Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTIC TASK FORCE 2023 MEETING

July 12, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Hans Buitendijk	**Oracle Health**	**Co-Chair**
Shelly Spiro	**Pharmacy Health Information Technology Collaborative**	**Co-Chair**
Pooja Babbrah	Point-of-Care Partners	Member
Chris Blackley	Prescryptive	Member
Shila Blend	North Dakota Health Information Network	Member
David Butler	Curatro, LLC	Member
Steven Eichner	Texas Department of State Health Services	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Summerpal Kahlon	Rocket Health Care	Member
Steven Lane	Health Gorilla	Member
Meg Marshall	Department of Veterans Health Affairs	Member
Anna McCollister	Individual	Member
Deven McGraw	Invitae Corporation	Member
Ketan Mehta	Micro Merchant Systems	Member
Justin Neal	Noble Health Services	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Naresh Sundar Rajan	CyncHealth	Member
Scott Robertson	Bear Health Tech Consulting	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Christian Tadrus	Community Pharmacy Owner	Member
Sheryl Turney	Elevance Health	Member
Afton Wagner	Walgreens	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Tricia Lee Rolle	Office of the National Coordinator for Health Information Technology	ONC Program Lead

Name	Organization	Role
Tegan K Boehmer	Office of Public Health Data, Surveillance, and Technology	Presenter

Call to Order/Roll Call (00:00:00)

Michael Berry
Good morning, everyone, and welcome to the Pharmacy Interoperability and Emerging Therapeutics Task force. I am Mike Berry with ONC, and we are always glad when you can join us. This task force meeting is open to the public, and your comments are welcome in Zoom chat throughout the meeting or during the public comment period that is held around 11:50 Eastern Time this morning. I would like to begin rollcall of our task force members, so when I call your name, please indicate that you are present. I will begin with our cochairs. Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Shelly Spiro?

Shelly Spiro
Good morning.

Michael Berry
Pooja Babbrah?

Pooja Babbrah
Good morning.

Michael Berry
Chris Blackley? Shila Blend? David Butler? Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Raj Godavarthi? Adi Gundlapalli? Jim Jirjis? Summer Kahlon?

Summerpal Kahlon
How are you?

Jim Jirjis
Jim Jirjis is here.

Michael Berry
Thanks, Jim. Thanks, Summer. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Meg Marshall? Anna McCollister? Deven McGraw?

Deven McGraw
Present, good morning.

Michael Berry
Ketan Mehta? Justin Neal? Eliel Oliveira?

Eliel Oliveira
I am here, good morning.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Here, good morning.

Michael Berry
Scott Robertson? Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Christian Tadrus is not able to join us today. Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Afton Wagner?

Afton Wagner
Hi, good morning.

Michael Berry
Good morning, everyone, and thank you so much. Now, please join me in welcoming Hans and Shelly for their opening remarks.

Hans Buitendijk
Shelly, do you want to start?

Opening Remarks (00:02:21)

Shelly Spiro
Yes, I will start. Good morning, everyone. Thank you for joining our continued very important work we are doing. We appreciate everybody's support. Continue to put your comments into the chat. We will be glad to look at them. I will turn it over to Hans.

Task 1 Short Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities (00:02:43)

Hans Buitendijk
Good morning, everybody. We really appreciate everybody joining again, both from the task force and the public, and a special welcome to Tegan Boehmer, who we will hear from shortly, so, welcome. We are going to progress with a couple different parts. We see in our agenda that is being displayed that we are going to begin with a review of some of the short-term recommendations that we have talked about in the prior meetings, then we will switch over and have a presentation by Tegan today, at which point in time we are going to then progress with the long-term recommendation discussion from there. So, today is going to be a little bit of a shifting over from short- to long-term, and starting to progress that in the spreadsheet, as we will see in a moment as well. Again, welcome. I am looking forward to the discussion and updates. Shelly, unless there is anything on the agenda that you or Mike wanted to highlight, I think we are ready to jump in. Anything else before we go?

So, clarifying the charge, at this point in time, we are in between short-term and long-term recommendations around public health emergency use authorizations and prescribed authorities, and then we will go into the next topics in, I believe, two weeks from now because next week, we will be on long-term recommendations as well. We are going to start that with looking back at our conversations that we have had. That is where Tricia Lee is going to share the spreadsheet, and we will start with looking at a little bit of reorganization that we did, given the comments made, and trying to begin blending that into a recommendation. So, can you start to share the spreadsheet that is marked as Topic 1, Recommendations? Is that visible right now? There it is. Great. So, what you see in this spreadsheet is slightly different than what we began with. What we began with is still available on another tab. It is another tab that has the red banner, Topic 1 Discussion Notes, at the bottom, and we are going to be focusing on the one that is marked as Topic Recommendations with the green bar at the bottom. So, that is where we will be looking at this point in time.

In the left-hand column is where, based on the comments and discussions that we had, we started to identify a number of different themes. As you gently scroll down, there is standard and data exchange, particularly

pharmacist/physician collaboration. The next one is going to be the pharmacist/public health, etc. So, we start to organize our comments in these different themes. We believe that we captured all, but double-check that they are there as well, or you may have some additional comments to add. What we then started to do, but did not intend to provide recommendations for everything, was to particularly look at the ones that we felt a little bit more comfortable with or wanted to have some examples of what would potentially translate into recommendations.

So, in Column B, the draft recommendation column and the rationale, is where we split it up in that cell into the short-term A and B topics, and they are repeated in each one, and then draft recommendations that we can discuss for each one of those. The fact that in Row 3, Column B, under short-term read, there is nothing yet there does not mean that we did not think there was nothing there at all, it is just that, as we are going to work through, we will identify what we would like to put in there as a recommendation that is applicable to that question. What we have to consider, though, is that if we do not have anything to recommend in a particular box, that is okay too, but we are going to go top to bottom in a moment to see if there are any major things that we want to put in these boxes and then work through. We are not going to stop at the long-term rows that you see today. That is part of the presentation today and the rest of the discussion later today, and next week, we are going to focus on that.

So, as we progress, if you have additional comments or thoughts on the standards of data exchange or any themes that you see during the meeting, we gather them as well. We are going to expand that in Column A, and then, between now and next week, we are trying to get as close as possible to a good set of draft recommendations that we can then fine-tune. That leads me to the last comment before we jump in. Today, we are not trying to get to final recommendations. We just want to make sure that the focus of a recommendation is captured in Column B as much as possible, and we are going to invite everybody on particular areas to draft what a recommendation could look like on the topic that we are talking about. So, again, we are not going to dot Is and cross Ts, but make sure that we capture the major intent of the recommendation. So, with that, first, are there any questions on the adjusted layout or comments from that before we jump in? I see a hand being raised. Summerpal, go ahead.

Summerpal Kahlon
Good morning, everyone. I just wanted to make a comment and see if the group has any thoughts. A lot of what is here is focused on data exchange, or information exchange, so to speak, but based on what the speakers last week mentioned, it seems there is also an issue of communication and data as a source of communication. So, I heard discussion of inventory, for example. “Do you have this drug in stock?” or “Has this person had their vaccine already? Is it okay to give them one?” So, I am curious, in lieu of having something like a giant, nationwide Teams chat, is there a role for something like direct messaging or some sort of vehicle for communication between the various points of care in addition to data flow? So, I just wanted to put that on the table and get any feedback there.

Hans Buitendijk
That is a great point. We have seen a little bit of that in some of the notes. If we go to public health, there is some information or discussion around inventory, and that would definitely be a potential actual recommendation in one of these themes to say we need to focus on the ability to provide more real-time communication and what we can do, whether it is direct or otherwise, to do that. So, do not look at Column B as everything that we translated in recommendation and did not see anything more. It was just a start to

begin the discussion today, and we are going to go from top to bottom, and identify missing pieces like that. So, they are all fair game to bring up and then start to put that in Column B as a direction of a recommendation and start to translate the comments and the questions that were raised in Column A into what we think ONC themselves, in collaboration with other parties in the industry, should be focusing on.

Steven Eichner
Hans, this is Steve Eichner. I just want to say, before I forget it later on, because I am likely to, that I think one of the other challenges in looking at messaging is looking at what becomes the source of truth for a particular patient in terms of looking at what is actually accurate at any given point in time. If we are looking at multiple sources of data, how quickly can you reconcile the different sources, or is there a single place that you can go as the truth for that patient?

Hans Buitendijk
Great point, and I think that will be something I certainly want to note, and in the right spot, is it something between pharmacist and physician that we are trying to figure out what the truth is and add it there, or is it more standards in data exchange? The sequence of the themes here was not in any particular order, other than along the lines of the sequence in which the comment came about. So, at this point in time, do not look at them as any higher or lower priority exclusive or inclusive of everything. We just started to organize like comments together. So, this will be a great point in pharmacist/physician if we feel it is the right place to do it, or maybe there is another one, and if we feel there is not a theme that comes up that is not covered, let's not hesitate to add an additional one where it is appropriate.

Steven Eichner
Just to follow up on that particular one, I am not sure that it is pharmacist/physician collaboration alone because you certainly have immunization registries in play as well.

Hans Buitendijk
Good point.

Steven Eichner
Not to prioritize one versus the other, but where does it go and where does everybody look at for the source of truth?

Hans Buitendijk
At this point in time, we can start to jump in, effectively, to Column B, but start with this one. What would be a recommendation on how to address and resolve understanding of a source of truth? So, it is a challenge. What would be a direction of a recommendation that you are thinking of that could help improve upon that?

Jim Jirjis
Can I ask a question about that? When you say "source of truth," it sounds like there are various truths. One is what is the patient's vaccination status. This is Jim Jirjis talking here, sorry. The second is do you have the vaccine available in the pharmacy? So, it probably depends on what data we are talking about, right? If we are trying to find immunization status for a patient, one could postulate that ought to be the immunization systems that are the source of truth, but if it is prescribing a medicine or wanting to administer

a vaccine, then the source of truth would have to do with supplies at either a pharmacy or a hospital. Steven, am I misunderstanding your focus?

Steven Eichner
No, you are entirely right. I am not looking for a single source of truth that is comprehensive. There may be multiple sources of truth that are applicable to a particular subset of information. What you may want to avoid is confusion over what is a single source of truth for a particular patient's immunization status. You might end up actually being in a place where there is an attachment in the patient's record that says, "Here is the source of truth that I know about for this particular patient." There may be differences, like an IIS in Texas versus an IIS in Virginia versus an HIE in Washington state.

Hans Buitendijk
Ike and Jim, would you be willing to consider that topic on how to enhance on the ability to understand what the sources of truth are, when and what, to work on that and come up with a draft recommendation for it?

Steven Eichner
I am happy to do so. I would love to have some participation with someone with a little bit more pharmacy and supply experience than I might have. Jim, I do not know if your background includes a bunch of stuff in that space, but I am not all that familiar with supplies, with the exception of what the state pharmacy may release for things like COVID-19 or other pieces. I do not want to miss something, and I would like to get a good, comprehensive recommendation, not just halfway there.

Jim Jirjis
Well, I think we would need provider pharmacists and HIE/public health.

Hans Buitendijk
If you are interested in helping with that, it would be great if we could pull a couple participants together in the chat, and they can draft that and bring it back into the spreadsheet after the meeting.

Steven Eichner
Sounds great.

Shelly Spiro
I think Pooja has had her hand up.

Hans Buitendijk
Yes, and I am just curious whether it ties into the first topic or whether it ties into another one, as we are trying to see where we can go through the different areas and start to touch upon them.

Pooja Babbrah
I think Cathy Graf may have just put this in the chat, but I just want to make sure that we are noting that, for the inventory, NCPDP has a standard they have been working on related to pharmacy inventory, so I think if you are pulling together a small group, let's make sure we pull in Margaret Weiker from NCPDP and others to address that because I think there may be some work already being done with that.

Hans Buitendijk
We probably would try to get members of the task force to come together, and if they could reach out to others, that would be great. Not to put you on the spot, Pooja, but if you would be willing to help facilitate some of that input or be part of that smaller group, it would be great.

Pooja Babbrah
I was just typing that in the chat. You guys can pull me in, and we will make sure to pull in the right folks.

Hans Buitendijk
Great, thank you. Then, let's just stop at each one fairly briefly. We are only going to go until the top of the hour, if I am not mistaken, and somebody will ring the bell when we get there.

Tricia Lee Rolle
You have until 11:10.

Hans Buitendijk
Okay, so that gives a couple extra minutes. Looking at the first one, standards and data exchange, again, let's look at the first two cells, the Short-Term A and Short-Term B, and not dive into Long-Term A at the moment. Those two draft recommendations were jotted down there between Pooja and me. Is that something we are generally okay with, do we have to fine-tune the Is and Ts, or is there something else in either of those where we would say there are other things we should recommend as well as a major topic? Anything that comes to mind? If there are none immediately now, during the meeting, jot them down after the meeting, add them to the spreadsheet, but we are starting to shift into that mode at this point in time. Is there anything that jumps out?

I am looking at some of the comments that were made looking at both Steven and Steven about the recommendation on impact of certification on EHR. Is there an opportunity to serve pharmacy HIT? That seemed to be something in here. Is this longer-term, and therefore we skip that for the moment, or is there something short-term we could do there as well? I see a hand up. Thank you, Steven.

Steven Lane
Hans, I will just jump in. Clearly, the certification of a new subset of health IT is a long-term opportunity, not something that could be pulled off quickly. There would potentially be years of lead-up to that, but it certainly is the case that certification is one approach that we have. Today, of course, we have the certification of the EHR systems used by providers, and potentially, that could be leveraged as a way to support the connectivity with pharmacies, especially from the provider side, making that more available and a lower barrier to entry, but I think the long term, as we have discussed in other task forces, the idea of looking at certification within other portions of the healthcare ecosystem, like public health and pharmacies, which we have talked about, could make a tremendous amount of sense.

Hans Buitendijk
So, effectively, for the short term, we should look at what we can do with the certification program with providers and focus on pharmacies already, and longer-term, what we will come back to is what can be specifically focused on pharmacies and pharmacists.

Steven Lane
That makes sense, yes.

Hans Buitendijk
I will jot a note down here, and then you might have additional thoughts to expand on that. Anybody else before we jump to the next topic of pharmacist/physician collaboration, particularly clinical data sharing?

Steven Eichner
Hans, my hand was up. This is Ike again. To glom on to Steven's point, I think another aspect of certification that might be easier to do in the shorter term as part of a longer-range strategy, or at least consider, is looking at interface certification so that, from a certified standpoint, you can certify the function of health information technology in terms of internal productions; you can also potentially look at certifying an interface to a particular kind of framework, such as what may be considered for public health, so that you are at least passing good information in standard formats and that both the sending and receiving systems would really want these actually being sent in the right and consistent formats. What you may do with it on each end may differ a little bit, but that might be a way of easing into a longer-term strategy.

Hans Buitendijk
Great point, and I have put an additional note there about some of the work that AIRA has been doing with IIS registries and otherwise, digging deep into the immunization flow, where they are starting to look at the actual individual interface as well to validate or learn from that. I see Jim, and then Fil.

Jim Jirjis
I have a quick question to Steven's point about certification being a long-term process. Are we suggesting that, because it is a long-term process, part of our recommendation is going to be that we weigh in on whether we recommend that get started? Because it may make some of these other, more focused certifications, like interfaces, something that people might adopt sooner. Are we suggesting that we ought to certify?

Hans Buitendijk
I am hearing that, and that would then be something for that fourth row. If we believe it is an appropriate thing to begin to work on that, that should be reflected in the long-term recommendation component. Later today or next week, we can further refine it. But yes, definitely consider that and put in your thoughts on what that would look like. What would be a good start, and what would already be feasible now?

Jim Jirjis
The reason I ask, Hans, is that I think we have all observed that it was beneficial to have certification for EHRs, but now that we are talking interoperability, we need public health certification, we need pharmacy certification… There are so many different entities that would need a certification program. One question I would ask of ONC is from a political perspective and cost perspective, is that something that is actually on the table and feasible to expand certifications to these other entities?

Steven Eichner
This is Ike. That is a great question, and not that it resolves the question per se, but the level of additional component is really thinking about what is being certified to what end, in other words, looking at certifying

a process within a particular application or a system, such as an interface, versus certifying how data is managed within a particular system. In other words, there could be two substantially different levels.

Jim Jirjis
That might actually be more doable, right?

Hans Buitendijk
Perhaps that is something to consider, and then we can come back to that with further refinement. What would that look like? It might not be certification. You might have some thoughts around if there are other methods to achieve the goal, which is that we have high-fidelity interoperability among systems that are not limited to the EHR side, not limited to just the IIS side, but that we look at all the interactions that are there. Sometimes, we can refer to interoperability being like a tango. You need two parties or more to make it happen, and otherwise, it does not work. It is not a one-sided event that happens. I would like to move along to the second one, but Fil, do you have anything in particular to standards, or are you ready to jump to the next one?

Fillipe Southerland
I will keep it short, Hans. I was going to suggest, per Steven's comment about previous recommendations, that we cross-reference some of the HTI-1 recommendations and build upon those for specialty EMRs. And then, I was also curious if USCDI Plus was a potential vector. Looking at the next use cases for USCDI Plus, could that play a part here in pharmacy data exchange?

Hans Buitendijk
I would agree that is pointing to HTI-1 comments in both those contexts. How can we manage USCDI, whether Plus or otherwise, to tailor the scope, and how can we address other certification challenges for specialty HIT and focused HIT? That would be great to add. Perhaps you might be able to pull some of those recommendations and see how we can blend that in either of these rows.

Shelly Spiro
Just to level-set, Hans, the term "specialty" has a whole different meaning in pharmacy, so I think that needs to be clarified to both the public and to those of us on the task force. I think it is important to know that when they are talking about specialty, they are talking about different types of care settings, such as long-term post-acute care, pediatrics, rehab, or pharmacy. These are considered specialty because pharmacy has a specialty section that is targeted to homecare or the use of specific drugs. I just wanted to level-set everyone.

Hans Buitendijk
Good point. That term can be used in a couple different ways in that regard. Let's move on to pharmacist/physician collaboration, where we had some comments. Looking at the first two cells there, we have a comment from Steven Lane for a recommendation, and we have a comment that we just picked up from Summer on the need to facilitate direct, real-time communication with pharmacists. Summer, can you clarify a little bit more? Were you particularly thinking about pharmacists, pharmacists and physicians, or anybody in that space?

Summerpal Kahlon

Most specifically between pharmacists and physicians, the prescription and fulfillment process, as well as any testing and related services that may come around that. I think it could be a broader set of stakeholders, but keeping focused on the short term, particularly public health emergencies, is the most crucial collaboration point.

Hans Buitendijk
Great. Would you be willing to elaborate on that and expand on the recommendation a little bit further in the spreadsheets?

Summerpal Kahlon
Sure. Do you mean right now, or just after the discussion?

Hans Buitendijk
No, it does not have to be right now. Right now, as you can see by the purple bar, somebody is in there and you may want to be careful, but after the meeting, there should not be much conflict in updating that.

Summerpal Kahlon
Yes, I can definitely do that.

Hans Buitendijk
Are there other recommendations from the discussion, other than these two that are in the short term so far? Are there any other ones that came to mind that should be captured in here, and any concern with the one that Steven Lane put in the Short-Term B cell? Steven, is there anything you would like to add and clarify there before we move on? If not, we will come back to that, but note that in Row 7, there is a comment from Adi, and we are not going to forget that. We will come back to that either later today or next week, when we have the chance to talk more about long-term in general. We are not going to leave that to the side. Looking, then, specifically at pharmacist/public health collaboration and data sharing, there is currently one there, ONC working with CDC and ASPR, and then, further thoughts there. Is there any consideration there, based on our conversation, to substantially add or subtract, or is there something else we can do where ONC can advance the efforts?

Steven Eichner
This is Ike. Can you zoom in a little bit? It is really tiny. That is so much better, thank you.

Hans Buitendijk
Okeydoke. Any thoughts there?

Jim Jirjis
It is Jim Jirjis with a couple quick questions. So, when we talk about pharmacy/public health collaboration, I think of a variety of different things. I think of availability of meds so that national stockpile resources, etc., can be appropriately allocated, but I also think about things like early detection. So, for example, if somebody is ordering a medication, that may be an independent signal, an order. Is it appropriate to look at whether ordering of pharmaceuticals could actually enhance awareness? Those are the two items where I am just curious if that is what we mean by this.

Hans Buitendijk
Tricia Lee, can you provide a little bit from a scope perspective, whether that ordering part, inventory/logistics from a pharmacy perspective, would fall within the charge? It sounds like it is borderline, so I would like to have your perspective on that.

Tricia Lee Rolle
It is all within scope.

Hans Buitendijk
Okay. Then, yes, Jim, it is fair to make suggestions in that space.

Jim Jirjis
I can add them, but I think the two would be availability of pharmaceuticals and signals to inform surveillance. Those would be my two suggestions. There may be more.

Hans Buitendijk
They sound like Short-Term B topics. Would you agree with that?

Jim Jirjis
I think so, and the two interplay together, too, because if we can get the data on what is being ordered more quickly, then we can anticipate shortages in supply, so the two are linked. They have separate value, but they are also linked, and they both sound like they could be short-term.

Hans Buitendijk
Any concerns with that from anybody? Ike, I see you have your hand up.

Steven Eichner
I was waiting to see if there was any concern, but I did want to make sure that the STLTs are recognized as being important stakeholders from the get-go because disaster response in particular is not only a national issue. State and local governments are very heavily engaged in a wide range of aspects in this space, including, as we experienced with COVID-19, looking at identifying needs and distributing pharmaceutical resources for things like COVID-19 vaccines. So, whatever is adopted at the national level also needs to recognize state interests and support states' data needs as well.

Jim Jirjis
Ike, just a quick comment. I assume that the way public health works is it always starts with local and state, so all these requirements would have to include the entire lifecycle of that data, which flows through the states, and states have important, major responsibilities.

Steven Eichner
Thank you for that. It is always very helpful to recognize in the recommendations that states do have a central role in these kinds of activities, and that there are differences between different jurisdictions, and there may be differences in needs that are not at a completely uniform landscape across the country.

Hans Buitendijk

Yes. Ike, in the first row, Row 8 in Column B, I already started to add STLTs, not just CDC and ASPR, but you may have additional thoughts there to expand and clarify that part. It was not meant to be limited, but I started out with CDC and ASPR.

Steven Eichner
Yes. Like looking at the diverse set of healthcare providers, it is important to recognize there is a diverse set of public health actors that come into play as well. We did not really include other emergencies specifically as related to, but slightly different, from public health, looking at emergency response in the field, like EMTs and the like, which get some data from public health, but they also may be getting data from other resources as well, including directly from healthcare.

Hans Buitendijk
Okay. Any other comments before we move on? It sounds like the intent behind the recommendations that are currently drafted in here is correct, but we need to make some updates and otherwise. If anybody else has a major topic to raise here, we want to make sure. Jim, it sounds like you are going to work through that a little bit further to draft your suggestions there. Okay, data capture. We had a couple of comments in there from Afton and Pooja. We started to show you to put in an initial recommendation for one of the two. Afton or Pooja, any other thoughts there that we should start to translate into recommendations or expand there?

Afton Wagner
Thanks, Hans. I started to think about this a little bit more in what I would put into recommendations. Something else that caught my eye as I was reviewing this was putting data standards in place so that data can be exchanged a little more easily. For example, if contributors are collecting race or gender in different formats, it could be hard to share if it is not all done in the same way, so that is something that I thought of, especially with Paxlovid and different information and immunizations. We are required to collect this information, but if we are not consuming it in the same format, it would not be easy, so I am trying to think of how to put that into a recommendation.

Hans Buitendijk
Okeydoke. When you have that, please drop that into B11 or 12, wherever it might fit. That would be great. Pooja, I see that you have your hand up.

Pooja Babbrah
I think one important topic that we probably need to dig into a little bit more, and I am sure Shelly can help bring experts to the table around this, is the eCare plan, and we talked about it briefly on the initial call, but that is the standard that is being used. It has been balloted at both HL7 and NCPDP to capture some information that pharmacists can share with physicians and payers. The one thing I have heard about this over time is that we need to think more about how we can codify some of the data. So, I do not know if that is something that we also want to do a small group on, but I would like to put that out there, as I think that is really important to be looked at and see where folks are at with that and see if there is additional work we want to do on that as a task force. Like I said, Shelly can probably give an update.

Hans Buitendijk

It probably would be very helpful to get a couple in that conversation. So far, within certification, it is being considered primarily with the mindset of how pharmacy care plan can be part of certification, and then, typically, the context is EHRs, i.e., on the provider side, more pharmacy in that context, but what does that mean for the pharmacists in the community or otherwise? I think it would be great if that could have some thoughts on how you would advance that for both the pharmacists in the community and the pharmacists within healthcare organizations. What recommendations would work? There was somebody else I am trying to recall who made a comment. I am going to say David, perhaps, made some comments about it last week, but there might be somebody else interested to join with that. I see Afton joined, thank you, and perhaps there is somebody else. So, if you can stick that in the chat, it would be great. Pooja, would you be willing to pull them together based on what the list ends up being?

Pooja Babbrah
Yes, absolutely.

Steven Eichner
Hans, this is Ike again. Somewhere between Pooja's comment and background certification, one specific instance of certification that may be worth paying attention to is looking at an interface between some system that the pharmacy is using and IIS. I do not necessarily want to say it should be the pharmacy's medication management system, but again, from a functional standpoint, one of the things that we noticed during COVID-19 in particular is that many pharmacies faced significant challenges in getting data into the IIS because they did not have software available to do so, and without mandating that that come out of their medication management system, that may not be the right place for it to be within their technical infrastructure, but somewhere in that space, it would be a good thing to have, if that makes sense.

Hans Buitendijk
Yes, that would be helpful to further explore as well. We are running into the clock with our agenda, so perhaps, Ike, you might have some additional thoughts, either additional questions or maybe a direction to go, and actually, I would be more than happy to collaborate with you on some thoughts on how that could go. All right, I really appreciate that. With that, we will come back to this. In the meantime, if you have thoughts, start to fill that out in the spreadsheet. As we start to go through, we are starting to get the pattern here, but at this point, we are going to shift over, and we would like to introduce Tegan Boehmer from U.S. Public Health Service, Acting Chief, Actionable Data Branch. There are a lot of different areas there. I also find the CDC very interesting. We get a lot of different centers in there, and the disseminate division as well. So, I am really looking forward to your presentation, and the time is yours.

Guest Presentation and Question and Answer (00:42:31)

Tegan K. Boehmer
Thank you. One thing I did not clarify was whether my presentation slides are part of this deck or I should share my screen. There they are. Great, thank you so much. So, good afternoon, everyone. As Hans said, my name is Tegan Boehmer, and yes, CDC has a new Office of Public Health Data Surveillance and Technology that was stood up in the last six months or so, maybe with the sole purpose to help us be better prepared for future public health emergencies and bring together a lot of our data-related efforts internally and with state and local health departments. My background is as a health scientist and epidemiologist, not as an informatician, so, hopefully, having listened to you guys over the last 30 minutes, this will still be informative as we explain some of what we did and the insights we tried to gain from therapeutics data

during the COVID-19 response. Am I able to advance my slides? Okay, this is our typical disclaimer. You can go to the next slide, please.

So, as you are all aware, there are emergency use authorizations for numerous outpatient treatments of COVID-19. At the Centers for Disease Control and Prevention, our focus was on really trying to understand who was receiving these medications, when and where they were receiving them, and trying to identify early if there were any inequities in the receipt of these medications that could be addressed to help improve our prevention and mitigation strategies. Things that I just heard you talking about related to ASPR and ordering are still public health, but our CDC emphasis really was on trying to identify and then minimize inequities, and so, we looked into multiple healthcare data sources that were available to us to try to garner some insights on this. Go ahead to the next slide. So, I will talk today about some of those data sources and how we acquired information particularly on oral antivirals.

So, in the summer of 2020, CDC began partnering with the Public Health Informatics Institute and PCORnet, the National Patient-Centered Clinical Outcomes Clinical Research Network, and we have a COVID-19 surveillance project, and we have been continuing to collaborate with them for three and a half years now. So, just as a really quick overview of PCORnet, it is a network of networks. There are about 65 participating entities or healthcare systems. Most of these are academic institutions, so one benefit of that is we can see an outpatient emergency department and inpatient continuum of care if it is all within that same, say, academic health system with a single EHR system.

PCORnet has about 30 million individuals seen across these sites each year. They cover many regions of the country, but are not necessarily geographically representative. The strength of PCORnet is that they all come together with a common data model, and then that allows them to query the data that is in the same format, and then, we primarily do that through a distributed approach, so the question or the data that we want is formulated in collaboration with PCORnet, then distributed. We have about 43 of the 65 sites participating in our project. They query their EHR data, then return aggregate results that are then combined into a larger aggregate table. So, at this point, we are working toward getting line-level data, but we do not have that in place yet. Next slide, please.

So, what we did with the PCORnet data was we wanted to capture, obviously, the medications of interest, and so, the intravenous or injectable medications such as monoclonal antibodies and Remdesivir were identified using national drug codes in the medication administration tables. In this case, one of the first papers we did was prior to the oral antivirals, and it only looked at monoclonal antibodies, so, at that point, we were only able to capture if the administration of the medication was done within that healthcare center. So, if it was at an external infusion center run by a partner or the state health department, it was likely not being captured in the EHR.

And then, in the era of oral antivirals, those were identified in PCORnet using the RxNorm codes and the prescription tables. Again, this is our indication that a physician wrote a prescription for the patient, and that is sort of where the chain ended. We do not know if the patient filled the prescription, and obviously, we do not know if they filled it once they took it. And then, this is prescribing within the healthcare system, so anything prescribed by a pharmacist in a test-to-treat-type scenario was not being captured.

One of the strengths of PCORnet and the reasons we had some publications on this related to racial and ethnic disparities is because we have pretty complete data on those patient characteristics, less than 20% missing ethnicity and less than 10% missing race. And also, because of the large sample size and the fact that we are looking at aggregate data rather than line-level data, we are able to keep race at a relatively detailed level, so we can look at native Hawaiian and other Pacific islanders separately from American Indian and Alaska natives, for example, and in a lot of other data sources, anything other than white, Black, or Asian are sort of grouped together as "other." At the time, we did not look at other social determinants of health, but these are some new developments within PCORnet, where they are using the patient's residential address to assign a social vulnerability score, a deprivation index, or even urban/rural status. Next slide, please.

So, here is what we did for this first analysis, where there were nearly 100,000 COVID patients age 20 and older. We looked at the percentage of patients that were seen in that healthcare system with a COVID diagnosis or positive lab test who were prescribed the medication, so we looked at that over time from January to July of 2022. The graphs here show race on the left and ethnicity on the right. We also looked at this in the age categories and by a few immunocompromised states. The disparities were noted by race and by ethnicity. I forgot to mention that these graphs show Paxlovid use. So, you can see the increase over time. It really picked up in April and May. For example, in the left graph, we see the thick black line representing patients of white race were being prescribed these medicines more often than patients of other races. Next slide.

Before I go on to the next data source, I have a few more comments about PCORnet. So, again, many different groups at CDC were exploring different data sources. As I mentioned, in terms of the validity of the electronic health record data, we are only capturing patients that sought care within one of the participating healthcare systems. We were not capturing medications for either prescription administrations or dispensing in settings that were not affiliated with the healthcare system.

So, I already mentioned pharmacies, but also, if it is an independent urgent care type facility, that likely would not be in the EHR. I have heard from one of my colleagues that they may see in the EHR that these encounters existed, but the data does not get pulled into the clinical data warehouse as analyzable or that becomes part of the common data model. However, we do see some that our estimates were similar to other published studies, and we also have some face validity. I did not show the graphs, but we saw higher levels of prescribing among older adults than younger adults, and we saw higher levels of prescribing among people who had immunocompromised conditions.

Here are some of the future directions we have discussed with PCORnet or things that they might be working on. We had about 40 sites participating. We were not able to include six of them in our analysis of Paxlovid because even as of August/September of 2022, they had not yet mapped these oral antivirals to the common data model, so there is just a little bit of a challenge there with particular healthcare systems, and you said it was particularly notable for medications that were under EUA. We did not have any examples of any other new, non-EUA medications, but that was one small challenge. And then, there are efforts under way to link the EHR data with claims or with pharmacy dispensing and vaccine registrations, as there are some future opportunities I think I may have heard you guys speaking of. Next slide.

So, the other data source was the ordering and dispensing data that came directly from the dispensing sites that were reported on a daily basis to the Department of Health and Human Services. That data does not include individual-level data. It is site-level data, and there is a ZIP code that comes along with that data, so CDC worked closely with HHS and ASPR to conduct a study looking at potential disparities or differences in dispensing by the social vulnerability of the ZIP code of that dispensing site, and as shown here, we also noted more courses being dispensed in the medium and low vulnerable populations. Next slide.

That was kind of what I was asked to talk about. In the ongoing email, when Tricia noticed I would have 10 minutes instead of five minutes, I included some information that we also did with claims data. In pharmacy claims data, one benefit of that is we are presumably seeing the vast majority of the community and retail pharmacies that are submitting claims. However, it does require the pharmacy to go through that step of submitting a claim, which I assume is pretty typical. I do not have any firsthand knowledge. You all on the phone call might, but we heard concerns during conversations that because there was no reimbursement for these medications since they were covered by the federal government, some pharmacies may have been less consistent and may not have submitted claims consistently, or they may have been undersubmitted.

Again, generalizability here is limited to insured populations. If there is an insurance claim, then they have insurance, but there are sources for Medicare and Medicaid as well. Most of the data CDC had access to at this time was commercial insurance, so then we get a little concerned about the representativeness of commercial insurance versus public insurance. Typically, the other limitation is that race and ethnicity are not available, so in one of our claims data sources, which is IQVIA, there is no race and ethnicity data with the pharmacy data.

We had another data source that was linked by a company called HealthVerity, which specializes in privacy-preserving record linkage, so the data we were licensing allowed us to be able to link claims data with other data sources, such as EHR and hospital billing data, but because of that linkage to EHR and some of the other data sources, we did have race/ethnicity to a much higher degree of missingness than what we saw in PCORnet, but the higher degree of missingness makes it hard to interpret and to trust those data. And then, of course, we are interested in timely data in a public health emergency, so adjudicated claims have a much smaller time lag than some other data sources. I was asked specifically to comment on any ability to identify test-to-treat patients from others, and that was a topic of many calls and discussions within CDC, and also calls that I have been on with other federal partners, and we have not identified a way to do that based on the information that we had and the data that we had access to. Next slide.

So, I think this is my summary slide. So, as we just said, with the data during or leading up to a public health emergency, I heard you guys talking about being able to use data for detection of anomalies and potential threats, so in all of those instances, we need the data to be accurate, fairly comprehensive, particularly on patient characteristics, and to be available to us in a timely manner. At this point, from a CDC perspective, we would say there is no gold standard. We relied on multiple data sources and looked for corroborating evidence across those data sources, and they all had different strengths and weaknesses in terms of the populations that they captured, how we captured the pharmacy data, whether it is a prescription or dispensing of the medication.

And then, in terms of thinking through potential future directions, here are some of the things that I and my colleague Adi Gundlapalli identified, and I can have him join in on the discussion if you would like to. First, this presentation I gave today is focused on equity, so, having demographic variables traveling with the pharmacy or the therapeutic data would be extremely helpful, whether it can be tied directly or something that can be linked in later, but having it be directly part of it seems potentially more feasible or ideal. We also had an example during the COVID pandemic to public health, and that was the federal retail pharmacy program vaccination data, so that might be a model that could be expanded to include therapeutics as well.

In talking with PCORnet, he had mentioned there are examples of certain healthcare systems tying pharmacy dispensing data with the electronic health record, but it is not being done in any sort of systematic, integrated way, and even when that is happening, it is in a way that the physician or the provider can see it in the EHR, but it does not necessarily become part of the data that might be of interest for folks to analyze at a population level. And then, just circling back to test-to-treat, I am not exactly sure how to tackle that beast, but there might be some opportunities. I will not dive into those too much. I think the next slide is just a thank you and a list of the references, so I appreciate your time and am happy to engage in the discussion and share our experience.

Shelly Spiro
Thank you, Tegan. We appreciate that and appreciate all the information that you provided. Great questions. One thing I would also ask to be included in the future is the long-term post-acute care. They have a different model. Sometimes they are very similar to the community pharmacy model, and sometimes they are very different, and depending on where the data is coming from, whether directly from the facility or from the pharmacy that is dispensing some of those medications, there can be some anomalies and duplications in data. Steven Lane, I think you have a question.

Steven Lane
Yes, thank you so much, and thanks, Tegan, for the excellent presentation. I had a question. Did you collect data especially around the use of antivirals, Paxlovid in particular, regarding other medications that individuals might have been taking at the same time or medications that may have needed to be modified as part of the treatment protocol?

Tegan K. Boehmer
We did not dive into that. I know there are the counterindications and reasons for why folks might not be prescribed one particular medication, such as Paxlovid. One way we got at that indirectly in our PCORnet analysis was we looked at each of the four medication types individually, so we did not look at the specific drugs, but one of the patterns you can see that is likely explained by the issue you raised is that as adults got older, the proportion taking Paxlovid was actually lower, but if you looked at all of the medications, including molnupiravir and, to some degree, outpatient remdesivir, those patients were also getting monoclonal antibodies a bit more often, so our hypothesis was that might have been due to some of the counterindications. We did use other medications as a way to identify compromised immunity, so it would be possible to do what you said, we just did not do it. So, for example, one of our immunocompromised groups was patients on corticosteroids or other cancer-treating drugs. It is possible to do that.

Shelly Spiro
Hans?

Hans Buitendijk
Thank you, and thank you, Tegan, for that presentation. There is one particular part that I have a question around, and that is one of your last slides with future directions as they relate to discussion around claims. Claims data is not always sufficient. It might be missing data, as you indicate, that would be helpful if it came along, or there might just not be a claim for the information for the medication that has been provided. I am curious about a little bit more of your thoughts. Is it always the best way to use, expand on, and enhance the claims transactions to include that, or are there alternatives that you are considering or gaps we need to think about that there are other paths by which the data could be made available as well so that we do not need to encumber claims transactions any more than they have to, and I am not saying that is not the right way to add to it, but it is always one of these questions. What is really the right data flow to make sure that data is shared and not reshared or encumbers another party to manage data that they otherwise do not need to? I am curious about your thoughts there.

Tegan K. Boehmer
That is probably getting a little bit outside of my wheelhouse in terms of not having a strong understanding of the flow of information. I agree with you that there are limitations to claims, which we have covered, and I do not have a solution for it, but it seems like there might be options for other data flows, and it probably is part of what your working group is looking at. I know Adi is on the call. If he has any thoughts based on our activities, I would encourage him to chime in as well. Shelly?

Shelly Spiro
Yes. One of the things that we can look at, because we have a similar problem with the prescription drug monitoring data, or PDMP, is a way to capture information on what the pharmacy is physically dispensing in relationship to controlled substances, but the data can be similar. There is also the use of ZIP codes. It is a requirement from the link to the Drug Enforcement Administration and what pharmacists have to do to link to the state boards of pharmacy. There are other ways of exporting data out of a pharmacy management system rather than a claim, as we know there are many anomalies with the claims-based data, but those anomalies can be less if we use a similar type of model that we are using for prescription drug monitoring data.

Tegan K. Boehmer
Yes, that sounds good.

Hans Buitendijk
Adi, it looks like you want to jump in.

Adi V. Gundlapalli
Thank you, and Commander Boehmer, thank you so much for presenting on our work and conveying it to the task force here. I am sure it will be helpful. The cochairs have really set the tone well here. My only comment would be it is going to be a balance between timeliness and completeness, and then following the flow of not just the prescription, but the actual dispensing of it from the pharmacy, just like Shelly said, because I think that is much more solid in being able to… You can send a prescription, but not all prescriptions may be filled within a timely manner, so I think getting those data are important. Hans, I respect what you are saying about claims data and the challenges.

However, in talking to people in the payer system and my experience, even the unadjudicated claims are pretty good for looking at trends and all of that. At the individual level, of course, we always have to be cautious, but the claims do not change that much. So, if you talk to people from the payers and the large system, they say the unadjudicated claims are quite good for looking at what is going on. There is very little change that occurs in the actual claim later on. So, as you are all mentioning, there is always a balance between timeliness and completeness, and for us, trends are quite important, and hopefully corroborating with other data sets. So, if we look at one large healthcare system or network, I think if we try to reproduce that in another system, the trends give us more confidence in public health insights and action. Again, thank you for this discussion, and I appreciate the opportunity to comment.

Hans Buitendijk
Thank you, and maybe just to clarify, I was not trying to imply not to use claims. The question was more of if there is data missing, is the best path to add it to the claims, or is there a better path, considering some of it is clinical data, to explore another path or a new path to get the data? It is not to remove the claims as a source.

Adi V. Gundlapalli
Absolutely, thank you.

Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities (01:08:03)

Hans Buitendijk
Any other comments before we close on this topic and go to a more general discussion around long-term, taking all this into account? Any other questions or comments? If not, then thank you very much for your overview and insight, and let's move to the last part of the agenda, where we are going to go back to the spreadsheet and generally talk about long-term. We can use the spreadsheet to make our notes, but this is meant to be a little bit more of an open discussion on what, based on this discussion, are other considerations that everybody has and what should be looked at for recommendations in the long-term space. If you want to navigate to one of the ones that has already started to be drafted, please draw us to that. If there is any nuance, then it is open discussion at this point in time. Who would like to jump in first? Otherwise, we are just going to go to the top of the spreadsheet and down again. Shelly, any particular area that you want to jump in based on the conversation before we just follow the grid?

Shelly Spiro
From a long-term standpoint, I think it is important that we look at the data elements that the CDC is really interested in from a public health standpoint on what pharmacies in all practice settings would be able to capture, including electronic case reporting, especially as pharmacies have more access to the patient at multiple times more than they might in going to their primary care providers, so this could be a way of ensuring that that information is what CDC would expect any healthcare provider to provide. Those of us in pharmacy would appreciate knowing exactly where the CDC needs to go in terms of public health for these types of data, not just focusing on the medications themselves, but where pharmacists have quite a bit of ability to capture clinical data that can also be included as they encounter the patient. Jim, and then Ike.

Jim Jirjis
Jim Jirjis here. Just to echo Ike's earlier comment, I think I would add public health, not just CDC, because I think the states have a tremendous benefit from the same types of insights, so it would be a collective effort. Hans, I was going to say if you are going through, looking to see who wants to focus on what, put me down for the public health subgroup, if that is what you are looking for.

Hans Buitendijk
That would be great, and tying those comments together, I am curious about the work USCDI Plus for public health has done already, trying to define a set of data of interest for public health in general. Are you suggesting that perhaps there needs to be a look at that data set and see, from a pharmacist perspective, what is relevant and what is not relevant, what is of interest to be shared with public health, or what is to be shared with the pharmacist. Are you looking in that direction, Shelly, to get a better sense of what data is of interest?

Shelly Spiro
Correct, and moreover, of all healthcare providers having a similar subset of data that pharmacy might not be aware is needed to be collected, such as race and ethnicity, which Tegan has talked about, and moreover, other types of case reporting data than can also be included. Pharmacies have access to quite a bit of data, and our system vendors need to understand what data points they need to be interested in collecting, whether for regulation or through policy and process. That is how we can work with our system vendors to expand those data fields once they have been identified and run through the regulatory process, that these are important pieces of data to collect, and I think that is what is important for the future. I want to go to Ike and Afton.

Steven Eichner
Thank you. I think it is important, as we look back at some of the HTI-1 work, that there is consistent recognition of patients' rights and patient privacy and recognition of being very careful about what data is shared, with whom, and under what circumstances, because there is an awful lot of data out there. Patients really do have an interest in their data and want to understand where it is being shared, with whom it is being shared, and for what purpose it is being shared, and that is bidirectional, to or from a pharmacy or pharmacist, in that space, so we need to make sure that we make some recommendations in that space that we respect patient confidentiality and data security issues.

Hans Buitendijk
Great point. I think it is the last theme at the bottom of the spreadsheet that might benefit from some additional thoughts and suggestions there, how privacy and consent should be managed, or where the gaps are in this particular space there. Great point.

Shelly Spiro
I just want to make sure, Hans, that whoever is making recommendations into this section realizes that pharmacy should be no different than any other practice setting in terms of privacy and consent. They follow the same HIPAA regulations, and so, I want to make sure that the privacy and security recommendations are in line with other privacy and security recommendations for all of the certified EHR vendors and others, that pharmacy should not be doing any different. Afton, I think you had a question.

Steven Eichner
This is Ike. Really quickly, if that is the case, then I would heartily suggest that the workgroup task force look back to the HTI-1 recommendations and discussion regarding data security, privacy, disclosures, and the like, and also pay some heed or give some attention to some of the other discussions that did not make it into the comments and recommendations from HTI-1 because they were out of scope, looking at, again, data privacy consent and a roadmap for sharing information, both upstream and downstream, about patient consent information and redisclosure.

Hans Buitendijk
Maybe along those lines, Ike, Tricia Lee is highlighting the last row there. Perhaps there are some areas which, in part, indicate also where Shelly was going, that there is wider applicability to that. Perhaps this is an area to look further at what else we can state here and how we can improve on that, and how there are also some short-term actions that can be taken.

Shelly Spiro
Afton, did you have a question?

Afton Wagner
I just had a comment, Shelly, and I lost my thought, so let me try to remember it, and I will come back to it.

Shelly Spiro
Okay, thanks.

Hans Buitendijk
Based on some of the comments made and a note earlier from Pooja about perspectives from the pharmacy information management system community, I am curious whether, in some of the conversations we have had whether any of the upcoming meetings and the topics that we have, that is something that would help further inform what these recommendations will be, particularly when we are talking about certification, managing privacy and consent, and managing a variety of capabilities, and that one would be looking at those systems to enable that. Pooja, I am curious whether you have some thoughts around that.

Pooja Babbrah
I have been following a lot of the chat. In a lot of the discussion, there seem to be some open questions about pharmacy practice management systems, and in the chat, I think Kim Boyd even mentioned the pharmacy EHRs. I just feel like we have been so focused on traditional EHRs that it may be worth having some experts, and as I mentioned in my comment, we have some on the line, but maybe we should bring some folks in to help show the functionality or explain the functionality in order for us to have better recommendations because this is the first time we are thinking about certifying for beyond just EHRs, so I think having some kind of presentation or discussion around that is going to be important for level-setting for the task force.

Hans Buitendijk
Do you think that as we consider that, we need to consider the differences or context of different settings, such as pharmacy systems in the community, pharmacy systems as part of larger health systems, or otherwise? If you have any thoughts around that, it would be great if you could pass them along.

Pooja Babbrah
Yes, I think so. I am not as familiar in the long-term care setting, so folks that have that experience can speak up, but within a health system, it is definitely different than a retailer community system that may be being used.

Hans Buitendijk
Thank you.

Shelly Spiro
Ike, we have one minute left before public comment.

Steven Eichner
I am going to take 20 seconds. I think it would be great to have input from a wide variety of vendors because there are a bunch of different environments, and I would like some different functions in terms of looking at inventory management versus patient care management and how those two things interface, so I think it would be really helpful to get an understanding about the variations across the space.

Shelly Spiro
Thanks. Steven?

Steven Lane
Just real quick, and we can come back to it after public comment, and maybe it was mentioned and I missed it, but do pharmacists engaging in onsite COVID-19 testing have a requirement to do case reporting to public health, and have any been doing ECR?

Shelly Spiro
No, there are no requirements.

Steven Lane
That is not good.

Shelly Spiro
If there are, they are state-specific or public health-specific.

Steven Eichner
There are or were requirements, at least in Texas, for any entity that was doing testing using an approved test to report test results to the state, as well as requirements for reporting COVID-19 vaccine administration to the state.

Jim Jirjis
Ike, was that done on paper? Because a lot of the ECR is so dependent upon the EMR.

Steven Eichner

This is not electronic case reporting, this is looking at lab reporting results and vaccine administration, and DSHS accepted things electronically. We expanded it to not necessarily require the use of HL7 or similar reporting because we recognized that some providers would not be able to ramp up that quickly, so we worked with providers as part of a national effort to accept some data using CSD format.

Shelly Spiro
I am going to cut out the conversation and let Mike do the public comment.

Public Comment (01:20:22)

Michael Berry
All right, great, thanks, Shelly. We are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if anyone raises their hand. I see Kim Boyd has raised her hand. Go ahead, Kim. You have three minutes.

Kim Boyd
Thank you again, task force members, for a very lively conversation about the importance of pharmacy interoperability and what you are focused on. I am Kim Boyd with Boyd Consulting Group, and I just want to reiterate what I had put in the chat previously. As you all continue to contemplate how interoperability works, not only between pharmacy and pharmacy management systems into other clinical practices with MDs and other specialty providers, but also across other pharmacies, take into consideration what ONC learned with the EHR certification process and some of the siloes that we have seen in that, and contemplate how to not have siloes in pharmacy interoperability as we expand. Thank you for the opportunity.

Hans Buitendijk
Thank you.

Michael Berry
Thank you. I am not seeing any other comments or hands raised, so I will turn it back to our cochairs.

Hans Buitendijk
There were a couple other individuals that made comments in the chat from the public, so if you have additional insights, that would be great. If not, then Shelly, I think we are back to the discussion. We were talking to Steven Lane about some considerations around case reporting. Is there anything additional, Steven, that you wanted to progress?

Steven Lane
Yes. I think it is a really interesting point, and thank you. Dr. Jirjis, for picking up on it. I think when we are talking about interoperability for pharmacists, what is really most important? There is certain data that pharmacists will need to be able to provide care safely, and there has been a lot of concern raised that they might not need everything, they might not need all the SDOH, family or social history, or whatnot, but they clearly need PAMI data if they are going to provide care effectively and safely. Similarly if that care is going to become part of coordinated, safe care for a patient, they need to communicate back to other members

of the care team what has been done. Sorry, Pooja, I put this in my chat earlier. PAMI is problems, allergies, medications, and immunizations, what is considered the core granular data.

So, I think we really want to assure appropriate interoperability for this care to be safe. ECR is a great example of how the care that is provided by the pharmacist needs to come back into the ecosystem of interoperability, and ECR is such an incredibly important tool. It seems to me that it is the sort of thing where it is great that states did some work on that, but I would think that if we have pharmacists making diagnoses and providing prescriptions based on those diagnoses, that information needs to come back into the system, and ECR is just one of the ways that it should come back, in addition to having that data all be available eventually through TEFCA, the national exchange framework. Thanks for the opportunity to clarify.

Hans Buitendijk
Steven, I would like to add to that some thoughts from prior discussions within HITAC and otherwise with reference to case reporting. A similar kind of conversation has come up in the laboratory space, where walk-ins started to occur, and therefore, it was not just that the lab that performs the test reports back and there is no interaction with the patient because it is from the ordering provider. They are actually the first one interacting with the patient, and in a sense, that is happening here as well, and therefore, having that notion that where a clinician is that first point of contact, assesses, obtains that information, and then identifies potential reportable situations, why not consider them in the same vein so that where it is then appropriate, case reporting to public health, reporting back to providers, or otherwise, it is indeed a fully closed loop across everybody in that way?

And, we are not trying to provide data flows in context of somebody else who was not the first one, or somebody who was the second one, but not the first one. So, that goes back to the larger question of what really would divide data flows to make sure they were as efficient, as optimized as possible, and easy to do, yet everybody gets access to the day-to-day and has authority to get access at the right time. Ike, I think your hand went up.

Steven Eichner
If it would be helpful, I would be happy to get one of my colleagues from public health to do a short presentation at a future task force meeting to differentiate between what is an electronic laboratory report and an electronic case report because they are not the same thing.

Hans Buitendijk
Understood. The question has come up as well of where there is additional data and where somebody is part of that test and treatment process, what are reasonable ways at that point in time? They are clearly distinct, as I think has been clearly established, but there is an analogy in that same scenario where labs do activities beyond tests or pharmacists beyond dispensing and providing medications that start to create some analogies there.

Steven Eichner
Right, and of course, it depends a little bit upon what particular condition you are speaking to and whether that condition is reportable in that particular jurisdiction, so there are some complexities, like everything else, and some exceptions to virtually every rule.

Hans Buitendijk
Right. We have two or three minutes left. Any other general comments on long-term that we have? As you see, we are up on the spreadsheet. Any particular ones that jump out that we can discuss in the last one or two minutes in Column B that you would like to add to?

Shelly Spiro
Steven?

Steven Lane
Sorry, I am not in Column B. I am stuck over in the chat. Shelly, you just made a really important point there, which is that you say pharmacists are not considered providers under the Social Security Act, but yet, they are considered providers under the information-sharing requirements, which is pretty darn confusing. It would seem to me that all the HHS agencies should get together and clarify if pharmacists are providers or not and if we need to support, treat, and enable them as providers or not. We cannot have it both ways.

Shelly Spiro
Thank you, Steven, for bringing that up. This is something that has caused problems, and we saw this in COVID, of trying to onboard pharmacists within public health services so that some of this data can be captured, and it has been a problem with health information exchanges and others in the past, and it is something that the pharmacy profession has tried to work through with HHS and even Congress on this issue, but has not been successful in moving this forward because most of it is linked to payment services, which do not score very well, and budgetary process with the government.

Hans Buitendijk
We are within about 30 seconds, give or take, of the top of the hour, so I think we have to wrap for today. We have had a great conversation and discussion and a great presentation. Thank you, again, to Tegan for providing that insight. We are going to continue next week with progressing the recommendations, so, between now and then, you will see a homework email come out, and the essence of that will be that wherever you see, particularly in Column B, an opportunity for a recommendation in either the short-term or long-term topic, to add that draft recommendation so that we can progress our review of those, understand that they can be included, and that they then can be moved forward towards finalization in the near future, but the key will be the essence of the recommendation in each of those categories, and if we do not have one, that is fine too, but we would like to populate as much as possible so that we can close it out on these topics and move to Topics 2, 3, and 4 after that. Shelly, any other comments?

Shelly Spiro
No. We are at the top of the hour, so, thank you, everyone, for all of your great comments and recommendations, and thank you, Excel team, for helping us, and to Tricia Lee, I appreciate all the hard work you are doing on this along with Mike, and Hans, I really appreciate all that you are doing in helping us get through this very important work. Thank you.

Hans Buitendijk
Take care, everybody. Great day.

Adjourn (01:30:26)