

Immunization History

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.

More information about the DSWG and data harmonization can be found here: [link to DSWG Core Surveillance Project Brief (pending)].

Background

Immunization history data is key to the surveillance of vaccine-preventable diseases. Quality data is important to understand vaccine coverage and inform decision making and public health action nationwide. Public health relies on this information for outbreak response, epidemiologic analysis, and various reports. This information enables public health to understand the impact of vaccination on disease severity and outcome and to investigate whether occurrence of a vaccine-preventable disease is related to vaccine failure (or waning immunity) or failure to vaccinate (including populations without availability of vaccines in childhood). To maximize data quality and to optimize the use of these data, the elements that are transmitted to CDC and analyzed as part of case notifications must be accurate in their collection and relevant to the national picture.

Immunization Information Systems (IIS), typically managed and maintained by the state or local health department, are the primary source of immunization records for the residents of a jurisdiction. All IIS are required to record a specific set of data elements that have been endorsed by the CDC in order to meet [IIS Functional Standards](#). These data elements include patient demographic elements such as name, address, and identifiers, as well as vaccination event elements, such as dates, products, and providers/locations pertaining to the specific vaccination event.

To maintain a complete and accurate record of immunizations, IIS must support the bidirectional transmission of immunization data for individuals, such as to and from healthcare providers that administer vaccinations. Such data is currently exchanged via standards and specifications in the [HL7 Version 2.5.1 Implementation Guide for Immunization Messaging](#). Some public health agencies have also been successful in establishing data exchange, at varying levels of automation, between the IIS and their case-based reportable disease surveillance system. This facilitates the population of immunization history information from the IIS to cases of vaccine-preventable disease within the system, which in turn allows for transmission of more detailed and accurate information to CDC. As this process can be resource intensive, not all jurisdictions presently have this capability.

In recent years, a standard set of immunization data elements was developed by the National Center for Immunization and Respiratory Diseases (NCIRD) at CDC for use in applicable condition-specific message mapping guides (MMGs) for the National Notifiable Diseases Surveillance System (NNDSS). This includes a repeating group to capture specific vaccination administrations relevant to the condition and a set of summary-level interpretative vaccine history questions (Table 1). Jurisdictions have different capabilities to capture and send data from their IIS within case notifications, and the intention of the two sets of data elements is to allow jurisdictions to transmit the group of data elements they have the best capability to collect and transmit. Although CDC considers many of these data elements to be of high

priority in case notifications, NCIRD has stated that the vaccination history repeating group is preferred if available since it provides detailed vaccine record information for each dose administered.

Table 1. Immunization History Data Elements Currently in Message Mapping Guides

Data Element	Description	Value Set
<i>Preferred Vaccination History Repeating Group Elements</i>		
Vaccine Type	The type of vaccine administered for the condition being reported	[Condition-specific value sets]
Vaccine Administered Date	The date that the vaccine was administered	N/A – Date
Vaccine Dose Number	The dose number in a series	N/A - Numeric
Vaccine Manufacturer	The company which manufactured the vaccine	MVX – Manufacturers of Vaccines (HL7 Standard Code Set)
Vaccine Lot Number	The lot number for the vaccine administered	N/A
Vaccine Expiration Date	The expiration date for the vaccine administered	N/A – Date
National Drug Code (NDC)	NDC from the vaccine's bar code can be used to obtain vaccine brand name and manufacturer	N/A
Vaccination Record Identifier	Vaccination record identifier	N/A
Vaccine Event Information Source	The information source for this vaccination record	Vaccine Event Information Source (NND)
<i>Interpretive Vaccine History Questions</i>		
Did the Subject Ever Receive a Vaccine Against This Disease	Did the subject ever receive a vaccine against this disease?	Yes/No/Unknown
Number of Doses Received on or After 1st Birthday*	The number of vaccine doses against this disease which the subject received on or after their first birthday	N/A - Numeric
Vaccination Doses Prior to Onset	Number of vaccine doses against this disease prior to illness onset	N/A - Numeric
Date of Last Dose Prior to Illness Onset	Date of last vaccine dose against this disease prior to illness onset	N/A – Date
Vaccinated per ACIP Recommendations	Was subject vaccinated as recommended by the Advisory Committee on Immunization Practices (ACIP)?	Yes/No/Unknown
Reason Not Vaccinated per ACIP Recommendations	Reason subject not vaccinated as recommended by ACIP	Vaccine Not Given Reason (CDC value set)
Vaccine History Comments	Comments about the subject's vaccination history	N/A

*Not included in all MMGs for vaccine-preventable conditions

Included in the interpretative vaccine history questions are two data elements pertaining to the [Advisory Committee on Immunization Practices](#) (ACIP), which is a federal advisory committee that provides guidance to the CDC regarding the effective control of vaccine-preventable diseases. The committee develops recommendations for the administration of immunizations, including ages when vaccines should be given, the number of doses, time between doses, precautions and

contraindications. The ACIP recommendations are updated each year and used by CDC to update the national pediatric and adult vaccination schedules. These vaccination schedules are [available online](#).

Core Surveillance Immunization Data Elements for Routine Case Notifications

The data elements below are those that the DSWG recommends to define as core surveillance data for case notifications to CDC. Data elements marked with an asterisk (*) did not reach the 80% consensus mark within the group but were supported by more than half of the participants. These are included here as core data elements with weak support from the DSWG. For each of these 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 2-8 below for definitions and additional information for each data element.

From the Vaccine History Repeating Group:

- Vaccine Type
- Vaccine Administered Date
- Vaccine Manufacturer
- Vaccine Event Information Source*

From the Interpretive Vaccine History Questions:

- Ever Vaccinated Against This Disease
- Vaccination Doses Prior to Illness Onset*
- Date of Last Dose Prior to Illness Onset*

It was reiterated by CDC on the DSWG calls that the intention of two sets of data elements is so that jurisdictions can choose to either fill out the Vaccine History Repeating Group or the Interpretive Vaccine History Questions, dependent on local capabilities. During future work on implementation, it may be beneficial to discuss utilizing the data element “Ever Vaccinated Against this Disease” separate from the two sets to allow clear communication for indication that no vaccines were received. More granular vaccination information can be communicated through either the Vaccine History Repeating Group or Interpretive Vaccine History Questions.

The following data elements were also discussed, but the group did not move to include them in core surveillance data for routine case notifications to CDC.

From the Vaccine History Repeating Group:

- Vaccine Dose Number
- Vaccine Lot Number
- Vaccine Expiration Date
- National Drug Code (NDC)
- Vaccination Record Identifier

From the Interpretive Vaccine History Questions:

- Vaccinated Per ACIP Recommendations
- Reasons Not Vaccinated Per ACIP Recommendations
- Vaccine History Comments

The above Vaccine History Repeating Group data elements were not included as core due to concerns about data quality or reliability of these fields. The two data elements related to ACIP recommendations from the Interpretive Vaccine History Questions were not included as core as it is difficult to apply an interpretation of the recommendations. For instance, an individual may have certain contraindications that would need to be considered as they may alter their recommendation for vaccination. Another struggle with these fields is that the ACIP recommendations can change over time, so determining these fields for adults based on the recommendations at an earlier time can be complicated. The elements Vaccination Record Identifier and Vaccine History Comments raised concerns about the potential for these fields to contain protected health information (PHI).

Several other immunization-related data elements are included in existing MMGs but are only relevant to specific conditions and would be outside the scope of core surveillance data for case notifications to CDC. Such data elements were mentioned briefly during workgroup meetings but not discussed at length in the context of core surveillance data.

Table 2. Core Surveillance Data Element for Routine CDC Case Notification – Vaccine Type

Vaccine Type	
Definition	The type of vaccine administered for the condition being reported
Standard Code for Transmission to CDC	LOINC: 30956-7 – Type [Identifier] Vaccine
Value Set or Coding System for Transmission to CDC	CVX codes – Vaccines Administered (HL7 Standard Code Set) Condition-specific value sets
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element should be part of the standard repeating block for immunization history.
Data Source Details*	
eCR CDA	ClinicalDocument/component/StructuredBody/component/section/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code
eCR FHIR	US Core Immunization Profile - Immunization.vaccinecode - Vaccine that was administered or was to be administered.
ELR	N/A
IIS HL7v2	RXA-5 Administered Code
USCDI v4	Immunizations data class: Immunizations: Vaccine product administered, planned, or reported.
USCDI+ Public Health: Case Reporting Use Case	Immunization Code: Definition: The code for the vaccine that was administered or was to be administered. Part of Immunizations data class

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

Table 3. Core Surveillance Data Element for Routine CDC Case Notification – Vaccine Administered Date

Vaccine Administered Date	
Definition	The date that the vaccine was administered
Standard Code for Transmission to CDC	LOINC: 30952-6 – Date and time of vaccination
Value Set or Coding System for Transmission to CDC	N/A – Date
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element should be part of the standard repeating block for immunization history.
Data Source Details*	
eCR CDA	ClinicalDocument/component/StructuredBody/component/section/entry/substanceAdministration/effectiveTime/value
eCR FHIR	US Core Immunization Profile - Immunization.occurrence[x] - Date vaccine administered or was to be administered.
ELR	N/A
IIS HL7v2	RXA-3 Date/Time Start of Administration
USCDI v4	N/A
USCDI+ Public Health: Case Reporting Use Case	Vaccination Administration Date: - Definition: The date the vaccination event occurred. - Part of Immunizations data class

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

Table 4. Core Surveillance Data Element for Routine CDC Case Notification – Vaccine Manufacturer

Vaccine Manufacturer	
Definition	The company which manufactured the vaccine
Standard Code for Transmission to CDC	LOINC: 30957-5 – Manufacturer name [Identifier] Vaccine
Value Set or Coding System for Transmission to CDC	MVX – Manufacturers of Vaccines (HL7 Standard Code Set)
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element should be part of the standard repeating block for immunization history. The value set contains codes of “OTH” for “Other Manufacturer” not present within the list (such as non-US companies) as well as “UNK” for Unknown Manufacturer.
Data Source Details*	
eCR CDA	ClinicalDocument/component/StructuredBody/component/section/entry/substanceAdministration/consumable/manufacturedProduct/manufacturerOrganization/name
eCR FHIR	US Core Immunization Profile - Immunization.manufacturer - Name of vaccine manufacturer
ELR	N/A
IIS HL7v2	RXA-17 Substance Manufacturer Name
USCDI v4	N/A
USCDI+ Public Health: Case Reporting Use Case	N/A

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

Table 5. Core Surveillance Data Element for Routine CDC Case Notification – Vaccine Event Information Source

Vaccine Event Information Source	
Definition	The information source for this vaccination record
Standard Code for Transmission to CDC	PHIN Questions: VAC147 – Vaccine Event Information Source
Value Set or Coding System for Transmission to CDC	Vaccine Event Information Source (NND)
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element should be part of the standard repeating block for immunization history. There was weak support for this data element’s inclusion in core surveillance data to include in routine case notifications to CDC.
Data Source Details*	
eCR CDA	N/A
eCR FHIR	US Core Immunization Profile - Immunization.primarySource - Indicates whether the data contained in the resource was captured by the individual/organization which was responsible for the administration of the vaccine rather than as ‘secondary reported’ data documented by a third party. - Boolean data type – A value of “true” means this data originated with the individual/organization which was responsible for the administration of the vaccine.
ELR	N/A
IIS HL7v2	RXA-9 Administration Notes
USCDI v4	N/A
USCDI+ Public Health: Case Reporting Use Case	N/A

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

Table 6. Core Surveillance Data Element for Routine CDC Case Notification – Ever Vaccinated Against this Disease

Ever Vaccinated Against this Disease	
Definition	Indicator that the patient has ever received a vaccine against this disease.
Standard Code for Transmission to CDC	PHIN Questions: VAC126 – Did the Subject Ever Receive a Vaccine Against This Disease
Value Set or Coding System for Transmission to CDC	Yes/No/Unknown
Abstracted/ Derived/ Created	Derived
Derived from (examples)	Vaccine Type/Immunization Code, Immunization Status
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element is part of the interpretive vaccine history questions that may be populated instead of or in addition to the standard repeating block. The response should consider receipt of any vaccination for the condition, including an incomplete series or non-US vaccinations.
Data Source Details*	
eCR CDA	ClinicalDocument/component/StructuredBody/component/section/entry/substanceAdministration/@moodCode
eCR FHIR	US Core Immunization Profile • Immunization.status • Indicates the current status of the immunization event.
ELR	N/A
IIS HL7v2	N/A
USCDI v4	N/A
USCDI+ Public Health: Case Reporting Use Case	N/A

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

Table 7. Core Surveillance Data Element for Routine CDC Case Notification – Vaccination Doses Prior to Illness Onset

Vaccination Doses Prior to Illness Onset	
Definition	Number of vaccine doses against this disease prior to illness onset
Standard Code for Transmission to CDC	LOINC: 82745-1 – Doses of vaccine given [#] –pre symptom onset
Value Set or Coding System for Transmission to CDC	N/A – Numeric
Abstracted/ Derived/ Created	Abstracted or Derived
Derived from (examples)	Number of Doses, Administration Dates, Vaccine Type/Immunization Code, Illness Onset Date
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element is part of the interpretive vaccine history questions that may be populated instead of or in addition to the standard repeating block. There was weak support for this data element’s inclusion in core surveillance data to include in routine case notifications to CDC. If a jurisdiction is not able to send the standard repeating block of vaccination information, this data element becomes more important to populate.
Data Source Details*	
eCR CDA	ClinicalDocument/component/StructuredBody/component/section/entry/substanceAdministration/repeatNumber
eCR FHIR	N/A
ELR	N/A
IIS HL7v2	N/A
USCDI v4	N/A
USCDI+ Public Health: Case Reporting Use Case	N/A

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

Table 8. Core Surveillance Data Element for Routine CDC Case Notification – Date of Last Dose Prior to Illness Onset

Date of Last Dose Prior to Illness Onset	
Definition	Date of last vaccine dose against this disease prior to illness onset
Standard Code for Transmission to CDC	PHIN Questions: VAC142 – Date of Last Dose Prior to Illness Onset
Value Set or Coding System for Transmission to CDC	N/A – Date
Abstracted/ Derived/ Created	Abstracted or Derived
Derived from (examples)	Administration Dates, Vaccine Type/Immunization Code, Illness Onset Date
Recommendations for Input Data Source(s)	Immunization Information System Case investigation eCR
Notes	This data element is part of the interpretive vaccine history questions that may be populated instead of or in addition to the standard repeating block. There was weak support for this data element’s inclusion in core surveillance data to include in routine case notifications to CDC. If a jurisdiction is not able to send the standard repeating block of vaccination information, this data element becomes more important to populate.
Data Source Details	
eCR CDA	N/A
eCR FHIR	N/A
ELR	N/A
IIS HL7v2	N/A
USCDI v4	N/A
USCDI+ Public Health: Case Reporting Use Case	N/A

Appendix A. Input Data Sources for Immunization Data

Electronic Case Reporting (eCR)

The CDA implementation guide for eCR includes an Immunizations Section (V3) template that communicates a patient's immunization status and immunization history as available within the electronic health record. The Immunizations Section (V3) in turn contains at least one substanceAdministration entry, which is in conformance with the Immunization Activity (V3) template and contains detailed information about each immunization administration. Each substanceAdministration entry can represent either an immunization that has already been received by the patient (moodCode = "EVN" for "event") or an immunization that a clinician intends for the patient to receive (moodCode = "INT" for "intent"). Each entry of substanceAdministration must also contain a statusCode that indicates the current status of the immunization event, where a value of "completed" indicates that the immunization has been completely given.

The eCR CDA implementation guide describes many additional variables that can be included in the substanceAdministration entry to convey various information about the immunization event. The following are examples pertaining to case surveillance:

- effectiveTime: Timestamp representing date/time of administration
- repeatNumber: Number of occurrences
 - Example: A repeatNumber of "3" means that the current administration is the third in a series.
- consumable/manufacturedProduct: Represents product information about the immunization substance (i.e., the vaccine)
 - manufacturedMaterial: The vaccine being administered, represented by a CVX code
 - manufacturerOrganization: Vaccine manufacturer

The US Core Immunization Profile in the eCR FHIR specification largely aligns with the Immunization Activity (V3) template in terms of how the data elements are defined and used. It requires that each immunization record that is exchanged according to the specification contains, in addition to patient identification information, the following elements:

- Status: Indicates the current status of the immunization event, where possible values are "Completed", "Entered in Error", and "Not Done".
- Vaccine code: Identifies the kind of vaccine administered, typically using CVX codes, but NDC codes should also be supported as a translation.
- Vaccine administration date: Represents the date/time of the administration

One element that is defined in the eCR FHIR specification but not in the CDA implementation guide is the primarySource data element, which is a Boolean element that indicates whether the immunization history was captured by the individual/organization that administered the vaccine (value = "true"). A value of "false" indicates that the data is a secondary report of an administration that was performed by a third party.

Electronic Laboratory Reporting (ELR)

ELR does not contain defined data elements related to immunization history.

USCDI and USCDI+

USCDI has contained an Immunizations data class since version 1. As of version 4, this data class still includes only one data element, Immunizations, defined as “vaccine product administered, planned, or reported”. Two different vocabulary standards must be supported: CVX – Vaccines Administered and the Vaccine National Drug Code (NDC) Directory. Several other immunization-related data elements, including lot number, vaccination administration date, and reason immunization not performed, are under consideration (Level 2) for a future version of UCSDI.

The Public Health domain of USCDI+ has adopted four data elements (see Table 9).

Table 9. Immunization History-Related Data Elements Included in USCDI+ Public Health Domain

Data Element	Definition
Immunization Code	The code for the vaccine that was administered or was to be administered.
Immunization Status	Indicates the current status (i.e., completed, entered in error, not done) of the immunization event.
Vaccination Administration Date	The date the vaccination event occurred.
Patient Assertion of Vaccine Credentials	Whether or not the patient asserts they have verifiable vaccine credentials.