Chapter 1: Establishing and Maintaining a Birth Defects Surveillance Program

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1.0 Introduction

A birth defects surveillance program's primary goal is to monitor the prevalence of specific birth defects within a defined region. Programs may have additional goals such as those related to research, public health promotion, or referral to services.

The National Birth Defects Prevention Network (NBDPN) promotes methods that increase national standardization across birth defects surveillance programs. State or regional birth defects surveillance programs should aim to align with the NBDPN recommendations and standards found throughout this manual to harmonize between different birth defects surveillance programs and produce data that can be pooled at a national level. NBDPN also promotes increased data utilization through data sharing agreements across birth defects surveillance programs when possible.

In this chapter, we provide an overview of the general operational areas and recommendations for establishing and maintaining a birth defects surveillance program.

1.1 Identifying Birth Defects Surveillance Program Goals and Objectives

Each birth defects surveillance program should have clear goals and objectives that drive the use of the collected data to improve public health at the local, state, and national level. While program goals may extend beyond birth defects surveillance alone, all goals should be directly informed by the relevant public health objectives.

- **Monitoring:** The primary purpose of birth defects surveillance programs is to establish baseline prevalence estimates, and monitor spatial and temporal changes. As the etiology of many birth defects is unknown, identifying changes in prevalence alerts ***public health authorities*** to possible environmental, infectious, maternal health, or other exposures that might be associated with birth defects, prompting further investigation to identify prevention opportunities.
- **Public Health Practice:** Birth defects can impact health and wellbeing across the lifespan. Data from birth defects surveillance programs can be used to identify populations at risk for birth defects, target prevention messaging, and plan public health services. Birth defects surveillance programs may also conduct outreach to impacted families, make referrals, and/or share data with critical partners to ensure families are connected to appropriate health, education, and social services that support health and wellbeing.
- **Research:** Birth defects surveillance data are used in clinical and public health research, often to identify etiologic factors to inform prevention efforts. Birth defects surveillance programs that provide data for research and collaborative studies advance our understanding of the causes, effects, and treatment of birth defects, which inform

implementation of prevention, intervention, and outreach strategies. In order to meet specific research aims, birth defects surveillance programs that participate in collaborative studies may need to enhance their methodology for case identification, investigation, and verification.

Recommendation 1.1.0: When establishing or updating a birth defects surveillance program, staff should engage in discussions with the public health agency's institutional leadership, legal advisors, pertinent IT staff, data reporting sources, partners, and key collaborators in order to ensure alignment with the program's mission and objectives.

Birth defects surveillance programs must plan their activities with respect to the level of support available from the organizing agency, the state's legislative inclinations, and the source(s) of program funding. When engaging with the organizing agency, legislators, funders, or the public, the birth defects surveillance program should clearly communicate how their surveillance data will be used to improve public health.

Refer to the NBDPN Data Utilization Assessment Tool for outcome measures that promote use of surveillance data.

1.2 Defining the Boundaries of Legal Authority

Authorizing language (e.g., legislation, administrative rule, etc.) supporting birth defects surveillance programs is important for several reasons including defining the purpose of surveillance activities, specifying the kinds of data or information to be collected, and designating who is responsible for the program activities. Over time, federal legislation has shaped the legal landscape for public health, including birth defects surveillance. Please refer to **Appendix 1A** for examples of authorizing language in state legislation.

Recommendation 1.2.0: Birth defects surveillance programs should work with their agency and/or health department to propose, amend, or add legislation or authorizing regulations that will shape and enable surveillance operations.

Defining the boundaries of legal authority and agency/program policies may address the type of information a birth defects surveillance program is allowed to obtain; which pregnancy outcomes are reportable (e.g., live birth, non-live birth, other pregnancy outcomes); the geographic catchment area for reportable conditions; maternal residency at the time of the pregnancy outcome; data sources required to report; requirements of the birth defects surveillance database; and other situational criteria. It is advisable to cite the birth defects surveillance program's authorizing language in communication with data sources.

Data reporting sources are those that report potential cases to the birth defects surveillance program. Most birth defects surveillance programs find it highly beneficial to secure legal authority to obtain or access additional pertinent medical information from data and information sources beyond those who are required to submit case reports. This facilitates further data collection for case investigation and case verification, and in some instances enables additional

case identification.

- *Example*: If the birth defects surveillance program wants authority to collect maternal information during the prenatal period, they may need to include the reportability or accessibility of prenatal information (regardless of the pregnancy outcome) in their authorizing language.
- *Example*: If the birth defects surveillance program wants to obtain records at a pertinent information source regardless of whether the birth defects surveillance program has first received a case report from the respective source, they may need to include access to medical information in their authorizing language.

1.3 Developing Birth Defects Surveillance Methods

Based on their authorizing language, goals, and objectives, birth defects surveillance programs should clearly define their procedures and workflow for surveillance activities. Major steps toward creating workflow are listed here and described in greater detail in the specified chapters and appendices:

- Define ***programmatic case inclusion criteria***, which are the characteristics that ensure a case is within the scope of a specific birth defects surveillance program (**Chapter 2**).
- Identify a standardized list of birth defects collected by the surveillance program, and provide ***birth defect case definition criteria*** for identification of reportable birth defects (**Appendix 2A**).
- Determine the set of ***data elements*** the program will collect and record to support the primary goal for surveillance, and any additional data elements that may help support other goals and objectives within the program's mission (**Chapter 3**, and **Appendix 3A**).
- Identify ***data sources*** to obtain case information, taking into consideration the data elements needed (**Chapter 3**), the health information classification systems and birth defects codes the program plans to use (**Chapter 4**), and which sources are of value to the case ascertainment process (**Chapter 5**, and **Appendices 5A** and **5B**).
- Develop and document procedures and policies for the birth defects surveillance program's operations. (**Appendix 1B**).

1.4 Developing the Birth Defects Surveillance Database

NBDPN recognizes that external and internal environments related to information technology (IT) are in a constant state of change. We encourage birth defects surveillance programs to work with their agency's leadership to determine their policies, standards, requirements, hardware, and software.

It can be challenging to communicate new or updated surveillance needs to an external professional (e.g., a centralized IT staffer, or an IT vendor). A birth defects surveillance program may find it beneficial to identify a person with expertise in IT language *and* knowledge of the birth defects surveillance program's authorizing language and objectives, then rely upon that individual to communicate the surveillance system needs to those who will design, develop,

build, update, and maintain the IT surveillance system.

A ***use case flow diagram*** may be helpful for communication between IT and program staff, as a technical tool that depicts the processes and procedures for data flow, key decision points/interactions involving the system staff, and expected information, data outputs, or data extracts. It also serves to inform key platform attributes desired for surveillance functions.

> **Recommendation 1.4.0:** The IT platform should use IT standards to support the requirements of the birth defects surveillance program.

The National Institute of Standards and Technology (NIST) has several resources for IT standards. Other resources for developing, improving, and preparing birth defects surveillance programs for new technologies are available through the Public Health Informatics Institute and Centers for Disease Control and Prevention.

1.4.1 Standardized Data Fields

The birth defects surveillance database should be designed with standardized data fields in order to increase operational efficiencies, facilitate data transactions and interoperability, and streamline data analysis and reporting.

Utilizing standardized fields helps create a highly functional database that can track reportable birth defects cases, capture data for each potential case, generate tracking reports that monitor surveillance functions, perform data pulls in response to data requests, and produce data quality reports for timeliness, completeness, and accuracy.

1.4.2 Capacity for System Modifications and Updates

The database platform should be designed with the flexibility to make system modifications and update other system functionalities (e.g., code structure, data elements, screens, new data collection applications, updating case records, etc.), in response to periodic changes in program workflow, state laws, federal regulations, and national standards.

1.4.3 Capacity to Monitor Transactions and Interactions

The database platform should be adapted to monitor all transactions and interactions with database applications. For example, the system should track:

- All sources of information through which a diagnosis is identified or reported
- Dates of all transactions and interactions
- Imports and exports (e.g., data extracts, data sets, etc.)
- Edits to the data
- Log of user interactions (e.g., log in, actions performed, etc.)

1.4.4 Record Linkage

Birth defects surveillance databases often have the capacity for extensive computerized ***record linkage***, allowing for the tracking of a child with a health-related condition from the point of identification through referral and access to services.

> **Recommendation 1.4.4:** Birth defects surveillance programs should utilize record linkage procedures to facilitate matching all reports to the correct case record, and for other surveillance functions.

Birth defects surveillance programs should determine if the agency uses a centralized record linkage software application and/or procedure, how this might impact birth defects surveillance program procedures, and determine the desired level of linkage probability. Additional guidance on record consolidation and linkage is discussed in **Chapter 5**.

1.4.5 Programmatic Data Management Functions

The database should function as an information management system that supports the surveillance functions and other programmatic areas of the birth defects surveillance program, including:

- Record linkage for matching
- Data source linkage (e.g., between data sources, for interoperability; see **Chapter 4** and **Chapter 5**)
- De-duplication, consolidation, and data quality (see **Chapter 5**, and also **Chapter 7** [June 2004 Edition])
- Linking data elements to explain relationships (see **Chapter 3**)
- Trigger and health information classification codes (see **Chapter 4**)
- Search functions
- Archiving data received and tracking changes
- Programmatic data management of procedures, processes, timeliness, user interactions

As a part of system development, birth defects surveillance programs should work with IT specialists to develop the set of information management technical documentation and other system requirements. This includes a data dictionary, tables, protocols for record retention and data archiving, a set of operational procedures (e.g., data quality, edits, checks, and timelines), and standardized IT procedures to secure the data.

1.5 Operational Areas for Birth Defects Surveillance Programs

For each reportable birth defect within the program's purview, birth defects surveillance programs should strive to identify as close as possible to 100% of all affected pregnancies. Well-trained staff and meticulous quality assurance are key to achieving this.

1.5.1 Train Birth Defects Surveillance Program Staff

Birth defects surveillance program staff must be appropriately trained with an understanding of the overall activities of the program and the specific skills required for their role within it. All staff should understand the importance of maintaining patient confidentiality and data security, and functioning within the bounds of the program's authorizing language and policies. Role-specific training should be conducted as needed related to birth defect case definition criteria (**Chapter 2**); data elements (**Chapter 3**); classification systems and birth defects codes (**Chapter 4**); data sources, case identification, abstracting and recording for case investigation, and case verification (**Chapter 5**); data analysis, and data quality.

1.5.2 Conduct Quality Assurances

Birth defects surveillance programs should engage in quality assurance procedures to monitor the accuracy, completeness, and timeliness of their data outputs. Methods for quality assurance are detailed in **Chapter 7** [June 2004 Edition].

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