Challenges and Priorities for Surveillance of Stillbirths: A Report on Two Workshops

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SYNOPSIS

Stillbirths, those with and without birth defects, are an important public health topic. The National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention conducted two workshops during April and July 2005. Both workshops explored the challenges of conducting surveillance of stillbirths. Workshop participants considered an approach that added the surveillance of stillbirths, those with and without birth defects, as part of existing population-based birth defects surveillance programs in Iowa and Atlanta. The workshops addressed three key aspects for expanding birth defects programs to conduct active, population-based surveillance on stillbirths: (1) case identification and ascertainment, (2) data collection, and (3) data use and project evaluation. Participants included experts in pediatrics, obstetrics, epidemiology, maternal-fetal medicine, perinatology and pediatric pathology, midwifery, as well as practicing clinicians and pathologists. Expanding existing birth defects surveillance programs to include information of stillbirths could potentially enhance the data available on fetal death reports and also could benefit such programs by improving the ascertainment of birth defects.

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Fetal deaths are an important public health problem with a tremendous emotional and psychological impact on families,^{1,2} and those that occur at 20 or more weeks of gestation (i.e., stillbirth or late fetal death) account for less than 1% of all births but nearly one-half of all perinatal deaths.³ In 2004, about 4.1 million live births and 25,655 stillbirths (fetal deaths at 20 or more weeks of gestation) were registered in the U.S.4 Significant racial disparity exists in the occurrence of stillbirths, with rates among non-Hispanic African American mothers at two to three times the rate of non-Hispanic white mothers.⁵⁻¹⁰ A number of risk factors for stillbirth have been identified, including low socioeconomic status, very young and advanced maternal age, obesity, multigravida, smoking, hypertension, diabetes, and congenital anomalies;¹¹⁻²³ however, the factors that contribute to most stillbirths remain unknown.²⁴⁻²⁶

One of the challenges to conducting epidemiologic studies of stillbirth has been the limited availability of reliable population-based surveillance data. By law, fetal deaths must be reported in the United States; however, reporting requirements and, to a lesser extent, the criteria used to define fetal death vary.²⁷ As a result, the use of fetal death reports (FDRs) as a source of surveillance data has been problematic.^{27–36}

In 2005, two birth defects surveillance programs, the Metropolitan Atlanta Congenital Defects Program (MACDP) and the Iowa Registry of Congenital and Inherited Disorders (IRCID), initiated pilot studies to examine the feasibility of leveraging the resources of existing birth defects surveillance programs to conduct surveillance of stillbirths. MACDP and IRCID are population-based birth defects surveillance systems that use active case finding methods to identify all infants or fetuses with birth defects. Trained abstractors regularly visit birth hospitals, pediatric hospitals, specialty clinics, and perinatal offices to systematically search available data sources for cases of birth defects.

MACDP was established in 1967 and is currently administered by the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention; it is described in detail elsewhere.³⁷ IRCID was established in 1983 through the joint efforts of the University of Iowa, the Iowa Department of Public Health, and the Iowa Department of Human Services, and is located within the College of Public Health at the University of Iowa.³⁸ The common objectives of these two stillbirth surveillance pilot projects are: (1) to evaluate the feasibility of expanding a population-based birth defects surveillance system to incorporate data from existing medical records on fetal deaths, (2) to monitor and report on the occurrence of fetal deaths in the surveillance population, (3) to serve as a registry for etiologic studies on fetal deaths, and (4) to serve as a resource for education and evaluation of prevention programs.

Using existing population-based birth defects registries that employ active case finding is a potentially novel approach to address the data gaps and limitations in FDRs. This approach is both advantageous and beneficial to birth defects surveillance programs for three primary reasons. First, it is more efficient because existing birth defects programs have the necessary infrastructure already in place to incorporate surveillance data on stillbirths. Second, existing programs that are responsible for surveillance of birth defects would benefit directly from these expanded activities because intensifying surveillance on stillbirths likely will increase the identification and ascertainment of birth defects.³⁹ Third, this approach may guide our understanding of the etiology of deaths occurring at various gestational ages. Furthermore, these intensified surveillance activities have the potential to inform, complement, and enhance existing fetal/infant mortality programs, and such programs should be involved in the development, implementation, and utilization of these surveillance activities when possible.

As a first step to planning for these pilot projects, two expert workshops were conducted during April and July 2005 to address three key aspects for active, population-based surveillance on stillbirths: (1) case identification and ascertainment, (2) data collection, and (3) data use and project evaluation. The primary objective for both workshops was to provide guidance on the implementation of the two pilot studies at IRCID and MACDP. Secondary discussion related to how other state-based birth defects surveillance programs might incorporate similar activities, including benefits and barriers. The objectives of the first workshop were to identify and address issues related to case definition and ascertainment, data collection and quality, and data use and project evaluation. The objective of the second workshop was to review approaches and challenges to the clinical-pathological aspects of stillbirth evaluation. Participants in these workshops included experts in obstetrics, maternal-fetal medicine, perinatology, midwifery, pediatrics, epidemiology, and pediatric pathology. This article summarizes the key findings of these two workshops.

CASE IDENTIFICATION AND ASCERTAINMENT

The first workshop addressed two essential issues: (1) establishing criteria for what to include as a stillbirth case and (2) identifying sources for case ascertainment. These issues were discussed to clarify active surveillance

of stillbirths (or late fetal deaths) within the existing framework of each participating birth defects surveillance program.

Definitions

There is no universally accepted definition of stillbirth that includes the criteria for gestational age or birthweight. The World Health Organization defines fetal death as "death before the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation, 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."40 The 1992 Revision of the Model State Vital Statistics Act and Regulations (Model Law) further clarifies this definition: "Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps."41 The National Center on Health Statistics (NCHS) uses this adapted definition of fetal death. The Model Law further recommends the reporting of fetal deaths based on weight (\geq 350 grams) and gestational age (\geq 20 completed weeks of gestation).⁴² The majority of states require reporting at 20 weeks of gestation or longer, but reporting requirements vary by state.²⁷

Workshop participants suggested two reasons to include the surveillance criteria of fetal deaths occurring at 20 or more weeks of gestation, or at 350 or more grams of weight, if the gestational age is not known. First, this inclusion is similar to the reporting requirements of most states and with the criteria NCHS uses when it reports national estimates on fetal death. Second, these gestational age and weight criteria reflect the lower limits that an active-based surveillance program could reasonably expect to capture. Fetal deaths that meet these criteria are usually managed in a hospital setting—sources of data with which active birth defects programs are already familiar.

Data on fetal deaths occurring at much lower gestational ages would require extensive resources to capture, and most programs would be unable to afford or justify the resources. It has been shown that lowering the gestational age range for reporting fetal deaths results in more complete reporting of fetal deaths. Moreover, because estimates of gestational age can be inexact, workshop participants suggested identifying and reviewing the records for fetal deaths beginning at 18 weeks of gestation to help improve the completeness of ascertainment for those deaths at 20 weeks of gestation and longer.⁴ It is possible that some fetal deaths recorded as occurring at 18 or 19 weeks of gestation may in fact be growth-restricted fetuses at 20 or more weeks of gestation. It is important to review these cases to render a judgment regarding inclusion based on information in the clinical record.

Stillbirths and induction of labor

Additional issues about case definition and inclusion concerned cases in which labor was induced with the intention of terminating the pregnancy. Cases in which labor induction is performed as medical management for intrauterine fetal death (IUFD) should, of course, be included as stillbirths, assuming the gestational age or birthweight criteria is met, as the fetus already has expired before the intervention. However, a fetal death certificate may be issued for induced termination of pregnancy (ITOP), or the purposeful termination of pregnancy for birth defects, inevitable losses (chorioamnionitis with preterm premature rupture of membranes and labor), and maternal medical complications (severe preeclampsia). These situations pose unique challenges for surveillance.

The Model Law includes the following definition for ITOP: "Induced termination of pregnancy means the purposeful interruption of an intrauterine pregnancy with the intention other than to produce a live born infant and which does not result in a live birth. This definition excludes management of prolonged retention of products of conception following fetal death." The medical record, however, may not contain the information necessary to determine whether the fetus had expired prior to the medical intervention, such as documentation of absent fetal heart tones, or a statement clearly indicating a fetal demise had occurred.

The extent to which ITOPs are misclassified as fetal deaths, and the circumstances in which they occur, are largely unknown. Workshop participants suggested that initial pilot studies investigate and further explore these issues about potential misclassification. Initial studies could use data from cases of birth defects medically managed by ITOPs ascertained by MACDP and IRCID for this purpose. These data are available and could be used to evaluate potential misclassification in FDRs. Participants also suggested that standardization of obstetrical documentation in these situations could prove helpful. Lastly, workshop participants suggested that guidelines and methods would need to be developed that incorporate all available clinical information to systematically determine inclusion status.

Out-of-hospital deliveries

Deliveries that occur outside of the hospital setting, in the absence of medical personnel, and then are presented to the hospital as a death are another consideration for case inclusion criteria. Under these circumstances, it is not always possible to determine whether the fetus was stillborn, or if the fetus lived for any length of time. In localities where a medical examiner is required to evaluate these deaths, information from their reports should be used to make this determination. If no medical examiner's report is available, then the information in the medical record can be used. In either case, a variable should indicate the location of delivery with documentation of the circumstances surrounding the delivery. This additional information will allow for these cases to be included in a surveillance system, as well as provide a method of evaluating and reporting these cases as a distinct group.

Assessment of gestational age

The workshop participants raised several issues regarding how gestational age is determined for fetal deaths. Often, the date of fetal death and the date of delivery are the same, but in some cases, the date of delivery may follow the date of fetal death by several days or longer-up to two weeks in some cases.⁴³ From a clinical perspective, the most accurate method for determining gestational age is considered to be early ultrasonography in the first trimester using the crown-rump length for dating.44 If no early ultrasound is available, then the physician's estimate or the date of the patient's last menstrual period can be used. Information should also be recorded that indicates whether a pregnancy resulted from assisted reproductive technology. The accurate determination of gestational age has important implications for public health research.45 For surveillance purposes, the workshop participants suggested that all of these gestational age estimates be collected so that studies considering gestational age could be conducted using a variety of methods.

Case finding

Workshop participants indicated that multiple sources would be required to ensure comprehensive case ascertainment. While fetal death is a reportable event by law in the United States, studies have shown that early stillbirths (i.e., deaths during 20–27 weeks of gestation) are underreported.^{27,29} Furthermore, the extent to which ITOPs and nonviable live births are misclassified is not well documented. Therefore, additional sources are needed, and programs employing active case finding are methodologically well suited to fulfill this need.

Existing sources for case finding used by birth defects surveillance programs to identify birth defect cases also can be used to identify stillbirths. These exist-

ing sources include birth hospitals, labor and delivery units, genetic testing laboratories, and perinatal offices. The pathology departments of pediatric hospitals also can be used to identify fetuses referred for autopsy by a perinatal pathologist. For birth hospitals, the disease indices lists (i.e., International Classification of Diseases, Ninth or Tenth Revision) used by the abstractors to identify potential cases should be updated to include codes that reflect the occurrence of a possible IUFD. An IUFD diagnosed at a perinatal specialty office also can be captured, if such locations are visited, with case follow-up and abstraction performed at the referral hospital for management and delivery.

For the pilot phase of each project, workshop participants encouraged the inclusion of additional data sources to assess their ascertainment value. Examples included emergency room departments and emergency medical service logs to assess how pregnancy complications or home births resulting in stillbirth are managed in the emergency room. This assessment might be particularly beneficial in areas where home birthing is more common. In addition, outpatient clinics affiliated with a birth hospital should be visited to assess whether IUFD would be managed in these settings. Birthing hospitals located in the surrounding counties that could potentially serve the residents of a surveillance population should also be visited.

The findings regarding definitions and case ascertainment are summarized in the Figure.

DATA COLLECTION

Upon development of a working case definition for ascertainment of fetal deaths at ≥ 20 weeks of gestation, or \geq 350 grams if the gestational age is not known, the panel of experts was asked what information should be collected. The panel was reminded that the collected information was for surveillance purposes, rather than research; thus, each program would be limited to medical chart review. Existing birth defects surveillance programs already contain the methods and infrastructure to collect basic demographic and epidemiologic information on the mother, the father, and the fetus. This information reflects the absolute minimum of data collection for monitoring purposes. Ample information must be collected to properly evaluate whether a case meets the inclusion criteria. This information includes the following: date of the last normal menses, early ultrasound dating, physician's estimate, date of delivery, date of fetal death diagnosis, presence of intrauterine growth restriction, and maceration.

For proper classification of pregnancy outcomes, additional information should be recorded. The

Figure. Summary of discussion issues and suggestions by topic during two workshops on stillbirth surveillance, April and July 2005

Торіс	Specific issues	Suggestions
Definition and ascertainment	Criteria for case inclusion: IUFD Nonviable neonatal deaths Terminations Out-of-hospital delivery	Fetal death at ≥20 weeks of gestation or ≥350 grams if age is unknown. Ascertain down to 18 weeks to increase completeness of cases ≥20 weeks. Capture nonviable neonatal deaths based on APGAR scores and documentation of heart rate or respirations to assess misclassification. Terminations for birth defects are captured as part of existing defects registry and are included. Labor-induced pregnancies for inevitable losses or maternal medical complications should be included to assess potential misclassification. Capture and document out-of-hospital deliveries.
	Sources for case finding	Multiple sources required. Link cases with FDRs. Include pathology departments as routine. Emergency rooms. Medical examiner offices. Assess outpatient procedure clinics for possible case finding. Delivery hospitals bordering surveillance catchment area. IUFD diagnosed at perinatal practices (if feasible) with follow-up at referral delivery hospital.
Data collection	Based on working definition, what information should be collected for surveillance?	Record basic demographic and epidemiologic information on the mother, father, and fetus. Indicate if prenatal records were available. Classify as antepartum vs. intrapartum.
	What information is needed to assess potential gestational age discrepancies and case inclusion criteria?	If available, record date of last menstrual period, early ultrasound dating, physician's stated estimate of gestational age, date of delivery, date of fetal death diagnosis, presence of intrauterine growth restriction, and extent of maceration.
	What information is needed to assess potential misclassification?	If available, record ultrasound documentation of the presence or absence of fetal hear tones before delivery, Apgar scores at one and five minutes, documentation of a heart rate or respirations, attempts at resuscitation, labor induction or augmentation, and extent of maceration.
	Risk factors and potential causes Completeness of medical record Information maintained in multiple locations (e.g., computers, pathology departments) Lack of required, standardized postmortem evaluation protocols	If available, record prenatal care history and number of visits. Record maternal medical history and comorbid conditions (including medications), such as hypertension, diabetes, obesity, and thrombophilic disorders. Record pregnancy complications such as abruption, placenta previa, antepartum hemorrhage, infections, cord complications, pregnancy-associated hypertensive disorders, preterm rupture of membranes, and labor. Record behavioral risk factors such as smoking, alcohol, and drug use. Record results of prenatal cytogenetic testing. Indicate what postmortem tests were conducted (e.g., autopsy, external fetal exam, placental histopathology, genetic testing, radiographs). Indicate if autopsy was specifically refused. Record the findings of postmortem tests. Assess use of evaluation protocols among health-care providers. Engage stakeholders to identify and address barriers in the use of evaluation protocols.
Data use and project evaluation	Short-term objectives for using collected data	Design studies involving data linkages to assess FDRs as a source of surveillance data for stillbirths. Completeness of ascertainment of cases. Completeness and accuracy of information recorded. Assess potential misclassification of cases in FDRs. Demonstrate the usefulness of expanding existing birth defects registries to include stillbirths for enhancing and improving upon the data in FDRs.
	Long-term objectives Classification of cases for surveillance purposes Understanding classification where postmortem evaluations and management are not standardized, uniform, or required	Ongoing monitoring of stillbirths. Make data available for further studies on etiology and risk factors. Develop and evaluate classification strategies for use in surveillance on stillbirths.

IUFD = intrauterine fetal death

FDR = fetal death report

presence of a heart rate or of definite respirations at delivery (recording Apgar scores or other documentation) will aid in properly differentiating between cases of fetal death and live births. Recording whether resuscitation efforts were attempted also will help to provide some clinical context to the delivery. Likewise, documentation of fetal heart tones (present or absent) on admission to labor and delivery, and if labor was induced or augmented, will aid in determining whether induction was conducted for medical management for fetal death, or as an intervention to terminate pregnancy because of a complication. If present, the degree of maceration also should be recorded. If the timing of death can be determined, it should be recorded to distinguish antepartum vs. intrapartum events.

A number of issues affect the availability and completeness of information in the medical record. The record may contain all or part of the prenatal obstetric history, and indicating whether this information was available at the time of abstraction, along with the number of prenatal visits, would be important. Postmortem evaluations such as autopsy, placental histopathology, radiographs, and cytogenetic and laboratory testing may have been conducted, and data collection and interpretation could be enhanced by indicating if these tests were done and whether the results were available at the time of abstraction. For a case in which test results could not be found in the medical record, other sources such as pathology, radiology, cytogenetic, and laboratory departments can be explored in an attempt to gather this information.

Postmortem evaluations pose special challenges for stillbirth surveillance. The collection of information in a systematic and consistent manner is important for the accurate and complete monitoring of stillbirths; however, there are no national standard guidelines or standard reporting procedures for evaluating stillbirths. Parental refusal, inadequate consenting procedures, reimbursement, and extensive fetal maceration also influence whether an adequate postmortem evaluation was performed. Placental histopathology, although frequently performed in cases of stillbirth, is often inadequate. The state of Iowa has made great progress in its attempt to overcome these limitations by developing and promoting a statewide stillbirth evaluation protocol. Use of the protocol is voluntary; however, a statewide perinatal care team regularly visits birthing hospitals to promote and provide education on using the protocol (Figure).

DATA USE AND PROJECT EVALUATION

Although two long-term strategic goals for these pilot projects are to establish ongoing enhanced surveillance of stillbirths and to provide a registry for further etiologic studies, the most immediate beneficial uses of the collected data would be for evaluative purposes to inform on many of the issues described previously. This information could be used to evaluate the limitations of vital statistical data as a source of surveillance data for stillbirths. These studies should provide guidance on completeness of case ascertainment, and they should evaluate the extent of potential misclassification of fetal deaths, live births, and ITOPs. This knowledge can be used to improve vital statistics programs.

Data linkage is a useful methodology for this work. It is well known that the recording of birth defects on birth certificates is unreliable;^{46,47} however, limited information is available about the reporting of defects on fetal death certificates.^{28,32,34} Using active birth defects programs as a comparison, the sensitivity, specificity, and positive predictive value of FDRs to record birth defects can be assessed. Likewise, the variables appearing on the FDRs can be benchmarked against active-based data abstraction methods to assess the records' completeness and accuracy. Fundamentally, an evaluation of these projects needs to show improvement of currently available information on FDRs, as well as improvements in the quantity and quality of data collected. Lastly, collaboration with stakeholders can be beneficial for raising awareness, promoting education, and developing and communicating prevention strategies (Figure).

DISCUSSION

Existing birth defects surveillance programs provide the necessary infrastructure and methodology to expand their surveillance capabilities to include stillbirths. Workshop participants agreed that clear definitions describing both ascertainment and reporting criteria of cases need to be established, with guidelines describing a systematic approach to reviewing the data. These guidelines should be consistent with the current approaches outlined in the Model Law and employed by NCHS for fetal deaths. These guidelines should include clear definitions and how to record the information sometimes necessary to distinguish among nonviable live births, antepartum and intrapartum fetal deaths, and ITOPs.

The collection of data for enhanced surveillance of stillbirths can be challenging and has many limitations and barriers to obtaining complete and accurate information. The extent of information to be collected will depend largely on program capabilities; however, basic demographic information is a minimum for data collection. Recommendations are needed to develop a standardized dataset for population-based surveillance of stillbirths. The ideal dataset would potentially reflect all available information necessary to inform on strategies to reduce risk factors, potential causes, and associated conditions with each event. Fetal autopsy and placental histopathology are two essential components to an adequate evaluation, but often they are not routinely performed in a systematic fashion. Long-term strategies involving multiple stakeholders are needed to improve the quality of data generated and recorded when stillbirth occurs. These strategies include the development of guidelines for postmortem evaluation, along with awareness, education, and training for health-care providers in the appropriate use of these protocols and guidelines. Likewise, ongoing awareness and training are needed at the state level to educate providers on the various reporting requirements for fetal death.

Although stillbirth is a relatively common occurrence compared with other adverse pregnancy outcomes, existing data sources are inadequate for population-based estimates on risk factors and for determining potential causes of stillbirth. Expanding existing population-based birth defects surveillance programs to include surveillance on stillbirths is one approach to address these data gaps. This approach has three potential advantages and benefits. The first is efficiency. Existing birth defects programs with active case finding have the necessary infrastructure already in place to incorporate surveillance data on stillbirths. For some programs, minimal effort would be needed for methodology and data collection revisions for this expansion; whereas others might require more intensive efforts. Significant legal, financial, and operational barriers will potentially pose formidable challenges for some state-based programs, and appropriate training for abstractors to begin these new activities would need to be readily implemented. This training would require standardization and need to include education on various maternal-fetal health issues, to include obstetric complication and placental pathology correlates.

Second, existing programs responsible for the surveillance of birth defects would benefit directly from these expanded activities. It is believed that congenital anomalies contribute to approximately 20%–25% of stillbirths,^{21,48} and increasing the ascertainment of stillbirths in these programs would help to further ensure the completeness of birth defects information. Third, this approach would enlighten efforts on etiology for gestational age at death. Fetal deaths occurring at ≥ 20 weeks of gestation are thought to have different

etiologies from earlier losses, and understanding the spectrum of potential causes in these later deaths will help with potential public health and clinical prevention strategies.

CONCLUSIONS

The suggestions and ideas resulting from these workshops are invaluable for planning the expansions of MACDP and IRCID to begin surveillance on stillbirths. Case definition and inclusion criteria are essential first steps to improving complete and accurate classification of pregnancy outcome. Multiple sources of information are needed for case finding. At a minimum, basic demographic and epidemiologic data should be collected. Additional information will be valuable to enlighten a number of issues: to provide a better understanding of risk factors and potential causes, to demonstrate the need for uniform and systematic evaluation guidelines and protocols, and to provide information to stakeholders for various purposes. Preliminary results from the MACDP and IRCID projects will illustrate the potential contributions that enhancing current stillbirth surveillance activities will provide, justifying the additional costs and resources needed for implementation and project maintenance.

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