort was made to enroll all mothers of eligible stillbirths. Data collection included maternal interview, prenatal care medical chart abstraction, and biological specimens. Enrollment began in March of 2006, and continued through September 2008.

For this analysis, records for SCRN-eligible stillbirths enrolled in Georgia and Utah from March 2006 – September 2008 were linked to fetal death certificates (FDCs) for all pregnancies with the death of only one fetus. We were unable to obtain FDCs for Texas, Massachusetts, and Rhode Island enrollees. Records were linked deterministically using one of four different identifiers constructed using portions of the mother's first and last name, mother's date of birth, and date of delivery. The identifiers were constructed as follows: 1) first letter of mother's first name, first two letters of mother's last name, last two letters of mother's last name, mother's date of birth; 2) first letter of mother's first name, first letter of mother's last name, mother's date of birth; 3) first letter of mother's first name, first letter of mother's last name, last letter of mother's last name, date of delivery; 4) mother's date of birth, date of delivery. A manual search of mother's date of birth, the first and last two letters of her last name, and a review of all FDCs reported within a 5 day span of the SCRN date of delivery was conducted for any SCRN stillbirths that did not link to an FDC using these identifiers.

We identified the number and proportion of individuals with missing FDC data for maternal and delivery characteristics, prenatal care, and medical risk factors for stillbirth. Chi-square and Fisher's exact tests were used to determine whether there were any differences in missing FDC data by state of residence, maternal race/ethnicity, gestational age, and whether the stillbirth was antepartum or intrapartum.

Due to the completeness of its data collection process, SCRN was used as the gold standard to which FDC data were compared. We identified the number and proportion of individuals with misclassified FDC data among those who did not have missing values for each variable under consideration in both data sources. Misclassification of FDC data was defined as any departure from the value reported by SCRN. Due to differences in the way that level of maternal education was collected by

SCRN and each state's vital records system, we were unable to assess misclassification of this variable. Chi-square and Fisher's exact tests were used to determine whether misclassification of FDC data was associated with state of residence, maternal race/ethnicity, gestational age, and whether the stillbirth was antepartum or intrapartum.

Since some misclassification of continuous variables may not be meaningful (e.g. a 2 gram discrepancy in birth weight), we also identified the *extent* of misclassification for gestational age and birth weight. The National Center for Health Statistics (NCHS) reports stillbirth rates using the following classifications of these variables: gestational age (20-23, 24-27, 28-31, 32-33, 34-36, 37-39, 40, 41, and 42 or more weeks' gestation), and birth weight (< 500, 500-749, 750-999, 1,000-1,249, 1,250-1,499, 1,500-1,999, 2,000-2,499, 2,500-2,999, 3,000-3,499, 3,500-3,999, $\geq$ 4,000 grams).[2] Using these categories, we determined whether an individual's membership in these groups changed as a result of FDC misclassification.

We also calculated statistical measures of agreement for categorical and continuous variables using Cohen's kappa[47] and Lin's concordance correlation coefficient (CCC),[48] respectively. To classify the level of agreement for categorical variables, we used the following guidelines suggested by Landis and Koch: $\kappa < 0.00$ – poor; $0.00 \leq \kappa \leq 0.20$ – slight; $0.20 < \kappa \leq 0.40$ – fair; $0.40 < \kappa \leq 0.60$ – moderate; $0.60 < \kappa \leq 0.80$ – substantial; $0.80 < \kappa \leq 1.00$ – almost perfect.[49] The only published guidelines for classifying the CCC were published by McBride for use in a laboratory setting.[50] These cut-offs are far too stringent for our purposes, and so we do not classify the level of agreement for continuous variables.

Finally, for each variable of interest, we plotted the proportion of individuals with missing data by the proportion of individuals with misclassified data to understand the joint effect of missing and misclassified FDC data. Data points closest to the origin indicate low levels of both missing and misclassified data and correspond to variables with the best data quality. Data points further from the origin reflect higher levels of missing and/or misclassified data and correspond to variables with poorer data quality.

This study was reviewed and approved by the Institutional Review Boards of each of the participating sites and the data coordinating center.

Results

There were 166 and 216 singleton stillbirth cases enrolled in the SCRN study in Georgia and Utah, respectively. Linked fetal death certificates (FDCs) were identified for 126 Georgia stillbirths and 208 Utah stillbirths (Table 6.1). During the surveillance period from March 2006 – September 2008, SCRN identified 47% of the FDCs reported for residents of DeKalb County and 91% of the FDCs reported for residents of Salt Lake County (data not shown). Most (n = 285) FDCs were linked using the first identifier. An additional 12 records were linked when the identifier included fewer characters from the mother's last name – this typically resulted in a match for women with hyphenated last names. Due to inaccurate reporting of mother's date of birth, an additional 13 records were linked when we considered the mother's initials and the date of delivery. Due to inaccurate reporting of mother's first and/or last name, an additional 17 records were linked using an identifier that only included mother's date of birth and the date of delivery. Seven additional records were linked through the manual searches. There were no statistically significant differences between SCRN stillbirths with and without a linked FDC, except for delivery year among Georgia enrollees.

Missing information was associated with county of residence; data were more frequently missing among DeKalb County stillbirths compared to those for residents of Salt Lake County (Table 6.2). Variables with particularly high levels of missing data were those for DeKalb stillbirths and included maternal education and ethnicity, receipt of prenatal care, number of prenatal care visits, smoking during pregnancy, first pregnancy, chronic hypertension, eclampsia, preeclampsia, and birth weight. Variables with low levels of missing data in both counties included maternal race, marital status, fetal sex, gestational age, and plurality. The frequency of missing data for these variables was not associated with maternal race/ethnicity (data not shown). Birth weight and number of prenatal care visits were more likely to be missing for losses occurring at 20-27 weeks' gestation compared to later losses (p-values: 0.01 and 0.03, respectively). Intrapartum stillbirths were more likely to be missing information on the receipt of prenatal care than antepartum stillbirths (p-value: 0.01).

Data were more likely to be misclassified for DeKalb County stillbirths than for Salt Lake County stillbirths (Table 6.3). Variables most frequently misclassified were number of prenatal care visits, gestational age, and birth weight. Variables with moderate levels of misclassification were maternal race, ethnicity, marital status, and smoking during pregnancy. Variables with the lowest levels of misclassification were receipt of prenatal care, fetal sex, and plurality. There was no evidence that misclassification of FDC data elements was associated with maternal race/ethnicity, gestational age, or the timing of the death relative to labor initiation (data not shown).

Changes in NCHS category membership for gestational age and birth weight due to misclassification are shown in Table 6.4. Among records where continuous week of gestational age was misclassified (N = 111), 64 (57.7%) were misclassified such that their membership in the NCHS gestational age categories changed as a result of the value reported on the FDC. Among records where continuous birth weight in grams was misclassified (n = 51), 9 (17.6 %) were misclassified such that their membership in the NCHS birth weight categories changed as a result of the value reported on the FDC.

The distributions of the difference between SCRN records and the FDC for gestational age, birth weight, and number of prenatal care visits are shown in Table 6.5. The majority of FDCs reported a gestational age within one week of the value reported by SCRN (Georgia: 71.4%, Utah: 95.2%). Some FDCs (Georgia: 15.9%, Utah: 2.4%) reported a gestational age that differed from the SCRN value by 4 weeks or more. Similarly, a majority of FDCs reported a birth weight within 9 grams of the SCRN value (Georgia: 68.2%, Utah: 90.3%), however a number of FDCs reported a birth weight that was different from the SCRN value by 51 grams or more (Georgia: 15.2%, Utah: 3.4%). The majority of FDCs reported the number of prenatal care visits a woman attended within one visit of the SCRN value (Georgia: 54.0%, Utah: 74.6%), however a large proportion of the FDCs differed from the SCRN value by two or more visits (Georgia: 46.0%, Utah: 25.4%).

Statistical and descriptive measures of agreement between FDCs and SCRN records are shown in Tables 6.6 and 6.7. Agreement was highest for maternal ethnicity, marital status, fetal sex, and plurality. Agreement was lowest for race (Georgia) number of prenatal care visits, gestational age (Georgia), and birth weight (Georgia).

When considering the joint effect of missing and misclassified data for Georgia enrollees, data quality was best for fetal sex, plurality, and marital status (Figure 6.1). Data quality was worse for ethnicity, first pregnancy, receipt of prenatal care, and smoking, primarily because of missing values. Gestational age was generally not missing but was often misclassified, whereas birth weight and number of prenatal care visits were more frequently missing and, when given, misclassified. In Utah, data quality was best for fetal sex, plurality, maternal race, ethnicity, receipt of prenatal care, smoking, and gestational diabetes. Data quality was worse for maternal race and birth weight, primarily because of missing data, gestational age, primarily because of misclassified data, and number of prenatal care visits due to both missing and misclassified data.

Discussion

We found varying degrees of missing and misclassified data for the FDC variables we examined. With only a few exceptions, the only variable associated with missing and misclassified data was county of residence. In both counties, certain variables tended to have higher data quality (lower levels of missing and misclassified data); these included fetal sex and plurality. Additionally, Utah had high data quality for the following variables: maternal race and ethnicity, receipt of prenatal care, smoking, and gestational diabetes. Variables with poorer data quality (corresponding to those with higher levels of missing and misclassified data) common to both states were maternal race, number of prenatal care visits, gestational age, and birth weight. Additionally, Georgia's FDCs had poorer data quality for maternal ethnicity, receipt of prenatal care, smoking, and first pregnancy.

This study reflects the FDC data quality for stillbirths to women who were eligible for enrollment by SCRN and were issued an FDC. FDCs were not found for 26% and 4% of SCRN-eligible women in Georgia and Utah, respectively. A discussion of underreporting of stillbirths is outside of the scope of this paper, but will be addressed in a forthcoming publication.

Our study has a few limitations. While we considered data collected by SCRN to be the gold standard, there may have been instances where the vital record contained correct information and the SCRN value was misclassified. We believe this to be a rare occurrence as SCRN took great care to collect the most accurate information for all study enrollees via medical record abstraction and maternal interview. Our study included all women who were enrolled in the case-control study; however not all women consented to participate in all portions of the study. For this reason, we were missing information in the SCRN database for comparison to the vital record for some women.

This study also has several strengths. This is the first study to examine whether missing and misclassified data on the FDC are associated with select maternal and delivery characteristics, as well as the joint effect of these biases. This is a population-based sample that represents approximately 47% of DeKalb and 91% of Salt Lake County stillbirths that occurred during the study period and were issued an FDC.

The high levels of missing and misclassified data in this study add to the literature that suggests that the quality of FDC data is lacking. Additionally, our study demonstrates that FDC data quality is not associated with maternal or delivery characteristics, but rather is associated with county of residence, which likely corresponds to the reporting area. Despite the potential usefulness of FDC data, FDCs have major limitations in their current state, which hamper their utility with respect to public health activities. The dramatic differences in FDC data quality between Georgia and Utah indicate that it is possible to obtain better records for fetal deaths and that there are ample opportunities for improvement in reporting of stillbirths. Efforts should be made to improve reporting of stillbirths, including reducing the number of records with missing values as well as improving the accuracy of the data reported. This could be done through linkage with electronic medical records, as well as waiting to finalize the FDC until all testing, including autopsy, is complete, and performing regular audits of data accuracy.

Table 6.1. Characteristics of 382 residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study, by county of residence and Fetal Death Certificate (FDC) linkage status, 2006-2008

	DeKalb County (N = 166)		Salt Lake County (N = 216)	
Characteristic	FDC Linked n (%)*	FDC Unlinked n (%)*‡	FDC Linked n (%)*	FDC Unlinked n (%)*§
Participants	126 (75.9)	40 (24.1)	208 (96.3)	8 (3.7)
Method of Linkage				
ID 1	103 (81.7)	--	182 (87.5)	--
ID 2	4 (3.2)	--	8 (3.8)	--
ID 3	5 (4.0)	--	8 (3.8)	--
ID 4	10 (7.9)	--	7 (3.4)	--
Manual Search	4 (3.2)	--	3 (1.4)	--
Maternal Characteristics				
Age†	27.0 (6.4)	26.9 (7.3)	28.2 (6.4)	29.1 (6.9)
Race/Ethnicity				
Non-Hispanic White	5 (4.0)	0 (0)	138 (66.3)	4 (50.0)
Non-Hispanic Black	94 (74.6)	32 (80.0)	5 (2.4)	0 (0)
Hispanic	17 (13.5)	2 (5.0)	50 (24.0)	3 (37.5)
Other	10 (7.9)	6 (15.0)	15 (7.2)	1 (12.5)
Education (completed years)				
0-11	23 (18.3)	5 (12.5)	20 (9.6)	1 (12.5)
12	21 (16.7)	10 (25.0)	41 (19.7)	2 (25.0)
13 or more	33 (26.2)	14 (35.0)	91 (43.8)	2 (25.0)
Unknown	49 (38.9)	11 (27.5)	56 (26.9)	3 (37.5)
Mother Married				
Yes	29 (23.0)	6 (15.0)	102 (49.0)	2 (25.0)
No	49 (38.9)	24 (60.0)	51 (24.5)	3 (37.5)
Unknown	48 (38.1)	10 (25.0)	55 (26.4)	3 (37.5)
Delivery Characteristics				
Delivery Year				
2006	26 (20.6)	17 (42.5)	52 (25.0)	0 (0)
2007	61 (48.4)	21 (52.5)	90 (43.3)	6 (75.0)
2008	39 (31.0)	2 (0.05)	66 (31.7)	2 (25.0)
Gestational Age†	28.1 (6.9)	26.3 (5.7)	28.8 (6.9)	25.1 (6.6)
Timing of Death				
Antepartum	73 (57.9)	29 (72.5)	138 (66.4)	4 (50.0)
Intrapatrum	53 (42.1)	11 (27.5)	70 (33.7)	4 (50.0)

* Values are n (%) unless otherwise stated

† Mean (SD)

‡ p-values for all differences between those with and without a linked FDC > 0.05, except for delivery year (p < 0.001)

§ p-values for all differences between those with and without a linked FDC > 0.05

Table 6.2. Frequency of missing data for select Fetal Death Certificate (FDC) data elements for 334 residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study, by county of residence, 2006-2008

Characteristic	Women with missing value on FDC		p-value
	DeKalb County (n = 126) n (%)	Salt Lake County (n = 208) n (%)	
Maternal Characteristics			
Age	0 (0)	0 (0)	--
Race	2 (1.6)	4 (1.9)	1.0
Ethnicity	19 (15.1)	0 (0)	< 0.0001
Education (completed years)	76 (60.3)	12 (5.8)	< 0.0001
Marital Status	0 (0)	0 (0)	--
County of Residence	0 (0)	1 (0.5)	--
Prenatal Care			
Received any Prenatal Care	47 (37.3)	0 (0)	< 0.0001
Number of Prenatal Care Visits	37 (29.4)	18 (8.7)	< 0.0001
Medical Risk Factors for Stillbirth			
Smoking During Pregnancy	76 (60.3)	0 (0)	< 0.0001
First Pregnancy	24 (19.4)†	*	--
Chronic Hypertension	126 (100)	0 (0)	< 0.0001
Gestational Diabetes	‡	0 (0)	--
Eclampsia	126 (100)	*	--
Preeclampsia	126 (100)	*	--
Delivery Characteristics			
Date of Delivery	0 (0)	0 (0)	--
Sex	3 (2.4)	2 (1.0)	0.37
Gestational Age	0 (0)	0 (0)	--
Birth Weight	20 (15.9)	13 (6.3)	0.0072
Plurality	4 (3.2)	0 (0)	0.020

* Variable not available in Utah vital records

† 2 women had SCRN values indicating “not applicable” for this variable – they have been removed from the denominator

‡ Variable not available in Georgia vital records

Table 6.3. Frequency of misclassified information for select Fetal Death Certificate (FDC) data elements for residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study, by county of residence, 2006-2008

Characteristic	Women with misclassified FDC information		p-value
	DeKalb County n (%)	Salt Lake County n (%)	
Maternal Characteristics			
Age (n = 334)*	4 (3.2)	4 (1.9)	0.48
Race (n = 328)	23 (18.6)	22 (10.8)	0.07
Ethnicity (n = 315)	2 (1.9)	7 (3.4)	0.72
Marital Status (n = 231)	6 (7.7)	7 (4.6)	0.37
County of Residence (n = 333)	11 (8.7)	3 (1.5)	0.0030
Prenatal Care			
Received any Prenatal Care (n = 201)	1 (2.1)	3 (2.0)	1.0
Number of Prenatal Care Visits (n = 192)	39 (78.0)	74 (52.1)	0.0014
Medical Risk Factors for Stillbirth			
Smoking During Pregnancy (n = 176)	4 (15.4)	7 (4.7)	0.06
First Pregnancy (n = 65)	4 (6.2)	†	--
Chronic Hypertension (n = 147)	‡	2 (1.4)	--
Gestational Diabetes (n = 160)	‡	6 (3.8)	--
Delivery Characteristics			
Date of Delivery (n = 334)	7 (5.6)	5 (2.4)	0.14
Sex (n = 238)	1 (1.3)	1 (0.6)	1.0
Gestational Age (n = 334)	68 (54.0)	43 (20.7)	< 0.0001
Birth Weight (n = 211)	32 (48.5)	19 (13.1)	< 0.0001
Plurality (n = 330)	0 (0)	0 (0)	--

* SCRN and vital records data availability differ for each variable – the total number of women with non-missing data in both sources is shown in parentheses

† Variable not available in Utah vital records

‡ Variable not available or completely missing in Georgia vital records

Table 6.4. Changes in NCHS gestational age or birth weight group membership among residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study with information misclassified on the Fetal Death Certificate (FDC), 2006-2008

	FDC Misclassification of Gestational Age			
SCRN Gestational Age (weeks)	n (%)	Classified at Earlier Gestations n (%)	No Change in Group Membership n (%)	Classified at Later Gestations n (%)
All Gestational Ages	111 (100)	27 (24.3)	47 (42.3)	37 (33.3)
NCHS Gestational Age Groups				
20-23	37 (33.3)	3 (8.1)	20 (54.1)	14 (37.8)
24-27	19 (17.1)	4 (21.1)	10 (52.6)	5 (26.3)
28-31	14 (12.6)	9 (64.3)	3 (21.4)	2 (14.3)
32-33	5 (4.5)	2 (40.0)	2 (40.0)	1 (20.0)
34-36	20 (18.0)	4 (20.0)	8 (40.0)	8 (40.0)
37-39	11 (9.9)	2 (18.2)	4 (36.4)	5 (45.5)
40	2 (1.8)	1 (50.0)	0 (0)	1 (50.0)
41	3 (2.7)	2 (66.7)	0 (0)	1 (33.3)
≥ 42*	0 (0)	NA	NA	NA
20-27	56 (50.5)	3 (5.4)	43 (76.8)	10 (17.9)
≥ 28	55 (49.6)	11 (20.0)	44 (80.0)	NA

	FDC Misclassification of Birth Weight			
SCRN Birth Weight (grams)	n (%)	Classified at Lower Birth Weights n (%)	No Change in Group Membership n (%)	Classified at Greater Birth Weights n (%)
All Birth Weights	51 (100)	3 (5.9)	42 (82.4)	6 (11.8)
NCHS Birth Weight Groups				
< 500	15 (29.4)	NA	12 (80.0)	3 (20.0)
500 – 749	7 (13.7)	0 (0)	5 (71.4)	2 (28.6)
750 – 999	6 (11.8)	0 (0)	6 (100)	0 (0)
1,000 – 1,249	3 (5.9)	1 (33.3)	2 (66.7)	0 (0)
1,250 – 1,499	2 (3.9)	0 (0)	2 (100)	0 (0)
1,500 – 1,999	5 (9.8)	1 (20.0)	4 (80.0)	0 (0)
2,000 – 2,499	6 (11.8)	0 (0)	6 (100)	0 (0)
2,500 – 2,999	4 (7.8)	1 (25.0)	2 (50.0)	1 (25.0)
3,000 – 3,499	2 (3.9)	0 (0)	2 (100)	0 (0)
3,500 – 3,999	1 (2.0)	0 (0)	1 (100)	0 (0)
≥ 4,000†	0 (0)	NA	NA	NA

* There were no SCRN cases with gestational age ≥ 42 weeks with a misclassified FDC value

† There were no SCRN cases with a birth weight ≥ 4,000 grams with a misclassified FDC value

Table 6.5. Distribution of misclassified information for select Fetal Death Certificate (FDC) data elements for residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study, by county of residence, 2006-2008

Characteristic	Women with misclassified FDC information	
	DeKalb County n (%)	Salt Lake County n (%)
Gestational Age* (n = 334)		
-13 weeks	0 (0)	1 (0.5)
-11 weeks	2 (1.6)	0 (0)
-10 weeks	1 (0.8)	0 (0)
-8 weeks	2 (1.6)	0 (0)
-7 weeks	1 (0.8)	0 (0)
-6 weeks	1 (0.8)	0 (0)
-5 weeks	3 (2.4)	0 (0)
-4 weeks	3 (2.4)	0 (0)
-3 weeks	5 (4.0)	0 (0)
-2 weeks	6 (4.8)	1 (0.5)
-1 week	18 (14.3)	19 (9.1)
0 weeks	58 (46.0)	165 (79.3)
1 week	14 (11.1)	14 (6.7)
2 weeks	3 (2.4)	1 (0.5)
3 weeks	2 (1.6)	3 (1.4)
4 weeks	2 (1.6)	0 (0)
5 weeks	2 (1.6)	0 (0)
6 weeks	1 (0.8)	0 (0)
7 weeks	0 (0)	2 (1.0)
8 weeks	0 (0)	2 (1.0)
13 weeks	1 (0.8)	0 (0)
15 weeks	1 (0.8)	0 (0)
Birth Weight† (n = 211)		
> 500g	3 (4.6)	2 (1.4)
201 – 500g	3 (4.6)	1 (0.7)
101 – 200g	3 (4.6)	0 (0)
51 – 100g	1 (1.5)	3 (2.1)
10 – 50g	11 (16.7)	8 (5.5)
1 – 9g	11 (16.7)	5 (3.5)
0 g	34 (51.5)	126 (86.9)
Number of Prenatal Care Visits† (n = 192)		
> 10 visits	3 (6.0)	3 (2.1)
6 – 10 visits	5 (10.0)	3 (2.1)
2 – 5 visits	15 (30.0)	30 (21.1)
1 visit	16 (32.0)	38 (26.8)
0 visits	11 (22.0)	68 (47.9)

* Difference between the SCRN value and the vital records value

† Absolute value of the difference between SCRN value and the vital records value

Table 6.6. Statistical measures of agreement between select Fetal Death Certificate data elements and data collected by the Stillbirth Collaborative Research Network for residents of DeKalb County, Georgia and Salt Lake County, Utah, by county of residence, 2006-2008

Characteristic	Concordance Correlation Coefficient* (95% Confidence Interval)		Kappa† (95% Confidence Interval)	
	DeKalb County	Salt Lake County	DeKalb County	Salt Lake County
Maternal Characteristics				
Race	--	--	0.51 (0.39, 0.62)	0.74 (0.64, 0.84)
Ethnicity	--	--	0.93 (0.83, 1.00)	0.91 (0.84, 0.97)
Marital Status	--	--	0.84 (0.71, 0.96)	0.90 (0.82, 0.97)
Prenatal Care				
Received Prenatal Care	--	--	0.79 (0.39, 1.00)	0.66 (0.29, 1.00)
No. of Prenatal Care Visits	0.54 (0.36, 0.67)	0.64 (0.55, 0.72)	--	--
Medical Risk Factors for Stillbirth				
Smoking During Pregnancy	--	--	0.43 (0.01, 0.86)	0.80 (0.66, 0.94)
First Pregnancy	--	--	0.83 (0.66, 0.99)	‡
Chronic Hypertension	--	--	§	0.87 (0.69, 1.00)
Gestational Diabetes	--	--	§	0.61 (0.32, 0.89)
Delivery Characteristics				
Sex	--	--	0.97 (0.92, 1.00)	0.99 (0.96, 1.00)
Gestational Age	0.89 (0.85, 0.92)	0.98 (0.97, 0.98)	--	--
Birth Weight	0.90 (0.84, 0.94)	0.98 (0.97, 0.99)	--	--
Plurality (n = 330)	--	--	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)

* Concordance correlation coefficient reported for agreement between continuous variables

† Kappa reported for agreement between categorical variables

‡ Variable not available in UT vital records

§ Variable not available in GA vital records

Table 6.7. Descriptive classification of levels of agreement between select categorical Fetal Death Certificate data elements and data collected by the Stillbirth Collaborative Research Network for residents of DeKalb County, Georgia and Salt Lake County, Utah, by county of residence, 2006-2008

Characteristic	DeKalb County	Salt Lake County
Maternal Characteristics		
Race	Moderate	Substantial
Ethnicity	Almost Perfect	Almost Perfect
Marital Status	Almost Perfect	Almost Perfect
Prenatal Care		
Received any Prenatal Care	Substantial	Substantial
Medical Risk Factors for Stillbirth		
Smoking During Pregnancy	Moderate	Substantial
First Pregnancy	Almost Perfect	*
Chronic Hypertension	†	Almost Perfect
Gestational Diabetes	†	Substantial
Delivery Characteristics		
Sex	Almost Perfect	Almost Perfect
Plurality	Almost Perfect	Almost Perfect

* Variable not available in UT vital records

† Variable not available in GA vital records

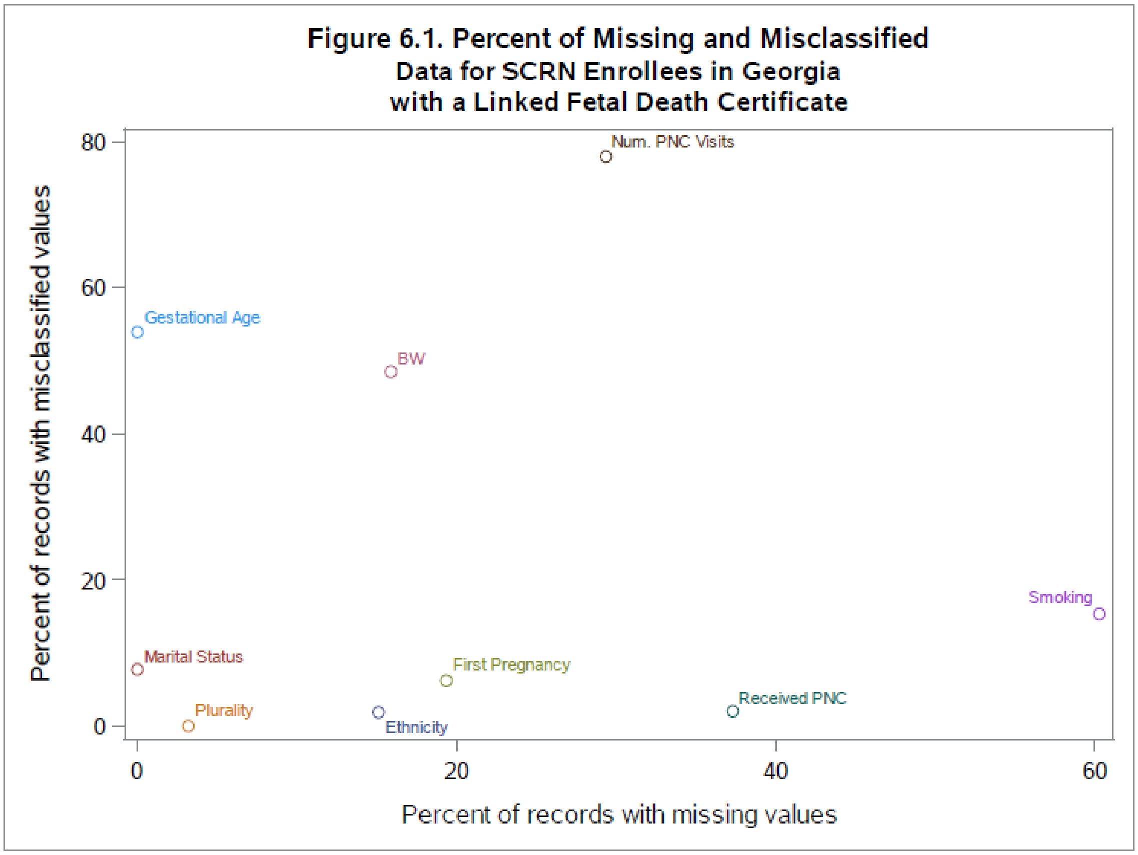
Figure 6.1. Percent of Missing and Misclassified
Data for SCRN Enrollees in Georgia
with a Linked Fetal Death Certificate
Percent of records with misclassified values
Percent of records with missing values
0
20
40
60
80
0
20
40
60
Num. PNC Visits
Gestational Age
BW
Smoking
Marital Status
First Pregnancy
Received PNC
Plurality
Ethnicity

CHAPTER 7:

DOES GESTATIONAL AGE REPORTED ON THE FETAL DEATH CERTIFICATE PROVIDE AN ESTIMATE OF THE GESTATIONAL AGE AT DEATH?

Does gestational age reported on the fetal death certificate provide an estimate of the gestational age at death?

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Objectives: To determine whether gestational age of stillbirths reported on fetal death certificates (GA_{FDC}) overestimates the gestational age at death (GA_{Death}), and whether this difference varies by maternal and delivery characteristics.

Methods: Singleton stillbirths enrolled in the Stillbirth Collaborative Research Network's case-control study of stillbirth in DeKalb County, Georgia and Salt Lake County, Utah were linked to fetal death certificates. An estimate of GA_{Death} as determined by a SCRN-derived algorithm was compared to GA_{FDC}. The difference between GA_{FDC} and GA_{Death} was categorized, and chi-square and ANOVA tests were used to determine whether there were any differences in the distribution of these categories by maternal and delivery characteristics.

Results: The fetal death certificate provided an accurate estimate of the gestational age at death for only 36% of the stillbirths. GA_{FDC} was within 1 week of GA_{Death} for 66% of the stillbirths, and GA_{FDC} overestimated GA_{Death} 22% of the time. The difference between GA_{FDC} and GA_{Death} was not associated with county of residence, race/ethnicity, or when the death occurred relative to labor initiation. This difference was associated with the gestational age at delivery (as reported by SCRN), such that losses *delivered* between 20 and 27 weeks' gestation were more likely to have a fetal death certificate that overestimated the GA_{Death}, and losses *delivered* after 27 weeks' gestation were more likely to have a fetal death certificate that underestimated the GA_{Death}.

Conclusions: Dating of all stillbirths needs improvement. Efforts should be made to improve gestational age reporting of stillbirths to provide accurate information to both families and researchers.

Key Words: stillbirth, fetal death certificate, gestational age at delivery, gestational age at death

Introduction

Accurate reporting of the gestational age of fetal demise is important for families, clinicians and researchers. Knowing when a death *in utero* occurred can offer insight for investigations into the cause of death, which may help families and physicians in planning for and monitoring subsequent pregnancies.[51] Further, most states use gestational age at death as a criterion for registration, beginning at 20 completed weeks' gestation for classifying the fetal death as a stillbirth.[2] Since the majority of stillbirths occur at least one day prior to delivery,[19] it is important to distinguish between the gestational age at death and the gestational age at delivery. The Stillbirth Collaborative Research Network (SCRN) estimated the gestational age at death among 620 singleton stillbirths; in that study, gestational age at delivery (calculated using an estimated due date) exceeded the estimated gestational age at death in 43.5% of the cases.[52]

Currently, the only nationally-available data for stillbirths are in the form of vital records. Previous research has questioned the validity of gestational age as reported on the fetal death certificate (FDC).[24,53,54] Among the many factors contributing to this problem, the guidance for delivery facilities regarding how to provide an estimate of gestation for the FDC lacks clarity.[55] This guidance indicates that facilities should report the *obstetric estimate of gestation at delivery* in completed weeks, and requests the following: "The best obstetric estimate of the infant's gestation in completed weeks based on the birth attendant's final estimate of gestation. This estimate of gestation should be determined by all perinatal factors and assessments such as ultrasound, but not the neonatal exam." While this guidance clearly indicates that reporting of gestational age should rely on information gathered during pregnancy, whether this captures the gestational age at the time the death occurred or the gestational age at delivery is unclear.

Using data from SCRN's population-based case-control study of stillbirth, we compared SCRN's estimate of the gestational age at death (GA_{Death}) to the gestational age that was reported on the corresponding FDC (GA_{FDC}). We sought to determine whether GA_{FDC} overestimated GA_{Death}, and whether this overestimate varied by any maternal or delivery characteristics.

Methods

SCRN conducted a multisite, population-based case-control study that enrolled mothers of stillbirths and a sample of live births at the time of delivery between March 2006 and September 2008. This study has been described in detail elsewhere.[33] The study took place in five clinical sites, each with corresponding catchment areas: Brown University (State of Rhode Island, and Bristol County, MA), Emory University (DeKalb County, GA), University of Texas Medical Branch—Galveston (Galveston and Brazoria Counties, TX), University of Texas Health Science Center—San Antonio (Bexar County, TX), and the University of Utah (Salt Lake County, UT). Hospitals were selected for participation such that at least 90% of all catchment area residents with deliveries ending in a stillbirth (gestation $\geq$ 20 weeks) or a live birth would be identified and potentially approached to consent in the study. Eligible residents were at least 13 years of age and identified for potential participation prior to hospital discharge. An effort was made to enroll all mothers of eligible stillbirths. Data collection included maternal interview, prenatal care medical chart abstraction, and biological specimens.

SCRN developed an algorithm for assigning GA_{Death} for each singleton stillbirth, which has been previously described.[52] This algorithm considered the date of the mother's last menstrual period and its certainty, ultrasound records, dates when the fetus was last documented alive and first diagnosed as dead, presence or lack of fetal maceration, and foot length measurement. The researchers first assigned an estimated due date and identified an interval during which the fetus must have died. They then combined this information with observations and measurements taken during the postmortem examination (where available) to estimate GA_{Death}. The estimated GA_{Death} in completed weeks computed with this algorithm is used in this report.

This analysis is restricted to the singleton stillbirths identified by SCRN between March 2006 and September 2008 in Georgia and Utah, as we were unable to obtain fetal death certificates (FDCs) for Texas, Massachusetts, and Rhode Island enrollees. A comparison of GA_{Death} to GA_{FDC} was only possible for women with a linked FDC. SCRN records were linked to FDCs deterministically using identifiers constructed using portions of the mother's first and last names, mother's date of birth, and date of delivery. A manual search was conducted for any SCRN stillbirths that did not link to an FDC using these identifiers.

We report descriptive statistics for maternal and delivery characteristics of SCRN stillbirths, stratified by county of residence and FDC linkage status. These characteristics include maternal age, race and ethnicity, education, marital status, delivery year, gestational age at delivery, and whether the death occurred before (antepartum) or after (intrapartum) the initiation of labor. Chi-square and t-tests were used to compare groups.

To determine whether GA_{FDC} overestimated GA_{Death}, we examined the difference between these values and report its distribution by county of residence. These differences were then categorized as follows: GA_{FDC} underestimates GA_{Death}, no difference between GA_{FDC} and GA_{Death}, and GA_{FDC} overestimates GA_{Death} by 1, 2, 3, or 4 or more completed weeks. Using these categories, we conducted chi-square and ANOVA tests to determine whether there were any differences in the distribution of these categories by maternal and delivery characteristics.

Results

There were 278 residents of DeKalb and Salt Lake Counties with singleton stillbirths enrolled by SCRN between March 2006 and September 2008; SCRN estimated the gestational age at death for all but two of these stillbirths. Thirty-four of the 276 stillbirths (12.3%) with an estimated GA_{Death} did not have an identifiable fetal death certificate (FDC) (Table 1). The proportions of stillbirths in this sample with a linked FDC in DeKalb and Salt Lake Counties were 74 and 97 percent, respectively. Stillbirths with and without a linked FDC were comparable with respect to maternal age, race and ethnicity, education, marital status, delivery year, and whether the stillbirth was antepartum or intrapartum. The gestational age at *delivery* was comparable between DeKalb County residents with and without a linked FDC; however Salt Lake County residents with a linked FDC occurred later in pregnancy than those without. A value for GA_{FDC} was reported on all linked FDCs.

The distribution of the difference between gestational age as reported on the FDC and the estimated gestational age at death ($GA_{FDC} – GA_{Death}$) is shown in Table 2, overall and by county of residence. Overall, GA_{FDC} differed from GA_{Death} 64% of the time (among these where GA_{FDC} did not equal GA_{Death}, 23% were underestimates, while 77% were overestimates). Gestational age as reported on the FDC was within one week of the estimated gestational age at death for 66% of the stillbirths. GA_{FDC} and GA_{Death} were the same in 33% of DeKalb County stillbirths and 38% of Salt Lake County stillbirths. Among DeKalb County residents, GA_{FDC} overestimated GA_{Death} in 35 of the 82 cases; 60% of these were within 2 weeks, and GA_{FDC} overestimated GA_{Death} by as many as 14 weeks. Among Salt Lake County residents, GA_{FDC} overestimated GA_{Death} in 84 of the 160 cases (53%); 63% of these were within 2 weeks, and GA_{FDC} overestimated GA_{Death} by as many as 17 weeks. GA_{FDC} underestimated GA_{Death} in 24 and 10 percent of cases in DeKalb and Salt Lake Counties, respectively.

There were no statistically significant differences in the distribution of the categories of the difference between GA_{FDC} and GA_{Death} by county of residence, maternal age, race and ethnicity, or whether the stillbirth was antepartum or intrapartum (Table 3). Losses that SCRN determined to have been *delivered* between 20 and 27 weeks were significantly more likely than losses *delivered* at 28 weeks' gestation or later to have FDCs that overestimated GA_{Death} by 2 or more weeks. Conversely, losses that SCRN determined to have been *delivered* at 28 weeks' gestation or later were significantly more likely than losses *delivered* between 20 and 27 weeks' gestation to have FDCs that underestimated GA_{Death}.

Discussion

The estimate of gestational age at delivery as reported on the fetal death certificate (FDC) agreed with SCRN's estimated gestational age at death in only 36% of the stillbirths in our study; however, the difference between these two values was within one week for an additional 30% of the stillbirths. A proportion of stillbirths with a gestational age at death within one week of the value reported to vital records might be explained by delivery attendants rounding to the nearest week, rather than reporting the gestational age in completed weeks. Differences between these values were not associated with county of residence, race/ethnicity, or the timing of the death.

Given that the timing of death for intrapartum stillbirths is known, we anticipated that the difference between GA_{FDC} and GA_{Death} would be greater for antepartum stillbirths compared to intrapartum stillbirths. Instead, we found that the difference between these values was not associated with the timing of death relative to labor initiation. This highlights inadequate dating of pregnancies in general, and stillbirths in particular, and suggests that efforts to improve reporting of gestational age for stillbirths are needed.

In Chapter 6, we examined the completeness and accuracy of FDC data among SCRN enrollees, which included a comparison of the gestational age at *delivery* as reported by SCRN to the value reported by vital records. Agreement between these variables was poor for residents of DeKalb County, and substantial for residents of Salt Lake County. Taken together, these studies indicate that gestational age as reported on the fetal death certificate provides neither a good estimate of gestational age at death nor delivery.

Although the current NCHS guidance for completing the FDC indicates that the neonatal examination should not be used to assign an estimate of gestational age,[55] including a measurement of fetal foot length (as described by Conway et al[52]) may be worthwhile to consider as a part of the process for assigning the gestational age in the next FDC revision. While this method is imperfect for fetuses with significant anomalies or severe growth restriction, improvement over the current reporting of gestational age seems likely and could be tested.

Accurate reporting of the gestational age of stillbirths is important at both the individual and population levels. For an individual, an accurate estimate of the timing of the stillbirth may provide clues into the cause(s) of death and could provide essential information for management of subsequent pregnancies. At a population level, accurately counting the number of stillbirths occurring in the United States is important and is impossible to do when some stillbirths are erroneously classified as having occurred earlier in pregnancy, or when earlier losses are misclassified as stillbirths.

Additionally, accurate dating of stillbirths will help researchers identify stillbirth trends by period of gestation in order to appropriately target interventions and ultimately reduce stillbirth rates.

Table 7.1. Maternal and delivery characteristics of 276 singleton stillbirths occurring to residents of DeKalb and Salt Lake Counties enrolled in the Stillbirth Collaborative Research Network study with an estimated gestational age at delivery, by county of residence and Fetal Death Certificate (FDC) linkage status, 2006-2008

Characteristic †	DeKalb County ‖ (N = 111)		Salt Lake County ‖ (N = 165)	
	FDC Linked	FDC Unlinked	FDC Linked	FDC Unlinked
Participants	82 (73.9)	29 (26.1)	160 (97.0)	5 (3.0)
Maternal Characteristics				
Age‡§	26.3 (6.2)	26.7 (7.8)	28.2 (6.4)	31.6 (7.8)
Race/Ethnicity §				
Non-Hispanic White	4(4.9)	0 (0)	107 (66.9)	2 (40.0)
Non-Hispanic Black	55 (67.1)	22 (75.9)	3 (1.9)	0 (0)
Hispanic	16 (19.5)	2 (6.9)	37 (23.1)	2 (40.0)
Other	7 (8.5)	5 (17.2)	13 (8.1)	1 (20.0)
Education (completed years) §				
0-11	23 (28.1)	5 (17.2)	20 (12.5)	1 (20.0)
12	21 (25.6)	10 (34.5)	41 (25.6)	2 (40.0)
13 or more	33 (40.2)	13 (44.8)	91 (56.9)	2 (40.0)
Unknown	5 (6.1)	1 (3.5)	8 (5.0)	0 (0)
Mother Married §				
Yes	29 (35.4)	6 (20.7)	102 (63.8)	2 (40.0)
No	49 (59.8)	23 (79.3)	51 (31.9)	3 (60.0)
Unknown	4 (4.9)	0 (0)	7 (4.4)	0 (0)
Delivery Characteristics				
Delivery Year §				
2006	18 (22.0)	11 (37.9)	39 (24.4)	0 (0)
2007	43 (52.4)	16 (55.2)	73 (45.6)	3 (60.0)
2008	21 (25.6)	2 (6.9)	48 (30.0)	2 (40.0)
GA at Delivery ‡⁞	27.1 (6.4)	26.8 (5.6)	29.3 (6.7)	21.6 (2.3)
Timing of Death §				
Antepartum	49 (59.8)	22 (75.9)	105 (65.6)	4 (80.0)
Intrapatrum	33 (40.2)	7 (24.1)	55 (34.4)	1 (20.0)

‖ Values are n (%) unless otherwise stated

† As determined by SCRN

‡ Mean (SD)

§ $p > 0.05$ for DeKalb and Salt Lake Counties

⁞ $p > 0.05$ for DeKalb County and $p < 0.001$ for Salt Lake County

Table 7.2. Distribution of the difference between gestational age as reported on the Fetal Death Certificate (GA_{FDC}) and estimated gestational age at death as determined by SCRN (GA_{Death}) for residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study with both estimated gestational age at death and a linked Fetal Death Certificate, overall and by county of residence, 2006-2008

GA_{FDC} – GA_{Death} (weeks)	Overall (N = 242)		DeKalb County (N = 82)		Salt Lake County (N = 160)	
	n (%)	Cumulative %	n (%)	Cumulative %	n (%)	Cumulative %
-6	1 (0.4)	0.4	1 (1.2)	1.2	0 (0)	0
-5	1 (0.4)	0.8	1 (1.2)	2.4	0 (0)	0
-4	2 (0.8)	1.6	0 (0)	2.4	2 (1.3)	1.3
-3	1 (0.4)	2.0	1 (1.2)	3.7	0 (0)	1.3
-2	12 (5.0)	7.0	8 (9.8)	13.4	4 (2.5)	3.8
-1	19 (7.9)	14.9	9 (11.0)	24.4	10 (6.3)	10.0
0	87 (36.0)	50.9	27 (32.9)	57.3	60 (37.5)	47.5
1	54 (22.3)	73.2	15 (18.3)	75.6	39 (24.4)	71.9
2	20 (8.3)	81.5	6 (7.3)	82.9	14 (8.8)	80.6
3	15 (6.2)	87.7	4 (4.9)	87.8	11 (6.9)	87.5
4	13 (5.4)	93.1	4 (4.9)	92.7	9 (5.6)	93.1
5	5 (2.1)	95.2	1 (1.2)	93.9	4 (2.5)	95.6
6	3 (1.2)	96.4	0 (0)	93.9	3 (1.9)	97.5
7	2 (0.8)	97.2	1 (1.2)	95.1	1 (0.6)	98.1
8	2 (0.8)	98.0	1 (1.2)	96.3	1 (0.6)	98.8
9	1 (0.4)	98.4	0 (0)	96.3	1 (0.6)	99.4
10	1 (0.4)	98.8	1 (1.2)	97.6	0 (0)	99.4
11	1 (0.4)	99.2	1 (1.2)	98.8	0 (0)	99.4
14	1 (0.4)	99.6	1 (1.2)	100	0 (0)	99.4
17	1 (0.4)	100	0 (0)	100	1 (0.6)	100

Table 7.3. Distribution of the relationship between gestational age as reported on the Fetal Death Certificate (GA_{FDC}) and estimated gestational age at death as determined by SCRN (GA_{Death}) for residents of DeKalb County, Georgia and Salt Lake County, Utah enrolled in the Stillbirth Collaborative Research Network study with both estimated gestational age at death and a linked Fetal Death Certificate, by county of residence, and maternal and delivery characteristics, 2006-2008

Characteristic †	Relationship between GA_{FDC} and GA_{Death}*						p-value
	GA_{FDC} Underestimated GA_{Death}	GA_{FDC} = GA_{Death}	GA_{FDC} Overestimated GA_{Death}				
			By 1 week	By 2 weeks	By 3 weeks	By 4 weeks or more	
County of Residence							0.10
DeKalb County	20 (24.4)	27 (32.9)	15 (18.3)	6 (7.3)	4 (4.9)	10 (12.2)	
Salt Lake County	16 (10.0)	60 (37.5)	39 (24.4)	14 (8.8)	11 (6.9)	20 (12.5)	
Maternal Race/Ethnicity							0.11§
Non-Hispanic White	10 (9.0)	41 (36.9)	28 (25.2)	13 (11.7)	8 (7.2)	11 (9.9)	
Non-Hispanic Black	14 (24.1)	20 (34.5)	11 (19.0)	3 (5.2)	2 (3.5)	8 (13.8)	
Hispanic	11 (20.8)	19 (35.9)	11 (20.8)	3 (5.7)	3 (5.7)	6 (11.3)	
Other	1 (5.0)	7 (35.0)	4 (20.0)	1 (5.0)	2 (10.0)	5 (25.0)	
Gestational Age at Delivery							0.007
20 – 27 weeks	11 (8.9)	43 (35.0)	25 (20.3)	13 (10.6)	8 (6.5)	23 (18.7)	
28 weeks or more	25 (21.0)	44 (37.0)	29 (24.4)	7 (5.9)	7 (5.9)	7 (5.9)	
Timing of Death							0.73
Antepartum	22 (14.3)	59 (38.3)	30 (19.5)	14 (9.1)	9 (5.8)	20 (13.0)	
Intrapartum	14 (15.9)	28 (31.8)	24 (27.3)	6 (6.8)	6 (6.8)	10 (11.4)	

* Values are n (row %) unless otherwise stated

† As determined by SCRN

‡ Mean (SD)

§ Due to small cell sizes, categories where GA_{FDC} overestimated GA_{Death} were collapsed for p-value calculation

CHAPTER 8: CONCLUSION

These studies demonstrate the wide range of variability in stillbirth reporting. The data for each of our analyses came from Utah and Georgia, which radically differ in data quality. Between January 1, 2007 and June 15, 2009, stillbirths were underreported in both Salt Lake and DeKalb Counties; and the degree of underreporting was far worse in DeKalb County. Among SCRN-identified stillbirths, the only difference between those with and without a fetal death certificate was for gestational age among Salt Lake County stillbirths; fetuses of Salt Lake County residents delivered between 20 and 27 weeks' gestation were more likely to have been missed by vital records than those delivered at 28 week's gestation or later.

Data quality, as determined by the proportion of records with missing and/or misclassified information, varied by county of residence as well as data item. Some variables, such as fetal sex, plurality, and maternal age were consistently and accurately reported in both counties. Data quality was good for most other variables reported in Salt Lake County, with the exception of the number of prenatal care visits a woman received, which suffered only moderately from missing values, but substantially from misclassified values. DeKalb County's fetal death certificate data quality was worse than Salt Lake County, and was impacted by high levels of both missing and misclassified information. Some variables, like parity, receipt of prenatal care, and smoking during pregnancy, suffered mostly from a high proportion of missing values. Other variables, like maternal race and gestational age, suffered more from incorrect reporting. Finally, birth weight and number of prenatal care visits suffered from a combination of high levels of both missing and misclassified information.

Finally, we found that the gestational age reported on the fetal death certificate rarely corresponded exactly to SCRN's estimate of the gestational age at death. We anticipated that the value reported on the fetal death certificate would either equal or overestimate the age at death; however, we saw that the value reported to vital records was *less* than SCRN's estimate for 15% of the stillbirths. Additionally, we hypothesized that the difference between the gestational age as reported on the fetal death certificate and the estimated gestational age at death would be smaller for stillbirths occurring after the initiation of labor, since the timing of the death is well documented in these cases. We did not observe any association between the timing of death relative to labor initiation and the difference between these two values. Taken together, these findings suggest that dating of all pregnancies, and stillbirths in particular, needs improvement.

The crux of stillbirth reporting in the United States lies with accurate dating of pregnancies, since most reporting areas use gestational age as the only criterion for reporting. In addition to improving the dating of pregnancies, we must impress upon delivery attendants the public health importance of reporting each pregnancy loss that meets the criteria for reporting in his or her reporting area. Since the causes of stillbirth tend to cluster by period of gestation, it is essential to have an accurate count of stillbirths by gestational age so that interventions aimed at reducing stillbirth rates can be targeted and evaluated.

Before infant death records were linked to birth certificates, the disparity in mortality between Non-Hispanic Black and Non-Hispanic White infants was not accurately documented. It wasn't until after the linkage of these records that researchers realized that the race of the infant was often misreported on the death certificate, and that the infant mortality data had been inaccurate. Given that vital records provide the only national data for stillbirth, they are key to what we do (and do not) know about this important public health issue that has been largely ignored in the United States. We must improve the quality of these data so that we can accurately describe the scope of the problem and identify areas where we can have the most impact in reducing stillbirth rates and disparities.

If improvements can be made in the reporting of stillbirths, fetal death certificates can be used to sample women who have had a recent stillbirth, using methodologies similar to those employed by the Pregnancy Risk Assessment Monitoring System (PRAMS) for studying women with a recent live birth.[56] In unpublished studies, we conducted both formative and pilot research to determine whether women with a recent stillbirth would be willing to answer questions about their experiences during pregnancy and around the time of the loss. In-depth interviews revealed that bereaved women and their advocates strongly supported the creation of a surveillance system for stillbirth. Many women did not know what had caused their stillbirth, and were hopeful that a new surveillance system could provide clues to help researchers identify at-risk fetuses and prevent other families from experiencing a similar loss.

Given the positive response we received during the formative research, we conducted a pilot study of the expansion of PRAMS to include stillbirths in Georgia to determine whether women would respond to a mailed survey about their experiences around the time of the loss. We received fetal death certificates for all stillbirths that occurred in Georgia between December 1, 2012 and February 28, 2013. These certificates contained demographic, delivery, and contact information. Surveys were mailed in June 2013, and we received responses from 49 of the 149 (33%) eligible women. Despite contacting women only 4-6 months after the loss, we had an invalid or missing address *and* telephone number for 26 (18%) of the women. If we exclude the women who never received any study materials, we achieved an adjusted response rate of 40%. Among women who we believe received our study materials, the only statistically significant difference between women who responded and those who did not was maternal race/ethnicity, such that Non-Hispanic White women were significantly more likely to respond than Non-Hispanic Black women. While the adjusted response rate of 40% may seem low, it is actually on par with the response rates that a new PRAMS site achieves when it first participates in the surveillance project. Further, unlike PRAMS, we were unable to offer incentives or rewards for participation. It is likely that an even greater response rate could be achieved by offering incentives or rewards.

Given the wealth of information that could be obtained from a PRAMS-like survey for stillbirth, further pilot studies are warranted. The quality of the data gained from this type of surveillance system rests on the underlying sampling frame of fetal death certificates. Improvements in the completeness of stillbirth reporting would not only help obtain an accurate count of the number of stillbirths occurring in the United States, but could also offer a more representative base from which fetal death certificates could be sampled to create a new surveillance system for stillbirth.

Despite a similar impact, in both magnitude and emotion, stillbirths have largely been kept in the shadows of the public health spot light that is shone upon infant deaths. We cannot continue to ignore the 26,000 lives that are lost annually in the United States due to stillbirth, nor can we turn a blind eye to the families who suffer these losses. Improvement of stillbirth surveillance, through improved dating and delivery attendant education, will allow researchers to better understand the magnitude of the problem and address it appropriately.

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