Meeting: CSTE Data Standardization – Signs, Symptoms, Clinical Manifestations -Data Element-Specific Team Meeting
Date: April 19, 2024
Attendees: 67

CSTE (4)	PHAs (34)	CDC (24)
Annie Fine Devra Barter Gillian Haney Rebecca Ruvane **JMC (4)** Erin Kough Grace Mallard Sam Spoto Sara Sanford **Unknown Affiliation (0)**	<u>DSWG Co-Chairs</u> Molly Crokett | MA <u>DEST Members</u> Claire Stump | AK Amy Lai |AZ Karene Thomas-Watts | CO Shawna Stuck | GA Andria Apostolou | IHS Jim Sainsbury | IN Lunden Espinosa | IN Dimple Patel | KY Jacob Chavez | LA Sue Soliva | MA Mario Beltran | MD Aaron Bieringer | MN Elizabeth Shiffman | MN Hanna Chakoian | MN Jesse Ellis | MS Kristen Merrell | MT Stella Tsai | NJ Isaiah Francis | NM Stephanie Moberg | NM Lea Moser | NV Theron Huntamer | NV	Luis Hernandez | GDIT Myrna del Mar González | GDIT Shawn Arshad | GDIT Angie Agunloye Fidel Desir Hailey Vest Hang Nguyen John Gerstle Katherine DeBord Lauren Korhonen Lesliann Helmus Marion Rice Mary Alao Melissa Pagaoa Nekole Locke Nicole Lindsey Nicolette Bestul Noreen Kloc Peter Boersma Rachelle Oseni Sandra Roush Sara Johnston Shelby Lyons Yuritzy Glez Pena **ONC (1)** Katie Tully

	Beth Isaac | NYC EJ Klingler | NYC Rob Laing | OR Greg Fowler | SC Sunanda Sarkar | SC Karen Arrowood | TX Steve Eichner | TX Alina Paegle | UT Brianna Rossi | VA Cher Levenson | WA Anna Kocharian | WI Suzanne Gibbons-Burgener | 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*):

DEST Opportunities for Participation

- DEST sign-ups are ongoing.
- **[Action Requested]** Please sign up for upcoming data elements on the DEST Sign-Up here.
- Upcoming data elements
    - Disability
    - Identifiers (Case/Event Related/Laboratory)
    - Medication/Treatment
    - Laboratory
    - Race/Ethnicity/Tribal Affiliation
    - Social Determinants of Health
    - Reporting Source
- DEST member expectations—members are not expected to write documents, lead meetings, or prepare slides. The goal is to keep members engaged in conversations about content during and between meetings.
- Active participation in polling, document review, discussion, and other input during and between meetings is expected.

DSWG Reminders

- SOGI recommendations draft is out to the wider DSWG for comment now through April 22
- The next general DSWG Call is on April 26 at 1 pm ET

Meeting Ground Rules

- 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.

In-Scope vs Out-of-Scope

- Focus on core data for surveillance and transmission to the CDC within selected data classes.
- We will work to identify standard definitions and value sets within that definition of core data.
- This is not a discussion of how to collect this data, frame questions in surveys or interviews, or implement these data standards. This is also not meant to impose limitations on how jurisdictions collect data.

Summary of Previous Calls

Previously in February

- In February when this group met we talked about the current use of two different repeating groups by MMGs called clinical manifestations and signs and symptoms. The content of what's in the value sets as "clinical manifestations" or "sign or symptoms" across conditions has a lot of overlap between the two, and it was decided by the group that there should be a core data class to encompass these values. The terminology we were using for the name on that call ended up as "clinical manifestations, including signs and symptoms", since the term clinical manifestations is inclusive of everything that would be defined as a sign or a symptom but can be more comprehensive terminology for things such as laboratory findings. Here we have simplified this a little bit for our official data element name and definition. It felt unnecessary to have such a long phrase as the name for the data element, so we've simplified the name to just clinical manifestations, but the definition retains the description that specifies this is inclusive of any signs or symptoms. These clinical manifestations should be identified using SNOMED codes when possible, but if needed local codes may be used.
- I just wanted to cover this again to make sure everyone has a chance to see where our verbal discussions landed on the February call. Does anyone have any strong disagreements with the definition as written here before we move on?
    - No dissent from the participants

Previously in March

- In March we had two calls focused on structures of this data class as well as exposures, risks, and underlying conditions where we asked informaticists who work on structuring their data into case notification messages to weigh in. Their general feeling for what structure is best for these data classes was that the structure should be whatever makes sense for a particular data class.
- From those who voted from CDC there was a strong preference for the repeating block structure, as it is easier to make adaptations to data elements without a lengthy review process and updates to value sets may not require jurisdictions to go through an onboarding process for an updated MMG. From jurisdictions, the preferred structure that is easiest to implement from their perspective was split between repeating

group, repeating element, and individual questions, likely reflecting differences in surveillance systems used across the US. If you don't know what I mean when I describe these different structures, don't worry, I will have an example later before it becomes more relevant to our conversation.

- One of the perceived benefits of the repeating group is that additional "child" data elements can be added into a data class more simply, however we heard from informaticists that having a structure of parent/child/child is more feasible than parent/child/grandchild. An example of what this means is that we may have the parent question in the repeating group be to select a clinical manifestation, like fever, and then the first child question would be to indicate yes/no/unknown for whether or not the person had a fever. Adding an additional data element of onset date is simpler if it is not dependent on the answer of "yes", just to the answer of fever.

Complications, etc.

How will data elements be sored into the data classes?

- Today I don't want us to get too caught up in dictionary definitions. These definitions are not meant to provide an academic reference point or impact how data are used or analyzed. They are specifically meant to provide some guidance for future message mapping guides. The idea is to pair the definitions with recommendations about structure to enable standardization when the CDC requests these types of data.
- So far for this data class we have defined there should be one core bucket, called clinical manifestations, that is defined as "clinical manifestations, including signs and symptoms, associated with a condition". Now we will determine if there should be a second bucket that can capture complications or other findings as we will go into further on the next slide.
- If two buckets exist, it would be up to CDC programs to decide where each value belongs for a certain condition. The example given here is that currently encephalitis is listed as a clinical manifestation in the lyme MMG, and as an infection type in RIBD. Our goal here is not to make definitions that can precisely indicate whether "encephalitis" belongs in our clinical manifestations bucket or in a separate complications and findings bucket. Our goal is to decide if there should be two buckets to ask about potentially different types of clinical information, and if this second complications bucket is also core.

Case Notifications to CDC

- Picking up where we left off in February, we had explained but not yet talked about these separate data elements in MMGs that capture the complications or presentation of an infection. These data elements on this slide are all transmitted separately from a different signs and symptoms or clinical manifestations data element. The most common phrasing for this type of data across conditions is "Complications", but "Infection Type" and "Clinical Findings" are also data elements that contain similar concepts. If you read through the examples here, you can see that the value sets include things that are a broader diagnosis or syndrome compared to what you would normally think of as a sign or symptom in the previously defined data class. The structure of this information varies across MMGs and includes the use of repeating groups, individual Y/N elements, or a "Select all that apply" type of approach.

Complications, etc.

- Our first topic to tackle today is if we should define a core data class that standardizes the structure of this information across all conditions. This would be a second core data class to encompass these concepts that are closer to a diagnosis than a symptom for conditions where this type of information is already collected separately from the signs, symptoms, or manifestations.
- As an alternative thought, currently these concepts are transmitted as separate things from signs and symptoms or clinical manifestations, but should they be combined into the core data class we already defined? That would be a second method of standardization.
- The third option would be that this separate data class should not be core, and this can be addressed in a condition specific manner.
- Before we start this discussion I actually want to do the poll to see where we stand as a group, and if we're split then we can have some discussion and poll again.

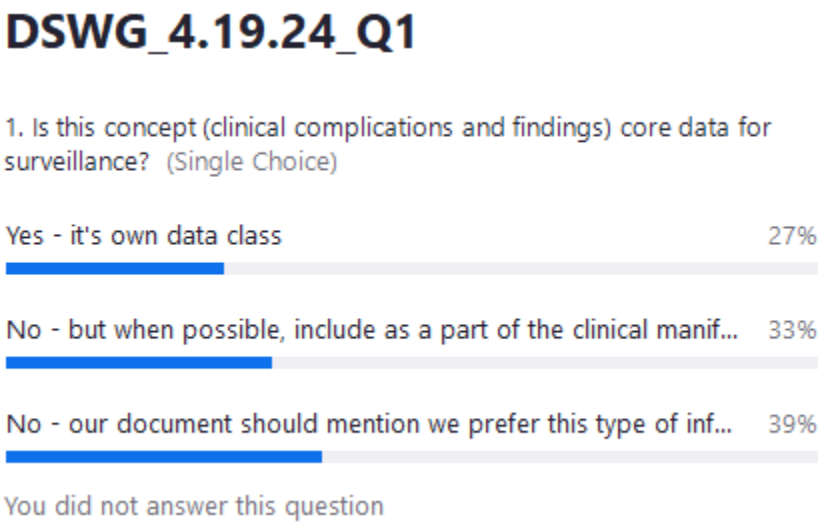
Polling process

- Same as last month, each poll question will have it's own slide, and today the answer choices are really going to vary by question. For the polls where we are asking if something is core or not, the goal is to reach 80% or more agreement, and ideally have additional discussion when not quite there.
- Data elements that receive at least 80% agreement are considered resolved with “strong support”. If for any questions we can't reach the target agreement of 80%, but still more than half the group is in agreement, these points have been included in previous recommendations documents as having "weak support".

Poll 1 – Definition

- First, we will poll on if clinical complications and findings should be considered core data for surveillance. A “yes” vote here means this should be a second core data class in addition to clinical manifestations. There are two versions of “No”- one of them indicates that you would prefer all of this information be transmitted in the first clinical manifestations core data class. The second “No” response indicates this information should not be considered core data for surveillance, although standardizing the structure of this information is still preferred.
- If we do think this is core, we can talk next about exact name and definition of this data class, so don’t let what I have currently named this data element distract you. Does anyone have any questions before we poll?
- Discussion
    - Suzanne Gibbons-Burgener: this can be a bucket of worms. If you consider complications like the severity of disease to be a complication. What do I do with some of the diseases I have. I'm interested in knowing if it's acute or chronic, if somebody develops a severe illness associated with it. So that's some of what I was thinking about might be considered a complication. But I'm not sure if that's how we would, if others would define that the same way.
        - Sam Spoto: Going back to the previous slide, I summarized what was done in current MMGs. Similar information collected across many conditions – these data elements are not necessarily asking “is this sever? Yes/no” but may be looking at specific diagnoses that would indicate severity so like acute respiratory distress syndrome or encephalitis. Does that help?
        - Suzanne: Yeah I noticed babesiosis has acute respiratory distress and so we use that for some of the fungal diseases to indicate that that’s a severe form of the disease.

- Poll Question: Is this concept (clinical complications and findings) core data for surveillance?
- Options: Yes – It's own data class| No- When possible, include as a part of the clinical manifestations data class. | No – Prefer this type of information is standardized in structure, but it is not core.



- Discussion of results
  - Suzzanne Gibbons-Burgener: I chose "no" because I don't want it to be core, I picked the middle one. My thought is if it's going to fit into clinical manifestations then it's fine to include as core. But, for the most part, I think som of the complications are their own disease to report like HUS. If we have a case of that, that's a separate report. I was torn between the two "no's"
  - Sue Soliva: I kept coming back to Arbovirus, it's all about neurological vs non-neurological cases and so type of infection that's core for those diseases in order to report them, we really want to know how many neuro vs non-neuro cases you have. I ended up voting yes strictly thinking about arbovirus – I feel like that's core data to know when you're reporting how many of each of those types of cases that you have. I also work with Hepatitis in which case I would say maybe it's not as important.
    - Suzzanne: Do they report those separately though, with arbovirus? Isn't there neuro-invasive and non-neuro invasive? Isn't that how it gets reported?
    - Sue: It does, there are two separate codes and we would depending on the type of infection they had. If it was encephalitis, miniguncephalitis or meningitis it would be flagged to go as neuro and if it was fever it would be flagged to go as a fever. So maybe we don't need to send the exact complication that made us think it was a neurological case
    - Signs and symptoms capture those questions as well, for the most part, our clinical manifestations is picking up the key things for our diseases, but this is like in addition to those we would want a particular complication to be core data.

- Lesliann Helmus: When I looked at the poll results I saw that over 70% of folks were saying no, it should not be core. But I did see interest in having it done in a standardized way. So maybe that's where people are really leaning. It sounds like people don't necessarily want it lumped into clinical manifestations because there are people who said it should be its own data class. And there are people who said "hey look, it needs to be standardized as being sent. " So maybe what we are really talking about is that it would be great if there were a consistent way to do it. But not necessarily core, it might be disease-specific, at least done consistently.
- Chat
  - Hanna Chakoian: Can anyone speak to chronic diseases and how this looks through that lens?
  - Shawna Stuck: Yes, arboviruses have different event codes for neuro and non-neuro
  - Nicole Lindsey: The specific type of neurologic manifestation is collected separately (encephalitis/meningitis) which we don't collect as signs/symptoms. We consider them 'syndromes'
  - Hanna Chakoian: Given this is for everyone I would support seeking out more chronic thoughts, especially if we remain as split as we were the first poll
  - Nicolette Bestul: In TBRD, we split the complications from the clinical manifestations for ease of analysis since there are particular complications we're interested in, however, we could pull these from one variable if needed.

- Poll re-opened, updated results below

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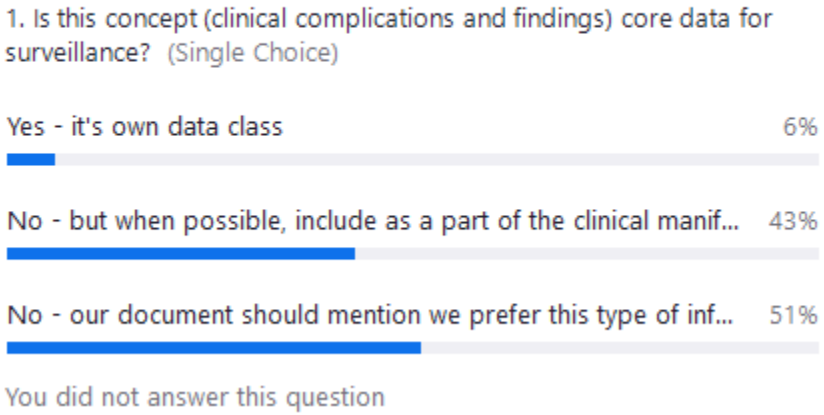


Data Class Indicator

Data Class Indicator

- An example of what we mean by data class indicator is shown in the first row of the table here. In the call last week for exposures, risks, and underlying conditions this was referred to as a "summative data element". It is intended to represent, using Yes/No or Unknown, if the person experienced any of the clinical manifestations listed in the data element below it. Last week there was general agreement that this should be included as core for the exposures, risks, and underlying conditions data classes.
- The minimum dataset for case notification during an emergency also includes a similar variable to indicate whether or not symptoms are present, followed by a second data element that lists the symptoms.
- So if clinical manifestations is implemented as a repeating group, an indicator element would ask if the person experienced any clinical manifestations, and a response of “no” may remove the need to transmit the individual elements from the repeating group.
- When we talked about this type of data element in the structure calls, the implementation of this is easy for jurisdictions who already have their surveillance system set up in a similar manner, and other jurisdictions seemed neutral about the ease of implementation of this type of summative element.

Data Class Indicator, 2

- Here are some examples for the data classes we’ve talked about in this group. (Ignore the second line here since we have not defined that as a second core data class.) (With two core data classes, each data class could have its own summative data class indicator.) I want to stick with the "poll then discuss then re-poll if needed" format so I will first just pause here to see if we have any questions? Then we’ll go to the next slide for a poll.
- Discussion
    - Suzanne Gibbons: For clarification on the clinical manifestations, we are now including not just symptoms but other clinical signs that could include imaging or blood work that indicates the person has a clinical manifestation right?
        - Sam Spoto: Yeah, that was the idea of kind of broadening it from just signs and symptoms to the clinical manifestations including signs and symptoms.
        - Suzanne: Ok because we are currently asking in our system whether somebody is “symptomatic” and a lot of times it gets marked “asymptomatic” but they have an abnormal chest radiograph. So I just wanted to make sure that we’ve now expanded ours

Poll 3 – Is it Core?

- For this poll, select if this summative indicator value should be core for either data class we talked about today. If you do not want it for either data class, select the option for neither. Any questions?
- For only one data class: If you think clinical manifestations should have this indicator data element, select clinical manifestations. If you do not, select neither.
- Discussion
    - Ej Klingler: inaudible
    - Sam Spoto: When we say that we’re expanding clinical manifestations to include things like potential laboratory or chest x-ray findings, it would be something like “does the person have an abnormal chest x-ray?” which I think someone would not be defined as a sign or

symptom. It’s not saying anything about the transmission of actual laboratory results. When we initially were doing our investigation into why there were these 2 repeating group structures, one of them called signs and symptoms, and one of them called clinical manifestations. When they all seem to contain very similar information. The response that we got back from some of the groups using the clinical manifestations ones where that they felt that some of the items they asked about in their list of signs and symptoms were not necessarily something you would call a sign or symptom. It might be something like a low white blood cell, count and so they just thought clinical manifestations was more inclusive language.

- Lesliann Helmus: I worry that clinical manifestations “Yes, no” as a category might be too broad to address this “symptoms present” core data element if it's part of the minimum data set for emergency response because there could be so many other things in there that we wouldn't necessarily consider symptoms. I mean, there are other indicators. So I wonder if we're getting ourselves into a problem area?
    - Suzanne: Wouldn't it be defined, though, by each individual disease? As to what was considered significant? I bring that up because as Covid was emerging we use chest radiographs. We used some of those indicators even as an emerging disease, evaluating. So I get what you're saying like what would an average person recognize as abnormal to their health in their own body?
    - Lesliann: You want to limit it
    - Suzanne: to that or not
- Lesliann: I think it's helpful. So it's the limitation we do is if we say clinical manifestations and they wanted those signs or symptoms that are relevant. So you, instead of getting signs or symptoms present, you're gonna get clinical manifestations, present or clinical manifestations “Yes” it means that they have to make sure they don't ask for clinical manifestations, that they wouldn't consider the kinds of things they're looking for in signs and symptoms. And maybe that's okay. Because we if we're just looking for, you know, is there evidence of disease that goes beyond infection. Maybe that's getting us where we want to be.
    - Suzanne: I think the logic is probably gonna be if somebody checks off or marks “Yes” for a particular Sign, Symptom or manifestation, That's on the list for that particular condition or disease. That's sort of how I think it's gonna happen. It would be more of a logic thing, instead of maybe having just a standalone in your surveillance system.
    - Lesliann: Yeah, I think the emergency data didn't include sending the symptoms. It was just symptoms present. And so that's where it gets a little fuzzy. But if “symptoms present” is the core, and if people are gonna be able to send symptoms because we make that core as opposed to just the minimum for emergency response, It may address the problem.
- Sam Spoto: when we came up with this with the cochairs the idea of this indicator value is specific to the list of what is in the following clinical manifestations, data element. So, as we said, it's kind of a summative data element to say, okay in the list that comes in the next question, did the patient have any of those things? Whereas you're right, Leslieann, in the emergency data use or emergency data set, it is more of a “do they have any symptoms?” that is less specific to any symptoms that might be listed somewhere.
- Lesliann: With Annie's question about “could we change from “symptoms present” to clinical manifestations? Indicator equals? Yes, I think that definitely is very doable, but this issue of you can be asymptomatic and still have clinical manifestations is part of what I was concerned about.

- Sam: So I think it sounds like for our data class here, if we're focused on what we're doing with clinical manifestations, we are interested in if they have a clinical manifestation. So even if a person perceives a problem and they are asymptomatic, they do indeed still have a clinical manifestation. That is what we want to cover here, does that sound correct?
- Lesliann: it sounds like the problem may be that clinical manifestation indicator is too broad if we're trying to identify signs and symptoms.
- Annie Fine: I think the real issue is actually what is important to know. In some ways it's important to know "does the person have clinical manifestations? But then sometimes I have to look at some of the case definitions to see if they specify symptoms versus clinical manifestations. It's an interesting question, because if they specify symptoms, then you need the symptoms to meet the case definition right? I actually think clinical manifestations is in some ways more informative because if they're consistent with the condition…The question is what's important to know for the emergency response and what's important to know for other purposes for case surveillance?
- Sara Johnston: There are other purposes for our data right? So if we're talking about public education and you are saying 70% of people with this illness reported were asymptomatic. So even if you don't have symptoms, you should talk to your provider, whatever that kind of education, then it does matter asymptomatic vs clinical manifestation.
- Annie Fine: That's a good point.
- Lesliann Helmus: It may be one of the issues is that minimum core data for emergency response, whatever we're calling it, the minimum data for emergency response is intended to be a minimum. It's not necessarily saying you would not ask for "did they have these specific symptoms?" It may be that the clinical manifestations would be "yes" but we also would want to be saying, "did they have this, this, and this so that we can make those other statements. Maybe it's not so much a concern about what label we put on this field, and that clinical manifestations indicator would be fine and gives us the broader information that is more biologically important.

- Suzanne Gibbons-Burgener: I think there's a huge difference in how people apply the word symptom, not saying it's right or wrong, but there are definitions for signs versus symptoms and I think they get used interchangeably a lot.
- Sam Spoto: We may be talking about 2 separate things. This was framed as a clinical manifestations indicator to tie into the question that comes below it, asking "is what I'm about to ask you "yes" but then we have a separate data element: "Is the patient symptomatic?" Maybe a better question here would be "Which of the following are core?" and have a clinical manifestations indicator, Is the patient symptomatic? Or neither.
- Lesliann Helmus: If there are going to be some specific symptoms asked and when they're of interest, maybe we should be expecting that they would be asked, so we don't necessarily need the different ones. And then that gets away from people having to figure out whether something's a sign or symptom or a clinical manifestation which is one of the issues we were addressing last time we talked and that Amy raises here.
- Suzanne Gibbons-Burgerner: This is for people who meet the case definition right? So we wouldn't be looking at transmitting data for people who don't meet the case definition, whether it's an emergency case definition or not. If you are using data for emergency disease reporting as hypothesis-generating, that's a lot of times what's happening right? Up front? And you're trying to determine what

questions should we be asking? Should we be adding other signs or symptoms to it? Should we be adding that a CBC has to indicate certain types of anemia, etc. I hate to see our entire efforts being sort of derailed for what is more of a hypothesis generating data collection.

- Molly Crockett: I probably agree with the path this conversation is going, that there may very well be certain signs and symptoms that need to be a part of the core set, but the clinical manifestations that extend beyond that are things like you'd find in a CBC and may not be subjectively experienced by the patient, may fit into that other category of questions that can be specific to certain conditions but not necessarily part of the core consideration and that leaves it a little more clear in terns of what you're asking. You're asking about things that are more subjectively experienced. I don't know all of the conditions particularly well and if a lot of them require a non-subjective clinical manifestation as part of the case definitions and that's that. Does anyone have a feel offhand as to how often these non-subjective symptoms or clinical manifestations come up?
  - Suzanne: From the less common disease that require a lot of diagnostics (endemic mycoses, arboviruses, etc) at what stage you're actually detecting it, whether it's an acute or chronic stage and sometimes it is almost by incidental finding that an abnormal chest radiograph comes about and you're doing additional workups to rule out cancer or other causes for the lung nodules. And that's when you find that the person has probably a chronic infection with something. In that situation they're not going to recall the acute clinical syndrome that they may have had if they had it at all, because some diseases just have such minor clinical signs that people don't notice them when they're initially infected
  - Molly: For a condition like that, would it still be fair to answer "no" to the symptoms question but then have a question that's part of the disease-specific set that addresses the clinical manifestations
  - Suzanne: Well we ask for that but we also look to see "was there abnormal chest imaging" and that is in the case definitions for these endemic mycosis that they need to have 2 or more of these certain symptoms or they could have one of these and one of those clinical criteria that they can have an abnormal pulmonary imaging. And then there's laboratory criteria that they have to meet as well, and there are epi linkages. So we are looking at different things as to wether they physiologically have an abnormality that's associated with the disease.
  - Molly: Would it feel like it was sufficient to communicate that information in disease-specific fields that maybe aren't core? B/c it's not a common situation. Lesliann or Sarah, do you have a feel for how often a non-subjective syptom would be important enough to the case definition that we should be thinking about expanding beyond what we typically think of when we say symptoms?
  - Annie: I can give an example of one like microcephaly in an infant exposed to Zika. If you measure it. You put it on a chart, and you, it's in an observation, the person might come in, and Parent might say, oh, I think my baby has small head, but I just think there's enough of them. Legionna legionella and pneumonia are other ones where usually they'll have symptoms. But there are important clinical manifestations that are used for the case definition that are important to know. Where I'm wondering if it really needs to be clinical manifestations, yes or no. But then, maybe symptoms yes or no, too…
  - Sam: These are 2 separate things. Molly, are you talking about undoing the first definition we already did to make our main data element clinical manifestations?

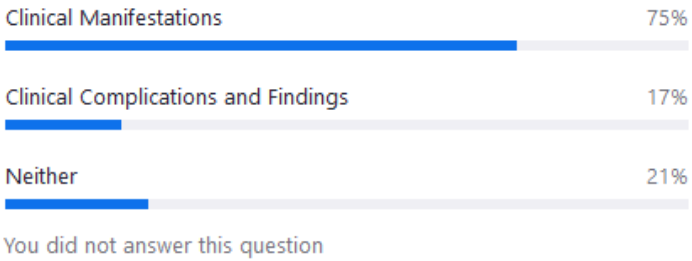
        - Molly: I'm just processing all of this and realizing that hearing the input from the other people dealing with conditions that I'm less familiar with is really helpful. Things I might say aren't important often enough for its own question, it's useful to hear. If this many people are confused about the overlap of the two maybe there are symptoms etc.
        - Lesliann: maybe it goes back to signs, symptoms and other clinical manifestations and we can pull those things out. Or do we just want symptoms and then signs and other clinical manifestations? I think for most people they're going to have to see what has been put on that list to know which category to put it on. We were trying to make it easy so they didn't have to search the list to figure out where to put it.
    - Sam: we're going to relaunch the poll. I think a clinical manifestations indicator would be, does the patient have anything in the list on in this following data element. So it's going to be condition-specific, and each condition would have its own value set for what's considered a clinical manifestation. And this indicator value set is asking in the following question, are any of the answers going to be "Yes" and can we sum up what the answers are in the following question. Then separately, there could be a data element for "is the patient symptomatic?" and that could be totally unrelated to our clinical manifestations including signs and symptoms data element. That is more about if the patient perceives that they are symptomatic or not and then neither would be neither of those things are core. Does that help everyone's understanding here?
        - Suzanne: And we are saying, symptomatic in the sense that the symptoms are consistent with the disease. Not that the person had a headache and headache isn't necessarily even in the case definition. Because there are a lot of people that feel crummy, but they don't necessarily have the symptoms for the particular disease.
        - Sam: yes, so is the patient symptomatic with symptoms associated with the condition
        - Suzanne: and again, it wouldn't have to be, even if we make both of them core, it could be disease-specific as well right?
        - Sam: yes
        - Suzanne: it's one or the other is what they want
        - Sam: yes, not all conditions would have to use each one of these data elements if it was not appropriate for that condition
- Chat
    - Katherine DeBord: so then this indicator would be different / in addition to the minimum core data element for an emergency, which is just symptoms present?
    - Good question, Katherine. We do need to address the fact that 'Symptoms present" is a core data element for the emergency response minimum data set. This category might be too broad.
    - Annie Fine: Is it clinical manifestations related to the condition? The hard thing is that sometimes it is not known whether they are related to the condition
    - Sara Johnston: Would people consider 'asymptomatic' the same as 'no clinical manifestations present'?
    - Annie Fine: Could the emergency core be changed to clinical manifestations present? Or to signs/symptoms present? I know it is supposed to be final but that is a pretty big difference since there are clinical manifestations that are not symptoms. No you can be asymptomatic but still have clinical manifestations (e.g., a sign like thrombocytopenia but still be asymptomatic)

- Hanna Chakoian: But symptoms by condition is within clinical manifestations? So include the clinical manifestations and you can calculate it off those answers, right?
  - Annie Fine: If you do have those child questions that is true. If you only have the yes/no then maybe not!
  - Hanna Chakoian: Then CDC should request the specifics! Assuming the structure we land on allows it which seems like a safe assumption.
- Amy Lai: Will investigator know how to definciate signs and sypmtoms vs clinical manifestations? and does public health's definition and the definitoin in healthcare setting align?
- Anni Fine: I think symptoms should be defined as something the patient experiences and reports rather than something that is found by some kind of examination or test
- Nicolette Bestul: Rickettsial uses clinical criteria for the case definitions and includes both what seems to be considered signs/symptoms and clinical manifestations. On the MMG we say clinical manifestations so that all can be included
- Annie Fine: Sometimes suspect cases are reported, during emergencies
- Karen ArrowoodFor syphilis, primary and secondary stages require specific symptoms to be present to meet the case definition. But we also have clinical manifestations that indicate nuerosyphilis, ocular syphilis, otic syphilis, or tertiary syphilis., which can present at any stage of syphilis.
- Elizabeth Schiffman: There are non-specific symptoms that are needed for a lot of vectorborne conditions in order to meet case definitions.
- Nicolette BestulCouldn't all fit under clinical manifestations? symptomatic and asymptomatic manifestations?
  - Hanna Chakoian: Yes, that is my understanding. And each condition will have condition specific manifestations listed, so we don't need to pull things out - the relevant specifics should be there to calculate off of
- Annie Fine: Yes agree Suzanne (though sometimes you cannot tell)
- Suzanne Gibbons-Burgener: What comprises "Clinical Manifestations" will be disease-specific and may only include symptoms. I prefer have the inclusive Data element.

- Poll Question: Select if any data class should use a summative indicator as part of core data for surveillance (select all that apply)
- Options: Clinical Manifestations | Clinical Complications and Findings | Neither
- Both are well above 50% so we can safely include these as core with weak support from the group.

DSWG_4.19.24_Q3

1. Select if any data class should use an indicator as part of core data for surveillance. (select all that apply) (Multiple Choice)

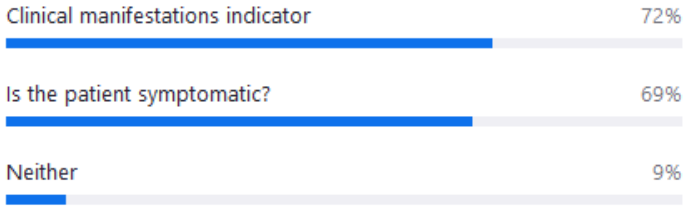


You did not answer this question

- Poll edited and relaunched, results below

DSWG _4.19.2024 Q3 v3

1. Which of the following should be a core data element? (Multiple Choice)



You did not answer this question

Structure

March Structure Calls- Review

- The structures that we are going to be talking about in a minute are visualized on this slide which we can reference later if necessary.
- The most straight forward are the individual questions shown on the right and boxed in green. These are separate questions and are included as such in message mapping guides. Examples here are did the person have a fever, did the person have a cough, and did the person have a

headache. These require quite a bit of approval at the federal level for additional questions to be added, which inhibits their flexibility for new mmg development and current mmg updates.

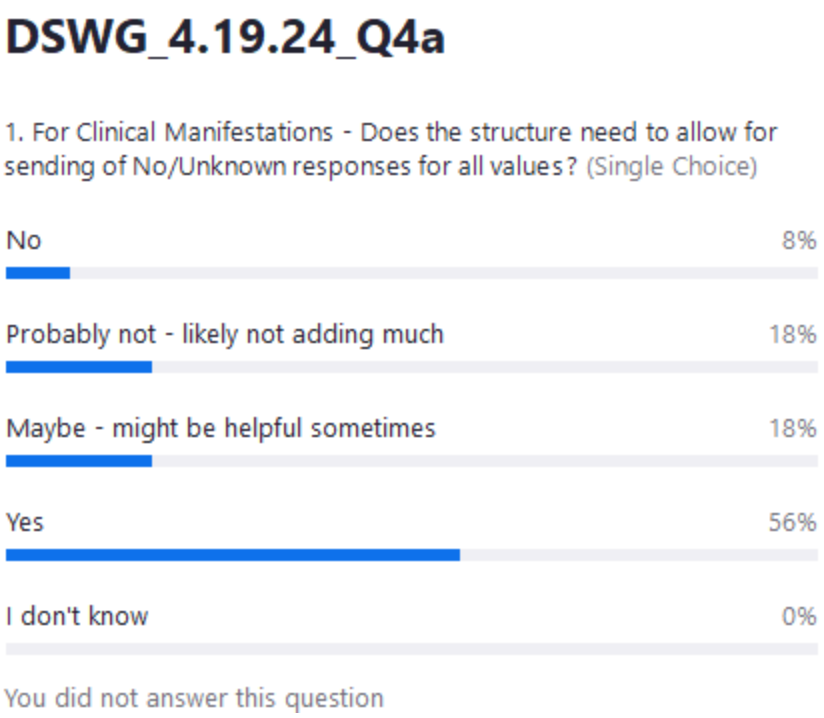
- Repeating Elements are on the top left and boxed in orange. These have a general question such as “Did the person have any of the following clinical manifestations?” and then answers are a select any that apply option from a value set. These limit a question to an indication of a positive result with no way to send No or Unknown values for each individual manifestation.
- Repeating groups are the bottom left and boxed in blue. These can have the same general question but one value set includes the clinical manifestations of interest, and a paired value set allows the selection of Yes, No, or Unknown for each manifestation.
- These are just examples of how they might look in a system and are not prescriptive.

Structure Recommendations

- For our recommendations document, we will summarize the information from our March discussions as I did at the start of this call, and include a rundown of the pros and cons of each structure type as voiced on those calls. We will leave exact structure decisions for future implementation, but there is one key epi consideration that I want to poll on here. The repeating block or individual questions allow for transmission of “no” versus” unknown” for each individual symptom. A repeating element, which is the “select all that apply” type of structure would not provide any distinction between “no” or “unknown” for individual symptoms.
- For these data classes specifically, is transmission of “no” versus “unknown” for each individual clinical manifestation important? Or is it acceptable to only transmit “yes” values?

Poll 4a

- For our poll here, we’re not really trying to reach a solid 80% but rather get an idea of how the group leans. Because of this, we have the straight-forward yes and no responses, but then also probably not, which is a less strong “No” and a “Maybe” which is a less strong “Yes.” Does anyone have any questions before we open this poll for clinical manifestations?
- Poll Question: For Clinical Manifestations – Does the structure need to allow for sending of No/Unknown responses for all values?
- Options: No | Probably Not- Likely not adding much | Maybe – Might be helpful sometimes | Yes | I don’t know
- 86% believe this is core



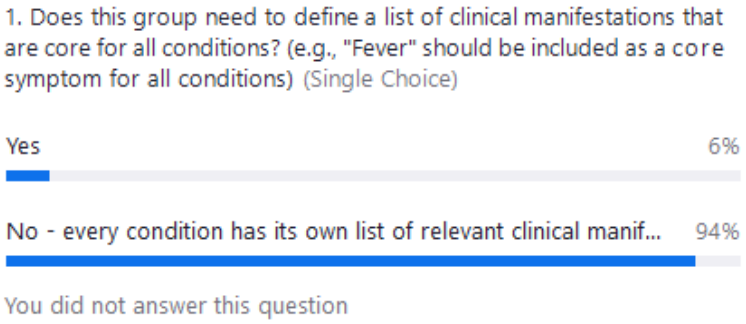
Final Loose Ends

Poll 5

- The goal of our work here was to talk about a consistent structure and definition for these data classes to be implemented across conditions as applicable, with the understanding that across conditions the value sets for signs, symptoms, and clinical manifestations vary widely. We did also mention on the first call though that we would see if the group thinks it's necessary to try and define a list of clinical manifestations that should be core for all conditions. This wouldn't be done on a call, but would be done in a follow up poll after this call. Does anyone have any questions about this before we poll?
- Discussion
    - Suzanne: Are you looking for whether we need to define what would be considered a core clinical manifestation or the standardization of fever.

    - Sam: The first one. So we should have a defined list that's applicable for all conditions like fever, headache, cough, condition-specific
    - Lesliann: Is that even realistic? We don't have a list that applies to all diseases
    - Sam: I think likely not, but I think because we talked about it on the first call, I just wanted to bring it up to see if anyone felt that way
    - Annie Fine: And this includes non-infectious as well as infectious?
    - Sam: yes
- Chat
    - Hanna Chakoian: Maybe not a core list, but it would be really nice to have standard way to ask about the same manifestations across conditions
    - Nicolette Bestul: I don't think it's possible since all conditions have their own list that would be required
    - Claire Stump – For gonorrhea, one of the complications is disseminated. Based on CSTE case definition, we need to be able we have to have it further defined as yes-likely, yes-probable, no, unknown.
- Poll Question: Does this group need to define a list of clinical manifestations that are core for all conditions? (e.g. "Fever" should be included as a core symptom for all conditions)
- Options: "Clinical Manifestations, including Signs and Symptoms" is core/Not core

DSWG_4.19.24_Q5



Next steps

- The next data classes to start in May include Disability, and Identifiers. Identifiers includes topics like outbreak identifiers, identifiers to link labs and cases, and identifiers to link maternal and infant cases. The link to sign up will be available with the follow-up information from this call.
- The Disability data class DEST is scheduled for May 10, 1-2pm ET
- The Identifiers data class DEST is scheduled for May 17, 1-2pm ET