Meeting: CSTE Data Standardization – Medications -Data Element-Specific Team Meeting
Date: July 12, 2024
Attendees: 48

CSTE (3)	PHAs (25)	CDC (17)
Becky Lampkins Gillian Haney Meredith Eddy **JMC (3)** Erin Kough Laura Lane Sam Spoto **Unknown (0)**	<u>DSWG Co-Chairs</u> Judie Hyun | MD Laura Erhart | AZ <u>DEST Members</u> Aaron Bieringer | MD Alan May | AR Alina Paegle | UT Annaliese.Mayette | NM Beth Isaac | NYC Cory Cline | NM Ed Hartwick | MI EJ Klingler | NYC Elizabeth Kessler | NV Elizabeth Lando-King | MN Elizabeth Schiffman | MD Janet O'Connor | SC Jessica Kumar | NY Jill Krause | NB Karene Thomas-Watts | CO Kayleigh Nerhood | GA Kristin Goldesberry | IL Lunden | IN Mario Beltran | MD Stella Tsai | NJ Stephanie Moberg | NM Steve Eichner | TX Theron Huntamer | NV	Angie Agunloye Doris McGinness Fatima S. Itir Cole Katherine DeBord Lauren Korhonen Laurie Barker Luis Hernandez | GDIT Mary Alao Nicola Thompson Noreen Kloc Peter Boersma Robert Pratt Sara Johnston Shawn Arshad | GDIT Sonya Zhan Sophia Cantor

**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*):

Medications Data Elements

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
    - Identifiers – second call 7/19
    - Laboratory – first call 8/9
    - Reporting Source – first call is 8/16
    - Race/Ethnicity/Tribal Affiliation
    - Social Determinants of Health
- 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

- DSWG members will soon receive draft recommendations for feedback, including
    - Exposures, Risk Factors, and Underlying Conditions
    - Signs, Symptoms, and Clinical Manifestations
    - Disability

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.

Medication Data Elements

Medications only – pulse check

- There was an acknowledgment of the original billing of this DEST as covering medications and treatments, however there was a shift and this call will now only cover medications.
- This call will not cover treatments will not get into ways to capture and transmit data related to non-pharmaceutical treatments, medical devices or other procedures.
- This path was taken to address the information most transmitted by current message mapping guides**.**
- Anyone who would like these other forms of treatment to be covered in future efforts was encouraged to share their input.

Medications: Current State (Cholera and Vibriosis)

- Here is an example of how medication data is collected in the Cholera and Vibriosis tab of the Foodborne and Diarrheal Disease MMG.
- Here, there is a non-repeating element that indicates whether an antibiotic is being used.
- This is followed by a repeating group to capture some of the details of the drug or drugs taken. Similar repeating groups and data elements are utilized in several other message mapping guides using similar or analogous Data element names and descriptions.

Medications: Current State (STD MMG)

- The STD MMG asks about which medication was administered, the start date, and the duration.
- It then goes beyond the other MMGs and captures additional information on the date treatment was prescribed and the dosage, route, and frequency.

Proposed Data Element: Medication Indicator

- The data elements being proposed today are a combination of the two approaches that were just outlined.
- First, there is a proposed Medication Indicator. This data element captures the most basic information – was a medication prescribed. With a Yes/No/Unknown value set, this data element makes no assumptions about whether a person filled the prescription or took the medication. It is just asking if something was prescribed for this condition.

Proposed Data Elements: Medication Repeating Group

- The second part of the proposed data element is a standard and universally useful repeating group for capturing information about the medications referenced in the Medication Indicator data element.
- Many of these data elements will be discussed further, but this base standard is currently proposed to include: Medication name and Medication status – for example, whether it is only known if a medication was prescribed or if there is confirmation that the medication was taken or administered Date Medication prescribed Date Medication started Date Medication ended

Medications: Core Surveillance?

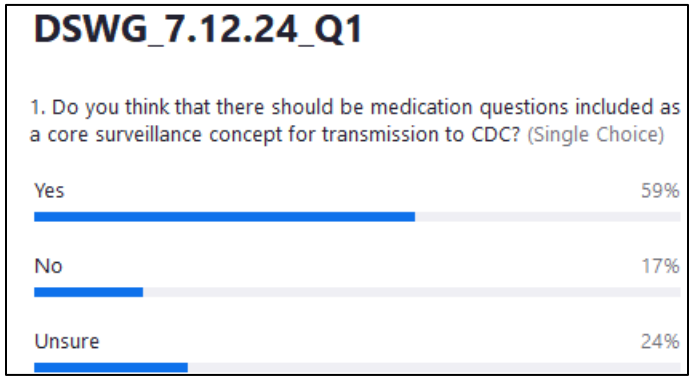
- The discussion will start today with the question of whether the members of this team think that medications as a data class should be something recommended as part of the core surveillance data set, which is to say that there would be a place for medication information in something like a GenV3 message mapping guide. Data might not need to be sent in those fields, but they would exist just in case they do need to be sent.

- Regardless of whether medications are included in core surveillance recommendations, we will be discussing these data elements today as part of information gathering. The discussion was focused on hearing thoughts and opinions about medications as a core topic.
  Discussion
  - EJ Klingler asked, regarding the STI STD MMG, if there's a mention of dose. If we adopted these medications for course surveillance, which do not include dose, would the recommendation for STI be to not report it in the Gen. V. 3 that we're considering? Instead, should they report this information in their own MMG?
    - Erin Kough noted that the idea is to have a universal base for the data, with the possibility for other CDC program areas to add specific details if needed. This base would serve as a standard, and program areas like STIs could include additional elements if necessary. The goal is to recommend a standard set of data elements that are consistent across different areas. If more details are required for certain areas, they would be specified separately, but they wouldn't be part of the standard base.
    - EJ replied that it made sense but also seems like it would require duplicative effort for the program to report the data both in a generic version and in their own specific version.
    - Peter Boersma noted that our intention is not to have duplicative information. We wouldn't have two repeating blocks with a large overlap. Instead, a condition-specific guide would start with these six data elements for medication. If additional information, such as dose, is needed, it could be added, but it would be in addition to the initial elements, which would only be sent once. There's a lot unknown about what the future generic version will look like, and it's being shaped by these and future conversations within this group. There is not a clear answer yet, but I can say that we wouldn't be asking for two repeating groups with a 75% overlap of data elements. Consideration is being made to reduce duplicative efforts.
  - Ed Hartwick commented that from his angle on this, is there an understanding of how many condition-specific MMGs currently ask about medications? If it's only one or two, it might be best to leave it as a condition-specific data group. However, if 90% of these MMGs ask for it, we should consider incorporating it into the more generic version 3 since everyone would be using it anyway.
    - Elizabeth Kessler noted that with the MMG, less than half includes information about treatment. From her experience on the program side, those programs have a standardized approach to what constitutes treatment for a disease. For example, for STDs, there are about five medications to monitor. When considering whether to apply a generic standard across all diseases, her answer is no, because not all diseases have clear guidelines on relevant treatments. If pulled from RxNorm, a patient's hospital records would list every medication, like saline or Tylenol, which may not be relevant for conditions like foodborne illnesses where only specific antibiotics are needed based on the bacteria or virus. Standardization of treatment information hasn't been achieved outside of STD, TB, and COVID.
    - Ed wondered if it would then make sense to have a more generic question like, "What medications were prescribed?" and then use the RxNorm dataset as potential variables for that. This approach would be quite open-ended, right?
    - Elizabeth replied that if a patient is in the hospital for a week. They can be on 20 different medications a day if they're getting administered things hourly. You would then see an entry for every single one of those.

- Ed clarified that the result might not be as filtered as we would like. Without specifying which medications are relevant, we might end up with an overload of data, such as all 44 medications administered in the hospital instead of just the five that are important.
- Elizabeth responded that yes, which is where we see the issue. If this approach were applied to GenV3 instead of the disease-specific MMG, it could become problematic. Therefore, if we continue using disease-specific MMGs, it would be beneficial to follow the same format for each. This consistency would make onboarding much easier.
- Erin Kough moved the conversation forward by noting the concerns addressed and that, and the conversation will revisit this topic later. She clarified that regarding the RxNorm value set, the plan is to use it to accept and validate any medication within the RxNorm terminology. However, program areas can suggest a subset of medications of interest for specific conditions. These suggestions would not be prescriptive lists but rather recommendations for jurisdictions. CDC aims to balance the need to update value sets by accommodating a broad range of data while allowing program areas to specify more relevant details. Peter can provide more insight into this approach. We'll discuss the RxNorm specifics further later in today's discussion.

Poll 1 (n= 29) – Medications as Core?

The first poll will help determine where the conversation might go today. The answer to this poll will not shut down discussions of these data elements for the day. It will give our team guidance as to what should or shouldn't be included in recommendations for something like a GenV3 MMG.



- Erin noted that it seemed most people think it's important, but the results indicate this is still undecided.

Proposed Data Element: Medication Indicator

- The conversation moved on to the next topic because it's something that also needs to be addressed. The group can decide later whether to poll it as core or not, and any poll at this point might be non-binding. Erin reminded the group that the DSWG is aiming for an 80-20 consensus, and about 57% of the group felt this should be considered. Here, we will discuss the idea of a general medication indicator that simply asks whether a medication was prescribed. Do you think this would be useful for the medication indicator? This question is relevant for both jurisdictions and program areas.

Discussion

- Elizabeth Schiffman commented that there's still room to recommend this as a core element. She understands the concerns about overwhelming medication lists from patient charts. However, she believes it could be useful as a core element. One approach could be for CDC programs to provide a list of specific drugs of interest so that only those are reported and any other medications are excluded. This might help manage the issue of long lists while still standardizing the data. Despite the challenges, it seems common enough to warrant standardization.
- Alan May noted that the use case for acute conditions is clear, as the medication should have been administered by the time we received the case report. However, defining the use case for chronic conditions is more challenging, as treatment may occur after the case investigation has been completed.
- Robert Pratt asked if we are planning to include a list of medications or if we should just have a field where people can indicate if a medication was prescribed. We're not considering a dropdown list with 200 medications, are we?
    - Erin noted that the implementation would depend on each jurisdiction, as every system is different. The idea is to allow states to submit whatever data they can if it aligns with RxNorm terminology. Additionally, to address Ed's previous question, currently, 10 out of 18 published MMGs include some form of medication information.
- Ed Hartwick commented that standardizing this variable is very important to reduce current variations. Standardization helps provide a clear reference for others and can guide improvements in EHR systems. However, when considering whether it should be a core element, we need to evaluate if it's beneficial to include something that's only relevant to just over half of the MMGs. If the other half doesn't prioritize medication information, including it as a core element might be seen as a waste of core space, potentially leading to situations where it's disregarded for certain conditions.
    - Erin Kough replied that this comment makes sense and wanted to emphasize that even as we vote on core elements, which have been our focus, CDC is keen on standardization. So, regardless of whether something becomes a core element, it's important to have these discussions because the goal is to achieve standardization across the board.
    - Peter Boersma added that, it might be helpful to think about this in terms of consistency. When we ask about this, we should do so in a consistent manner. Let's discuss the best way to frame these questions so that they are uniform wherever they are used. Although we may not fully know what it will look like, our goal is to ensure it appears the same across all uses.
    - Ed agreed with this as a key point for standardization. By having a well-defined set of standardized variables, programs can easily create MMGs with a consistent medication template. This way, when a program needs to include medication information, they can use this pre-established template, making it straightforward to integrate and adjust as needed.

Proposed Data Element: Medication Repeating Group

- Now, we will focus on the idea of a standardized, base repeating group. The idea here is to establish a universal base for medication repeating groups to make sure that all programs are collecting similar data in the same format. Ideally, this would help jurisdictions more efficiently onboard and would allow for comparability of data on the CDC side. CDC program areas would be able to add questions to the standard, base

repeating block for individual conditions, and program area needs. We want to consider what would be included in such a standard and decide if the repeating group should be recommended for core surveillance.

Proposed Data Element: Medication Repeating Group (table)

- Here are the proposed data elements for discussion. We will have further discussion of the details of most of these data elements after a couple more general polls about the repeating group itself. In general, do these make sense as a repeating block? Or is there anything that this group does not like?

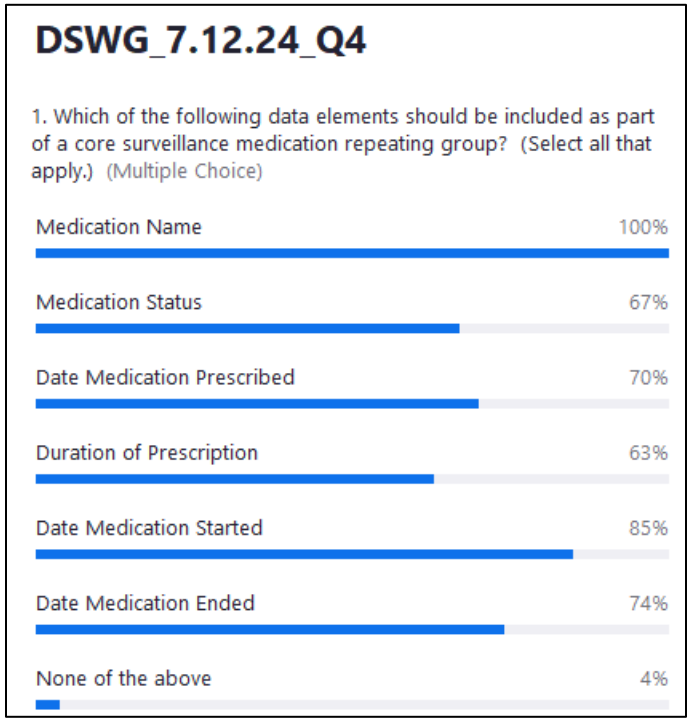
  Discussion

  - Ed Hartwick wondered if the value sets for "prescribed," "administered/taken," and "unknown" are mutually exclusive or if they can overlap. For instance, could a medication be both prescribed and administered/taken or could it be administered/taken without being specifically prescribed?
    - Erin commented that this is indeed a confusing area, and we will explore this further. The key question here is whether having a clear distinction between terms like "prescribed," "administered/taken," and "unknown" would be helpful or not.
    - Elizabeth Schiffman noted support for having a standardized method for collecting data. However, fields like medication status and dates (started, ended) can be challenging to gather and may not be useful for some conditions. That said if there's a way to provide only the relevant data if desired and clear guidelines on how to do so, there wouldn't be a problem with these fields.
    - Erin clarified that RxNorm supports both generic and brand names. The base would cover essential elements, with additional details like dosage added for specific needs, such as STIs or other conditions requiring tracking of medication usage. Think of it as a base layer (the cake) with the flexibility for programs to add their own specifics (icing and decorations). With that in mind, a determination was made to proceed to poll four to help gauge opinions on a standardized medication repeating group.

Poll 4 (n = 27) – Medication Repeating Group data elements

Select what you think would be reasonable in a standard, base medication repeating group regardless of it being technically considered "core." For

example, if medications are not included in a GenV3, we still want to establish a standard repeating group for use within condition-specific MMGs.



Proposed Medication Value Set

- Now we have discussed some of the higher-level questions, we would like to spend a little time on the details. First, we will discuss the updated suggested value sets for the medication names. The proposed solution is based on RxNorm, which is a terminology that contains all medications (generic and branded) available in the US market.
- RxNorm functions by looking across 14 source vocabularies, including CVX and SNOMEDCT-US, and groups the data into concepts. As an example, RxNorm might collect many Naproxen concepts from its source vocabularies and group these as synonyms of one single concept, which they define as the concept indicated at the bottom of the figure here. The system will take values like Naproxen and concepts from its source vocabularies, grouping them as synonyms under a single concept. The proposed value set for the medication name data element includes all RxNorm values. To clarify, all RxNorm sets will be accepted and validated for onboarding purposes. The goal is to allow jurisdictions to submit their data with minimal system maintenance needed to align with a more specific value set. CDC program areas can suggest condition-specific subsets of RxNorm values, but all submitted items, even those outside the suggested subset, will be accepted.

Proposed Medication Value Set (continued)

- The proposed value set for the Medication Name data element is that all RXNorm values will be accepted and passed validation. The idea behind this is to hopefully allow jurisdictions to send what they have without an unreasonable amount of system maintenance to try to fix up whatever they might receive from outside data sources to match a more specific value set. CDC Program areas would be able to suggest condition subsets of RxNorm values, but anything could be accepted, even those items not included in the suggested subset. Would this aid or hinder Jurisdictional onboarding work? Would this still fulfill the needs of CDC program areas?

  Discussion

  - Peter Boersma provided additional clarification that the CDC will be looking for medications received for that condition.
  - Erin Kough clarified that we specifically want to address the inclusion of medication names like Naproxen rather than broad categories such as ibuprofen prescribed in hospital settings. The question is whether this approach would help or hinder jurisdictional onboarding work and if it meets the needs of CDC program areas. Do jurisdictions find this approach easier compared to the current specified list? Or does it make a difference?
  - Ed Hartwick noted that he had a couple of technical questions, such as whether there will be a good API to query RxNorm or if we'll need to manage and update these lists ourselves. On the positive side, having a single, specific list of medications in a dataset is appealing. Over the years, managing multiple lists for different conditions has been somewhat burdensome. A unified list would simplify this process and reduce confusion. However, if the list includes every possible medication, we might still need filters to exclude irrelevant items, like ibuprofen, unless it is specifically of interest. Overall, I see more benefits than drawbacks to this approach.
    - Erin noted that in the comments, it was stated that UMLS has APIs to RX Norm codes.
  - Steve Eichner had a couple of quick points. First, the new proposed final rule from ONC (HCI) references a specific version of RxNorm standards, though he was unsure which version, but it's mentioned in the proposed rule dated December 4, 2023. Second, if flexibility is allowed for using different versions of RxNorm, it's important to specify which version is being used when submitting data. This ensures that the CDC can accurately interpret the data based on the correct version number.
  - Alan May wondered if RxNorm is hierarchical. For example, can a jurisdiction submit just "Naproxen," or do they need to provide a more detailed concept that includes specifics like dosage and route, along with "Naproxen"?
    - Peter Boersma confirmed that, yes, RxNorm is hierarchical and includes relationships like "has the ingredient of" or "is an ingredient of," allowing for both general and specific codes. This means jurisdictions can submit a broad code like "Naproxen" or a more detailed code with specifics like dosage and route. CDC can then use these relationships to interpret and integrate the data. Jurisdictions might only know the high-level drug information, but the system allows for flexibility, accommodating both detailed and general submissions. This approach balances the need for detailed data with the practicalities of what jurisdictions can provide.
  - Alan May added that it's likely that EHRs provide detailed descriptions, including dosage and route, for medications administered. However, in some jurisdictions, like ours, we have limited EHR usage and might not fully adopt EHRs for some time. For the foreseeable future, we will continue to gather medication information from case interviews or physical records, such as faxed medical records.

        - Erin Kough noted that the goal of this effort is to capture all relevant medication information, whether it comes from case interviews, faxed records, or, eventually, EHRs. The idea is to allow submissions at any level of detail within RxNorm, up to the ingredient level, to ensure that all data can be captured and utilized effectively.
        - EJ Klingler agreed that EHR adoption will take time, and we often receive data from faxes or provider reports that might not align perfectly with recommendations. My question is, can we submit unusual or non-standard dosages using RxNorm? For instance, if a medication is prescribed in an atypical dosage for a specific disease, will RxNorm accommodate such variations?
        - Peter Boersma commented that, yes, current medication value sets include various levels of RxNorm codes, so you can submit general codes like "Naproxen" as well as more detailed or nuanced codes. If you receive a more specific code, you can send that directly without needing to map it to a higher-level code.

Proposed Medication Status DE

- Our next topic of discussion is the proposed medication status values. We specifically asked whether the current value set, which includes "prescribed," "administered," and "unknown," is sufficient. We've also added "taken" to address cases where medication use is reported during a case interview, such as asking if a patient completed their course of antibiotics. The question is whether this set of values effectively differentiates between what was prescribed and what was taken. The intention is that "prescribed" indicates that a medication was prescribed but doesn't confirm if it was taken, while "taken" would mean the medication was both administered and consumed. If a medication was administered and taken, it would not be necessary to also state "prescribed and taken," as the assumption is that all administered medications were initially prescribed. We are seeking input on whether this approach is helpful or if there are better ways to capture this information.
  Discussion
    - Elizabeth Schiffman noted that as a vector-borne disease specialist, this question about medication status is not very useful. She felt we could only confirm whether a medication was prescribed and not much more. However, she recognized that other disease areas might have different perspectives. Overall, this data element seems to have limited utility.
    - Elizabeth Kessler understood Elizabeth's perspective, especially from an STD and hepatitis standpoint, where distinguishing between prescribed, administered, and taken is crucial. The recommendation is to include this data element but allow programmatic discretion. It should be included as a potential data point but not mandated for all programs. The idea is to provide flexibility, making it optional for programs to collect this information based on their needs. Additionally, there's a consideration about separating "administered" and "taken" in the value set. In certain contexts, particularly in programs focused on issues like antibiotic resistance, separating these could offer more valuable insights, as it distinguishes between what was reported by the patient and what was administered.
    - Beth Isaac had a question about clarifying the definitions of "administered" and "taken." Specifically, she expressed concerns about whether these terms refer to starting or completing a course of medication and how they are intended to be interpreted in the context of the data element.
        - Erin Kough commented that the question/discussion seeks clarification on the definition of "administered" and "taken," particularly whether these terms refer to the entire course of medication or just the initiation of treatment. The aim is to gather input and clarify how these terms should be interpreted.

- Peter Boersma noted the discussion highlights that the terms "administered" and "taken" are intended to be broad, indicating that a medication was started or taken. The goal is to keep the definition high-level rather than specific to various scenarios. Feedback on how these terms should be applied is encouraged.
- Beth replied that from the perspective of pertussis treatment, distinguishing between initiated and completed medication is crucial. However, it's acknowledged that the importance of this distinction may vary depending on the condition and investigation level.
- Ed Hartwick noted that the idea is to approach data variable construction by distinguishing between "administered" and "taken" as separate values, given that they serve different purposes and contexts. For example, in tuberculosis (TB) management, the specifics of medication administration versus patient-reported adherence can be crucial. To address this, a suggested approach is to create a standardized list of acceptable values for medication status—such as "administered," "taken," and "prescribed"—that can be selected from a predefined set of options. This would provide flexibility while ensuring that the data collected remains relevant and useful across various conditions. The goal is to maintain a level of standardization while allowing for some customization based on specific needs.

Proposed Medication Duration

- The last discussion point is regarding the duration of a prescription and medication start and end dates. Are these capturing what should be captured? For example, the prescribed duration vs. how long the meds were taken. What happens if there are refills? Are these realistically captured in a reliable way?

  Discussion

  - Elizabeth Schiffman noted that from a vector-borne perspective, the prescribed duration is often the most accessible and reliable data. Relying solely on start and end dates may lead to incomplete data. Therefore, it would be beneficial to collect the prescribed duration while acknowledging that obtaining accurate end dates can be challenging.
    - Ed Hartwick agreed it would be beneficial to have the ability to collect this.
  - Alina Paegle noted that from an ECR perspective, medication-specific analyses reveal that the medication activity template includes guidance for distinguishing between administered and prescribed medications. This template also provides information on dates and duration, which helps make these distinctions. Therefore, she would support including all three elements—prescribed duration, medication start date, and end date—if feasible.
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Next Steps

- Look out for the next steps for this DEST via email.
- Upcoming team meetings
  - 7/19, 1-2 pm ET, Identifiers
  - 8/9, 1-2 pm ET, Laboratory

- 8/16, 1-2 ET, Reporting Source
- The next large DSWG call will be on August 30, 2024.