Core Case Notification Data Element Recommendations: Pregnancy

This document was developed by the Data Standardization Work Group (DSWG) of the Council of State and Territorial Epidemiologists (CSTE) Surveillance Practice and Implementation Subcommittee (SPIS) as a part of a larger data harmonization effort. It will be published and maintained in a repository on the CSTE website.

The DSWG identified and standardized the data elements to utilize in the transmission of core surveillance case data to the Centers for Disease Control and Prevention (CDC). Core surveillance data classes and data elements are those that apply across many conditions and, in general, are not specific to any single condition or condition family. In each recommendation document, the DSWG provides common definitions, value sets/code sets, structure, and interpretation notes for each identified data element that is designated as core. The DSWG does not provide questions which would be used to populate the recommended data elements. More information about the DSWG and data harmonization can be found here.

The structure of this document is as follows:

Background

Pregnant people and infants are uniquely vulnerable because they have special clinical needs, and for certain conditions pregnant people have a disproportionate burden and more severe clinical disease than nonpregnant people. The range of pregnancy-related data that is currently collected across conditions extends from a yes/no indication of pregnancy status at a particular time to pregnancy outcomes and their associated dates. Some case investigations are more intricate, gathering detailed information about the pregnancy, pregnancy history, and neonate (e.g., parity, delivery methods, and the infant's birth weight). The lack of existing standards for capturing pregnancy status goes beyond public health data to clinical health records; therefore, standardization of this data has been previously considered by multiple work groups.

The 2017 Office of the National Coordinator (ONC) Public Health Task Force convened to develop recommendations on how to capture pregnancy status in an electronic health record (EHR) and exchange that data with public health entities, with the maternal follow up done for the Zika virus dxeak as a use case. The group identified a set of minimum public health data elements for pregnancy (Table 1) and recommended the expanded use of electronic laboratory reporting (ELR) to transmit pregnancy status using the Ask on Order Entry method, where the patient's pregnancy status is captured upon laboratory test order.

In 2019, the Center for Disease Control and Prevention's (CDC) Data Harmonization as a Service effort attempted to harmonize and standardize pregnancy status data elements being collected by CDC during emergency response. Of 87 pregnancy questions across 19 CDC data sources, seven data elements were identified as critical for use in an emergency response (Table 1).

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Table 1. Pregnancy data elements included in recommendations by earlier ONC and CDC efforts.

Pregnancy Data Element	2017 ONC Public Health Task Force	2019 Data Harmonization as a Service
Pregnancy Status	✓	✓
Pregnancy Status Date Recorded	✓	
Estimated Delivery Date (EDD)	✓	✓
Gestational Age (alternate to EDD)	✓	
Date Gestational Age Determined (alternate to EDD)	✓	
Pregnancy Outcome	✓	✓
Pregnancy Outcome Date	✓	✓
Postpartum Status	✓	
Recently Pregnant		✓
Birth Weight		✓
Multiple Gestations		✓

In 2020, the Division of Birth Defects and Infant Disorders (DBDID) in CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) worked on harmonizing data elements across multiple systems to support longitudinal, linked birthing parent-baby surveillance and infant outcome surveillance. The resulting data elements were categorized into two data collection time points: maternal health history (collected at first prenatal visit) and pregnancy outcome (neonatal assessment at delivery). A subset of those data elements that overlap with other pregnancy-related working groups are listed below (Table 2).

Table 2. Pregnancy data elements included in CDC's DBDID data harmonization efforts.

Maternal Health History (collected at first prenatal visit)	Pregnancy Outcome (neonatal assessment at delivery)
• Date of last menstrual period • Gravidity • Parity • Estimated date of delivery • Estimated date of delivery based on (method used to calculate the mother's estimated date of delivery)	• Pregnancy outcome • Date of delivery • Gestational age at delivery

In 2022-2023, CSTE convened a Pregnancy Status Reporting Workgroup through the Maternal and Child Health subcommittee with collaboration from the Surveillance and Informatics subcommittees. This workgroup's objective was to identify methods for improving the capture of pregnancy status, focusing on cases of COVID-19 but with the intention to extend the findings to other conditions. The resulting recommendations from the Pregnancy Status Reporting Workgroup focused on describing the use of electronic laboratory reporting (ELR) and electronic case reporting (eCR) for transmission of pregnancy status and provided guidance for jurisdictions on codifying a requirement to report pregnancy status for certain conditions. Their guidance document described the inclusion of pregnancy status and estimated date of delivery (EDD) within model administrative code language, reiterated the capture of pregnancy status through the Ask on Order Entry method, and defined how to best transmit pregnancy status through the use of specified fields within HL7 v2 messages in ELR. The guidance document also describes the potential for capturing pregnancy status through eCR but acknowledges that currently pregnancy information is often not available within electronic initial case reports (eICRs).

Core Surveillance Pregnancy Data Elements for Routine Case Notifications

The following data elements were considered by the DSWG membership to be core surveillance data under the umbrella of the pregnancy data class. For each of the pregnancy-related data elements, there is no pre-defined default value for what should be transmitted when the data element has not been populated. Refer to Tables 3-4 below for definitions and additional information.

- Pregnancy Status
- Estimated Date of Delivery (EDD)

The following data elements were also discussed, but consensus was not reached to include them as core surveillance data included in routine case notifications to CDC.

- Gestational Age
- Pregnancy Outcome

Discussion among DSWG members indicated that gestational age may be more common to come across in a medical record; however, collection of gestational age would also require a secondary variable of "gestational age recorded date" and potentially a variable indicating the method used to determine gestational age. EDD can stand alone in terms of providing the timing of the pregnancy in relation to the condition. EDD was determined by DSWG members to be a core data element for surveillance with 85% support. Gestational age received only 18% support for inclusion as a core data element.

Pregnancy outcome is present in multiple condition-specific message mapping guides (MMGs) containing disparate value sets. A proposed value set discussed included the following options: Still Pregnant, Induced Abortion, Intrauterine Fetal Death < 20 weeks, Intrauterine Fetal Death >= 20 weeks, Perinatal Death, Live Birth – At Term, Live Birth – Premature. Group discussion resolved with general agreement that pregnancy outcome should not be considered a core data element. While collecting pregnancy outcome is very important for certain conditions, several different factors contributed to a lack of support for making it a core element. It is important for a relatively small number of conditions, with varying value sets and needs, and in general, pregnancy outcome by itself is insufficient to meet the need for those conditions. Pregnancy outcome may be better captured along with other necessary pregnancy/outcome/delivery elements in more focused follow-up for these conditions rather than as a core surveillance element. Furthermore, there is a sensitivity to collecting and storing information on certain pregnancy outcomes due to the potential for criminalization or other legal ramifications in some jurisdictions as it relates to the responses, amidst a shifting legal landscape.

The workgroup also considered other data elements related to pregnancy present in MMGs: Premature Infant, Gestational Age Determination Method, Infant Number, Number of Pregnancies, If Mother Has Given Birth in US, Number of Births Delivered in US, Birth Weight, Last Menstrual Period, and Number of Total Live Births. The group was polled and 97% of respondents indicated none of the additional data elements should be considered core data for case surveillance.

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Table 3. Core Surveillance Data Element for Routine CDC Case Notification – Pregnancy Status

Pregnancy Status	
Definition	Pregnancy status of the person at the time of the event (CCCD*)
Standard Code for Transmission to CDC	LOINC: 77996-7 Pregnancy status at time of illness or condition
Value set or coding system	77386006 | Pregnant 60001007 | Not pregnant UNK | Unknown
Abstracted/ Derived/ Created	Derived
Derived from (examples)	Pregnancy status as indicated at the time of the event
Recommendations for Input Data Source(s)	• Case investigation • eCR
Notes	Pregnancy status is intended to be captured in relation to the condition for case notification. For instance, a person that is pregnant at the CCCD and subsequently delivers would be identified as "pregnant" for their pregnancy status. For cases where notification to public health occurs after delivery, circumstances may arise where the CCCD is a known onset date of illness prior to delivery or a laboratory specimen collection date the day of delivery, and in those instances the person should be marked as "pregnant". If the onset date, lab dates, and diagnosis dates are unknown in this example, CCCD would be the date reported to PHA and therefore the person should be marked as 'not pregnant'.
Data Source Details	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/Social History Section/Pregnancy Observation/observation/code HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/Pregnancy Section/Pregnancy Observation (SUPPLEMENTAL PREGNANCY)/observation/code
eCR FHIR	US Public Health Pregnancy Status Observation • Observation.code = LOINC: 82810-3, Pregnancy status • Observation.value = Value set: US Public Health Pregnancy Status (http://hl7.org/fhir/us/ecr/ValueSet-us-ph-pregnancy-status.html)

ELR	Ask on Order Entry method (as implemented for COVID-19 cases; not used routinely):
	• OBX-3 (question): 82810-3^Pregnancy status^LN
	• OBX-5 (result):
	  ○ 77386006^Patient currently pregnant (finding)^SCT
	  ○ 146799005^Possible pregnancy (situation)^SCT
	  ○ 60001007^Not pregnant (finding)^SCT
	  ○ UNK^Unknown^NULLFL
	Some jurisdictions have success extracting pregnancy information from the following fields:
	• OBR.13 Relevant Clinical Information
	• OBR.31 Reason for Study

	• NTE.3 Comment
USCDI v6	Pregnancy Status • Definition: State or condition of being pregnant or intent to become pregnant. • Part of Health Status Assessments data class
USCDI+ Public Health: Case Reporting Use Case	Pregnancy Status • Definition: State or condition of being pregnant or intent to become pregnant. Examples include but are not limited to pregnant, not pregnant, and unknown. • Part of the Health Status Assessments data class and the Pregnancy Information data class

* The Calculated Case Counting Date (CCCD) is the earliest date available of six component dates and is referenced as the time of the event.[1]
** Additional information on input data sources for pregnancy data can be found in Appendix A.

Interpretation Notes

There are conditions where pregnancy at any point during chronic infection is important clinically and for public health response (e.g., HIV, hepatitis B), and there may be a desire to capture information about multiple pregnancies over time. However, data transmission to CDC for these situations is out of scope of this definition and should be addressed with a condition-specific approach.

For eCR, the defined value set within the HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 includes an option for "possible pregnancy". This value is not relevant for public health case notification and is not included within the public health value set. Without further confirmation of pregnancy status during case investigation this value would be captured as "unknown".

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[1] Data Standardization: Workgroup Proposal for Standardized Case Counting Date. Council of State and Territorial Epidemiologists. 2024.
https://cdn.ymaws.com/www.cste.org/resource/resmgr/2015weston/DSWG_BestPracticeGuidelines_.pdf

Table 4. Core Surveillance Data Element for Routine CDC Case Notification – Estimated Date of Delivery (EDD)

Estimated Date of Delivery (EDD)	
Definition	Estimated date of delivery of the pregnancy
Standard Code for Transmission to CDC	LOINC: 11778-8 Delivery date Estimated
Value set or coding system	N/A - Date If the date is unknown, this data element may be left blank.
Abstracted/ Derived/ Created	Abstracted Derived
Derived from (examples)	If only gestational age is known from the medical record, the EDD can be estimated from the gestational age and date of documentation of the gestational age. The EDD is 40 weeks of gestational age, which is also 280 days from the first date of the last menstrual period. A person with a gestational age of 20 weeks and 3 days on January 1, 2020, would be 137 days from their EDD of May 17, 2020. A suggested method for calculating if only the weeks of gestational age are known (e.g., 16 weeks) is to utilize an assumption of XX weeks and 3 days (e.g., 16 weeks and 3 days), so the estimated value will be within 4 days of the actual EDD.
Recommendations for Input Data Source(s)	• Case investigation • eCR
Notes	This data element should only be captured when the pregnancy status of a case is “pregnant”.
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/Social History Section/Pregnancy Observation/Estimated Date of Delivery/observation/value HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/ Pregnancy Section/Pregnancy Observation (SUPPLEMENTAL PREGNANCY)/Estimated Date of Delivery (SUPPLEMENTAL PREGNANCY)/observation/value
eCR FHIR	US Public Health Pregnancy Status Observation • Observation.component: sliceEstimatedDateOfDelivery.value[x]
ELR	N/A
USCDI v6	N/A
USCDI+ Public Health: Case Reporting Use Case	Estimated Date of Delivery • Definition: The estimated due date (EDD) is the date that spontaneous onset of labor is expected to occur. • Part of the Pregnancy Information data class

*Additional information on input data sources for pregnancy data can be found in Appendix A.

Appendix A. Input Data Standards and Data Sources for Pregnancy Data

See Tables 3-4 for a summary of where core data element pregnancy-related information may be found within data transmitted to public health using existing standards (eCR, ELR) or how data may be captured within EHR systems for electronic data exchange (USCDI).

Electronic Case Reporting (eCR)

The eICR Clinical Document Architecture (CDA) implementation guide (Release 2, Standard for Trial Use 1.1) captures pregnancy status as an assertion within the Pregnancy Observation. A negation indicator can be used to indicate the patient was not pregnant during the timeframe specified within the Pregnancy Observation. The Pregnancy Observation also may contain an entry for the EDD.

The eICR CDA implementation guide (Release 2, Standard for Trial Use 3.1) includes an optional Pregnancy Section that contains information about a patient's current and past pregnancy history. This section, if present, would include a required Pregnancy Observation (SUPPLEMENTAL PREGNANCY) template, an optional Last Menstrual Period template, and an optional Postpartum Status template. The Pregnancy Observation template represents both the pregnancy status, using one of the following codes: pregnant, possibly pregnant, not pregnant, and unknown; the associated date range would provide an indication of when the given pregnancy status was known. In addition to the pregnancy status and its effective date, the template contains the following templates that provide further information:

- Estimated Date of Delivery (SUPPLEMENTAL PREGNANCY)
- Estimated Gestational Age of Pregnancy
- Pregnancy Outcome
- Date of First Prenatal Care Visit for This Pregnancy
- Total Number of Prenatal Care Visits for This Pregnancy
- Pregnancy Plurality
- Pregnancy Related Finding

The FHIR implementation guide for eCR uses the US Public Health Pregnancy Status Observation profile to represent a patient's pregnancy history. This profile is defined similarly to the corresponding specifications for pregnancy from the CDA implementation guide. The subject of the profile is the birthing parent, and information includes the pregnancy determination method, determination date, and recorded date of the pregnancy status.

Electronic Laboratory Reporting (ELR)

During the COVID-19 pandemic, pregnancy status was accommodated by laboratories as one of the "Ask at Order Entry" fields, where the OBX-3 question field was populated with 82810-3^Pregnancy status^LN. The result, represented in OBX-5, would be one of the following codes:

- 77386006^Patient currently pregnant (finding)^SCT
- 146799005^Possible pregnancy (situation)^SCT
- 60001007^Not pregnant (finding)^SCT
- UNK^Unknown^NULLFL

Pregnancy status is not commonly captured within laboratory information management systems and there is no field within defined ELR standards to capture pregnancy status. While not standardized, some jurisdictions have found success utilizing the fields Relevant Clinical Information (OBR.13), Reason for Study (OBR.31), and/or Comments (NTE.3) to extract information on pregnancy status.

USCDI and USCDI+

The most recently finalized version of USCDI (version 6) includes one pregnancy-related data element, Pregnancy Status, which is defined as the "state or condition of being pregnant or intent to become pregnant". This data element is currently included in the Health Status Assessments data class, which includes various health-related assessments such as functional status, disability status, and use of alcohol or other substances. However, a new Pregnancy Information data class is currently being

considered for inclusion in a subsequent version of USCDI. This proposed data class includes EDD, but also consists of fourteen additional proposed data elements (Table 5).

USCDI+ supports domain specific data element lists and includes a set of data classes for Public Health use, including data classes for a specific use case of Case Reporting. Within this Case Reporting use case, Pregnancy Status is present in both the Health Status Assessments data class and the Pregnancy Information data class, maintaining the same definition as USCDI v6. The Pregnancy Information data class contains nine other pregnancy related data elements (Table 5), including Estimated Date of Delivery with a definition of "The estimated due date ... is the date that spontaneous onset of labor is expected to occur."

Table 5. Pregnancy-related data elements in USCDI or USCDI+ Public Health Domain

Data Element	Description	USCDI Level	USCDI+ Use Case
Pregnancy Status	State or condition of being pregnant or intent to become pregnant.	v6	Case Reporting
Estimated Date of Delivery	USCDI: The expected date of delivery (i.e. the due date). USCDI+: The estimated due date (EDD) is the date that spontaneous onset of labor is expected to occur.	0	Case Reporting
Corrected Estimated Due Date	The Estimated Due Date that has been corrected during the period before birth.	0	N/A
Gestational Age	The estimated gestational age (in weeks, or weeks and fraction of week) of the pregnancy at the time of the health care encounter (in contrast to the gestational age at birth), beginning from the time of fertilization. Needs to be correlated with the date the gestational age was documented. Gestational age (written with both weeks and days) is calculated using the best obstetrical estimated delivery date (EDD) based on the following formula: Gestational Age = (280 - (EDD - Reference Date))/ 7	0	Case Reporting
Gestational Age Determination Date	USCDI: The date on which the estimated gestational age of pregnancy was determined. USCDI+: Represents the date on which the estimated gestational age of pregnancy was determined.	0	Case Reporting
Gestational Age Determination Method	Method for estimating gestational age, e.g., ultrasound, date of LMP.	0	Case Reporting
Number of Fetal Deaths this Delivery	The number of fetal deaths in this delivery.	0	N/A
Number of Prenatal Visits	The total number of prenatal visits for the mother.	0	N/A
Mother's Delivery Weight	The weight of the mother at the time of birth/delivery.	0	N/A
Mother's Prepregnancy Weight	The weight of the mother before becoming pregnant.	0	N/A

Plurality	The number of fetuses delivered live or dead at any time in the pregnancy regardless of gestational age, or if the fetuses were delivered at different dates in the pregnancy. (“Reabsorbed” fetuses, those which are not “delivered” (expulsed or extracted from the mother) should not be counted.) Include all live births and fetal losses resulting from this pregnancy.	0	N/A
Pregnancy Intention Screening	Screening patient for their desire to become pregnant in the next 12 months in order to determine which reproductive health services may be relevant to offer the patient in that encounter.	0	N/A
Multiple Gestation	Multiple gestation is pregnancy with more than one baby at a time. Examples include pregnancy with twins, triplets, and quadruplets. Multiple gestation is a type of high-risk pregnancy that occurs in approximately three percent of pregnancies.	0	N/A
Planned Pregnancy	Assessing patients for planned pregnancy information reduces the risk of adverse health effects for the woman, fetus, and neonate by working with the woman to optimize health, address modifiable risk factors, provide education and interventions.	0	N/A
Last Menstrual Period (LMP)	Date of the first day of the last menstrual period.	0	Case Reporting
Postpartum Status	USCDI: The postpartum status of a patient, i.e. whether or not the patient is in the postpartum period. USCDI+: The postpartum status of a patient. If the template is present, the patient is in the postpartum period.	0	Case Reporting
Pregnancy Status Determination Method	Method used to determine whether a woman is pregnant or not, for example blood tests, urine tests, and ultrasound scans.	N/A	Case Reporting
Estimated Date of Delivery Determination Method	Method used to estimate the date of delivery, e.g., data from LMP, ultrasound etc.	N/A	Case Reporting