

Collection, Use, and Protection of Population-Based Birth Defects Surveillance Data in the United States

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Received 29 September 2007; Accepted 9 October 2007

Birth defects surveillance systems collect population-based birth defects data from multiple sources to track trends in prevalence, identify risk factors, refer affected families to services, and evaluate prevention efforts. Strong state and federal public health and legal mandates are in place to govern the collection and use of these data. Despite the prima facie appeal of “opt-in” and similar strategies to those who view data collection as a threat to privacy, the use of these strategies in lieu of population-based surveillance can severely limit the ability of public health agencies to accurately access the health status of a group within a defined geographical area. With the need for population-based data central to their mission, birth defects programs around the country take their data stewardship role seriously, recognizing both moral and legal obligations to protect the data by employing numerous safeguards. Birth defects surveillance systems are shaped by the needs of the community they are designed to serve, with the goal of preventing birth defects or alleviating the burdens associated with them. *Birth Defects Research (Part A) 79:811–814, 2007.* © 2007 Wiley-Liss, Inc.†

Key words: birth defects; surveillance; population-based; data protection

To protect the health of a population, public health programs require accurate and timely data concerning health problems affecting that population, ranging from infectious diseases to chronic conditions such as cancer and birth defects. Central to the success of public health programs is their ability to collect identifiable information regarding these conditions to perform their assessment and assurance functions, as well as to guide policy decisions (Teutsch and Churchill, 2000). With the expanding use of technology by public health professionals, both policy makers and the general public have increasingly begun to ask questions about the nature of, need for, and potential concerns raised by population-based surveillance programs. This article focuses on the development of and need for birth defects surveillance systems and explains how these systems safeguard the information collected.

ESTABLISHMENT OF AND NEED FOR BIRTH DEFECTS SURVEILLANCE SYSTEMS

Birth defects surveillance systems were established to meet a need for continual monitoring of birth defects. Birth defects are conditions that: (1) result from a malfor-

mation, deformation, or disruption in one or more parts of the body; (2) are present at birth; and (3) have serious, adverse effects on the affected person’s health, development, or functioning (CDC, 2006). Following the thalidomide exposures of pregnant women in England and Europe in the 1960s, many countries established birth defects programs to monitor environmental exposures and their associations with birth defects prevalence. Against this backdrop, the CDC established the Metropolitan Atlanta Congenital Defects Program in 1967. This was the first program in the United States to use an active case ascertainment methodology. Many U.S. pro-

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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Published online 6 December 2007 in Wiley InterScience (www.interscience.wiley.com).

DOI: 10.1002/bdra.20420

grams established during the 1970s and 1980s focused on monitoring environmental exposures associated with birth defects, whereas programs established in the 1990s and 2000s have tended to focus more on monitoring the referrals of children with birth defects (and the families of those children) to medical and social services. The ultimate goal of all birth defects programs, however, is to prevent these conditions or alleviate the burden associated with them.

Birth defects surveillance systems were designed to address community concerns by identifying risk factors, tracking trends in prevalence, referring affected individuals and families to social and medical services, guiding service provision and policy development, and evaluating prevention efforts. Although the cause of approximately 70% of all birth defects is unknown, most birth defects are thought to arise from interactions between genetic factors and environmental factors such as environmental exposures, infectious diseases, and maternal risk behaviors. The efforts of birth defects monitoring programs contributed to research findings in the 1980s and early 1990s, showing that maternal use of folic acid can reduce the incidence of NTDs (anencephaly and spina bifida) by 50–70%. In response to these findings, health officials now recommend that all women capable of becoming pregnant take 400 mcg of folic acid daily. Furthermore, recent surveillance data from birth defects programs suggest that maternal use of folic acid may also offer limited protection against cleft lip and palate defects and some congenital heart defects (Canfield et al., 2005).

Birth defects monitoring programs play an especially important role in identifying those risk factors that do not necessarily fall in line with expectations. Discovering these factors is of the utmost importance as this may suggest other prevention strategies. For example, advanced maternal age has long been associated with an increased risk for a variety of birth defects; however, population-based monitoring helped show that the risk for an abdominal wall defect called gastroschisis is actually lower among children of older women (Williams et al., 2005a), a counterintuitive association that may point to new prevention strategies. Birth defects surveillance programs have also been established in response to community concerns about clusters of specific conditions. The Texas Birth Defects Epidemiology & Surveillance (TBDES) Program was created in 1993 in response to a cluster of NTDs that many community members believed was caused by local pollutants (TBDES, 2007). Similarly, the establishment of New York's Congenital Malformations Registry (CMR), following the environmental disaster uncovered at Love Canal in the late 1970s, reflected a recognition by public health officials that environmental factors can contribute to the occurrence of birth defects (New York CMR, 2005; Sekhobo and Druschel, 2001). To evaluate the extent to which environmental exposures are associated with birth defects, monitoring programs perform cluster investigations to determine how birth defects are distributed around affected areas. These studies allow health professionals to address community concerns about environmental exposures, as well as to provide scientific data used to make important resource-allocation and policy decisions. For example, the data obtained by birth defects programs support the development and targeting of information and prevention programs to specific at-risk groups, such as Hispanic

women, who have the highest rates of babies born with NTDs, about the importance of folic acid (Williams et al., 2005b). Continued research and monitoring by birth defects programs will provide additional findings and recommendations.

This information is immeasurably valuable given the personal and societal costs of birth defects, which are the leading cause of infant deaths and often contribute to life-long disabilities. In 2004, birth defects accounted for 20% of all infant deaths in the United States (Minino et al., 2006). During this period, hospitalizations for complications associated with birth defects were longer than and more than twice as costly as hospitalizations for other conditions; and the hospital costs to treat those principally admitted for birth defects totaled \$2.6 billion, excluding physician's fees (Russo and Elixhauser, 2007). Additionally, Robbins et al. found that the average hospital charge for an uncomplicated birth in 2003 was \$1,844, while the average charge was \$199,597 for the birth of a child with a hypoplastic left heart syndrome and \$192,781 for the birth of a child with common truncus arteriosus; similarly, the average length of stay for newborns with uncomplicated births was 2.1 days, whereas the average length of stay for those requiring surgical repair for gastroschisis was 41.0 days (CDC, 2007). As these examples illustrate, the financial and personal burdens attributable to birth defects in our country are tremendous, and birth defects programs play a crucial part in the effort to alleviate that burden.

POPULATION-BASED APPROACH TO BIRTH DEFECTS SURVEILLANCE

An essential role of birth defects programs is to monitor the prevalence of these conditions and to identify factors that cause the defects in a given population. Generally, the monitored population consists of all infants born to residents within a defined catchment area. Population-based assessments help public health professionals determine the impact of a health condition on an entire population as well as on specific demographic subgroups within that population. Without access to the entire population's health data, public health officials would not be able to make prevalence calculations or evaluate the risk factors affecting the members of the population.

Accurate estimates of the prevalence and impact of birth defects in a given population are less likely if based on the results of less comprehensive surveillance strategies, such as an "opt-in" program, which require that parents provide documented consent to share information regarding their children. This type of approach was shown to result in a lower rate of enrollment in cancer and diabetes registries than a population-based approach (Verity and Nicoll, 2002); it also affected consent for further contact from families who had a baby with a lethal birth defect (Law et al., 1988). Refusal by even a small percentage of the population to participate in birth defects surveillance activities can greatly distort estimates of the prevalence of rare birth defects if the children of parents who refuse to participate have elevated rates of the conditions. Results from such opt-in surveillance activities can thus provide a false message of reassurance that birth defect rates are not rising when in fact a growing health problem threatens children and families. Despite the *prima facie* appeal of opt-in and similar strat-

egies to those who view data collection as a threat to privacy, the use of these strategies in lieu of population-based surveillance can severely limit the ability of public health agencies to accurately access the health status of the populations they serve.

Regulatory and Legislative Authority

Traditionally, public health programs have been allowed access to data sources containing individual health-related information, including vital records, hospital discharge records, and other medical information sources. This data access is granted through public health authority, an authority given by government to an agency or authority of the United States, states, territories, political subdivisions of states or territories, American Indian tribes, or an individual or entity acting under a grant of authority from such an agency as part of an official mandate with responsibilities for public health matters (CDC, 2003). In addition, many states have specific laws that further mandate how birth defects data are collected and used. For example, North Carolina Public Health Law § 130A-131.16 ("birth defects monitoring program established; definitions") outlines the establishment of the birth defects program and mandates specific reporting and confidentiality requirements for the program (PHLNC, 2007).

In response to community concerns about data collected by birth defects programs and who has access to the collected data, some state legislatures have mandated the establishment of advisory committees to guide the implementation and operations of birth defects programs and to assist these programs in developing data-collection and reporting guidelines. Generally, these advisory committees include medical and public health professionals as well as interested community members, such as parents of affected children. For example, a Kentucky law mandating the establishment of such advisory committees (KRS chapter 211 #665) states:

The secretary shall appoint a committee to advise on the implementation of the Kentucky birth surveillance registry. The advisory committee shall have representation from the disciplines of obstetrics and gynecology, pediatrics, genetics, epidemiology, biostatistics, hospital administration, state agency service providers, parents of children with congenital anomalies, or high risk conditions, and consumers. Other disciplines may be represented at the discretion of the secretary (KBSR, 2007).

In addition to being governed by public health authority and state laws, birth defect surveillance activities are also subject to federal laws and regulations such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Family Educational Rights and Privacy Act, the Privacy Act, the Public Health Service Act, and the Freedom of Information Act (NBDPN, 2004). Of these, HIPAA may be the most consequential, given that it has recently been in the forefront of data-release and privacy discussions for birth defects programs.

Implemented by the Department of Health and Human Services' Office of Civil Rights, HIPAA provides strict guidance for the collection, storage, protection, and use of health-related information, with strong protections for the privacy of individuals' health information. In its implementation of HIPAA, the Office of

Civil Rights recognized the importance of the general public health authority and of state laws enacting programs to protect the public's health. Under the Privacy Rule of HIPAA § 164.512 ("Uses and disclosures for which an authorization or opportunity to agree or object is not required"), covered entities may disclose protected health information, without the written authorization of the person to whom the information pertains, to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability. Purposes for which the law authorizes the disclosure of personal health information include the reporting of disease, injury, and vital events, and the conduct of public health surveillance, investigations, and interventions (CDC, 2003). Thus, these public health programs are required to follow the strict guidance of HIPAA in regards to collecting, storing, and providing privacy protections for health-related data but are allowed access to the individual-level data necessary for public health surveillance.

Data Protection and Security

With the need for population-based data central to their mission, birth defects programs around the country take their data stewardship role seriously, recognizing both moral and legal obligations to ensure the data's protection. For example, legislation governing the South Carolina Birth Defects Surveillance and Prevention Program states:

All birth defects information collected by the department in the birth defects program is confidential and must be used solely for the purposes provided in this chapter. The department shall maintain confidentiality in regard to:

- (1) data ascertainment;
- (2) data and record retention;
- (3) epidemiological study and reporting;
- (4) research uses;
- (5) referral for services for children and families;
- (6) identifying data obtained from health and medical records; and
- (7) data obtained from any source for any other use.

... Any use and disclosure of birth defects information must be governed by applicable confidentiality procedures of the department, using written confidentiality agreements and applicable laws. Information that is disclosed must be used only for purposes approved by the department. The program shall keep an accurate record of all persons allowed access to birth defects information for research or other authorized purposes. Records are not required to be kept on information shared with providers or families pursuant to the referral for services procedures in Section 44-44-130 and on data provided pursuant to Section 44-44-110 or Section 44-44-120. Records of access must be retained for six years and open to public inspection. Persons allowed access to data must be required to sign and maintain confidentiality agreements. A person who violates any of the confidentiality provisions of this chapter or an agreement entered into pursuant to this chapter is guilty of a misdemeanor and, upon conviction, must be fined not more than one thousand dollars or imprisoned not more than one hundred eighty days (South Carolina Legislature On-line, 2007).

States vary in their approach to implementing data-control safeguards, but general strategies involve hardware, software, personnel, and training. For example, the California Birth Defects Monitoring Program has a "confidentiality requirements and procedures" document that describes employee training and confidentiality agreements; special laptop requirements; and requirements for paper record handling, computer security, the storage and disposal of materials, and building security (CBDMP, 2000). In a typical state program setup, birth defects data are maintained on secure networks protected by dual front- and back-end firewalls with around-the-clock monitoring. Electronic access to these data is restricted to specifically authorized public health personnel via HIPAA compliant transmission. Similarly, physical access to data servers is limited to a small number of database/network managers. Before being authorized to access birth defects data, all personnel receive instruction in protecting the confidentiality of the data and acknowledge their personal responsibility and liability for doing so. In a typical state surveillance program, these data are kept in limited-access rooms within controlled-access buildings that require photo ID or electronic key cards for admission, and the security and operations of these systems are monitored and reviewed by the state's departments of information technology and security.

CONCLUSION

Birth defects surveillance systems are shaped by the needs of the community that they are designed to serve, and the data collected by these systems are protected by extensive legal and public health safeguards. To accomplish their mission, birth defects surveillance programs must be able to collect population-based birth defects data from both administrative datasets and related medical sources. Experiences from incidents such as New York's Love Canal and the Texas NTDs cluster show the importance of continuously collecting population-based data. The need for these data is as great today as it has ever been. Only through concerted efforts can birth defects programs and their partners identify new risk factors for birth defects, refer affected children and their families to social and medical services, and prevent serious birth defects currently affecting one in every 33 babies in the United States, defects that can lead to disabilities and premature death.

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