Appendix 4.2

Descriptions of Recommended Data Variables

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Format for Variable Descriptions

Variable Name   Name of data collection variable

Definition   Definition of data collection variable

Justification   Reason the birth defects program may want to include variable in its database

Source   Where variable comes from – abstracted, derived, created

Location   Data sources and location within data sources where variable is most likely to be consistently found

Type   How variable should be stored – text, number, date, code (letters and/or numbers), checkbox

Checks   Any limits, ranges, or other criteria the variable should meet

Comments   Other notes or comments about the variable

Options   Recommended options for the variable

Infant Variables - Recommended

Variable Name	***Text description of birth defect***
Definition	Description of diagnosis

Justification   A birth defect may be diagnosed based on more than one procedure or examination. Moreover, two procedures or clinicians may provide different details about the birth defect. For example, one procedure may report that the infant had a myelomeningocele, while a second may mention a lumbar spina bifida. These should all be combined into a single description such as lumbar myelomeningocele. Or one procedure may mention the infant had a cleft lip and palate, while a second notes that the cleft lip was only on the left side of the mouth. These should be combined into something like left cleft lip and palate.

The birth defect description recorded in text format in the data makes it easier to assign disease codes when the medical record is no longer available.

Source   Abstracted

Location
- Mother's delivery medical record (prenatal care record, labor and delivery record, prenatal diagnostic procedure reports)
- Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record, birth certificate worksheet)
- Vital records

Type   Text

Checks   Every case should have at least one diagnosis description (unless the birth defects program includes non-malformed controls). A case may have more than one diagnosis description. Every diagnosis description should have a corresponding code and vice versa.

Comments   See Chapter 5 on Classification and Coding.

Infant Variables - Recommended

Variable Name	***Date of death***
Definition	The date when the death occurred
Justification	The date of death permits the birth defects program to know that most postnatal procedures will not occur after this date, the exceptions being such procedures as autopsies, cytogenetic analyses, and other laboratory analyses.
	The delivery date for a live birth along with the date of death can be used to determine length of survival. Researchers can use this to calculate survival rates for specific lengths of time.
Source	Abstracted
Location	• Mother's delivery medical record (prenatal care record, labor and delivery record, prenatal diagnostic procedure reports) • Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record) • Vital records
Type	Date
Checks	This field should only be filled out if the pregnancy outcome is "live birth". The date of death should be on or after the date of delivery.

Variable Name	***Birth Length***
Definition	Length of newborn at birth
Justification	In conjunction with gestational age, birth weight, and head circumference, length can be used to assess prenatal growth retardation, a characteristic of fetal alcohol syndrome. However, these circumstances account for only a small subset of cases a birth defects program will collect, and it may not be worth collecting the information on all cases.
Source	Abstracted
Location	• Infant's medical record (labor and delivery record) • Vital records in some states
Type	Number
Checks	Edit checks for range and for consistency with gestational age are recommended.
Options	Best collected as centimeters.

Infant Variables - Recommended

Variable Name	***Apgar score***
Definition	Clinical assessment score of newborn at delivery
Justification	Apgar scores are a gross measure of early neonatal health. If the scores are low, that means that the newborn had cardiorespiratory problems immediately after delivery. These problems may or may not be related to a birth defect in the infant. For example, some postnatal complications that correlate with low Apgar scores (intestinal perforations, intraventricular hemorrhage) overlap with problems caused by birth defects.
Source	Abstracted
Location	• Infant's medical record (labor and delivery record), birth certificate work sheet. • Vital records
Type	Code
Checks	Values from 0 through 10 or coded unknown/not applicable.
Comments	Apgar scores at 1 minute, 5 minutes, and 10 minutes are often available. Vital records generally provide 1- and 5-minute scores, with a change to 5- and 10-minute scores for low 5-minute scores being implemented nationwide.

Variable Name	***Birth order***
Definition	Order of delivery for multiple births.
Justification	Birth order is the order in which infants of a multiple gestation pregnancy are delivered. In cases of multiple gestation pregnancies, delivery records might not refer to the infants or fetuses by name but by some other designation such as Twin A and Twin B. This might make it difficult to determine which vital records a particular infant or fetus should be linked to. Vital records may record birth order. Thus birth order might be useful for linkage with vital records in cases of multiple gestation pregnancies. However, other variables such as infant or fetus sex and birth weight might prove as useful for linkage.
Source	Abstracted
Location	• Infant's medical record (labor and delivery record), birth certificate worksheet. • Vital records
Type	Number
Checks	Must be less than or equal to plurality.

Infant Variables - Recommended

Variable Name	***Cytogenetic analyses performed***
Definition	Whether or not a cytogenetics analysis was performed.
Justification	Certain structural birth defects are associated with chromosomal abnormalities (Boudjemline et al., 2001; Bullen et al., 2001; Torfs and Christianson, 1998). Structural defects in the presence of a chromosomal abnormality are often considered to be secondary to or the result of the chromosomal abnormality. Such cases may not be considered suitable for research into potential environmental causes of structural defects. And analyses of the proportion of structural defects associated with chromosomal abnormalities often are based on the number of cases where the karyotype is known, because some of the cases without a chromosome analysis may be expected to have chromosomal abnormalities. Infants with certain chromosomal abnormalities also have higher mortality and morbidity than infants without chromosomal abnormalities. Thus it may be important to know whether a chromosomal abnormality is present when deciding whether to refer cases for intervention or prevention activities.

It is also important to know whether a chromosome analysis was performed at all, even if the results of the analysis are not in the medical record. If time and resources are available, and the chromosome analysis results are considered important, the birth defects program may attempt to track down the results of the analysis. Knowledge that a chromosome analysis was not performed (e.g., because the parents refused) or that a chromosome analysis failed will prevent a birth defects program from wasting resources searching for chromosome analysis results that do not exist.

Source	Abstracted
Location	• Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record)
Type	Number/Code
Checks	Must be yes, no, or unknown.

Infant Variables - Recommended

Variable Name	***Diagnostic tests and procedures performed***
Definition	Method used to reach diagnosis.
Justification	Different procedures can be used in the diagnosis of a birth defect. Moreover, procedures differ in their accuracy and reliability in diagnosing certain birth defects. For example, Down syndrome can usually be considered to be more definite when it is based on a chromosome analysis than on a physical examination of the infant/fetus. Thus it is often not enough to know that a birth defect was mentioned in a medical record; it is important to know how the birth defect diagnosis was made. Moreover, the researcher may only be interested in birth defects identified by particular procedures. For example, researchers may only be interested in cases of a heart defect identified through fetal echocardiography.
	If a birth defects program has clearly defined case inclusion criteria (e.g., infants and fetuses with certain birth defects are only included if diagnoses were made by certain procedures), then basic research can be conducted. An example would be for a birth defects program to only include cardiac defects diagnosed by echocardiography, cardiac catheterization, prenatal ultrasound, or autopsy.
Source	Abstracted
Location	• Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record)
Type	Code
Checks	Any limits, ranges, or other criteria the data variable should meet.
Comments	Must develop an appropriate coding structure or select a coding standard such as CPT coding to aid in capturing and tabulating the information.
Options	May collect primary diagnostic method using a specific hierarchy based on diagnostic accuracy or include multiple procedures fields.

Infant Variables - Recommended

Variable Name	***Autopsy performed***
Definition	Indicates whether an autopsy was conducted.
Justification	The autopsy is considered one of the more definitive procedures for identifying structural birth defects.
	However, even if an autopsy is performed, the autopsy information is not always added to the medical record. As long as a birth defects program has clearly defined case inclusion criteria (e.g., infants and fetuses with certain birth defects are only included if diagnoses were made by certain procedures), then basic research can be conducted. An example of such inclusion criteria would be for a birth defects program to only include cardiac defects diagnosed by echocardiography, cardiac catheterization, prenatal ultrasound, or autopsy.
Source	Abstracted
Location	• Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record)
	• Death certificate, fetal death report.
Type	Code
Checks	Not applicable for live births still living.
Options	Values would include yes, no, or unknown/not applicable.

Infant Variables - Recommended

Variable Name	***Physicians of record***
Definition	Physician(s) identified as being responsible for admission and discharge records.
Justification	A birth defects program might want to have information on the physicians of record in order to obtain additional information, to determine if all appropriate referrals were made, to alert physician to need for folic acid recommendations, or to obtain permission to contact the family.
Source	Abstracted
Location	• Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record) • Newborn metabolic screening data • Vital record
Type	Data are stored as text (names and addresses)
Checks	N/A
Comments	To be useful, this information should include name and address for the physician. Allow for 40 characters for entry of each name. There may be interest in collecting multiple physicians and their role, as in pediatrician, obstetrician, or family practice physician to clarify appropriate physician depending upon circumstance.

Maternal Variables - Recommended

Variable Name	***Date of last menstrual period (LMP)***
Definition	First day of last menstrual period
Justification	Date of LMP, along with date of delivery, can be used to calculate gestational age at delivery. Gestational age at delivery can be used for determining if a spontaneous fetal death or pregnancy termination meets the case definition for the registry.
Source	Abstracted Derived (see comments)
Location	• Mother's delivery medical record (prenatal care record, labor and delivery record) • Infant's delivery medical record (prenatal care record, labor and delivery record) • Vital records
Type	Date
Checks	The LMP date must be before the date of delivery, estimated date of delivery, prenatal ultrasound date, and prenatal and postnatal procedure dates. The LMP date should not be more than one year before the date of delivery, estimated date of delivery, prenatal ultrasound date, and prenatal procedure dates.
Comments	If the LMP date is recorded in both the prenatal records and the admission interview, use the LMP date in the prenatal records. If more than one LMP date is found in the prenatal records, record the earliest LMP date in this field.
Options	See Chapter 3 on Case Definition for further information.

Maternal Variables - Recommended

Variable Name	***Date of ultrasound***
Definition	Date of the earliest identified ultrasound used to assess gestational age
Justification	Date of ultrasound, along with gestational age at time of ultrasound and delivery date, can be used to calculate gestational age at delivery.
Source	Abstracted
Location	• Mother's delivery medical record (prenatal care record, labor and delivery record) • Infant's delivery medical record (prenatal care record, labor and delivery record)
Type	Date
Checks	The date of ultrasound field should only be filled in when the gestational age at ultrasound is also known. The ultrasound date must be before or on delivery date and postnatal procedure dates and after the LMP date. The ultrasound date should not be more than 10 months before the date of delivery.
Comments	Only record information present in the medical record. DO NOT calculate gestational ages or dates. If multiple ultrasounds were done to determine gestational age, record the date of the earliest ultrasound.

Maternal Variables - Recommended

Variable Name	***Gestational age at time of ultrasound***
Definition	Gestational age (in weeks) at the time of ultrasound, as estimated by the earliest ultrasound performed
Justification	Gestational age at ultrasound combined with date of pregnancy outcome can be used for determining if a spontaneous fetal death or pregnancy termination meets the case definition for the registry.
	Certain diagnoses are considered birth defects only when the infant is of a particular gestational age. For example, patent ductus arteriosus is common among premature infants and is only considered a birth defect if found in infants born at term.
Source	Abstracted
Location	• Mother's delivery medical record (prenatal care record, labor and delivery record) • Infant's delivery medical record (prenatal care record, labor and delivery record)
Type	Number
Checks	This field should only be filled in when the date of ultrasound is also known. The gestational age at ultrasound should range between five menstrual weeks and birth.
Comments	Only record information present in the medical record. Do not calculate gestational ages or dates.
	If multiple ultrasounds were done to determine gestational age, record the date of the earliest ultrasound.

Variable Name	***Mother's medical record number(s)***
Definition	Birth mother's medical record number(s)
Justification	A medical record number allows facilities to retrieve records more easily.
Source	Abstracted
Location	• Mother's delivery medical record (face sheet)
Type	Code
Comments	The mother may have more than one medical record at a given hospital. Medical record numbers may also be very long. Allow for up to 12 alphanumeric characters for this field. The birth defects program should make certain the computer program allows for entry of the entire medical record number.

Maternal Variables - Recommended

Variable Name	***Prenatal diagnosis***
Definition	The diagnosis made before birth by prenatal diagnostic procedures and tests and neither confirmed nor ruled out by postnatal procedures and tests
Justification	Prenatal diagnostic procedures used to detect structural birth defects may not be considered to support as definitive a diagnosis as postnatal procedures, and prenatal detection of a birth defect is frequently considered to be tentative. Often physicians will attempt to verify or refine the prenatal diagnosis postnatally, such as through physical examinations, x-rays, or ultrasounds of the live birth or through autopsy of fetal deaths and elective terminations. Thus birth defects program staff should determine whether postnatal procedures and tests were performed and the results of such procedures and tests. However, postnatal confirmation or clarification of prenatally detected birth defects may not always be possible. In such cases the diagnoses identified through prenatal diagnostic procedures and tests are the best information available. Thus it may be useful for the birth defects program to indicate those diagnoses based solely on prenatal procedures.
Source	Abstracted
Location	- Mother's delivery medical record (prenatal care record, labor and delivery record, prenatal diagnostic procedure reports) - Infant's medical record (face sheet, admission summary, discharge summary, procedure reports, consultation reports, labor and delivery record, birth certificate worksheet) - Vital records
Type	Checkbox
Comments	Prenatal cytogenetic tests may also be considered suspect. Depending on the source of the cell sample used, the sample could have been contaminated by maternal cells. Or, as in the case of chorionic villus sampling, any chromosomal abnormalities identified may be limited to the source of the cell sample and may not affect the fetus. However, prenatal cytogenetic tests are usually considered to be of greater validity than prenatal procedures for identifying structural defects.

Maternal Variables - Recommended

Variable Name   ***Mother's Social Security number***

Definition   Birth mother's Social Security number

Justification   The mother's Social Security number, in association with other fields such as plurality and county of residence, can be used to avoid duplication of records in the registry.

The birth defects program can employ the mother's Social Security number to link to other data sets, such as the Medicaid database.

Source   Abstracted

Location
- Mother's delivery medical record (face sheet, prenatal care record)
- Infant's medical record (face sheet, prenatal care record, birth certificate worksheet)
- Vital records

Type   Number

Checks   Medical records may sometimes confuse maternal and paternal information. The mother's and father's Social Security numbers should not be the same.

Variable Name   ***Census tract of maternal residence at pregnancy outcome***

Definition   Census tract number of birth mother's residence at the time of the outcome of the index pregnancy

Justification   The geographical areas in most cluster investigations to date have been counties, cities, or particular zip codes. However, in the future, cluster and other investigations may focus on geographical areas defined in other ways. Knowing the census tract number at delivery may allow investigators to determine which cases qualify to be included in such future investigations.

Source   Derived
Abstracted (from vital records files)

Location
- Vital records

Type   Number

Maternal Variables - Recommended

Variable Name	*Mother's telephone number*
Definition	Birth mother's most recent telephone number: area code and telephone number
Justification	The mother's telephone number is needed so that researchers and social workers can contact the family.
Source	Abstracted
Location	• Mother's delivery medical record (face sheet) • Infant's medical record (face sheet)
Type	Number
Comments	Enter the area code and seven-digit telephone number. If the area code is not known, enter only the seven-digit telephone number. Note that the telephone number found in a tertiary care facility is more likely to be current than the telephone number at the birth hospital.

Variable Name	*Mother's education*
Definition	Birth mother's highest level of education attained
Justification	Education can be used as an indicator of socioeconomic status (SES). Collecting maternal education would allow the birth defects program to evaluate its relationship to birth defect risk.
Source	Abstracted
Location	• Birth certificate worksheet • Birth certificate, fetal death report
Type	Code
Checks	Any limits, ranges, or other criteria the data variable should meet.
Comments	Since maternal education is not reported consistently in medical records, this information can be obtained more easily by linking to vital record certificates.
Options	Method for storing the information should permit identifying cases with less than high school, high school, some college, and college graduate.

Maternal Variables - Recommended

Variable Name	***Prior pregnancy history***
Definition	Prior live births and fetal deaths to the birth mother
Justification	Information can be used to identify women with a significant history of fetal loss or infant death.
Source	Abstracted
Location	• Mother's delivery medical record (prenatal care record, labor and delivery record, prenatal diagnostic procedure reports)
Type	Number
Comments	This information reflects the number of prior live births and fetal deaths the mother has experienced. Vital record would provide prior live births now living and prior live births now deceased. Medical record can provide parity and gravida.

Variable Name	***Prenatal care***
Definition	Information on the initiation and extent of prenatal care
Justification	Data on prenatal care (such as month of prenatal care and number of prenatal visits), may be useful to a birth defects program. Knowing that the mother did or did not have prenatal care may be useful for birth defects program staff in evaluating other fields on the form. E.g., if it is known that the mother did not have prenatal care, there is less likelihood of finding information on prenatal tests or mother's medical history. And prenatal care may be used as an indication of other factors such as socioeconomic status (SES).
	However, birth defects usually occur before pregnancy is recognized and prenatal care can begin. Furthermore, prenatal care may not be consistently or accurately reported in the medical record – the mother may move or change health care providers or the prenatal care visit information may not be counted consistently. There may be differences of opinion as to what qualifies as a prenatal visit.
Source	Abstracted Derived
Location	• Mother's delivery medical record (prenatal care record, labor and delivery record, prenatal diagnostic procedure reports)
Type	Number
Checks	Range checks and consistency with woman's age
Comments	The information to be considered for inclusion would be month prenatal care began and number of prenatal visits.
Options	The prenatal care information can be summarized using the Kotelchuck or possibly the Kessner Index to standardize the information for more meaningful analysis.

Paternal Variables - Recommended

Variable Name	*Father's date of birth*
Definition	Date of birth for father
Justification	The birth defects program may employ the father's date of birth in addition to other fields to link to other data sets, such as Medicaid. Paternal age may be associated with risk for certain birth defects (McIntosh et al., 1995; Olshan et al., 1994). The information can be useful in studies of paternal occupational or exposure cohort studies into associations with birth defects in progeny.
	The birth defects program can use the father's date of birth and infant's date of delivery in order to calculate the father's age at delivery. The father's age at delivery can then be used in analyzing birth defect rates by paternal age.
Source	Abstracted
Location	• Medical record, birth certificate worksheet • Birth/fetal death, death record
Type	Text
Checks	Range checks for father's ages under 12.

Variable Name	*Father's name*
Definition	Name of father
Justification	The birth defects program may employ the father's name in addition to other fields to link to other data sets, such as vital records or Medicaid.
	However, information on the birth father is not consistently found in medical records or vital records.
Source	Abstracted
Location	• Medical record and birth record worksheet • Birth/fetal death and death record
Type	Text
Comments	The name may be a single field or may be stored as separate first, middle, last, and surname suffix fields. Separate fields greatly facilitate record linkage. Providing 25 character fields for first, middle, and last names should be considered.

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Paternal Variables - Recommended

Variable Name	***Father's education***
Definition	Father's highest level of education attained
Justification	Socioeconomic status (SES) can influence risk of having an infant with a birth defect. Collecting paternal education would allow the birth defects program to evaluate its impact on birth defect risk.
Source	Abstracted
Location	• Birth certificate worksheet • Birth/fetal death record
Type	Code
Checks	Consistency between father's age and education
Comments	Since paternal education is not reported consistently in medical records, this information can be obtained more easily by linking to vital record certificates.
Options	Method for storing the information should permit identifying cases with less than high school, high school, some college, and college graduate.

Variable Name	***Father's race***
Definition	Race of father
Justification	The birth defects program can use the birth father's race in order to evaluate differences in birth defect rates and examine program goals and activities by paternal race.
Source	Abstracted
Location	• Birth certificate worksheet • Birth/fetal death record
Type	Code
Comments	Racial categories and codes used by birth defects surveillance programs should be compatible with the federal standards in current use for race.

Paternal Variables - Recommended

Variable Name	***Father's ethnicity***
Definition	Ethnicity of father
Justification	Ethnicity is a designation separate from race. The birth defects program can use the father's ethnicity in order to evaluate differences in birth defect rates or outreach effort goals and activities by father's ethnicity.
Source	Abstracted
Location	• Birth certificate worksheet • Birth/fetal death record
Type	Code
Checks	Should be valid code.
Comments	Must develop a code structure that meets registry needs and reflects available data on ethnicity. Should be compatible with federal standard for ethnicity classification.

Variable Name	***Father's Social Security number***
Definition	Social Security number of the father
Justification	The birth defects program can employ the father's Social Security number to link to other data sets, such as the Medicaid database.
Source	Abstracted
Location	• Medical record, birth certificate worksheet • Birth/fetal death record
Type	Number
Checks	Medical records may sometimes confuse maternal and paternal information. The mother's and father's Social Security numbers should not be the same.