Meeting: CSTE Data Standardization – Pregnancy Data-Element Specific Team Meeting
Date: September 15, 2023
Attendees: 59

CSTE (1)	PHAs (25)	CDC (30)
Becky Lampkins	Co-Chairs	Alli Ertl
	Laura Erhart (AZ)	Allie Tuttle
JMC (3)	Molly Crockett (MA)	Amanda van Rest
Erin Kough		Ashley Townes
Laura Lane		Elanah Wafer
Susan Downer	Annalyse Bergman (AL)	Erin Miller
	Dimple Patel (KY DPH)	Hazel Shah
	Eman Addish (Philadelphia)	Jane Yang
	Hailey Vest (IN)	Jerome Leonard
	Hanna Chakoian (MN)	Kasey Diebold
	Heather Marshall (MDHHS)	Katie Fullerton
	Judie Hyun (MD)	Kaylea Nemechek
	Karene Thomas-Watts (CDPHE)	Kristin Delea
	Kimberly Johnson (NYC)	Lesliann Helmus
	Madeline Kemp (WI)	Lisa Romero
	Margret Watkins (WV)	Lizzi Torrone
	Maria Jaurretche (DC)	Luis Hernandez
	Melanie Epstein-Corbin (CA)	Meeyoung Park
	Monique Birmiel (IN)	Melissa Pagaoa
	Rachel Amiya (WA DOH)	Myrna del Mar Gonzalez-Montalvo
	Rachel Quinlan	Nicki Roth
	Rob Arciuolo (NYC)	Noreen Kloc
	Robbie Snyder (CDPH)	Peter Boersma
	Tia Falzarano (MI)	Robert Pratt
	Trish McLendon (CA)	Sandy Price
	Vajeera Dorabawila (NYSDOH)	Sandy Roush
	Vicki Stewart (WA)	Sara Johnston
	Yuritzy Gonzalez Pena (OR)	Stacey Martin

		Sundak Van Tong

**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***):**

CSTE Data Standardization Pregnancy Data Element-Specific Team Meeting

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.

Administrative Updates

- Hospitalization – currently seeking feedback on draft recommendations, deadline 9/15/23.
- Travel – a draft will be going out soon so be on the lookout for that.

Data Element-Specific Teams

- Team member expectations – there is no expectation for members to write documents, lead meetings, or prepare slides. The goal is to keep members actively engaged in conversations around content during and between meetings.
- There is an expectation of active participation for polling, document review, discussion, and other input both during and between meetings.

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 common definitions and value sets within that definition of core data.

Core Data FAQ

- Core data transmission does not mean it's required for transmission.
- It is okay to leave these blank or unknown if the information is not available, not a priority, or not useful for specific conditions.
- The data elements should also be relevant to many conditions.

Pregnancy

Potential Core Data elements

- These were the initial, potential court elements that were previously discussed.
- The Pregnancy Status Workgroup recommends capture through ELR for certain conditions; It is present as a data element in ECR, but it is not consistently populated. The recommended value set is pregnant, not pregnant, possibly pregnant, and unknown. Currently in Gen v2 the values are yes, no, unknown.
- Estimated data delivery is currently in one MMG for one condition, is present as a data element, but is not consistently populated. This is recommended by the Pregnancy Status Workgroup as a minimum data element to include in regulatory language.

- Today we will discuss in detail “pregnancy outcome.” Some form of this exists for 12 conditions in MMGs but different value sets are used across conditions. It's not currently in the ECR implementation guide, but it is present as a data element and version 3.1.

Potential Core Data Elements (continued)

- The DSWG previously voted on Pregnancy Status, defined as a core data element with 81% consensus with the with the value sets of yes known and unknown.
- Estimated data delivery and pregnancy outcome, both of those were split around 2/3 of people saying they were core data elements and 1/3 indicating they were not core. These are the ones we’ll be discussing further on today’s call.

Timing of Pregnancy

- Estimated data delivery was proposed as a core data element to capture the timing within a pregnancy associated with the event. About 2/3 of the people on the call last time with the greater data standardization and work group, supported it as a core data element, but it did not hit 80% approval. There was additional discussion in that chat from the previous meeting, however, that gestational age might be more reliable and readily available.
- **Discussion (chat)**
    - Sundak: Gestational Age - Many of them are there. Are you referring to Clinical or Ultrasound?
        - Erin: This has not been defined yet and there is still some uncertainty around that variable and might require extra data elements to capture that information as well.
    - Judie Hyun: I have generally found that EDD was easier to obtain than gestational age.
    - Vajeera: Probably too much to have both.
    - Margaret: gestation is easier to collect and report than delivery date. but that doesn't mean we cannot ask for and report delivery date (if we have it)
    - Nicki Roth: Is there an opportunity to include EDD or gestational age?
    - Van: To get it you must do it multiple ways
    - Yuritzy: I feel like if you have one you can estimate the second one.
    - Robert Pratt: New to this discussion. If we define this as a core data element, would we need to include this question whenever we ask whether pregnant at diagnosis?
        - Laura E: Not necessarily. This would allow us the place across conditions to submit the data to CDC. But it would not need to be collected for all conditions that collect pregnancy.
        - Robert: Thank you.
    - Robbie: Approaching through the lens of "how do we use this information" - which would be most helpful to achieve that?
    - Sundak: Last Menstrual Period (LMP) could also help gestational age / Pregnancy status - would also help to know if they are possibly pregnant.
    - Yuritzy: Outside of this topic but I am wondering if we have defined the age for collecting pregnancy. Is it 15-45y/o? 15-49 y/o? or is it by disease specific?

        - Lesliann: I think the intent is that the data element would be available for all cases. (Keep in mind that it is a data element and not a "question").
    - Erin Miller: Could someone give some examples of how this element is used, data quality issues they've experienced, etc.?
        - Nicki Roth: trimester of infection
- **Discussion (talking)**
    - Van (CDC): I just want to comment that yes, this is an important concept to get some sort of gestational age dating. I think this is important for all exposures that our program monitors we have been doing sort of longitudinal surveillance for like 5 or 6, nationally notable, notifiable diseases. Our experience is that we end up having 3 variables. If you want gestational age, it's helpful to capture the least 3 concepts. But the question that you're asking in terms of should it be core? I mean that's if it's going to be core, but you can only select one, I think that's a very complicated question, but if you say gestational age is important, I will say yes. So just going to put it out there, but yes, we, I think other folks have mentioned LNP, but we capture ADD, gestational age at birth, LMP, and I think depending on the exposure, you might capture women who are in the midst of pregnancy but then others that have completed pregnancy and so sourcing various types of gestational age dating has been helpful these across the 4 or 5 exposures that we've been working on.
    - Molly: from a jurisdiction perspective, I've always found it easier when the data element that I'm focusing on can act solo. So, EDD is a date that is concrete and time on its own. Whereas gestational age is needed, you need to know as of when. And, as soon as there's a second variable that's required to be able to use the first variable to me that ups the difficulty factor by a lot. I've defaulted to EDD in my own work, but I just wanted to kind of chime in with that.
        - Robbie (chat): I like that perspective thanks Molly. Agreed from California.
        - Eman (Chat): Same for hep outreach we use EDD.

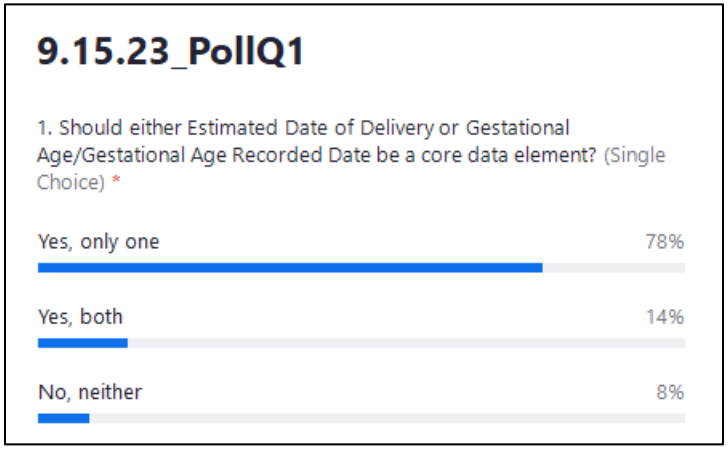
Polling Process

- We'll work to ensure there are no outstanding questions before we launch the poll.

Polling – Timing of Pregnancy

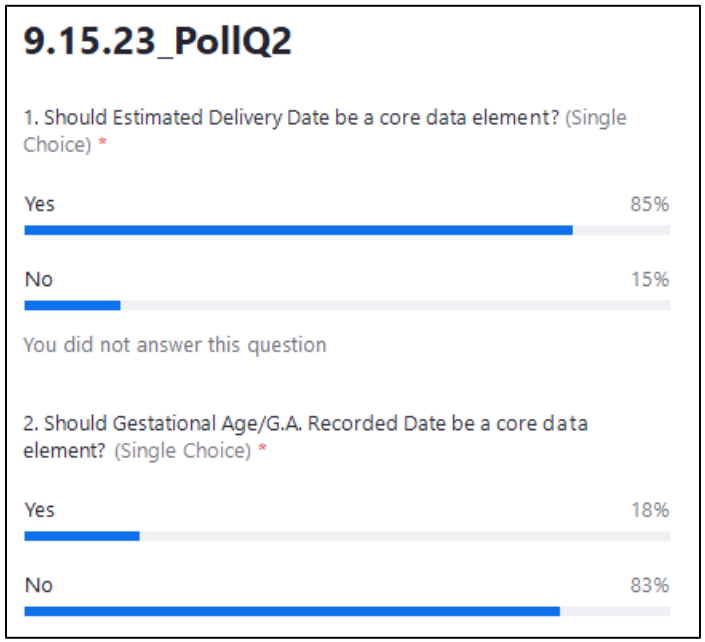
- Should either estimated date of delivery or gestational age/gestational age recorded date be a core data element?

- Results for Q1 (n=36); Yes only 1 = 28; Yes both= 5; No, neither = 3



Polling – Timing of Pregnancy

- Should estimated delivery date be a core element?
- Should gestational age/GA Recorded date be a core data element?
- Discussion
    - Can anybody provide examples of how data elements are used?
        - Robbie Snyder: The most direct way that we use this is in monitoring and tracking congenital syphilis and thinking about how to intervene to prevent congenital syphilis infections prior to birth, so that's a very direct use case for us here. To be specific we use an estimated delivery date for that. We could use gestational age, but for our purposes estimated delivery date is better kind of in line with what Molly was saying before we'd have to calculate estimated delivery date from gestation, to use that information.
        - Laura Erhart: The date helps to provide general context for pregnancy. This gives us timing for the event at hand whether it's salmonella or COVID, even if we don't know exactly where in the pregnancy they are.
        - Erin: Yes, and I do know that is used in Zika tracking as far as both knowing potential impacts and doing follow up with labor and delivery and other after birth elements.
- Results for Q2 (n = 40)
    - Q1 Yes =34; No = 6
    - Q2 Yes 7; No= 33



- This shows consensus. Therefore, we can move forward using estimated delivery date as a core data element and we will table gestational age as a core data element.

Pregnancy Outcome Value Sets – Bug or Feature

- The next data element is one that is seen in many disease-specific message mapping guides. Its value sets are quite variable. This is displayed in the table as color coded to indicate matches, though they might not be the same. As we went through and tried to come up with a meaningful outcome data set or value set. We did try to take out anything that was more disease specific such as live birth, or CRS. We kept it outcome focused. So, this is our suggested value set (next slide).

Pregnancy Outcome Suggested Value Set

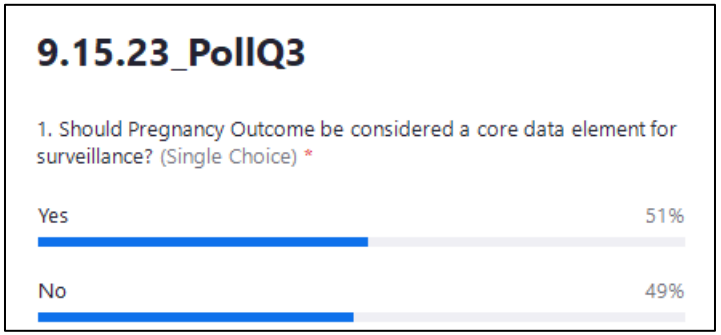
- (See slide for suggested value set details)
- Open Discussion on whether pregnancy outcome should be a core data element and comments about the suggested value set (chat)
    - Van Tong: I generally like the value sets because they are very inclusive.
    - Rob Arciuolo: how would you report intrauterine fetal death, with unknown gestational age.
    - Yuritzy: for disease that you follow up through pregnancy do you set the outcome when disease was diagnosed or at delivery?
    - Robbie Snyder: my comment is a not this train of thought so we can finish this piece and I can chime in
    - Erin Miller: You said 12 conditions use this variable, 12 out of how many?

        - Laura E: Out of maybe for 60-80.
        - Erin: The idea is that it's in those 12 but would it be better situated in a cross-disease setting. I don't know exactly out of how many conditions are, but I believe that sounds like a good estimate.
    - Sundak: You may want to mention pregnancy related data elements with skip logic. EDD and Pregnancy outcome would be answered only if Pregnancy status = pregnant. Pregnancy Status - Core element
        - Laura E: Agreed - we would include that in the guidance.
    - Jerome Leonard: What time span are we defining as the perinatal period to record perinatal deaths?
        - Erin Kough: This is a great question. When we were trying to review the value sets, there was so much variability this would be something that we could set a definition for, but right now we just wanted to make sure that perinatal meant more around the time of birth instead of you know, the second half of the pregnancy, whereas in other value sets, it was kind of lumped in with death during pregnancy. We thought this would be important for things such as I know Zika has perinatal death, group B strep.
    - Leslian: Want to ensure that we capture consistently across diseases.
    - Lesliann: Would this be sufficient
      Elective termination of pregnancy.
      Live birth
      Intrauterine fetal death
      Spontaneous abortion
      Non-live birth not otherwise specified.
        - Robbie Snyder: That is helpful framing, maybe related to my comment then.
- Discussion (verbal)
    - Robert Pratt: I would like more discussion on this. Would this be a follow-up to Gen v2 question. If it is, "was patient pregnant at the time of the event" then these seem to all be periphery. If there was already a live birth, then they would not have pregnant at the event or if they're still pregnant. We're not just reinforcing what you've already answered. So, I'm having a hard time understanding the granularity of this question.
        - Laura E: That's a good question. I'm happy to hear other perspectives from other participants in the group. I think one of the one of the pieces in this value set is still pregnant and so if that's the level of information that folks have at the time that they invest investigation is completed and the information is collected and that is a valid option. I think for some conditions then knowing the pregnancy outcome is a very important part of the information for pregnancy. And so, it could be information that is collected at the time of initial report or the investigation for some conditions. It could be something that's for follow-up. But again, happy to hear other thoughts on that.
        - Robert Pratt: So, this would be more, in terms of people that would be asking the question about the infection or condition, not at time of event. It would be something that there would be an expectation that you would ask the first question at diagnosis or at the time the event occurred or and the second one. Or the patient was released from being treated.
        - Lesliann (chat): Follow-up would not be expected for all pregnancies. This is a way to capture the information if known.

        - Laura E: This wouldn't necessitate that we are asking for follow-up for all cases, that would be much more on a case by case or condition specific basis of whether follow-up is needed. There would also be certain circumstances where at the time of maybe kind of a single investigation or single report, then both things are true. The patient was pregnant at the time of the events, say at the onset. And, by this point in time a live birth or one of the other options has occurred.
    - Erin: Reminder this would not be expected to be captured for all pregnancies. It would be a way to capture the information if known and it is not necessarily associated with the timing of the event.
    - Laura E: Part of the question for you all is, is this relevant. Is this information we would want to collect for significant conditions, and should it be part of the core data set we're sending. We don't have to fill it in for all the conditions where it doesn't apply or if we don't have the information. But is it something we should include in that general data set we're sending. A piece of that is that if we include that as an option, then we will try to land on a value set. If there is too much variation, we may determine that is should not be in the core data set. This is going back to do we want this as a data element that could be relevant across multiple conditions.
        - Molly: If you don't believe it belongs in core then it's okay to say that. It doesn't mean we're saying it's not important or it should not be collected. The focus is whether it should be part of the core or not.
        - Robbie Snyder: Thank you. Yeah, that was really helpful framing because my comment is around whether or not it's core, because I certainly see the value of this for specific conditions. One of the things that we talked about in California as it relates to our STI surveillance, but I think it relates to other conditions of the implications of capturing this information as it relates to abortion, fetal loss, and otherwise in the political landscape that we live in where people can be criminalized and I worry that, making this core and including it in more pieces or more opportunities for that information to be used.
        - Laura Erhart: Yeah, I appreciate that context. Thinking through it in that framing also of, if there is a concern within your own jurisdiction about the potential for criminalizing for responses it certainly is an option not to include the data. It is something to be sensitive to.
        - Erin: When the JMC team was reviewing we have been taking that into consideration, so we definitely appreciate those comments.

Polling - Pregnancy Outcome

- Should pregnancy outcome be considered a core data element for surveillance?
- Results (n = 43); Yes = 22; No = 21



- **Discussion**
  - Laura Erhart: Opened the floor for discussion.
  - Lesliann: I work at CDC and surveillance activities. One of the requests that has come from multiple areas is that we define a core data set that would be used for emergency response. So that when there's a new disease, everybody could have a way to share information ahead of time. This is the basic data we're going to ask for, and they have clearly said they really want to make sure that pregnancy and pregnancy status and pregnancy outcome if it's available. Certainly, pregnancy status, maybe not so much pregnancy outcome is included, but it does seem like this is a piece of information is important where we have it available to know about the pregnancies. Given that we're not going follow up on every case, but if we are seeing a pattern where we're having negative outcomes, it seems like it's important to be able to pick that up at the epidemiologically and to ask it consistently across diseases. We're trying to say every case must have it, but we're saying if you're going to ask it, please ask it this way because we want to make sure that it's being done consistently. And so, some consistency here I think would be helpful.
    - Rob Snyder (chat): that would be lovely if there were a core set for emergency responses.
    - Erin: To clarify to Lesliann, were you speaking as a case for including this in the core surveillance for emergency responses or were you implying there would be a separate emergency response set?
    - Lesliann: If we were going to have it as a core element for emergency response, we should probably have that as a core element for any disease for a case that was being collected. If you're collecting this data if you're sending this data, this is the way to consistently send it. As a core element should it just be a core element all the time of something that's always available that you could send on a case, and you could send it the same way.
    - Sara Johston: this is Sarah Johnston and acting branch chief for the data standards branch at CDC within the office of public health data surveillance and technology. We've got kind of 2 efforts that are overlapping right now. One is this data standardization effort for case surveillance, which will drive what we ask for at CDC for case data and case notification. And then we also have, as Lesliann was mentioning, looking at the core data that's needed or the minimum data that's needed for case surveillance to see a case notification to CDC during an emergency response for situational awareness. So those two are

kind of in some way overlapping activities. We want to bring all those minimum data elements that are proposed into conversations here to get them for the refined. But also, this conversation brings a broader set of data elements that we'd like to standardize across conditions for case notification to CDC. So, whether it's an emergency or not, we'd like to use this broader set of data elements across conditions at CDC as the set that would you build upon if you had additional detail that was needed for that data class, but these would be the data elements to start with.

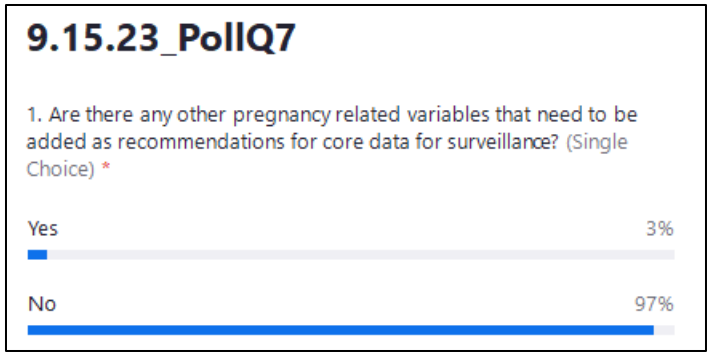
- Laura Erhart: For those that said no to this question, is this more regarding the value set proposed, is it that you don't think it is relevant for enough conditions, or other items like challenges of collecting the information?
  - Melanie (chat): I voted no because of the challenge of collecting this info.
  - Robbie Snyder (chat): unfortunately, political reality.
  - Dimple (chat): challenges in collecting this info.
  - Annalyse (chat): It is more the ways the data could be used in my jurisdiction.
  - Molly (verbal): speaking as a jurisdiction. I had voted no for this record surveillance for a lot of the reasons you mentioned. It's few enough versus the overall size of the notifiable diseases group. But not only that, but within those few where it's required, the concerns there are so different, that's the reason that those data sets are so different. And yes, I think they can still be standardized, but there are specific concerns and specific reasons when pregnancy outcome is being analyzed and used and it's beyond general surveillance in most cases I think and that's why I voted no.
- Erin: Okay, based on this we will move beyond the other value sets for this instance and move on.

Other potential data elements related to pregnancy.

- These are other data elements found during background research. (*See slide deck for more details*)
- Many of these are related to the mom or A lot of these are about. Related to the mom or the baby, not necessarily to the pregnancy. Does anybody have anything that either is listed here or is not listed here that they would like to bring to the group to talk about? This is your chance to bring something to the table that we haven't discussed.

Polling – Additional Pregnancy Variables

- Are there any other pregnancy related variables that need to be added as recommendations for core data for surveillance?
- Results: Poll 4: (n = 32); Yes = 1; No = 31



- Erin: Looks like most people feel good about what we've come together to discuss today. For the individual who voted for more variables, please feel free to submit information to us on our feedback form for consideration.

Next Steps

- JMC will move forward on Pregnancy recommendations draft.
    - We will share the draft for feedback when it's ready for the Data Element-Specific Team comment before it is shared with the broader DSWG.
    - Please be sure to keep an eye out for the request and we look forward to your input.
- Industry and Occupation will take on this time slot beginning October 20. Feel free to sign up for other data element-specific teams on the interest form here
- Additional input is always welcomed from DSWG members on the form located here.