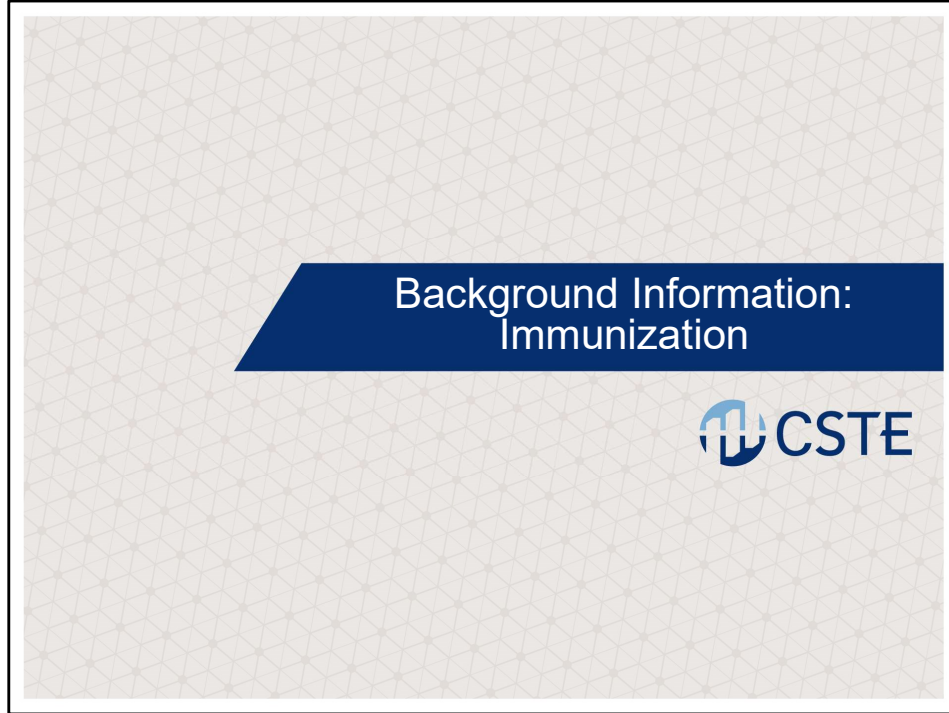




In this presentation we will take a closer look at how various standards or workgroups have defined data elements related to Immunization.

Potential data elements related to Immunization



- Vaccine Type
- Vaccine Administered Date
- Vaccine Dose Number
- Vaccine Manufacturer
- Vaccine Lot Number
- Vaccine Expiration Date
- National Drug Code (NDC)
- Vaccination Record Identifier
- Vaccine Event Information Source
- Did the subject ever receive a vaccine against this disease
- Vaccinated Per ACIP Recommendations
- Reasons Not Vaccinated Per ACIP Recommendations
- Vaccination Doses Prior to Onset
- Date of Last Dose Prior to Illness Onset
- Vaccine History Comments
- Number of Doses received Before 1st Birthday
- Source of Mother's Vaccine Information
- Were Any of the Children Living in the Household Immunized With Rubella-Containing Vaccine

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Typical immunization-related data elements include those on the left, which capture information specific to an individual immunization event. These often include concepts like the type of vaccine administered, date it was administered and dose number, and vaccine product information such as manufacturer, lot number, and expiration date.

There are also more public health or epidemiologically-oriented immunization data elements such as whether or not vaccination occurred before illness onset, whether vaccination occurred before a particular birthday, or how the vaccine series received by a person aligns with the recommendations, and source of vaccine information. The data elements on this page may seem familiar as they come from the message mapping guides (MMGs) that currently describe how information should be transmitted for case based surveillance from jurisdictions to CDC's National Notifiable Diseases Surveillance System (NNDSS).

CDC endorsed data elements

- | | |
|-----------------------|----------------------------|
| ○ Patient Demographic | ○ Vaccination Event |
| ▪ Name | ▪ Manufacturer name |
| ▪ Address | ▪ Route of administration |
| ▪ Identifiers | ▪ Vaccination event ID |
| | ▪ Product |
| | ▪ Site of administration |
| | ▪ Ordering provider |
| | ▪ Sending organization |
| | ▪ Responsible organization |

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Immunization Information Systems (IIS) are the primary source of immunization records for jurisdictional residents. IIS are centralized population-based repositories of immunization related information that are generally run by the health department.

The CDC maintains an endorsed set of data elements that are needed by an IIS to record patient demographics and vaccination events to meet the IIS Functional Standards. Any IIS should store these data elements.

The data elements are separated into two categories, patient demographics and vaccination event. Patient demographics contains data elements such as patients name, address, and identifiers. Vaccination Event contains data elements related to the vaccination, such as manufacturer, product, and route of administration. Vaccination Event also contains data elements related to the provider, such as ordering provider, and the facility, such as sending and responsible organizations.

Interoperability with Immunization Information Systems



IG: HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, 2018 Update

○ Data elements include:

- Administered Code (Value set: CVX)*
- Administered Code (Value set: NDC)*
- Date/Time Start of Administration
- Substance Manufacturer Name (MVX)
- Substance Lot Number
- Substance Expiration Date
- Administration Notes
- Substance/Treatment Refusal Reason
- Administered Amount
- Administering Provider
- Administration Site
- Route

○ Future directions: Bulk FHIR

* Required in all four versions of U.S. Core Data for Interoperability (USCDI)

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IIS's support requesting, sending, and receiving immunization histories for individuals. Information in an IIS is currently exchanged via standards and specifications in the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging. An area of active development for future transmission capability is the **bulk FHIR query**, which would allow a single request containing a list of person identifiers and demographics to be matched to records within the IIS to provide vaccination information for those individuals.

A jurisdiction's IIS can be a valuable source of information for the data elements requested within the NNDSS MMGs. Developing the ability for your surveillance system to receive information about vaccination history from your IIS may be something your jurisdiction can consider as a part of Data Modernization planning. Listed are some of the data elements from the implementation guide for immunization messaging that align closely with the vaccination related data elements present in the NNDSS MMGs.

Among these vaccination data elements listed on this slide, the only one explicitly required in the U.S. Core Data for Interoperability (USCDI) is the Administered Code, which is labeled “Immunizations” in USCDI. It captures the vaccine product administered, planned, or reported and is represented by CVX codes and National Drug Codes (NDC).

Vaccination Administration Date (Level 2)

The date the vaccination event occurred.

Vaccination Event Record Type (Level 2)

Indicates whether the vaccination event is based on a historical record or was administered at the facility submitting the data.

Immunization Status (Level 2)

Indicates the current status of the immunization event.

Reason Immunization Not Performed (Level 2)

Indicates the reason the immunization event was not performed.

Immunization Code (Level 2)

The code for the vaccine that was administered or was to be administered.

Lot Number (Level 2)

The lot number for immunizations.

In addition to the Immunizations data element discussed on the previous slide, 6 other data elements within the immunization class have been proposed for inclusion in USCDI and are listed at Maturity Level 2. Level 2 data elements are mature in their documentation and use and may be considered for inclusion within future versions of USCDI.

In addition, Patient Assertion of vaccine credentials, a patient report of what vaccinations they've had, is at maturity level 0. This means that additional work is needed before it will be considered for inclusion in a future version of USCDI.

Electronic Case Reporting



- HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2
 - Immunization-related data elements include:
 - ☐ Immunization Status
 - Status (given/not given/other) (LOINC 11369-6)
 - Date
 - Vaccine Code (CVX Vaccines Administered Vaccine Set)
 - ID
 - Dose Quantity
 - Performer
 - ☐ Vaccine Credential Patient Assertion

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Electronic case reporting, or eCR, uses HL7 Clinical Document Architecture (CDA) as the standard for reporting of case data from health care to public health. The **Electronic Initial Case Report** (eICR) implementation guide calls out two major immunization-related elements:

1. The first, **Immunization Status**, captures the patient's current immunization status and pertinent immunization history, with data elements such as status, date, vaccine code, and ID.
2. The second, **Vaccine Credential Patient Assertion**, transmits information when the patient indicates that they have received a vaccination.

Note that the C-CDA template contains additional data elements related to Immunization that are not specifically called out as eICR data elements. If this information is present in the EHR, they are automatically included in the eICR.

HL7® Fast Healthcare Interoperability Resources (FHIR)

- **HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR)**
 - **US Realm 2.1.0 - STU 2 US**
 - Specifies resources and transactions for eCR for FHIR standard
 - US Core Immunization Resource Profile:
 - status
 - vaccineCode (CVX)
 - patient
 - occurrence
 - doseNumber
 - manufacturer
 - lotNumber
 - primarySource
 - statusReason
 - doseQuantity
 - performer
 - site
 - route
 - expirationDate
 - identifier

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FHIR uses the US Core Immunization Resource Profile to capture information on vaccinations administered. It defines a structure to transmit the CVX code for the vaccine, the date administered, and where the vaccine was administered, and can capture dose number, manufacturer, identifier, and lot number. The FHIR observation resource can also capture patient-reported vaccinations.

Case Notifications to CDC Message Mapping Guides (MMGs)



Vaccine History Repeating Group (VHRG)

- FDD S. Typhi and S. Paratyphi, RIBD H Flu, RIBD N meningitidis, ABCs Invasive Pneumococcal Disease, ABCs N meningitidis, ABCs H influenzae, COVID-19, Pertussis, Varicella, Mumps, Rubella, Congenital Rubella Syndrome, and Measles

Data Element (DE) Name	DE Identifier Sent in HL7 Message	Data Element Description	Data Type	Value Set Name (VADS Hyperlink)
START: Preferred Vaccination History Repeating Group Section				
Vaccine Type	30956-7	The type of vaccine administered for the condition being reported	Coded	Vaccine Type (NND)
Vaccine Administered Date	30952-6	The date that the vaccine was administered	Date	N/A
Vaccine Dose Number	30973-2	The dose number in a series	Numeric	N/A
Vaccine Manufacturer	30957-5	The company which manufactured the vaccine	Coded	Manufacturers of vaccines (MVX)
Vaccine Lot Number	30959-1	The lot number for the vaccine administered	Text	N/A
Vaccine Expiration Date	VAC109	The expiration date for the vaccine administered	Date	N/A
National Drug Code (NDC)	VAC153	NDC from the vaccine's bar code can be used to obtain vaccine brand name and manufacturer	Text	N/A
Vaccination Record Identifier	VAC102	Vaccination record identifier	Text	N/A
Vaccine Event Information Source	VAC147	The information source for this vaccination record	Coded	Vaccine Event Information Source (NND)
END: Preferred Vaccination History Repeating Group Section				

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Multiple conditions include vaccination information in the message mapping guide for case notification.

The information is used in case based surveillance for multiple purposes:

- It helps public health understand the impact of vaccination on disease severity and outcome.
- It is used to understand whether occurrence of a vaccine-preventable disease is related to "vaccine failure" or to "failure to vaccinate" .
- And the information is used in outbreak response, epidemiologic analysis, annual summaries, and other reports.

Across the MMGs, the vaccination data is structured in two ways – the vaccine history repeating group and the interpretive vaccine history questions.

This slide shows the conditions that currently use the Vaccine History repeating group and the information included: vaccine type, administration date, dose number, manufacturer, lot number, expiration date, national drug code, record identifier, and event information source. Because it is a repeating group, one instance is sent for each vaccination.

Case Notifications to CDC Message Mapping Guides (MMGs)



Interpretive Vaccine History Questions:

- Varicella, COVID-19, Rubella, Pertussis, RIBD H Flu , RIBD N meningitidis , ABCs Invasive Pneumococcal Disease, ABCs N meningitidis , ABCs H influenzae, Congenital Rubella Syndrome, Measles, Hepatitis v2 (draft)

Data Element (DE) Name	DE Identifier Sent in HL7 Message	Data Element Description	Data Type	Value Set Name (VADS Hyperlink)
START: Interpretive Vaccine History Questions				
Did the Subject Ever Receive a Vaccine Against This Disease	VAC126	Did the subject ever receive a vaccine against this disease?	Coded	Yes No Unknown (YNU)
Vaccination Doses Prior to Onset	82745-1	Number of vaccine doses against this disease prior to illness onset	Numeric	N/A
Date of Last Dose Prior to Illness Onset	VAC142	Date of last vaccine dose against this disease prior to illness onset	Date	N/A
Vaccinated per ACIP Recommendations	VAC148	Was subject vaccinated as recommended by the Advisory Committee on Immunization Practices (ACIP)?	Coded	Yes No Unknown (YNU)
Reason Not Vaccinated Per ACIP Recommendations	VAC149	Reason subject not vaccinated as recommended by ACIP	Coded	Vaccine Not Given Reason
Vaccine History Comments	VAC133	Comments about the subject's vaccination history	LongText	N/A
END: Interpretive Vaccine History Questions				

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- In addition to the vaccine history repeating group, many guides include interpretive vaccine history questions, and some use these interpretive questions in place of the vaccination repeating group. The interpretive questions provide summary information that is useful to public health and often includes calculations or additional information for concepts such as vaccination doses prior to onset or vaccinated per ACIP recommendations.
- The Advisory Committee on Immunization Practices (or ACIP) develops recommendations for U.S. immunizations, including ages when vaccines should be given, the number of doses, time between doses, and precautions and contraindications. The ACIP recommendations are updated each year and are available online.
- Because these are summary questions, they are not included in a repeating block.

Jurisdiction examples



- New York
 - Get Dose Date, Vaccine Type, Manufacturer from IIS
- Arizona
 - Standardization of vaccine sections across conditions:
 - Date, Manufacturer, Vaccine Type and Lot Number
 - Interpretative vaccine section for vaccine-preventable diseases
 - Vaccinated? / Has the patient received any vaccines against [X]? (Y/N/U)
 - Number of doses prior to illness onset
 - Date of last dose prior to illness onset
 - Reason not fully vaccinated?

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It is helpful to look at what a few states have done to standardize immunization history information in their case surveillance system.

New York State gets dose date, manufacturer, and vaccine type from their IIS for an automated match.

Arizona's efforts to standardize the vaccine section across conditions focused on four fields for each dose administered-- Date, Manufacturer, Vaccine Type and Lot Number – the three New York State uses, plus lot number. Currently the surveillance system does not pull data directly from the immunization registry, but they have coding that runs outside the system to match case and IIS data so that they can batch upload the results into these fields. For most conditions, the same set of fields is used to store the vaccine info regardless of source (such as IIS, case interview, medical record, etc.). For COVID the information was set up differently, with a section showing data verified in the IIS and a separate section for investigation-collected data. The benefit of having these split out is that it provides a little more insight into potential data certainty.

Many of Arizona's vaccine preventable diseases also have an interpretive vaccine section that may include questions such as:

- Vaccinated? / Has the patient received any vaccines against [X]? (Y/N/U)

- Number of doses prior to illness onset
- Date of last dose prior to illness onset
- Reason not fully vaccinated?

These get at the epidemiologically-relevant information and are included in several MMGs, but may require complicated logic and/or human interpretation of the vaccine and case data. Challenges are much higher for COVID than for other vaccine preventable diseases, due to the volume of cases, larger data quality issues with the vaccine data (at least in initial phases) and proximity of onset and administration dates for many cases. Considerations included whether to bring in ALL doses or only VALID doses (appropriately spaced, age-appropriate, etc.), or only doses prior to onset of illness.

Although they use the same data elements consistently across conditions, Arizona does allow some variation in the data element name by condition, as shown on the next few slides, and drop-down options reflect the relevant values for each condition.

Jurisdiction examples



- Arizona (COVID-19)

ASIS COVID Vaccine Information (Use ONLY for info verified in ASIS)	
Date of 1st vaccination ?	
Vaccine Manufacturer ?	
Vaccine Type (CVX code) ?	
Lot #	
Date of 2nd vaccination ?	
Vaccine Manufacturer ?	
Vaccine Type (CVX code) ?	
Lot #	
Date of 3rd vaccination	
Vaccine Manufacturer	
Vaccine Type (CVX code)	
Lot #	
Date of 4th vaccination	
Vaccine Manufacturer	
Vaccine Type (CVX code)	
Lot #	

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If you look at the information for the first vaccination, you can see that for COVID-19, the screen captures the date of first vaccination, vaccine manufacturer, vaccine type, and lot number

Jurisdiction examples



- Arizona (Pertusis)

Vaccine History	
Vaccinated? (Received any doses of pertussis-containing vaccines)	Yes ▼
Vaccination 1	
Vaccination Date	
Vaccine Type (*Unlikely to be available if patient born before 1989)	▼
Manufacturer	▼
Lot Number	
Vaccination 2	
Vaccination Date	
Vaccine Type (*Unlikely to be available if patient born before 1989)	▼
Manufacturer	▼
Lot Number	

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For pertussis, you can again see the four fields of vaccine date, vaccine type, manufacturer, and lot number, but there is also a general question asking if the patient received any doses of pertussis-containing vaccine.

Jurisdiction examples



- Wisconsin
 - Data elements from IIS available in surveillance system:
 - Vaccination date
 - Vaccine type
 - Vaccine manufacturer
 - Lot number
 - Vaccine administration route
 - Vaccine refused
 - Vaccine refused date
 - Date Immunization Information System was last queried

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The data elements pulled from the Wisconsin IIS into the state's surveillance system are listed on the slide and include:

- Vaccination date
- Vaccine type
- Vaccine manufacturer
- Lot number
- Vaccine administration route
- Vaccine refused
- Vaccine refused date
- Date Immunization Information System was last queried

Additional data elements available in the IIS are rarely pulled into the Surveillance System. Within the surveillance system is an easy-to-use button to query the Wisconsin Immunization Registry. Users are accustomed to clicking it to obtain clients' immunization histories. The data matching algorithm allows the user to select and verify the patient's record prior to populating the surveillance system record. Challenges noted by Wisconsin include identifying whether the immunization history in the surveillance system is populated from the IIS or manually, the need for data validation queries to verify the accuracy of matching, and duplicate vaccination records in the surveillance system when users click the query button multiple times.

Jurisdiction examples



- Wisconsin

COVID19 - Vaccination History

ID-002
Vaccination date: 01/19/2022
Vaccine manufacturer: Pfizer
COVID19 vaccine type: Pfizer COVID-19 Vaccine
Lot number: 987654321
Vaccine Refused:
Vaccine refused date:
Delete
Add

ID-001
Vaccination date: 11/04/2021
Vaccine manufacturer: Moderna
COVID19 vaccine type: Moderna COVID-19 Vaccine
Lot number: 123456789
Vaccine Refused:
Vaccine refused date:
Delete

COVID19 Vaccination Summary

ID	Vaccination date	COVID19 vaccine type	Vaccine manufacturer	Lot number	Vaccine Refused	Vaccine refused date
002	01/19/2022	Pfizer COVID-19 Vaccine	Pfizer	987654321	..	...
001	11/04/2021	Moderna COVID-19 Vaccine	Moderna	123456789	..	...

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This example from Wisconsin shows the vaccination history and summary from a test record for a COVID-associated hospitalization. The same form is used with influenza- and RSV-associated hospitalizations and pediatric mortalities. DEs captured here include vaccination date, vaccine type, lot number, manufacturer, vaccine refused, and vaccine refused date.

Topics For Consideration



- Should either or both the Vaccine History Repeating Group and Interpretive Vaccine History Questions be considered core data elements?
 - CDC programs have received differing feedback where jurisdictions prefer one template over another depending on their internal processes/resources.
 - Reminder, defining something as a core data element means it will be standardized across conditions, but does NOT require the data elements to be populated for all cases or conditions.
- Are only some of the data elements within these groups core?
 - Previous feedback has indicated the ACIP recommendation fields are difficult to populate for some.
 - Are there any fields within these groups that are difficult to populate? Would modifications to the data elements help with this?

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Here are some questions to consider prior to the Immunizations data class call on December 15th.

Should either of the MMG templates discussed, the Vaccine History Repeating Group or the Interpretive Vaccine History Questions, be considered core data elements? Would all of the data elements within a group be considered core data elements, or only a subset?

Does your jurisdiction find one of these templates easier to populate over the other? Are there modifications that could be made to any of the data elements within these groups to support jurisdictional ability to populate them?