
Table of Contents

Introduction.....	i
--------------------------	----------

Chapter 1 The Whys and Hows of Birth Defects Surveillance – Using Data

1.1 Introduction.....	1-1
1.2 Rationale	1-2
1.2.1 What Is the Rationale for Conducting Birth Defects Surveillance?	1-2
1.2.2 Why Is Birth Defects Surveillance Important?.....	1-2
1.2.3 How Do Birth Defects Surveillance Data Benefit Other Programs?.....	1-3
1.2.4 What Are the Barriers to Collection and Full Utilization of Birth Defects Surveillance Data?	1-4
1.3 Synopsis of Key Steps in Establishing State-Based Birth Defects Surveillance Programs	1-5
1.3.1 Defining the Objectives and Purposes of the Program	1-5
1.3.2 Considering Legal Issues.....	1-6
1.3.3 Engaging External Support.....	1-6
1.3.4 Leveraging Resources	1-7
1.3.5 Considering Record Linkage.....	1-7
1.4 Uses of Surveillance-Based Birth Defects Data.....	1-9
1.4.1 Prevalence Studies.....	1-9
1.4.2 Epidemiologic Studies.....	1-10
1.4.3 Assessing Mortality Associated with Birth Defects	1-12
1.4.4 Estimating the Need for Services	1-12
1.4.5 Referral to Services	1-13
1.4.6 Program Evaluation.....	1-13
1.4.7 Clinical Research.....	1-14
1.4.8 Using Birth Defects Data in the Future	1-15
1.5 References.....	1-16

Chapter 2 Legislation

2.1 Introduction.....	2-1
2.2 Legislation, Regulation, and Authority	2-2
2.3 Key Elements of Model Legislation	2-3
2.3.1 Designation of Agency Authority.....	2-3
2.3.2 Purpose and Priorities.....	2-3
2.3.3 Access to Data and Records	2-4
2.3.4 Ability to Share Data while Maintaining Confidentiality.....	2-4
2.3.5 Terminology and Definitions	2-5
2.3.6 Opt-out Clauses	2-5
2.3.7 Advisory Committee	2-6
2.3.8 Funding.....	2-6
2.4 Federal Laws	2-8
2.4.1 Health Insurance Portability and Accountability Act (HIPAA)	2-8
2.4.2 Family Educational Rights and Privacy Act (FERPA).....	2-13
2.4.3 Privacy Act.....	2-14
2.4.4 Public Health Service Act	2-14
2.4.5 Freedom of Information Act 5 USC §522 (FOIA)	2-15
2.4.6 Advocacy.....	2-16
2.5 References.....	2-17

Chapter 3 Case Definition

3.1 Introduction.....	3-1
3.2 What Is Meant by a ‘Birth Defect’	3-2
3.3 Terminology	3-3
3.4 Case Definition Criteria	3-6
3.4.1 Diagnoses to Be Included	3-6
3.4.2 Residence	3-6
3.4.3 Pregnancy Outcome	3-7
3.4.4 Gestational Age	3-8
3.4.5 Age at Which Defects Are Diagnosed.....	3-9
3.4.6 Pregnancies Resulting from Assisted Reproductive Technology	3-10
3.5 Case Definition and Sensitivity and Specificity.....	3-11
3.6 References.....	3-12

Chapter 4 Data Variables

4.1 Introduction.....	4-1
4.2 Criteria to Be Considered in Selection of Data Variables.....	4-2
4.2.1 Type of Case Ascertainment	4-2
4.2.2 Program Objectives	4-2
4.2.3 Data Characteristics.....	4-3
4.3 The Origins of Data Variables	4-4
4.4 The Formats of Data Variables	4-5
4.5 Data Variable Logic Checks	4-6
4.6 Data Variable Location	4-7
4.7 Risk Factor Variables.....	4-8
4.8 Data Variable Tables.....	4-9
4.9 References.....	4-12

Chapter 5 Classification and Coding

5.1 Introduction.....	5-1
5.2 Disease Classification Systems.....	5-2
5.2.1 Description and Format	5-2
5.2.2 ICD-9-CM and the 6-digit CDC Code – A Comparison	5-3
5.3 Classification Issues That Affect Surveillance Systems	5-4
5.4 Guidelines for Effective Coding	5-6
5.5 Coded Data Quality Issues.....	5-8
5.6 Tips and Hints	5-10
5.7 References.....	5-11

Chapter 6 Case Ascertainment Methods

6.1	Introduction.....	6-1
6.2	Terminology.....	6-2
6.3	General Surveillance Development	6-4
6.3.1	Plan and Document	6-4
6.3.2	Identify Data Sources	6-5
6.3.3	Obtain Knowledge about Individual Data Sources.....	6-5
6.3.4	Implement Data Quality Procedures.....	6-6
6.3.5	Evaluate Surveillance Method and Analytical Capability	6-6
6.4	Birth Defects Surveillance – Approaches to Case Identification.....	6-7
6.5	Active Case Ascertainment.....	6-8
6.5.1	Characteristics of Active Case Ascertainment	6-8
6.5.2	Approach to Active Case Ascertainment.....	6-9
6.5.3	Data Quality Issues in Active Case Ascertainment	6-10
6.5.4	Active Case Ascertainment Surveillance Evaluation	6-11
6.5.5	Tips and Hints in Active Case Ascertainment.....	6-11
6.6	Passive Case Ascertainment.....	6-13
6.6.1	Characteristics of Passive Case Ascertainment	6-13
6.6.2	Approach to Passive Case Ascertainment	6-14
6.6.3	Data Quality Issues in Passive Case Ascertainment	6-15
6.6.4	Passive Case Ascertainment Surveillance Evaluation	6-16
6.6.5	Tips and Hints in Passive Case Ascertainment.....	6-16
6.7	Data and Case Identification Sources	6-18
6.8	Sources of Information in a Data Source	6-21
6.8.1	Medical Records.....	6-21
6.8.2	Type of Documentation in the Medical Record	6-22
6.8.3	Maternal Delivery Medical Record	6-23
6.8.4	Prenatal Medical Record	6-23
6.8.5	Cytogenetic Laboratory Reports.....	6-24
6.8.6	Autopsy, Pathology and Laboratory Reports.....	6-25
6.9	Infant Risk Factors in Case Identification.....	6-26
6.10	References.....	6-27

Chapter 7 Data Quality Management

7.1	Introduction.....	7-1
7.2	Criteria for High-Quality Data.....	7-2
7.3	Terminology.....	7-3
7.4	Data Sources and Quality.....	7-4
7.5	Timeliness Versus Thoroughness and Completeness	7-5
7.6	Quality Control and Quality Assurance	7-6
7.7	Quality Control and Quality Assurance in the Surveillance Database.....	7-8
7.8	Quality Improvement Methods	7-9
7.9	References.....	7-23

Chapter 8 Statistical Methods

8.1 Introduction.....	8-1
8.2 Measuring Birth Defect Occurrence	8-2
8.2.1 Multiple Birth Defects in the Same Child	8-2
8.2.2 Counts, Ratios, Proportions, and Rates	8-2
8.3 Calculating Prevalence at Birth.....	8-4
8.3.1 Basic Calculation for Prevalence at Birth.....	8-4
8.3.2 Numerator and Denominator Issues	8-5
8.4 General Types of Prevalence	8-6
8.4.1 Crude Prevalence.....	8-6
8.4.2 Specific Prevalence	8-6
8.4.3 Adjusted or Standardized Prevalence	8-8
8.5 Descriptive Epidemiology	8-12
8.6 Confidence Intervals	8-15
8.6.1 About Confidence Intervals.....	8-15
8.6.2 Comparing Prevalence Values Using Confidence Intervals.....	8-19
8.7 Issues to Consider If Data Reveal Unusual Patterns	8-22
8.7.1 Changes in Medical Diagnoses and Technologies	8-22
8.7.2 Changes in Reporting and Case Ascertainment.....	8-22
8.7.3 Changes in the Population at Risk.....	8-23
8.7.4 Random Variation	8-23
8.8 References.....	8-24

Chapter 9 Data Management and Security

9.1 Introduction.....	9-1
9.2 Functional Data Processing System Features	9-2
9.3 Hardware.....	9-6
9.4 Software	9-7
9.5 Process Standards.....	9-9
9.5.1 Inputs.....	9-9
9.5.2 Instructions on Proper Submission of Data	9-9
9.5.3 Initial Review and Query.....	9-10
9.5.4 Receipt and Logging of Shipments	9-10
9.5.5 Forms and Batch Control Procedures	9-11
9.6 Data Entry	9-12
9.7 Record Linkage.....	9-16
9.8 Record Consolidation.....	9-17
9.9 Feedback to Data Sources/Abstractors	9-18
9.10 Security	9-19
9.10.1 Personnel Issues	9-19
9.10.2 Transportation and Information Handling.....	9-20
9.10.3 Physical Security	9-21
9.10.4 Computer Security.....	9-22
9.10.5 Policy on Release of Data.....	9-22

Chapter 10 Data Collaboration and Dissemination through the NBDPN

10.1 Data Collaboration and Dissemination through the NBDPN	10-1
---	------

Chapter 11 Data Presentation

11.1 Using Data for Decision-Making.....	11-1
11.1.1 The Data-to-Action Continuum	11-2
11.1.2 Products of the Data-to-Action Transformation	11-2
11.2 Stage 1 – Data Provision.....	11-4
11.3 Stage 2 – From Data to Information	11-5
11.3.1 Providing Contextual Information—Person, Place, and Time.....	11-5
11.3.2 Missing or Unknown Data.....	11-6
11.3.3 The Importance of Comparison	11-6
11.3.4 Approaches to Measuring Occurrence—Prevalence Versus Incidence	11-8
11.3.5 Level of Focus	11-9
11.3.6 Risk Factors and the Importance of Timing with Respect to Exposures	11-10
11.3.7 Privacy and Data Suppression	11-11
11.3.8 Geographic Information Systems (GIS)	11-12
11.4 Stage 3 – From Information to Knowledge.....	11-13
11.4.1 The Receiver—Understanding the Audience and its Information Needs	11-14
11.4.2 The Objective(s)—Determining the Purpose of the Presentation	11-14
11.4.3 The Message—Developing Content and Ensuring Clarity	11-14
11.4.4 The Medium—Ensuring Its Appropriateness	11-23
11.4.5 The Sender—Being Aware of Biases	11-27
11.4.6 Pulling It All Together.....	11-27
11.5 Stage 4 – From Knowledge to Action.....	11-29
11.6 References.....	11-32

Appendices

Chapter 2 Legislation

Appendix 2.1 Sample State Legislation	A2.1-1
Appendix 2.2 Table of Birth Defects Legislation	A2.2-1
Appendix 2.3 Definitions Used to Determine Covered Entity Status Under the Privacy Rule	A2.3-1
Appendix 2.4 Office of Civil Rights (OCR) HIPAA Privacy Regulation Text.....	A2.4-1

Chapter 3 Case Definition

Appendix 3.1 Birth Defects Included in the Case Definition of the National Birth Defects Prevention Network	A3.1-1
Appendix 3.2 NBDPN Abstractor's Instructions*	A3.2-1
Appendix 3.3 Examples of Conditions Considered to Be Minor Anomalies	A3.3-1
Appendix 3.4 Conditions Related to Prematurity in Infants Born at Less Than 36 Weeks Gestation	A3.4-1

Chapter 4 Data Variables

Appendix 4.1 Descriptions of Minimum (Core) Data Variables	A4.1-1
Appendix 4.2 Descriptions of Recommended Data Variables.....	A4.2-1

Chapter 5 Classification and Coding

Appendix 5.1 Texas Disease Index*	A6.1-1
Appendix 5.2 6-Digit CDC Codes*	A6.1-1

Chapter 6 Case Ascertainment Methods

Appendix 6.1 Data Source Described in Detail – Vital Records	A6.1-1
Appendix 6.2 Data Source Described in Detail – Hospital Data Sets.....	A6.2-1
Appendix 6.3 Data Source Described in Detail – Hospital and Patient Services Logs	A6.3-1
Appendix 6.4 Data Source Described in Detail – Genetic Services	A6.4-1

Chapter 7 Data Quality Management

Appendix 7.1 Data Sources Descriptive Assessment Tool	A7.1-1
---	--------

Chapter 11 Data Presentation

Appendix 11.1 Data Suppression.....	A11.1-1
Appendix 11.2 Use of Geographic Information Systems (GIS) to Map Data	A11.2-1
Appendix 11.3 Data Users Matrix	A11.3-1
Appendix 11.4 What Type of Chart or Graph Should I Use?	A11.4-1

*This document may be viewed or downloaded from the NBDPN website at:
<http://www.nbdpn.org/bdsurveillance.html>