Meeting: CSTE Data Standardization – Immunization Data History -Data Element-Specific Team Meeting
Date: December 15, 2023
Attendees: 53

CSTE (2)	PHAs (33)	CDC (10)
Becky Lampkins Gillian Haney **JMC (7)** Erin Kough Grace Mallard Laura Lane Natalie Raketich Sam Spoto Sara Sanford Susan Downer **Unknown Affiliation (1)** Elise Balzer	<u>DSWG Co-Chairs</u> Laura Erhart | AZ Molly Crockett | MA <u>DEST Members</u> Karene Thomas-Watts | CO Andria Apostolou | IHS Jim Sainsbury | IN Lunden Espinosa | IN Jason Geslois | KS Lamyaa Shaban | MA Ed Hartwick | MI Mario Beltran | MI Aaron Bieringer | MN Hanna Chakoian | MN Jesse Ellis | MS Alison Keyser | NE Stella Tsai | NJ Molly Yang | NJ Stephanie Moberg | NM Isaiah Francis | NM Emma Stanislawski | NM Amanda van Rest | NV | CDC Foundation Elizabeth Kessler | NV Lea Moser | NV	Abhilasha Saxena | GDIT Angie Agunloye | GDIT Doris McGinness | GDIT Luis Hernandez | GDIT Myrna del Mar González | GDIT Allison Miller Danielle Tack Peter Boersma Noreen Kloc Sandy Roush

	Theron Huntamer | NV EJ Klingler | NYC Beth Isaac | NYC Maribeth Hoyle | OR Sam Hawkins | OR Greg Fowler | SC Annie Bergman | SD Chris Dumas | SD Amy Bogucki | TN Li Jiao | TX Anna Kocharian | WI	

**SOME INDIVIDUALS DIALED IN; THE NAMES ARE UNKNOWN, AND THEY ARE LEFT OFF OF THE ATTENDANCE*

HIGH-LEVEL MEETING NOTES (*REFER TO MEETING SLIDES FOR MORE DETAIL AS NEEDED*):

Meeting Ground Rules and Updates

- We welcome everyone's opinions and active participation from jurisdictions, CDC programs, CSTE membership, etc.
- As we work through data elements/classes, we strive for 80/20 consensus.

Data Element-Specific Teams (DEST)

- DEST member expectations – members are not expected to write documents, lead meetings, or prepare slides. The goal is to keep members engaged in conversations around content during and between meetings.
- There is an expectation of active participation in polling, document review, discussion, and other input during and between meetings.
- **[Action Requested]** Please sign up for upcoming data elements on the DEST Sign-Up here.
- After SOGI or Industry and Occupation wrap up, the next data elements will be
    - Exposure/Risk/Underlying Conditions
    - Immunization History

Core Data: In Scope for DSWG

- Focus on core data for surveillance for transmission to CDC within selected data classes.
- We will work to identify standard definitions and value sets within that definition of core data.

Core Data FAQ

- Identification as core does not mean it is required to fill in or send an answer for every core data for every case; it is okay to leave it blank or unknown.

- Data, elements, and data classes should be considered core if they are relevant for many conditions.
- A good way of thinking of this is if we were to create a GenV3 MMG, would it make sense to include that data element here as core?

IMMUNIZATION HISTORY Background

Background Information: Immunization

- This presentation will cover how various standards or workgroups have defined data elements related to Immunization. Hopefully most of you had the opportunity to review the background information sent out ahead of this call. For those who haven't we're going to review a few background slides briefly to ensure we're all on the same page, but for more detailed information please review the pre-recorded material.

Potential data elements related to Immunization

- This slide has a list of potential data elements related to immunizations. Typical 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).

Immunization Information Systems

- 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 patient's 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.

Case Notifications to CDC: Message Mapping Guides (MMGs)

- 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 the occurrence of a vaccine-preventable disease is related to "vaccine failure“ or "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) cont.

- 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.

DEST for Discussion

Discussion: Immunization

- Now that we've covered some background we're going to move on to the discussion portion of our call today.

Discussion

- First let's go over the overall impressions from the group on these two sets of data elements. The vaccine history repeating group has some data elements that may be able to be filled out via a case interview, but the information is specific enough for each vaccination that some of it may be difficult to ascertain during an interview and more easily accessible for jurisdictions that have a connection between their IIS and case-based surveillance system. For the interpretive vaccine history, these questions may be more easily addressed during a case interview and summarize information that might also be present within the repeating group.
- We will delve into the specific data elements more on the next few slides, but does anyone have any strong feelings about the idea of these templates as a group? Is it important that both of these templates become core data, or is one more important than the other? Should any immunizations-related data elements be core? We will talk about the data elements individually on the next slides, but this first piece of the discussion is more about what is useful as a core data element for immunizations, if it's necessary to make an entire set of questions core, and if one of these groups seems more appropriate to be designated as core over the other.
- Sandy Roush: Addressed background regarding the repeating group and non-repeating group. These data elements are meant to accommodate jurisdictions in either side of the practice. Some jurisdictions only send repeating groups and some jurisdictions only send the non-repeating group. At the time this was decided it was intentional.

- The repeating groups is lifted and shifted from the HL7 components in IIS so that jurisdictions would not have to map. So the code sets the valid values and element, it's a lift and shift to allow for electronic consumption of IIS data, if that's the practice in the jurisdiction. Some vaccine date, type, and manufacturer are what we call priority – their sort of tier one. So that might be something for folks to review when you're considering later. Each individual data element, that perhaps some of the vaccine history should be identified as core and maybe other components not so much.
- Sam Spoto: Someone asked in the chat "just wondering if the situation Sandy referred to is still true, or if more states would be able to use IIS data now. Sandy, do you have any idea if you've seen a shift in the number of states able to send the repeating group or not?
- Sandy Roush: It is still very diverse, but not all jurisdictions have the ability. Not all IIS are "opt out" right? So sometimes the IIS is not the most robust source of data for vaccine history for certain VPDs. The jurisdiction practice for gathering that data is diverse. Having both the repeating group and the interpretive group has been a very good decision and is still necessary given the diversity of practice in the jurisdictions. Importantly both don't have to happen. I would recommend allowing the flexibility for those partners to decide which way they want to ingest the data has been a great decision.
- Noreen Kloc (in chat): the division of Viral hepatitis received the same feedback during our pilot in the summer and fall of 2023. So it sounds like that's more evidence of recent feedback indicating it's still the same thing.
- Sandy Roush: We asked jurisdictions " is this bothering you, is there anything we can do better?" And none of them said that they would prefer otherwise because again, I will repeat that it's optional to do one or the other, they can send both if they want.
- Sam Spoto: As we talk about what is core keeping in mind that naming something is core does not necessarily mean it is required to be sent by all jurisdictions. We're just ensuring it's transmitted the same way across all cases where immunizations are relevant.

Vaccine Repeating Group

- The first group of data elements in yellow - These relate to when a patient received a certain dose of vaccine and seem like the most basic subset of questions within this group that directly convey epidemiologically relevant information. The second group of four elements is more specific to the product that was actually administered, and may help identify potential failure issues seen related to a specific manufacturer or lot. The final two data elements indicate the record identifier for that vaccination event and the source for where the information on this vaccination was obtained.

Vaccine Repeating Group cont.

- Starting with the first group of three, does anyone have any thoughts on whether these three data elements are important as core or not? At the jurisdictional level are there any complications or issues with collecting any of these?
- Laura Erhart: Vaccine dose number isn't always collected but can be implied from the order of the dates.
- Aaron Bieringer: you can't always determine the dose number and series based on the dates b/c some doses are truly not valid and they wouldn't count as one of the numbers in the series, so there is a dose validity value that we can save or calculate and send along but you can't always just say "there are these five doses and they're in this order so this is dose 1, 2, 3, 4, 5.
- Sam Spoto: so, it sounds like dose number is a little complicated in its collection and might fall a little bit along the same lines as those ACIP guidelines we'll talk about in the next group. But CVX and Administered Date seem pretty straightforward.

Vaccine Repeating Group cont.

- Moving on to the second group of specific vaccine product information, does anyone have any thoughts on whether these four data elements are important as core or not? At the jurisdictional level are there any complications or issues with collecting any of these?
- Allison NE: These elements are important. One challenge in NE is that reporting to your immunization registry is not mandated so for any vaccine that is not in our immunization registry, those elements would be difficult to get. We are working on connecting the organization registry with our disease surveillance system so it will become easier for us to report those.
- Molly Crockett: The majority of cases the majority of the time, manufacturer would fit into that category because there can be major differences in how that's stored or what you can infer about formulation, etc. To me, lot number, expiration date, and drug code are nice to have if you're looking into a failure or if you have it from an IIS but I would not think of them as core elements that are necessary on most cases most of the time.
- Sam Spoto: Theres some talk in the chat. I don't believe we're currently reporting the NDC. Someone else says the New Jersey IIS did collect those data elements. But NDC data collected rate is pretty low. Facilities are able to send, but whether or not they do is up to them and is not required. So there may be difference in being able to fill in something like NDC
- Sandy Roush: To avoid deluding the importance of what is core/super important, the lot number, expiration date, and NDC code are tier 2/priority 2. We don't chase these down.

Vaccine Repeating Group cont.

- Finally, on to the third group of information that is less related to the vaccine and more related to how the information was obtained. Does anyone have any thoughts on whether either of these data elements are important as core or not? At the jurisdictional level are there any complications or issues with collecting any of these? Before we start to talk about it I'm going to go to the next slide to show what the value set for the last data element is, but then we will come back to this slide.
- Sandy Roush: The vaccine event information source is really important because the security of the confidence we have in vaccine history is influenced by parent's memory or written record, or IIS. Helps us tease out things that are not making sense with regard to test results and vaccine history and exposures, things like that. There are certain rules for vaccine dose being counted or not counted as an actual dose. It needs a written record. The Vaccine event information source is in NCIRD's surveillance realm right there with the vaccine date, type, and manufacturer.

Vaccine Event Information Source Value Set

- These are the concepts within the value set for the information source for the vaccination record.
- Aaron Bieringer: I totally agree with everything Sandy just said, but I want to put some context around it when we talk about historical in the sort of immunization information system world that does not mean something that happened previously/chronologically, it means something that did not happen here at this facility. So when we're talking about historical, it's really "this is a record that somebody else created and gave to me." So it has much less confidence than the 00, we call that administered most of the time, which is like a record that "I created. I administered this dose. I know that this is the right lot number and the right date and the right product." Whereas all of the other ones, you start to have less and less confidence in the data b/c they are not your data. So I agree, this is a really important concept to have, so that you can understand how much weight do I really want to give this entry.

- Anna Kocharian: A proxy data element that we collect, or similar to the source of the record, we added a field that once the button is clicked in our surveillance system that calls an API connection into our IIS and pulls in the information, a system date is populated that says something like last time the button was clicked to retrieve that information. So that field being completed with a date field allows us to know that it was accessed from the IIS.

Polling Process

- Now we're going to poll on the data elements within the vaccine history repeating group. The goal is to reach 80% or more agreement on a data element as core or not core, while identifying and discussing any major points of dissention.

Core Data FAQ

- A reminder as we vote for a core data element, data elements should be considered core if they are relevant across conditions. Just because we define a data element as core does not mean that it is required to be filled out for every case. Particularly in this case, voting for these immunizations data elements are core does NOT mean that data would be transmitted for conditions where there are no existing immunizations. For this data class it's more important to think about "which of these data elements should be sent and defined in a standard way for all conditions where immunizations are applicable?"

VHRG Poll 1

- Poll Question: Select all of the data elements that should be considered core data elements.
- Options: Vaccine Type (CVX), Vaccine Administered Date, Vaccine Dose Number, None of these
- Sam Spoto: We have reached 80% consensus for CVX and Administered Date. Dose Number only reached 58% consensus for a core data element.

VHRG Poll 2

- Poll Question: Select all of the data elements that should be considered core data elements.
- Options: Vaccine Manufacturer (MVX), Vaccine Lot Number, Vaccine Expiration Date, National Drug Code, None of these
- Sam Spoto: 80% consensus reached for vaccine manufacturer and in order decreasingly lower for the other data elements.
- Chris Dumas: Couldn’t the national drug code be derived from the manufacturer or whatever we’re getting there? Is it a necessary element to collect?
- Aaron Bieringer: I’ll give my opinion on that. No, you can have several NDC that all map to the same CVX or MVX pair. So, if you want NDC to do NDC things, you should explicitly be asking for it and getting it. You should not be assuming it from other data.
- Danielle Tack: Lot number and dose number, are these not being rated as important b/c of availability of the data vs. importance of the data?
- Sandy Roush: The program is happy to receive this data if it’s available. It’s also fine with not receiving the data if it’s not available. Say for lot number, if we get somewhere we think there’s a lot number situation that would have been a call and discussion in the investigation.

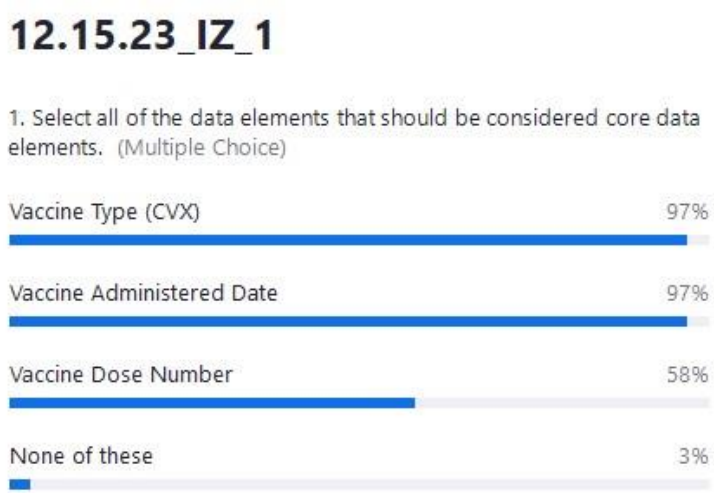
VHRG Poll 3

- Poll Question: Select all of the data elements that should be considered core data elements.
- Options: Vaccination Record Identifier, Vaccine Event Information Source, None of these

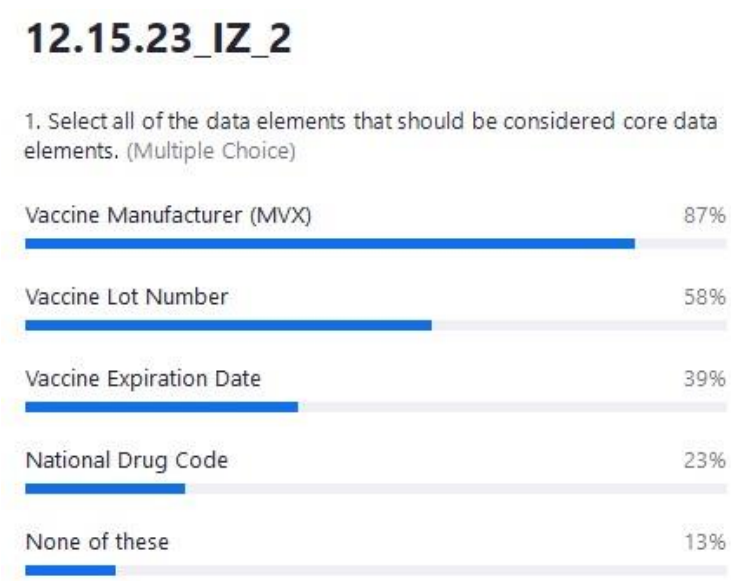
- Gillian Haney: Would vaccine record identifier be considered an identifiable variable under HIPAA, correct? I'm just wondering if this should be discussed as part of an identifiable element as part of data that are sent to CDC.
- Sandy Roush: I believe that the IIS have used or are moving to privacy-preserving record linkage kind of identifying processes. I don't know the answer right now to your question.
- Aaron Bieringer: PPRL is something that CDC is pushing for us to use. It is not widely adopted, and I would not say that it is being adopted very quickly. But there is movement, it's happening. I know our jurisdiction, we have like a legal block, so I don't think you should assume that all of these will be nonidentifiable through PPRL. I don't know that that makes them identifiable on their own. For us in Minnesota, this would just be like a distinct number like our internal identifier for this vaccination, but that information by itself wouldn't get you any client information. I guess if you were like, we're really in our system, you could use that to find the person, but I don't think that I would consider it identifiable
- Gillian Haney: Would you consider it akin to a medical record number? That is a listed HIPAA identifiable element. I would think it is, I just think that should be considered.
- Aaron Bieringer: I don't think I can answer it. Something that we should think about.
- Sam Spoto: Vaccine event information source reached 67%, lower on the vaccine record identifier. We are not going to have time to go through the interpretive group polls but I will send out a between-meeting poll to all of the people in this group to discuss some of the elements from today that were higher than 50% but did not quite reach core status.

Polling Results

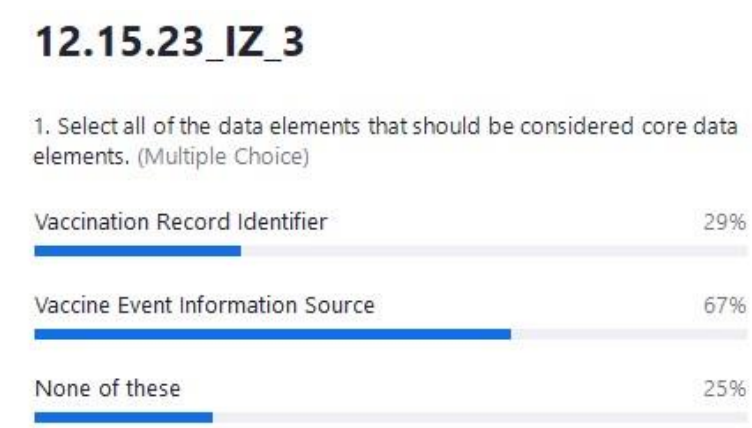
Poll 1 (n = 31)



Poll 2 (n = 31)



Poll 3 (n=24)



Next Steps

- We will hold another Immunization History meeting on January 19, 2024.
- Complete the Immunization DEST Poll by January 5, 2024. This poll will gather thoughts and opinions to guide the flow of conversation going into the second meeting on January 19th.
- The next full DSWG meeting is scheduled for February 9, 2024.
- Sign up for upcoming data element-specific teams in the interest form here
- Additional input is always welcomed between meetings from DSWG members on the form located here.