# *Appendix 3A: Data Elements for Population-Based Birth Defects Surveillance*

**Contents**

# List of Core and Enhanced Data Elements

This appendix provides the data elements that the National Birth Defects Prevention Network (NBDPN) recommends birth defects surveillance programs collect. **Table 3A** lists the Core and Enhanced data elements (in alphabetical order), then each data element is described in detail thereafter.

**Table 3A**

| NBDPN Recommended Data Elements | | |
|---|---|---|
| **Core Tier** | | |
| **Infant** | • Age-at-Diagnosis<br>• Birth Certificate ID<br>• Birth Order<br>• Birth Weight<br>• Delivery Date<br>• Delivery Location<br>• Diagnosis Code(s) - NBDPN Birth Defect Case Definition Codes<br>• Diagnosis Code(s) – Other Classification Systems | • Gestational Age<br>• Infant Medical Record Number(s)<br>• Name<br>• Plurality<br>• Pregnancy Outcome<br>• Sex<br>• Source of Report<br>• Unique Case ID |
| **Mother** | • Mother's Date of Birth<br>• Mother's Ethnicity<br>• Mother's Medical Record Number(s) | • Mother's Name<br>• Mother's Race<br>• Mother's Residence at Time of Pregnancy Outcome |
| **Enhanced Tier** | | |
| **Infant** | • Death – Autopsy Performed<br>• Death – Date of Death for Live-Born Infant<br>• Death – Death Certificate ID<br>• Death – Fetal Death Certificate/Report ID Number<br>• Death – Underlying Cause of Death<br>• Diagnostic Tests and Procedures | • Method of Determining Gestational Age<br>• Responsible Party's Address<br>• Responsible Party's Name<br>• Responsible Party's Telephone Number<br>• Verbatim Description of the Birth Defect(s) |
| **Mother** | • Education Level of Mother<br>• Gravidity<br>• Parity<br>• Prenatal – Date of First Prenatal Visit | • Prenatal – Date of Last Prenatal Visit<br>• Prenatal – Month Prenatal Care Began<br>• Prenatal – Number of Prenatal Visits |

# Detailed Descriptions of Data Elements

## General Information on Data Element Descriptions

Each data element description in this appendix is presented in the format shown here. The category definitions below are used consistently across all data element descriptions.

| **Name of Data Element for Collection** ***Infant / Maternal Data Element**** | |
|---|---|
| **NBDPN Tier Level** | NBDPN recommendation on the importance of collecting the data element:<br>• ***Core*** indicates that the data element is fundamental for all birth defects surveillance programs to collect on all cases.<br>• ***Enhanced*** indicates that the data element is potentially of significant use. Birth defects surveillance programs should strive to collect it, if possible. |
| **Definition** | The definition of the data element for collection. |
| **Data Element Format** | How the data element should be stored or converted for shared use: text, number, date, alphanumeric, code, checkbox. |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Reason a birth defects surveillance program may want to include the data element in its database. |
| **Data Source** | Possible source(s) of the data element; whether it is collected or derived from data sources, or created by the birth defects surveillance program; and location within data sources where the data element is most likely to be consistently found. For data elements with multiple potential sources, sources are specified in priority order from highest to lowest preference (based on **Standards Table 5.1.1**). |
| **Timing of Availability at the Data Source** | Guidance on when the data element may be available at the data source, and the optimal timing for collection of the data element (relative to the prenatal and postnatal course of the case). Considerations for timing of collection include prenatal course, birth, transfers, treatments, death, etc. |
| **Quality Assurance Checks** | The minimum limits, ranges, or other criteria the element should meet. Criteria used may include *missing value, allowable value*, and *consistency*. |
| **Additional Considerations** | |
| Any additional considerations that may influence how a birth defects surveillance program collects the data element, including operational variables, extended definitions of the data element, and interrelationship with other data elements. | |

*Infant data elements are denoted by black table headers. Maternal data elements are shown with pink

# Core Data Elements

| **Age-at-Diagnosis** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The age of the child when the birth defect was first diagnosed, or when the signs and symptoms were first recognized as potentially representing the defect. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The frequency and likelihood of diagnosing certain birth defects varies by age. Some birth defect cases may be diagnosed during the prenatal period or immediately after delivery, while other birth defects may not be apparent/diagnosed for weeks, months, or even years after birth.<br><br>NBDPN recommends that birth defects surveillance programs aim to *identify* 95% of birth defects cases by 6 months past the date of delivery (**Recommendation 5.1.0**), and maintain the ability to *ascertain* and report case counts for all cases diagnosed on or before the first birthday (**Standard 2.1.5)**.<br><br>NBDPN recognizes that many birth defects surveillance programs have legal authority to ascertain cases diagnosed beyond a child's first birthday. Programs can continue per their state's disease reporting requirements and their programmatic goals and objectives. However, programs should retain information about the age-at-diagnosis so that cases diagnosed after the child's first birthday can be excluded from data submitted to NBDPN. |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Maternal medical record (for prenatal diagnosis)<br>• Laboratory results<br>• Other administrative database (e.g., all payers claim database) |
| **Timing of Availability at the Data Source** | May be available during prenatal period or postnatal period, depending when signs or symptoms of the birth defect were detected and diagnosed. |
| **Quality Assurance Checks** | *Missing value criteria:* Age-at-diagnosis should not be missing if the data source includes the date of diagnosis, and date of delivery and/or information on gestational age.<br><br>*Allowable value criteria:* We recommend using a data field in which the age-at-diagnosis is categorized generally as either prenatal; on or before the first birthday, or after the first birthday.<br><br>If a more specific age-at-diagnosis is to be recorded, allowable values |

| | |
|---|---|
| **Quality Assurance Checks, continued** | include the age at the time of diagnosis in postnatal months (during first year of life), or years (after the first birthday). For prenatal diagnosis, enter the weeks of gestation at the time of diagnosis, and designate it as prenatal to distinguish it from postnatal age.<br><br>Alternatively, a date of diagnosis (month, day, and year) can be entered, with the database programmed to compare that date against the date of delivery (for postnatal diagnosis) or gestational age timeline (for prenatal diagnosis) to calculate the age-at-diagnosis.<br><br>*Consistency criteria*: Data should be checked if age-at-diagnosis is prior to 6 weeks gestation, or after 3 years of age. |

**Additional Considerations**

Many birth defects are apparent during gestation or soon after delivery. However, certain birth defect types tend to take longer for the diagnosis to manifest, or for the level of severity to become fully understood. This may require birth defects surveillance programs to follow some cases over time as the diagnosis is modified in response to more accurate diagnostic procedures and evaluations by subspecialized clinicians to reach the most specific final diagnosis possible (**Recommendation 5.3.3a**). Birth defects surveillance programs should become familiar with the data being reported to them and develop standard procedures for documenting when birth defects were first diagnosed.

Example of determining age-at-diagnosis: The prenatal diagnosis of a congenital heart defect may be suspected from an obstetric ultrasound or fetal anatomy scan. Follow up with a fetal echocardiogram or MRI confirms the presence of a congenital heart defect. After birth, when a postnatal echocardiogram or MRI is performed on the infant, the exact congenital heart defect diagnosis may be modified. In some cases, the full nature of the congenital heart defect may only be identified at the time of surgery. Because age-at-diagnosis refers to the age of the child when the defect was diagnosed, ***or*** when the signs and symptoms were first recognized as potentially representing the defect, in this example the age-at-diagnosis would be the age at the prenatal ultrasound or fetal echocardiogram.

| **Birth Certificate ID** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A unique identifier assigned to a birth certificate and maintained by vital records and birth defects surveillance programs. |
| **Data Element Format** | Numeric, or alphanumeric (format determined by the source) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Maintaining this ID in both vital records and the birth defects surveillance program ensures the ongoing ability to link to birth records, which is important because the birth data may be corrected by the vital records office after the first linkage.<br>The birth certificate is the legal, validated, consolidated source for details of the birth event. |
| **Data Source** | May be abstracted or assigned from:<br>• Vital record (birth certificate) |
| **Timing of Availability at the Data Source** | Upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This ID must not be missing if any birth certificate data are available to the birth defects surveillance program.<br>*Allowable value criteria:* This ID should not be the same as any medical record number for the infant or the mother. |
| **Additional Considerations** | |
| The birth certificate is a source of data on medical history and health information about the infant and mother that may not be available from other sources. Vital records are checked and queried at the local, state, and national levels and corrected or amended by the vital records office as needed.<br>In certain states, the birth defects surveillance program may not be permitted to store the actual birth certificate number (the "Birth Number" or "State File Number" by which the birth is registered in the state where it happened), for reasons of privacy and security. When unable to store the number, the birth defects surveillance program should have the capacity to link to the birth certificate, or to assign a report number and a key that enables retrieval of the actual birth certificate number. | |

| **Birth Order** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The order in which infants of a multiple gestation pregnancy are delivered. If not a singleton pregnancy and birth, specify 1 (born 1st of the multiples), 2 (born 2nd of the multiples), etc. For multiple deliveries, it is the order this infant was delivered *in the set* for *this* gestation. Include all live births and fetal losses. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The birth order, recorded on birth and fetal death certificates, can be useful for linkage with the correct medical record in cases of multiple gestation pregnancies, especially if delivery records do not refer to the infants or fetuses by name.<br>Recording the birth order can help ensure that records for siblings from a multiple gestation pregnancy (twins, triplets, etc.) are not inadvertently mistaken for duplicate records and merged or deleted. |
| **Data Source** | May be abstracted from:<br>• Infant medical record<br>• Vital record (birth certificate) |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Blank for unknown. Blank for singleton gestation.<br>*Allowable value criteria:* An integer greater than 0. Check on any integer greater than 5.<br>*Consistency criteria*: Must be less than or equal to plurality. |
| **Additional Considerations** | |
| Only pertinent at the time of delivery, and only in cases with plurality. Birth order does not apply during prenatal gestation time frame, only at pregnancy outcome.<br>Birth order refers to cases of plurality (e.g., 1st, 2nd, or 3rd of a set of triplets from *this* gestation), and not the parity of the mother overall. | |

| **Birth Weight** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | Weight (in grams, or pounds and ounces) of the infant or fetus at delivery. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The birth weight may be needed for determining whether the case meets programmatic case inclusion criteria (**Standard 2.1.3**). |
| **Data Source** | May be abstracted from:<br>• Infant medical record<br>• Maternal medical record (for non-live births)<br>• Vital record (birth certificate, or fetal death certificate) |
| **Timing of Availability at the Data Source** | May be obtained after pregnancy outcome, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Missing values are possible. Attention is needed to ensure the value used for missing (such as 999) is considered when converting between metrics so that it cannot be misinterpreted as a weight.<br>*Allowable value criteria:* If the weight is ≤ 227 grams, or ≥ 5,000 grams, the weight should be checked. |
| **Additional Considerations** | |
| The data source may report birth weight in grams, or pounds and ounces, or pounds with decimals. The birth defects surveillance program may decide to record the weight in the units reported by the data source, or in a uniform fashion for all cases in the database (e.g., always in grams). If recording birth weight in uniform fashion, the birth defects surveillance program must be able to convert between units while collecting the data, or use data fields with computerized calculation functions. | |

| **Delivery Date** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | Date of delivery regardless of pregnancy outcome (i.e., for a live birth or a non-live birth). |
| **Data Element Format** | Date (including month, day, and year) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | In conjunction with other fields such as mother's last name, this field helps to identify a case uniquely.<br>Recording the date of delivery also helps with temporal monitoring for surveillance (e.g., disease incidence rates over time).<br>NBDPN recommends that birth defects surveillance programs aim to *identify* 95% of birth defects cases by 6 months past the date of delivery (**Recommendation 5.1.0**), and maintain the ability to *ascertain* and report case counts for all cases diagnosed on or before the first birthday (**Standard 2.1.5)**. Collecting the date of delivery helps track those metrics. |
| **Data Source** | May be abstracted from:<br>• Infant medical record<br>• Maternal medical record (for non-live births)<br>• Vital record (birth certificate, or fetal death certificate) |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria*: Every live birth should have a date of birth, and every non-live birth should have a date of delivery. If any of the three parts of the date (month, day, year) are missing, all known elements of the date should be recorded (in separate fields if necessary).<br>*Allowable value criteria*: The date should include month, day, and year. The range for month is 1 to 12; range for day is 1 to 31; and the year is captured as four digits (YYYY).<br>*Consistency criteria*: The date of delivery for a live or non-live birth should be after the dates of the first and last prenatal care visits, if available. |
| **Additional Considerations** | |
| For programs that collect date of diagnosis (rather than age-at-diagnosis), the date of delivery can be used in conjunction with the date of diagnosis to calculate the age-at-diagnosis. | |

**CORE TIER**

| **Delivery Location** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | Location where the delivery or pregnancy outcome occurred. |
| **Data Element Format** | Code or text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Mother and infant records at the delivery facility often provide important information not found in tertiary care facility records. The birth defects surveillance program can use the delivery location (e.g., hospital, midwifery, residence, etc.) to identify which data source may be best suited to provide the delivery records.<br><br>Regardless of whether the delivery occurred inside or outside of a health care facility, the birth defects surveillance program may employ the delivery location in addition to other fields to help link to other data sets, such as vital record.<br><br>The location where the delivery occurred also allows the birth defects surveillance program to provide facility-specific statistics. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record<br>• Attendant (non-facility births only) |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This field should always be filled out and must be a valid location, unless the delivery location was unknown (such as when the baby was left at a safe haven without any accompanying information).<br><br>*Allowable value criteria:* For births in a facility, give the name of the facility where the delivery took place, including the facility's National Provider Identification (NPI) or the state hospital code. For non-facility births, include the city/town or location of birth, the county, and the type of place where the birth occurred (e.g., home/residence). For enroute births, code the intended destination. If the event occurred in international air space or waters, enter "plane" or "boat." |
| **Additional Considerations** | |
| None. | |

| **Diagnosis Code(s) - NBDPN Birth Defect Case Definition Codes**<br>***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A standard set of numbers developed by NBDPN to categorize a text description of a diagnosis for the set of birth defects monitored by NBDPN. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | NBDPN promotes the use of coded information that is comparable across birth defects surveillance programs, especially for conditions that are reported to NBDPN. Health information classification and coding schemes with different diagnosis code definitions impact NBDPN's ability to aggregate accurate data across birth defects surveillance programs. To promote reporting of timely, accurate, and complete data in a standardized manner, NBDPN has developed diagnosis codes to use for NBDPN Data Call requests. |
| **Data Source** | Assigned by:<br>• Birth defects surveillance program |
| **Timing of Availability at the Data Source** | May be assigned once diagnosis is identified. |
| **Quality Assurance Checks** | *Missing value criteria*: All cases that include one of the 48 birth defects defined in **Appendix 2A** of the NBDPN Surveillance Guidelines should include at least one code for this value.<br>*Allowable value criteria*: Each case may have multiple codes. All codes should be in the standard NBDPN Birth Defect Case Definition Code format available from NBDPN. |
| **Additional Considerations** | |
| The NBDPN Birth Defect Case Definition Codes only apply to the 48 birth defects provided in the NBDPN Birth Defect Case Definition Criteria as described in **Appendix 2A** (see summary table on page 2A-8, or find the code included with each birth defect description). This value can remain empty if a birth defects surveillance program ascertains a diagnosis that is not included in the NBDPN code set.<br>Note that diagnosis codes from other health information classification systems (e.g., ICD, CDC/BPA, BD-STEPS, NBDPS), or from custom coding systems used within a birth defects surveillance program, should be entered in the "*Diagnosis Code(s) – Other Classification Systems*" data element field instead. | |

| **Diagnosis Code(s) – Other Classification Systems** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A standard set of letters, numbers, or other symbols used to categorize a text description of a diagnosis. |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Diagnosis codes from health information classification systems provide a consistent way to represent information from a case, and standardize communication about it. Using standardized diagnosis codes with consistent definitions for birth defects is imperative, as it eliminates the need to sort through slightly differing descriptions of the *same* defect, and distinguishes *different* defects within the same organ system.<br><br>Birth defects surveillance programs should strive to use the most specific code possible given the case information available (**Recommendation 5.3.3a**), and ensure that all defects involved in each case are coded (**Recommendation 5.3.3b**). |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Maternal medical record<br>• Vital record<br>• Provider or laboratory reports<br>• Administrative data sets (e.g., hospital discharge) |
| **Timing of Availability at the Data Source** | May be available as-reported from data source the during prenatal period or postnatal period (e.g., as a result of prenatal testing, or after birth, after a treatment/procedure, after infant death), or assigned by the birth defects surveillance system once diagnosis is identified. |
| **Quality Assurance Checks** | *Missing value criteria:* Every case should have at least one birth defect diagnosis code, or use standardized missing value codes. This field for diagnosis codes from other classification systems can be left blank if a birth defects surveillance program *only* assigns NBDPN Birth Defects Case Definition Codes.<br><br>*Allowable value criteria:* Each case may have multiple codes; all should have the standard diagnostic code format for the corresponding health information classification system.<br><br>*Consistency criteria*: Every diagnosis description should have a corresponding code. |

**Additional Considerations**

The birth defects surveillance program database should accommodate a minimum of 20 unique diagnostic codes per case.

See **Appendix 2A** for details of potential health information classification system diagnosis codes associated with the NBDPN-recommended set of birth defects for surveillance.

The birth defects surveillance program may arrive at the code(s) to be entered in the database through any of these methods, or combinations of these methods:

- Accepting the diagnosis code as reported by the data source
- Manually coding based on abstraction and records review
- Utilizing computer-assisted coding (e.g., Natural Language Processing)

NBDPN recognizes that diagnosis codes are available from several different established health information classification systems (e.g., ICD, CDC/BPA, BD-STEPS, NBDPS; see **Chapter 4**), along with diagnosis codes that various birth defects surveillance programs have customized for their own use. This data element accepts diagnosis codes from any of those systems, per each birth defects surveillance program's operational preferences.

If the diagnosis is received from the data source as a text description (rather than a diagnostic code), the birth defects surveillance system should select a coding system (e.g., NBDPN, ICD-10-CM) and assign the appropriate code associated with the reported diagnosis.

Note that NBDPN Birth Defect Case Definition Codes should be entered in *that* data element field instead.

| **Gestational Age** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | Completed weeks of gestation at the time of delivery, as derived from prenatal ultrasound, last menstrual period, postnatal exam, etc. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Gestational age can be used to determine whether a pregnancy outcome meets the programmatic case inclusion criteria for the birth defects surveillance program (see **Standard 2.1.3**). |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after the pregnancy outcome/delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Gestational age should not be missing if the method of determining gestational age is known.<br>*Allowable value criteria:* Any value less than 9 weeks or greater than 44 weeks should be checked.<br>*Consistency criteria*: If the pregnancy outcome is live birth, gestational age less than 20 weeks should be checked. The birth defects surveillance program may want to check for consistency with birth weight. |
| **Additional Considerations** | |
| Gestational age can be derived via several methods, and conflicting gestational age information may be reported in the medical record. The birth defects surveillance program should only record the most accurate gestational age if multiple conflicting gestational ages are available, with the highest accuracy from prenatal ultrasound at < 14 weeks; intermediate accuracy from the date of last menstrual period or a prenatal ultrasound at ≥ 14 weeks; and lowest accuracy from clinical exam after delivery (see **Chapter 2**: **Section 2.1.4**). | |

| **Infant Medical Record Number(s)** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A unique identifier assigned by the source from which the information was obtained to identify an individual (the index infant for the case) who received health care from that organization. |
| **Data Element Format** | Number, or alphanumeric (format determined by the source) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | A medical record number allows facilities to retrieve an individual's records easily. Although it may be possible to locate medical records using the patient's name and date of birth, the infant's medical record number is particularly helpful if the birth defects surveillance program has a name different than that recorded at the data source. |
| **Data Source** | May be abstracted from:<br>• Infant medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* For live births, the case must have at least one medical record number for the infant.<br>*Allowable value criteria:*<br>**1.** Multiple medical record numbers are possible. Medical record numbers from different sources should be different, unless the sources are within a single organization (e.g., a health care consortium).<br>**2.** All medical record numbers for the infant must be different from all medical record numbers for the mother. The mother's medical record number may be used by the data source to identify a fetal death, but would not be allowable in this field. |
| **Additional Considerations** | |
| Medical record numbers are not the same as visit, service, or encounter numbers.<br>Medical record numbers may be very long. The birth defects surveillance program should allow for entry of the entire medical record number. Multiple numbers are likely if the infant receives care from more than one organization. Although not standard practice, a single organization may assign multiple medical record numbers to the same person, so it is important to identify each number for a given data source and to check for data entry errors (e.g., transpositions). | |

| **Name** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A word or set of words by which an infant, fetus, or potential case is known, addressed, or referred to (e.g., first, middle, last name(s), suffix). |
| **Data Element Format** | Text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The birth defects surveillance program should record all the names for easier record finding, matching, linkage, and de-duplication. |
| **Data Source** | May be abstracted from:<br>• Vital record<br>• Infant medical record |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Every case must have at least one name, and should generally have two names (first and last). To establish the existence of missing names, there should be separate fields for each component of the name.<br>*Allowable value criteria:* A case may have one or more aliases ("also known as" or AKA). Multiple names are possible.<br>*Consistency criteria:* If the infant's last name is hyphenated (e.g., the legal name includes the father's last name and the mother's maiden name), both names should be in the last name field. |
| **Additional Considerations** | |
| Individual field lengths of at least 50 characters are recommended to avoid truncated names.<br>If the name of the infant, fetus, or potential case is the same as the father's or mother's name, or a combination of the two, mismatches in the spelling should be checked.<br>The birth defects surveillance program should consider recording all aliases, with a standardized method of identifying their order of occurrence, to remain current with name use or name changes.<br>The name may change over time, particularly a child's full name. For the sake of linkage, names on the vital record should be retained and considered to be the name of record. If there are name changes across the scope of the medical records, updates should be made in separate fields. | |

| **Plurality** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The number of fetuses delivered live or non-live at any time in the pregnancy, regardless of gestational age or if the fetuses were delivered at different dates in the pregnancy. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The purpose of specifying the plurality and birth order is to disambiguate the cases – align the correct baby with the correct case data for the correct defect(s). The plurality, in association with other fields such as county of residence and mother's social security number, can be used to avoid duplication of records in the birth defects surveillance program. Documenting plurality, in combination with birth order, can be used to ensure records for twins, triplets, or other multiples are not inadvertently merged.<br><br>Documenting the plurality also helps alert the birth defects surveillance program to the potential for other possible vital records. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record (*if it is the only source available*) |
| **Timing of Availability at the Data Source** | May be obtained after the pregnancy outcome/delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This field should always be filled out.<br><br>*Allowable value criteria:* The value should be a whole number, $\geq 1$. |
| **Additional Considerations** | |
| Since some twin pregnancies are anomalous, such as conjoined twins, there may not be the expected two vital records for a pregnancy that is identified as a twin pregnancy.<br><br>Plurality during pregnancy may differ from plurality at date of delivery (e.g., fetal reduction, vanishing twin). "Reabsorbed" fetuses, meaning those which are not "delivered" (expulsed or extracted from the mother), should not be counted. | |

| **Pregnancy Outcome** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | Outcome of the index pregnancy, which can include live birth, fetal death, and/or other pregnancy loss (e.g., induced terminations). |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The pregnancy outcome, in conjunction with gestational age fields, may determine whether a record meets programmatic case inclusion criteria.<br><br>Best practices indicate birth defects surveillance programs would distinguish between the outcomes of live birth, fetal death, and elective termination.<br><br>Part of the mission of the birth defects surveillance program may be to refer families to health services. Since only live births would be referred to many of the services, it is important to know whether a given case is a live birth.<br><br>Knowing which cases are elective terminations aids in evaluating trends in prenatal diagnosis, as well as evaluating the impact of prevention strategies such as folic acid supplementation and fortification. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after the pregnancy outcome/delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This field should always be filled out, except in cases of prenatal diagnosis where the pregnancy has not yet ended.<br><br>*Allowable value criteria:* Live birth, Fetal death, or termination. Unspecified non-live birth, Unknown. |
| **Additional Considerations** | |
| See **Chapter 2** for additional descriptions of pregnancy outcomes.<br><br>For prenatal diagnoses, this data element is typically left blank until the pregnancy outcome occurs, then updated with a value. Birth defects surveillance programs may consider adding a value "ongoing" to indicate that the pregnancy is still underway at the time a prenatal diagnosis was recorded, then amend the value upon occurrence of the pregnancy outcome. | |

**CORE TIER**

| **Sex** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The biological sex of the infant or fetus. |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The birth defects surveillance program can use the sex of the infant or fetus to evaluate differences in birth defect rates by sex. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after the pregnancy outcome/delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Every record should have sex recorded unless it was not possible to determine upon delivery (e.g., early fetal death).<br>*Allowable value criteria:* Male, Female, Ambiguous, Unknown (or Unstated). |
| **Additional Considerations** | |
| If a karyotype was performed, the sex should match the karyotype, except in rare cases of such discordances as XY females and XX males. If there is a discordance, birth defects surveillance programs should use the sex listed in the infant medical records/vital record. | |

**CORE TIER**

| **Source of Report** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A place, person, or thing from which the data were obtained. |
| **Data Element Format** | Code (representing the data source), or Text (naming the data source) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The source of report allows the birth defects surveillance program to identify which data source supplied the information or case report. This is important for resolving data edit issues, confirming the data, and conducting audits of facility reporting.<br>The data source fields permit the birth defects surveillance program to evaluate the usefulness of specific data sources. |
| **Data Source** | Abstracted |
| **Timing of Availability at the Data Source** | May be obtained upon identification of a potential case, or further investigation of the case. When case data are received, the source of that data is recorded. |
| **Quality Assurance Checks** | *Missing value criteria:* This field should not be missing.<br>*Allowable value criteria:* Standard codes (hospitals, clinics, laboratories, autopsy, etc.) unique to each program/organization. Multiple sources are possible for a given case. |
| **Additional Considerations** | |
| It is useful to record all data sources for a given case. For example, an infant may be identified with a birth defect at the delivery hospital, tertiary care hospital, cytogenetic laboratory, etc. (see **Chapter 5**).<br>It is useful to maintain a list of potential data sources and standard codes for them (hospitals, clinics, laboratories, autopsy, etc.), which may be unique to each birth defects surveillance program.<br>Birth defects surveillance programs may find it helpful to develop a sense of the expected number of reports or cases typically received from each data source, to help identify potential source reporting concerns. | |

| **Unique Case ID** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A code or number that uniquely identifies each case or record. |
| **Data Element Format** | Number, or alphanumeric (format determined by the birth defects surveillance program procedures) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | With a unique ID code, the birth defects surveillance program can refer to a particular case more easily than having to refer to a set of other elements. For example, it is easier to refer to "case ID 1234567" than to "case of John Doe, date of birth DD/MM/YYYY, born to mother, Jane Doe."<br><br>The unique case ID permits easy linkage between multiple case reports and/or data sets if each report or data set contains the ID as one of its fields. This is essential for data transfer and processing, so that data for a particular case does not get mixed up with data from other cases. |
| **Data Source** | As cases are added, each case is assigned a unique case ID created by:<br>• Birth defects surveillance program |
| **Timing of Availability at the Data Source** | May be assigned upon identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* This field should not be missing. Every infant/fetus in the birth defects surveillance database must have a unique ID.<br><br>*Allowable value criteria:* Only one ID per case. The value should not be the same as any other unique case ID in the database. |
| **Additional Considerations** | |
| None. | |

| **Mother's Date of Birth** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The birth mother's date of birth. |
| **Data Element Format** | Date (including month, day, and year) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Mother's date of birth can be used to facilitate matching with other data sources.<br><br>The birth defects surveillance program can use the mother's date of birth and infant's date of delivery to calculate the mother's age at delivery, which can be used in clinical review, demographic reporting, and research on the relationship between birth defects and maternal age. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* Every record should include the mother's date of birth, except when the mother's identity is unknown (such as when the baby was left at a safe haven or abandoned). If any of the three parts of the date (month, day, year) are missing, all known elements of the date should be recorded (in separate fields if necessary).<br><br>*Allowable value criteria:* The date should include month, day, and year. The range for month should be 1 to 12; range for day is 1 to 31; and the year should be captured as four digits (YYYY).<br><br>*Consistency criteria*:<br>**1.** Maternal age calculated outside of the range of 12 to 49 years suggests the need for verification.<br>**2.** Medical records may sometimes confuse maternal and paternal information. If the mother's date of birth is the same as the father's date of birth, the birth defects surveillance program should check whether the dates are correct. |
| **Additional Considerations** | |
| None. | |

**CORE TIER**

| **Mother's Ethnicity** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A category of social group that has a common national or cultural tradition. |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Ethnicity is a designation separate from race. The birth defects surveillance program can use the maternal ethnicity to evaluate differences in birth defect rates by mother's ethnicity. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* Every record should include the mother's ethnicity except when the mother's ethnicity is unknown (i.e., not listed in medical records or on the vital record), or when the mother's identity is unknown (such as when the baby was left at a safe haven or abandoned).<br>*Allowable value criteria:* Ethnic categories should be compatible with the National Center on Health Statistics (NCHS) standards in current use for ethnicity. More than one ethnicity category may be selected. |
| **Additional Considerations** | |
| Ethnicity data can be further specified into subgroups within the NCHS standard categories if there are ethnic populations of special public health interest in the birth defects surveillance program's catchment area, as long as data can still be aggregated into NCHS standard categories. | |

**CORE TIER**

| **Mother's Medical Record Number(s)** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A unique identifier assigned by the source from which the information was obtained to identify an individual (the mother of the index fetus or infant) who received health care from that organization. |
| **Data Element Format** | Number, or alphanumeric (format determined by the source) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | A medical record number allows facilities to retrieve an individual's records easily. Although it may be possible to locate medical records using the patient's name and date of birth, the birth defects surveillance program may have a name different than that recorded at the data source. |
| **Data Source** | May be abstracted from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* The case must have at least one medical record number for the mother, except when the mother's identity is unknown (such as when the baby was left at a safe haven or abandoned).<br>*Allowable value criteria:*<br>**1.** Different sources may each assign a distinct medical record number, and each of these medical record numbers should be recorded.<br>**2.** A mother's medical record number is unique and should not match the infant's medical record number, or any other person's identification numbers. |
| **Additional Considerations** | |
| Medical record numbers are not the same as visit, service, or encounter numbers.<br>Medical record numbers may be very long. The birth defects surveillance program should allow for entry of the entire medical record number. Although not standard practice, a single organization may assign multiple medical record numbers to the same person, so it is important to identify each number for a given data source and to check for data entry errors (e.g., transpositions). | |

| **Mother's Name** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A word or set of words by which the birth mother of the index infant or fetus is known, addressed, or referred to: (e.g., first, middle, last name(s), suffix). |
| **Data Element Format** | Text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The birth defects surveillance program should record all the names – first, middle, last, maiden, and suffix (if used) – for easier record finding, matching, linkage, and de-duplication. |
| **Data Source** | May be abstracted from:<br>• Vital record<br>• Maternal medical record<br>• Infant medical record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* Every record must include at least one name for the mother, and should generally have two names (first and last), except when the mother's identity is unknown (such as when the baby was left at a safe haven or abandoned). To establish the existence of missing names, there should be separate fields for each component of the name.<br>*Allowable value criteria:* A mother may have one or more aliases ("also known as" or AKA). Multiple names are possible.<br>*Consistency criteria*: If the mother's last name is hyphenated (e.g., her legal name includes her married and maiden names), both names should be in the last name field. |

| **Additional Considerations** |
| --- |
| Individual field lengths of at least 50 characters are recommended to avoid truncated names.<br><br>If the mother's name is the same as the name of the infant, fetus, or potential case, mismatches in the spelling should be checked.<br><br>The birth defects surveillance program should consider recording all aliases, with a standardized method of identifying the order of their occurrence, to remain current with name use or name changes.<br><br>The birth defects surveillance program should be aware of the handling of parents' names in cases of adoption.<br><br>The name may change over time, particularly maternal surnames. For the sake of linkage, names on the vital record should be retained and considered to be the name of record. If there are name changes across the scope of the medical records, updates should be made in separate fields. |

| **Mother's Race** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The race(s) that best describes what the mother considers herself to be. |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The birth defects surveillance program can use the mother's race to present data on birth defect rates by maternal race in descriptive epidemiology. |
| **Data Source** | May be abstracted from:<br>• Vital record<br>• Maternal medical record<br>• Infant medical record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* Every record should include mother's race except when the mother's race is unknown (i.e., not listed in medical records or on the vital record), or mother's identity is unknown (such as when the baby was left at a safe haven or abandoned).<br>*Allowable value criteria:* Racial categories should be compatible with the National Center on Health Statistics standards in current use for race. More than one racial category may be selected. "Unknown" is an acceptable value in the situations described above. |
| **Additional Considerations** | |
| None. | |

| **Mother's Residence at Time of Pregnancy Outcome** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The geographic location where the mother was living at the time of the outcome of the index pregnancy: street address, city, county, state, and zip code; or equivalent. |
| **Data Element Format** | Code or text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Geographic location is needed to determine if a case falls within the birth defects surveillance program's catchment area to confirm that it meets programmatic case inclusion criteria. It is also used for descriptive epidemiology. |
| **Data Source** | May be abstracted from:<br>• Vital record<br>• Maternal medical record<br>• Infant medical record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Missing value criteria:* Maternal residence should be the physical address not the mailing address, if they differ. Maternal residence should not be a P.O. Box unless there is no physical address in any record for the mother.<br>*Allowable value criteria:* If there is a physical address, there should be separate fields for street address, apartment number, city, county, state, and zip code.<br>*Consistency criteria*: It may be advisable to process data through geocoding software to correct self-reported residency attributes (e.g., zip, county, etc.). |
| **Additional Considerations** | |
| A case may have multiple addresses listed for the mother. For surveillance purposes, the address on the vital record (when available) should be used to determine whether the residence meets the programmatic case inclusion criteria for mother's residency (see **Recommendation 2.1.2b**).<br>See **Chapter 2: Section 2.1.2** on residency status for special considerations regarding mother's residence at the time of pregnancy outcome. | |

# Enhanced Data Elements

| **Death – Autopsy Performed** *Infant Data Element*<br>If applicable | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | Indicates whether an autopsy was conducted. |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Knowing whether an autopsy was performed will identify an additional potential source of information, signaling the birth defects surveillance program to seek the autopsy report.<br><br>An autopsy report may give further information on the cause of death, and possibly additional details about the birth defect that enable assigning the most specific diagnosis code(s) possible (**Recommendation 5.3.3a**). Morphology findings during autopsy can be used to assess whether the birth defect diagnosis was *Accepted* versus *Confirmed* (**Appendix 2A**).<br><br>Knowing that an autopsy was performed also prompts the birth defects surveillance program to watch for corrections to the fetal or infant death data by the vital records office after the first linkage. |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Vital record (fetal or infant death certificate)<br>• Fetal death report |
| **Timing of Availability at the Data Source** | May be obtained once the vital record (i.e., fetal death certificate or infant death certificate) is accessible. |
| **Quality Assurance Checks** | *Missing value criteria:* Should not be missing if the child died. If "Not Applicable" code is used when child is living, this data field should not be missing a value in any case captured by the birth defects surveillance program.<br><br>*Allowable value criteria:* Yes, No, Unknown, or [*Optional*] Not Applicable |
| **Additional Considerations** | |
| A birth defects surveillance program may elect to identify the type of autopsy performed (e.g., anatomical, gross, partial gross, surgical). | |

| **Death – Date of Death for Live-Born Infant** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | The date of demise after a live birth, which generally consists of a month, day, and year. |
| **Data Element Format** | Date (including month, day, and year) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The date of death for live-born infant permits the birth defects surveillance program to know that most postnatal procedures will not occur after this date, with the exception of autopsy, cytogenetic analyses, and other laboratory analyses.<br><br>The delivery date for a live birth along with the date of death can be used to determine length of survival and appropriate follow-up contact. |
| **Data Source** | May be abstracted from:<br>• Infant medical record<br>• Vital record (infant death certificate)<br>• Maternal medical record |
| **Timing of Availability at the Data Source** | May be obtained after infant death, following autopsy, or upon availability of a death certificate. |
| **Quality Assurance Checks** | *Missing value criteria:* This field should only be filled out if the pregnancy outcome is live birth, and the live born child is known to have died. If any of the three parts of the date (month, day, year) are missing, all known elements of the date should be recorded (in separate fields if necessary).<br><br>*Allowable value criteria:* The date should include month, day, and year. The range for month should be 1 to 12; range for day is 1 to 31; and the year should be captured as four digits (YYYY).<br><br>*Consistency criteria*: The date of death should be on or after the date of delivery, and on or after any date of prenatal ultrasound or prenatal diagnostic procedure. |
| **Additional Considerations** | |
| When applicable, this field can be used for date of death beyond infancy. | |

| **Death – Death Certificate ID** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A unique identifier assigned to a death certificate and maintained in vital records and birth defects surveillance programs. |
| **Data Element Format** | Number, or alphanumeric (format determined by the source) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Maintaining this ID in both vital records and the birth defects surveillance program ensure the ongoing ability to link to death records, which is important because certified data may be corrected or amended. For example, the cause of death listed on the vital record may change later based on a delayed autopsy.<br><br>The death certificate is the legal, validated, consolidated source for the occurrence and causes of death including autopsy information, infant's name at time of death, and demographic information about the decedent and family. |
| **Data Source** | May be abstracted or assigned from:<br>• Vital record (infant death certificate) |
| **Timing of Availability at the Data Source** | May be obtained once the infant death certificate is accessible. |
| **Quality Assurance Checks** | *Missing value criteria:* This ID must not be missing if any death certificate data are available to the birth defects surveillance program.<br><br>*Allowable value criteria*: This ID should not be the same as any medical record number for the infant or the mother. |
| **Additional Considerations** | |
| The death certificate is a validated source of data that may not be available from other sources because death records are checked and queried at the local, state, and national levels, and corrected or amended by the vital records office, as needed.<br><br>In certain states, the birth defects surveillance program may not be permitted to store the actual death certificate number (the "Death Certificate Number" or "State File Number" by which the death is registered in the state where it happened), for reasons of privacy and security. When unable to store the number, the birth defects surveillance program should have the capacity to link to the death certificate, or to assign a report number and a key that enables retrieval of the actual death certificate number. | |

| **Death – Fetal Death Certificate / Report ID Number** ***Infant Data Element***<br>If collected by the birth defects surveillance program | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A code or number that uniquely identifies a fetal death. This identifier is assigned to a fetal death certificate/report and maintained by the vital records and birth defects surveillance programs. |
| **Data Element Format** | Number, or alphanumeric (format determined by the source) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Maintaining this ID in both the vital records and the birth defects surveillance program ensures the ongoing ability to link to fetal death records, important because the fetal death data may be corrected (e.g., autopsy report) by the vital records after the first linkage. |
| **Data Source** | May be abstracted or assigned from:<br>• Vital record (fetal death certificate) |
| **Timing of Availability at the Data Source** | May be obtained once the fetal death certificate/report is available. |
| **Quality Assurance Checks** | *Missing value criteria:* This ID must not be missing if any fetal death data for the non-live born infant are available from vital record.<br>*Allowable value criteria:* This ID should not be the same as any medical record number for the mother. |
| **Additional Considerations** | |
| In certain states, the birth defects surveillance program may not be permitted to store the actual fetal death certificate number (the "State File Number" by which the fetal death is registered in the state where it happened), for reasons of privacy and security. When unable to store the number, the birth defects surveillance program should have the capacity to link to the fetal death certificate, or to assign a report number and a key that enables retrieval of the actual fetal death certificate number. | |

| **Death – Underlying Cause of Death** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Core |
| **Definition** | A standard set of letters, numbers, or other symbols used to categorize a text description of the underlying cause of death. |
| **Data Element Format** | Code |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Understanding categories of mortality among persons with birth defects contributes to epidemiological goals of identifying trends, risk factors, and co-morbidities associated with birth defects. |
| **Data Source** | May be abstracted from:<br>• Vital record (fetal or infant death certificate) |
| **Timing of Availability at the Data Source** | May be obtained once the vital record (i.e., fetal death certificate or infant death certificate) is available. |
| **Quality Assurance Checks** | *Missing value criteria:* The underlying cause of death should not be missing if the fetal or infant death certificate ID is available.<br>*Allowable value criteria:* Each case may have only one underlying cause code; all codes should meet the cause of death coding standards and format used by the vital records program. |
| **Additional Considerations** | |
| When applicable, this field can be used for cause of death beyond infancy.<br>The cause of death coding system used by the vital records program follows a specific set of coding rules and procedures. The manual coding of cause of death/underlying cause of death within a birth defects surveillance program may or may not align with the vital record procedures. Birth defects surveillance programs should review the vital records office procedures and adapt to their process accordingly. | |

| **Diagnostic Tests and Procedures** *Infant Data Element* | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | Description of prenatal and/or postnatal diagnostic procedure(s) performed to help identify, diagnose, characterize, and/or treat a birth defect. |
| **Data Element Format** | Code or text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Knowing that a diagnostic test or procedure was performed is useful for case identification, and the details/results help with case investigation.<br><br>Results from each test or procedure may give additional information about the birth defect that enables assigning the most specific diagnosis codes possible (**Recommendation 5.3.3a**), and assessing whether the birth defect diagnosis is *Accepted* versus *Confirmed* (see criteria in **Appendix 2A**). |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Maternal medical record<br>• Laboratory reports |
| **Timing of Availability at the Data Source** | May be available during prenatal period or postnatal period (e.g., as a result of prenatal testing, or after birth, after a treatment/procedure, after infant death). |
| **Quality Assurance Checks** | *Missing value criteria:* Each case should have at least one diagnostic test or procedure, or state that the diagnosis was based solely on physical exam.<br><br>*Allowable value criteria:* Multiple procedure listings are permitted. Text (if used) should be the concise, consistent name of the procedure. Codes (if used) should conform to the range and format of the health information coding system used. Codes for screening, examination, or diagnostic procedure should follow an established standard.<br><br>*Consistency criteria*: If the case has multiple birth defects, each procedure/description should be associated with the correct diagnosis code and text (e.g., in a case with both atrioventricular septal defect *and* duodenal atresia, the procedures related to the AVSD should be associated with the diagnosis code for AVSD, while the procedures related to duodenal atresia should be associated with the diagnosis code for duodenal atresia). |

**Additional Considerations**

This data element includes both prenatal and postnatal tests. The dates associated with diagnostic tests and procedures will identify the context.

Birth defects surveillance programs should collect data on the following diagnostic tests and procedures with a role in case definition or classification of the defect, as detailed in **Appendix 2A**:

- Autopsy
- Genetic testing (CMA, FISH, karyotype, MLPA)
- Imaging (cardiac catheterization, angiography, CT, echocardiogram, MRI, ultrasound, X-ray)
- Prenatal procedures to obtain specimens (amniocentesis, CVS)
- Surgery (open or endoscopic, for exploration or repair)

When further information is available to accompany the code for the diagnostic test or procedure performed, and when resources permit, programs may find it helpful to include the following (in separate fields) in the description:

- Date of the procedure or test
- Organ system(s) involved in the procedure
- Indication (i.e., the possible birth defect or condition(s) that prompted the procedure)
- Provider type who performed procedure or interpreted the results (e.g., pediatric cardiologist)
- Specimen type (if any) obtained or analyzed (e.g., fluid from amniocentesis, peripheral blood)
- Whether the test was screening, preliminary, or diagnostic.

The best data source(s) for prenatal diagnostic tests or procedures can vary widely, and may or may not be the same sites where pregnancies are electively terminated after a prenatal diagnosis is made.

| **Method of Determining Gestational Age** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | Method of calculating completed weeks of gestation. |
| **Data Element Format** | Code or checkbox |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | The accuracy of the stated gestational age depends on the method used to determine it. Given the importance of gestational age to checking whether a case meets programmatic inclusion criteria, it is important to know how precise the age determination might be. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Infant medical record<br>• Vital record (*if it is the only source available*) |
| **Timing of Availability at the Data Source** | May be obtained after the pregnancy outcome, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Should not be missing if gestational age is ≥ 20 weeks.<br>*Allowable value criteria:* Allowable methods can include prenatal ultrasound with a reported gestational age of less than 14 weeks; date of the last menstrual period (LMP); prenatal ultrasound with a reported gestational age of 14 weeks or greater; or clinical examination after delivery. |
| **Additional Considerations** | |
| Programs should use the most accurate gestational age for determining if a case meets programmatic inclusion criteria. If multiple methods are available, the gestational age that was calculated using the most accurate method should take priority (see **Chapter 2: Section 2.1.4**).<br>• Highest accuracy: Prenatal ultrasound at < 14 weeks<br>• Intermediate accuracy: Date of last menstrual period, or a prenatal ultrasound at ≥ 14 weeks<br>• Lowest accuracy: Clinical exam after delivery<br>If applicable, the date of *in vitro* fertilization or artificial insemination is the most exact means of calculating gestational age, and thus preferred in those situations. | |

| **Responsible Party's Address** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The most recent mailing address of the responsible party: street address, apartment number, city, county, state and zip code; or equivalent. |
| **Data Element Format** | Text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Including the responsible party's address as a data element may directly support a birth defects surveillance program's objectives outside of basic surveillance, such as referral to services and outreach. |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Vital record (birth certificate)<br>• Other administrative database (e.g., immunization registry, metabolic screening database) |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This field could be unknown.<br>*Allowable value criteria:* Should be completed if the name of the responsible party is completed. |
| **Additional Considerations** | |
| There should be separate fields for the street address, apartment number, city, state, and zip code.<br>Fields should be of sufficient length that no street or city name is truncated. | |

| **Responsible Party's Name** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | A word or set of words by which the person taking custody of the child is known (e.g., first, middle, last name(s), and suffix). |
| **Data Element Format** | Text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Including the responsible party's name as a data element may directly support a birth defects surveillance program's objectives outside of basic surveillance, such as referral to services and outreach. |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Vital record (birth certificate)<br>• Other administrative database (e.g., immunization registry, metabolic screening database) |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This field could be unknown.<br>*Allowable value criteria:* This data element should contain at least the first and last name of the responsible party. Multiple names are possible.<br>*Consistency criteria*: If the baby is discharged home with the mother, this data element should match the mother's name. Otherwise, it should be different from the mother's name. |
| **Additional Considerations** | |
| Individual field lengths of at least 50 characters are recommended to avoid truncated names.<br>If there is more than one responsible party, or more than one full name, the birth defects surveillance program should record all the names – with separate fields for first, middle, last, and suffix (if used) – for easier record finding, matching, or linkage.<br>If the name of the responsible adult is the same as the infant, mismatches in the spelling should be checked.<br>The birth defects surveillance program should consider recording all aliases, with a standardized method of identifying the order of their occurrence, to remain current with name use or name changes. | |

| **Responsible Party's Telephone Number** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | Most recent telephone number of the responsible party. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Including the responsible party's telephone number as a data element may directly support a birth defects surveillance program's objectives outside of basic surveillance, such as referral to services and outreach. |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Vital record (birth certificate)<br>• Other administrative database (e.g., immunization registry, metabolic screening database) |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This field could be unknown.<br>*Allowable value criteria:* Should be completed if the name of the responsible party is completed.<br>*Consistency criteria*: This field should contain a valid phone number, including area code. If applicable, include extension. |
| **Additional Considerations** | |
| None. | |

| **Verbatim Description of the Birth Defect(s)** ***Infant Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The exact clinical description of the birth defect provided by health care professionals in the medical record or case report. |
| **Data Element Format** | Text |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Collecting and reviewing the description of the birth defect enables birth defects surveillance programs to arrive at an accurate diagnosis code for reporting (see **Recommendations 5.3.3a** and **5.3.3b**). |
| **Data Source** | May be abstracted or derived from:<br>• Infant medical record<br>• Maternal medical record (for prenatal diagnosis) |
| **Timing of Availability at the Data Source** | May be available during prenatal period or postnatal period (e.g., as a result of prenatal testing, or after birth, after a treatment/procedure, after infant death) once diagnosis has been identified. |
| **Quality Assurance Checks** | *Missing value criteria:* Each case should have at least one description of a birth defect included in the medical record.<br>*Allowable value criteria:* This data element should be the exact language used in the medical record describing the birth defect(s). |
| **Additional Considerations** | |
| The verbatim description of the birth defect can help with assigning the most specific diagnosis code possible, and help indicate the certainty of the diagnosis. If the case data include multiple descriptions of the same birth defect, priority should be given to the description associated with a confirmatory diagnostic procedure (see the *Confirmed* category of the case description in **Appendix 2A**) rather than descriptions associated with items from the *Accepted* category.<br>A birth defects surveillance program may elect to track multiple descriptions with notation of the health care professional (e.g., pediatrician, primary care provider, specialist) who provided the description. Priority may be given to a description from a specialist for the organ system the birth defect involves (e.g., prioritize a pediatric cardiologist's description of congenital aortic valve stenosis). | |

| **Education Level of Mother** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The number of years of school completed or the highest degree attained by the mother. |
| **Data Element Format** | Code (corresponding to degree or level), or Number (corresponding to total number of years of school completed) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Collecting maternal education would allow the birth defects surveillance program to evaluate its relationship to birth defect risk.<br>Education can be used as an indicator of socioeconomic status. |
| **Data Source** | May be abstracted or derived from:<br>• Birth certificate<br>• Fetal death report/certificate |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case. |
| **Quality Assurance Checks** | *Consistency criteria*: Check data if maternal age is ≤ 16 years while education is listed as >12 years or high school graduate. Check data if the number of years of education exceeds 25. |
| **Additional Considerations** | |
| None. | |

| **Gravidity** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The total number of times the mother has been pregnant (including a currently ongoing pregnancy), regardless of the duration and outcome. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Information can be used to identify mothers with a history of live born infants who died, a history of fetal loss, and/or for whom the index pregnancy is not the first pregnancy. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Pregnancy history (gravidity and parity) should be known for every case with a pregnancy outcome, except when the mother's identity is unknown.<br>*Allowable value criteria:* The value for gravidity should be a whole integer. Gravidity should always be at least 1 for birth defects surveillance cases, as the mother was pregnant with the index case at a minimum.<br>*Consistency criteria*:<br>**1.** Gravidity should be greater than or equal to parity.<br>**2.** A pregnancy resulting in more than one fetus should be counted as only one pregnancy. |
| **Additional Considerations** | |
| Gravidity is often recorded in shorthand in the medical record in conjunction with Parity. For example, **G2**P1 indicates a **G**ravidity of **2** (i.e., the mother has been pregnant two times).<br>Gravidity is counted at the time the pregnancy is confirmed, meaning *while* the pregnancy is underway, not delayed until the time of pregnancy outcome. A currently ongoing pregnancy counts toward the total number of times the mother has been pregnant. | |

| **Parity** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The number of pregnancies a mother has carried to ≥ 20 weeks of gestation, regardless of whether the outcome was a live birth or non-live delivery. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | Information can be used to identify mothers with a history of live born infants who died, a history of fetal loss, and/or for whom the index pregnancy is not the first pregnancy to reach viability. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* Pregnancy history (gravidity and parity) should be known for every case with a pregnancy outcome, except when the mother's identity is unknown.<br>*Allowable value criteria:* The value for parity should be a whole integer.<br>*Consistency criteria*:<br>**1.** Parity should include all prior pregnancies that were carried to ≥ 20 weeks of gestation, regardless of pregnancy outcome beyond that time.<br>**2.** Parity should be less than or equal to gravidity.<br>**3.** In pregnancies with more than one fetus, parity still only increases by 1 for that birth/delivery event. |
| **Additional Considerations** | |
| Parity is often recorded in shorthand in the medical record in conjunction with Gravidity. For example, G2**P1** indicates a **P**arity of **1** (i.e., the mother has been pregnant two times, and one of the pregnancy outcomes was a delivery at ≥ 20 weeks of gestation).<br>Parity increases only *after* the delivery has occurred. If the parity number was obtained from prenatal records (meaning prior to delivery), it would subsequently need to be adjusted (increased by 1) following a birth/delivery beyond 20 weeks of gestation. | |

| **Prenatal Care – Date of First Prenatal Visit** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The month, day, and year during the index pregnancy when the mother first received prenatal care from a physician or other health care professional, or attended a prenatal clinic. |
| **Data Element Format** | Date (including month, day, and year) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | For public health purposes: This information can contribute to measures of the appropriateness of prenatal care the mother received during pregnancy.<br><br>For case purposes: This date marks the beginning of the window during which prenatal diagnosis of a birth defect may occur. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case if one or more prenatal visits have already occurred. If the value is potentially unknown or zero, obtain this value after pregnancy outcome. |
| **Quality Assurance Checks** | *Missing value criteria:* This value should not be missing (unknown is acceptable). If any of the three parts of the date (month, day, year) are missing, all known elements of the date should be recorded (in separate fields if necessary).<br><br>*Allowable value criteria:* Date; unknown; no prenatal care. The date should include month, day, and year. The range for month should be 1 to 12; range for day is 1 to 31; and the year should be captured as four digits (YYYY).<br><br>*Consistency criteria*:<br>**1.** This date must occur on or before the baby's delivery date, but not more than 10 months (or 300 days) before the baby's delivery date.<br>**2.** This date should occur after day 0 of the gestational age timeline. |
| **Additional Considerations** | |
| A birth defects surveillance program can collect either the month in pregnancy when prenatal care began, or the date of first prenatal care visit.<br><br>If a birth defects surveillance program collects this data element, it should be collected for both live and non-live births. | |

| **Prenatal Care – Date of Last Prenatal Visit** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The month, day, and year during the index pregnancy when the mother last received care from a physician or other health care professional, or attended a prenatal clinic prior to pregnancy outcome. |
| **Data Element Format** | Date (including month, day, and year) |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | For public health purposes: This information can contribute to measures of the appropriateness of prenatal care the mother received during pregnancy.<br><br>For case purposes: In cases without an address available in the vital record, the mother's residence on the date of the last prenatal visit can be used instead, to determine whether the residence meets programmatic case inclusion criteria. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Missing value criteria:* This value should not be missing (unknown is acceptable). If any of the three parts of the date (month, day, year) are missing, all known elements of the date should be recorded (in separate fields if necessary).<br><br>*Allowable value criteria:* Date; unknown; no prenatal care. The date should include month, day, and year. The range for month should be 1 to 12; range for day is 1 to 31; and the year should be captured as four digits (YYYY).<br><br>*Consistency criteria*:<br>**1.** This date must occur on or before the baby's delivery date, and on or after the date of the first prenatal care visit.<br>**2.** This date should not be more than 10 months (or 300 days) before the baby's delivery date. |
| **Additional Considerations** | |
| None. | |

| **Prenatal Care – Month Prenatal Care Began** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The number of the month during the index pregnancy (second, third, fourth, etc.) when the mother first received prenatal care from a physician or other health care professional, or attended a prenatal clinic. |
| **Data Element Format** | Code or number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | For public health purposes: This information can contribute to measures of the appropriateness of prenatal care the mother received during pregnancy. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained any time after identification of a potential case if one or more prenatal visits have already occurred. If the value is potentially unknown or zero, obtain this value after pregnancy outcome. |
| **Quality Assurance Checks** | *Missing value criteria:* This value should not be missing (unknown is acceptable).<br>*Allowable value criteria:* Enter 1-9 to indicate the month. Enter 0 (or the birth defect surveillance program's established code) for no prenatal care. Enter unknown if the value is not available. |
| **Additional Considerations** | |
| As an alternative to collecting the month prenatal care began, a birth defects surveillance program can collect the date of the first prenatal care visit and the date of delivery, then calculate this value. If utilizing a calculated value, the birth defects surveillance program should use a standard method each time such a calculation is made.<br>If a birth defects surveillance program collects this data element, it should be collected for both live and non-live births. | |

| **Prenatal Care – Number of Prenatal Visits** ***Maternal Data Element*** | |
|---|---|
| **NBDPN Tier Level** | Enhanced |
| **Definition** | The total number of prenatal care visits to a physician, other health care provider, or prenatal clinic during the index pregnancy. |
| **Data Element Format** | Number |
| **Birth Defects Surveillance Program Specific Considerations** | |
| **Justification** | For public health purposes: This information can contribute to measures of the appropriateness of prenatal care the mother received during pregnancy. |
| **Data Source** | May be abstracted or derived from:<br>• Maternal medical record<br>• Vital record |
| **Timing of Availability at the Data Source** | May be obtained after delivery, or upon availability of the vital record. |
| **Quality Assurance Checks** | *Allowable value criteria:* The range is 0-70; Missing; or Unknown. The number should be checked if it exceeds 42 (one visit per week for ~9 months).<br>*Consistency criteria*: This number should only be 0 if mother had no prenatal care. It should only be 1 if the date of first prenatal care visit is the same as the date of last prenatal care visit. |
| **Additional Considerations** | |
| None. | |