Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTIC TASK FORCE 2023 MEETING

June 21, 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

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. On behalf of ONC, I would like to thank our Task Force members for volunteering their time and perspective to this important work, but I would also like to especially thank Hans Buitendijk and Shelly Spiro for agreeing to serve as cochairs of this Task Force. I am also joined by Tricia Lee Rolle, who will be serving as the ONC program lead. 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 will be 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 if you are here. I will begin with our cochairs. Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Shelly Spiro?

Shelly Spiro
Good morning, and welcome, everyone.

Michael Berry
Pooja Babbrah?

Pooja Babbrah
Good morning, I am here.

Michael Berry
Chris Blackley?

Chris Blackley
Good morning.

Michael Berry
Shila Blend? David Butler? Steve Eichner will be joining us a little bit later. Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Adi Gundlapalli? Jim Jirjis is not able to join us today. Summerpal Kahlon?

Summerpal Kahlon
Good morning, everyone.

Michael Berry
Steven Lane?

Steven Lane
Good morning. Happy to be here.

Michael Berry
Meg Marshall? Anna McCollister? Deven McGraw?

Deven McGraw
Good morning, everybody.

Michael Berry
Ketan Mehta? Justin Neal?

Justin Neal
Good morning, everyone.

Michael Berry
Eliel Oliveira? Naresh Sundar Rajan?

Naresh Sunder Rajan
Good morning.

Michael Berry
Scott Robertson? Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Christian Tadrus? Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Afton Wagner?

Afton Wagner
Good morning.

Michael Berry
Thank you so much, everyone, and now, please join me in welcoming Hans and Shelly for their opening remarks.

Shelly Spiro
You can go first, Hans. Go ahead.

Opening Remarks/Task Force Introductions (00:02:30)

Hans Buitendijk
Okeydoke. Good morning, everybody. I really appreciate everybody joining for this topic. It is a very important and very interesting topic as well on pharmacy. If I understand correctly, it has been a little while since this topic had this much Task Force-focused attention, so it is a great opportunity to identify and work through what our charge is, how we can advance the area of interoperability around pharmacy in a number of different contexts, and I look forward to working with everybody to identify some opportunities and recommendations to advance that space even further. Thank you very much, and I will pass it to Shelly.

Shelly Spiro
Good morning, everyone. I am so pleased to see several colleagues, old friends, and others who are able to participate and join us. I am honored to be asked to be a cochair along with Hans. Hans's experience is extensive in this area of helping to run these Task Forces, and I am very pleased to be able to help with this process. I just want to thank Tricia Lee for all her hard work in putting this group together, and also thank the ONC staff, Mike Berry, and others who have really helped us, especially those who are not on the HITAC, get integrated into this process, so I just want to thank the ONC staff, Hans, the other HITAC members, and especially our subject matter experts that were asked to join to get this very, very important work done. Thank you, and we will begin.

Hans Buitendijk
On that note, I think we are going to start with introductions. I would suggest that we go through the list, which I believe is on the screen, as I am trying to find my screen and am on a separate screen, with all the attendees, and run through that. Given the size of the group, I think 20 seconds is roughly the time we have allotted to this, so it is going to be a whirlwind, but throughout the discussion, we are surely going to catch up more on background and context as well. Shelly, do you want to start us and then go to me, and we will run through?

Shelly Spiro
Sure. So, just to remind everyone, we want you to state your name, your organization, your title, and your role, and as Hans said, please make sure we limit it to 20 seconds. So, I am Shelly Spiro, the Executive Director of the Pharmacy HIT Collaborative, and am extremely pleased to be here and to cochair this group.

Hans Buitendijk

My name is Hans Buitendijk with Oracle Health, the Director of Interoperability Strategy. I am currently a member of the HITAC as well, and am in a couple of the activities around the industry. One hat that I might be wearing a fair amount is the EHRA, a group of EHR vendors in HL7 development. It is great to see Scott, as we have collaborated for quite a few years, and there are a couple of other areas, so I look forward to working with you.

Shelly Spiro
I think we should just go down the list. We will start with Pooja, go all the way down to Anna, then start back up on the list at Deven. Pooja, you are up first.

Pooja Babbrah
Great. Hi, everyone. I am Pooja Babbrah, the Pharmacy PBM Practice Lead for Point of Care Partners, a health IT consulting company, and I am also on the board of NCPDP, so I will be wearing that hat once in a while, and am the prior board chair for NCPDP. I am excited to be here and working with all of you.

Shelly Spiro
Thank you. Chris, you are next.

Chris Blackley
Hi. I am Chris Blackley, cofounder and CEO for Prescriptive Health. We are a healthcare technology company providing services to pharmacy and health systems.

Shelly Spiro
Shila?

Hans Buitendijk
If she is here today… I think it is David.

Shelly Spiro
David? Sorry.

David Butler
Hi, I am David Butler, President of Curatro, and I spent about 15 years working with Teradata, with TIBCO, and at Oracle Health, Hans, and I now provide some similar services consulting with healthcare and life sciences companies on better use of information technology in relational systems and such.

Hans Buitendijk
I do not think Ike is on yet.

Shila Blend
This is Shila. I just wanted to note my apologies. I was having a few computer issues, so I was late, but I am present.

Shelly Spiro
Do you want to introduce yourself? Go ahead.

Shila Blend
I am Shila Blend. I am the Health IT Director here for North Dakota Health Information Network in North Dakota. My background is as a nurse. I worked in our health department, and I have a PhD with a focus on health systems. Our network also has been working closely with pharmacies to work on projects to make them more interoperable in sharing and benefiting from health information exchange.

Shelly Spiro
Thank you. Rajesh?

Rajesh Godavarthi
Good morning, Raj here. I am from MCG Health. My background is a little bit of interoperability on burden reduction using prior auth for other services, so we have implemented that, and I am very excited for this group to see how we can bring some of those lessons to this. As well, I have the pleasure of working with Hans and a few others in different companies across the industry, but am very excited to be part of this group today. Thank you very much.

Shelly Spiro
Thank you. I do not think Adi is here. Jim?

Hans Buitendijk
I think Jim is out too today.

Shelly Spiro
Jim is out too. Summer?

Summerpal Kahlon
Good morning, everyone. I am Summerpal Kahlon. I go by Summer, so feel free to call me that. I am the founder and medical director of Rocket Healthcare. I am a physician by background, dealing in internal medicine and infectious diseases, and I worked for a long time in health IT and diet-based care, so I look forward to working with this group here.

Shelly Spiro
Nice to see you, Summer. Steven?

Steven Lane
Good morning. I am Steven Lane, a practicing family physician and clinical informaticist in northern California. I serve as the Chief Medical Officer at Health Gorilla, which is a nationwide HIE, HIN, and health data platform that is in the process of becoming one of the first QHINs to support the TEFCA, and I am super excited to be here and very interested in medication data interoperability and all that can do to improve care.

Shelly Spiro
Thank you, Steven. Is Meg with us?

Hans Buitendijk
I did not see her yet.

Shelly Spiro
Okay. Anna?

Hans Buitendijk
I do not think so either.

Shelly Spiro
Okay. Deven?

Deven McGraw
Good morning, everyone. I am Deven McGraw, the lead for data stewardship and data sharing at Invitae, which is a clinical genetic testing company. My particular interest in this Task Force is pharmacogenetics and how genetic information can be helpful to prescribers in terms of getting the right medication prescribed for patients. Thank you.

Shelly Spiro
Ketan?

Ketan Mehta
Hi, this is Ketan Mehta. I am the CEO at Micro Merchant Systems. Our flagship product is called PrimeRx Pharmacy Management System. It is being used by thousands of pharmacies across the country. We are all about pharmacy interoperability. We like to be connected and make sure the pharmacist has the ability to provide the care that the patients need through these different Task Forces, and this is my first time over here, so I am glad to be a part of this group.

Shelly Spiro
Excellent. Justin?

Justin Neal
Good morning everyone. I am Justin Neal, Vice President of Patient Support and Data Services at Noble Health Services. We are a specialty pharmacy, part of KPH Healthcare, so we transcend a lot in the pharmacy space. This is my first time here as well, so I am really excited to take what I do in my day job, finding friction points that we have with patients and reporting those over to our partners to make sure we are finding better ways to take care of everybody, so I am happy to join today. Thanks.

Shelly Spiro
Thank you. Eliel is not here. Naresh?

Naresh Sunder Rajan
Good morning, this is Naresh. I am the Chief Data Officer for CyncHealth, and my background is in informatics, more along the lines of standards development. I served in the PMIX Technical Architecture

Subcommittee, which is a prescription information exchange standards organization for the pharmacy or PDMP programs across the states. I am excited to be here. Thank you.

Shelly Spiro
Thank you. Scott Robertson?

Hans Buitendijk
I did see him.

Scott Robertson
Hi, I am Scott Robertson. My mute button did not work the first time. I am a pharmacist, and after many years in health IT standards development and policy at Kaiser Permanente, I have now founded Bear Health Tech Consulting, and I am fairly active in the field, currently the cochair for the Pharmacy Workgroup in HL7, and am looking forward to this task group. Thank you.

Shelly Spiro
Thanks, Scott. Alexis?

Alexis Snyder
Good morning. I am Alexis Snyder, a patient and stakeholder engagement specialist located in the Boston area. I have a focus on patient-centered outcomes research, health equity, and health IT, with personal lived experience as a caregiver, giving patient and caregiver perspective to this group in complex care, rare disease, and disability. I am happy to be here with you today.

Shelly Spiro
Great. Fil?

Fillipe Southerland
Hi, good morning. I am Fil Southerland, Director of Health at Yardi Systems. We are an EHR in the long-term post-acute care space and interested in this workgroup, just from the perspective of specialty EHRs and long-term care workflows, so I am looking forward to the discussion.

Shelly Spiro
Thanks, Fil. I do not see Christian. Sheryl?

Sheryl Turney
Hi, I am Sheryl Turney, and I represent Elevance Health, which is a healthcare company that offers behavioral, pharmacy, and complex care solutions that promote public health. I lead the interoperability area for Elevance Health, and am really excited to be working on this committee, and hopefully will engage some of my partners across the organization that focus on pharmacy to help improve our recommendations. Thank you.

Shelly Spiro
Great. Last but not least, Afton?

Afton Wagner
Thanks, Shelly. My name is Afton Wagner. I am the Senior Manager of Pharmacy Policy and Technical Standards at Walgreens. Walgreens operates more than 9,000 stores in all 50 states. I am a pharmacist by background, and have worked for a long time in healthcare policy, health IT, and pharmacy standards development, and just in thinking about what the future holds for pharmacy and the pharmacist's value in the healthcare system, working together and exchanging information is going to be critical to our industry, so I am very excited to be part of the Task Force.

Hans Buitendijk
Thank you. It is great to hear everybody's fantastic background. When we look at the topics, I am sure we will have plenty of opportunity to jump down in details and otherwise, but before we go to the next part, Shelly, maybe just some quick housekeeping on chat and how we use it so that, as we dive in, everybody is aware of that. Some of you have served on HITAC workgroups or committees before; others are new.

What you will notice is there is a good amount of use of the chat going on throughout the entire conversation, and we encourage everybody to take advantage of that. They will be part of the record. For the Task Force members, please be aware that if it is to hosts and panelists, it is internal only and will not be on the record, but if you type to everyone, then it will be part and everybody can see it. This also means we welcome the public today. You are able to participate in the chat as well, and Mike will correct me if that is incorrect, but you would be able to. However, you will not be able to speak until the public comment period at the end, so there can be an interaction using the chat, but not in terms of dialogue during the initial part. With that, Shelly, I think we can jump in and see how this unfolds.

Shelly Spiro
Sounds great. Thank you, everyone, and thank you for all those great introductions. You did a great job staying on time, and I really appreciate that. Thanks, Hans, for the update on the chat. The chat is very important, especially for those who are not on the panel. This will allow the public to also give us questions as the talk goes in. It looks like Eliel joined us. Before we get started, Eliel, do you want to introduce yourself?

Eliel Oliveira
Yes. My name is Eliel Oliveira at the Dell Medical School at UT Austin, Texas. Nice to be here.

Task Force Charge, Timeline and Work Plan (00:16:59)

Shelly Spiro
Thank you so much. Let's go to the next slide. It looks like Tricia Lee has lost her power, so I am going to take over her part, if that is okay with everyone. Tricia Lee, just jump in if you get back on. This is our overarching charge, to identify recommendations to support interoperability between pharmacy constituents and the exchange of information necessary for medication management, patient safety, and consumer engagement. That is really what the charge of this Task Force is. What we have done is broken out some of our charges, and our recommendations to the HITAC are due on November 9th. That means that in October, we are going to have to make sure we have completed all of our reporting and all of our recommendations into a report, and that will then be presented to the HITAC on November 9th.

Our specific charges have four portions or topics. Our first topic is related to public health emergency use authorization and prescribing authorities, and that is what we are going to start with today. Our second is to identify opportunities and recommendations to improve interoperability between pharmacy constituents, prescribers, pharmacists, pharmacy benefit managers, dispensers, payers, intermediaries, prescription drug monitoring programs, public health agencies, health information exchanges, third-party service providers, consumers, etc. for pharmacy-based clinical services and care coordination. Our third topic will be to identify standards needs to support prescribing and management of emerging therapies, including, but not limited to, specialty medications, digital therapeutics, and gene therapies. Our fourth topic will be to identify policies, technology needs, and considerations for direct-to-consumer medication services. So, those are our four charges, and we will be going over the work plan to see how we break that apart, so I think we can move on to the next slide.

Thank you, Steven. For those of you who are following the chat, Steven just let us know that for the panelists, it is not possible to use the chat for private communications with members of the public. If you respond to the public chat comment, it will also be shared with all the hosts and panelists, so if you think that you are being private, do not. Use your own direct messaging tools if you want to talk to somebody by themself.

So, this is the draft timeline for the HITAC Task Force, and Tricia Lee has done a really good job of putting together how we will break out this really important work. We have a lot of weekly meetings coming up, but we have a few weeks when we will not have meetings due to conflicts of the cochairs or ONC staff. So, this is our first week, and it is June 21st, I believe. Is that when summer begins? We will see. Hopefully. So, this is our kickoff meeting, and then we will go through Topic 1, and we have broken it out into short- and long-term types of goals. Just remember we will be having invited guests come in as subject matter experts for certain topics, so we will be communicating that with you as we move forward.

So, our first topic today is public health emergency use authorization and prescribing authorities. We will be going through that, so I am not going to read it. We will be going through that in our discussion today because we decided not to have subject matter experts present at this particular meeting because we wanted to have time to really go through the process and understand where we are within the work plan and answer any specific questions for subject matter experts and our HITAC members that are part of the actual Task Force. Next week, on June 28th, everything is the same time on Wednesdays for now. It could change if something comes up, or we might change the date, but we are pretty well scheduled for this time. Mike, I hope you are listening, and please correct me if I am wrong on anything. Mike Berry is our gatekeeper and our controller for ONC, and we really appreciate all his help in keeping us honest in our work that we are doing.

So, next week, we will have subject matter experts come in and talk to us on the short-term public health and emergency use authorization prescribing authorities. We are going to miss the next week, which is the week of Independence Day, our national holiday, so we will be missing that week, and then, if you go to the next slide, Week 4 will be July 12th. This is where we come into the long-term portion of this Task Force related to public health, emergency use authorization, and prescribing authority. On Week 5, July 19th, we will continue with our long-term topic and the public health portion.

And then, in our fifth meeting, which is July 26th, unfortunately, Hans has a hard stop and will not be here, so you will have to just listen to me. You will be missed tremendously, Hans, but I have confidence in the ONC staff and others who have driven these processes from the HITAC to help me get through Topic 2, which is identifying opportunities and recommendations to improve interoperability between pharmacy constituents. And then, we will have another break on Week 7, which is August 2nd. We know that this is summertime and people are out and have made previous arrangements, so both Tricia Lee and Hans will be gone on August 2nd, so we will not have a meeting on that day, so if you enjoy or plan your away time during those off times, it would be really great. Go to the next slide.

Week 8 will be August 9th, in which the topic will be identifying opportunities and recommendations to improve interoperability between pharmacy constituents. Then, in Week 9, which will be August 16th, our seventh meeting, we will have some SMEs come in, and on Week 8 as well. Also, on Week 9, we have to provide an update on August 17th to the HITAC, so if you are not sure on how to find the HITAC meetings, you can search for the HITAC calendar, see when those meetings are, and register for those meetings if you want to listen in. For Week 10, which is August 23rd, we will continue our Topic 2 topic, and also, we will have a discussion on the draft final recommendations for Topic 2. So, after we finish each topic, we will also come up with some draft recommendations, and this is used in order to update the HITAC at the different times that we will be updating them. Go to the next slide.

On Week 11, August 30th, again, we will start Topic 3 and work on our draft recommendations. If you see the last column, this is where you will start to see the subject matter experts that will be invited that are not part of the panel, but those panelists that have expertise can certainly weigh in as the subject matter experts are speaking about the topics. Again, we will have another break at Week 12. There will be no meeting because that is the week of another holiday, Labor Day, so take advantage of that time off. For Week 13, September 13th, unfortunately, I will not be able to attend that meeting, so Hans will be taking that over to continue our work on Topic 3. For those of you who are interested, this is where we will be discussing digital therapeutics, which is an emerging area also. In Week 14, which is September 20th, we will continue our work with Topic 3, and we will be discussing more on gene therapy. I know some of you are interested in pharmacogenomics and gene therapy, and this is where we will be discussing that, on that week. Go to the next slide.

So, we are rounding about to the end. As we are getting closer, Week 15th, is September 27th, and we will continue with our Topic 3, and we will have additional SMEs if needed. This is where we will need to do our discussion for our draft final recommendations on Topic 3 to the HITAC. And then, on October 4th, we will begin our work on Topic 4, which is identifying policies, technology needs, and considerations to direct-to-consumer medication services. That takes us to Week 17, which is October 11th, where we will continue our topic in this area, and then discussions on the draft final for Topic 4. Go to the next slide.

We are on our last slide for our work plan, and this is on Week 18, which will be October 18th, and unfortunately, Hans is not going to be able to join us on that day. Again, I am looking for other HITAC members to help me as we continue our process, and this is also the week, on October 19th, when the Task Force will provide an update to HITAC on our progress of this particular Task Force. Then, we go to Week 19, and this is where we will start our discussion to finalize our recommendations to the Task Force report, so this is really important work, and then, on November 1st, we will do the discussions if we need to and continue the work.

We have to have our recommendations completed in the first part of November. Hopefully, by that October 25th meeting, we will have all those recommendations done, and then Hans and I will be working on getting that full. If we need time, we will reconvene to finish the recommendations on Weeks 19 and 20, and then, on Week 21, we will have a little extra time if we need to wrap things up, and then, November 9th is the presentation of the final recommendations to HITAC and when the final HITAC vote will occur. Now, does anyone have any questions about the four topics or about the work plan? I have Steven. Your hand is raised.

Steven Lane
Yes, thank you, and thank you so much for going through that so clearly. Those topics are excellent. Deven mentioned the topic related to pharmacogenomics, which I think is an add-on. I have particular interest in the whole area of supporting the integration of medication data from EHRs and pharmacies to support automated medication and reconciliation. I think there are a lot of topics under this larger umbrella of pharmacy data interoperability, and I am just wondering if our scope is firmly limited to the topics that have been presented, or are we going to have the opportunity to slip in some other ideas or recommendations related to pharmacy interoperability and emerging therapeutics? I just want to understand. With a lot of Task Forces, we have historically colored a little bit outside the lines and figured out ways to get input on the related and tangential topics back to HITAC, so I just wanted a little bit of guidance on that as we kick this off.

Shelly Spiro
Tricia Lee, I think you are back on now. If you are not comfortable with answering that question, Hans and I will try to take it.

Tricia Lee Rolle
I am perfectly fine to answer. I am logged in twice, so I am hearing myself doubled. I am sorry that I was not able to have a good connection here. So, yes, specifically on that topic, pharmacogenomics, that third task topic around emerging therapeutics, there is mention of any other emerging therapeutic areas the Task Force has identified, so we do welcome you all recommending additional areas and places that ONC needs to be taking a look. To the second part of your question, about how much room the committee has to, as was described, color outside the lines, we would like you to stick with the tasks that have been assigned to you.

Because this is a process where we will be making recommendations and will be noting on the discussion, at the cochairs' discretion, you are very much welcome to have parking lot items or recommendations for future work, so there is a lot to cover with this specific charge and set of tasks that we really want you to actually address, but if there are areas that are tangential or just a little bit more closely related that you think are relevant enough, you can certainly recommend that ONC takes a further look at that, but we really want to spend the time that is allotted, especially for a task group of this size, to addressing the particular tasks on hand. I hope that is helpful.

Hans Buitendijk
Maybe to add onto that, if I heard Steven correctly, one of the elements was medication reconciliation. Perhaps that might start to drift a little bit across that fuzzy line that always exists there, but if you have a

thought or suggestion as you go through where we are going to capture the information, if we put it in there, we can still look at it and say if it is too far out of the boundary or still inside and keep it there. That one might one of those. Perhaps it is not as pharmacy-centric as other areas, and Tricia, correct me if I am wrong, but I understand it is really meant to focus from a pharmacist's perspective on the different connectivity and interactions with others, where medication reconciliation may or may not be, depending on how you define that area. I am not sure whether that helps or hinders, Steven.

Steven Lane
Thanks, Hans.

Shelly Spiro
Pooja?

Pooja Babbrah
Thanks. I just have more of a procedural question. Do you want us to email the cochairs and you, Tricia Lee, if there are topics we want to add? How best do we want to handle that?

Hans Buitendijk
There might be a couple ways. After this topic, we are going to look at how we are going to start to gather documents, thoughts, ideas, and draft recommendations, so we can look at where you could put in some of those ones, but if you have a particular topic to make sure, I would suggest you ping the cochairs, Tricia, and Mike, and then we can find out particularly if they might be ones of interest to have a speaker on if you have somebody, and you raised that question in the chat as well. If anybody has a suggestion around the topics that we have, please let us know, and then we can identify who, when, etc., but if you are not sure, then by all means, just ping us and we will figure it out.

Pooja Babbrah
Perfect, thank you.

Shelly Spiro
Any other questions or comments before we move on? All right, let's move on, then. Thank you, everyone, for that great discussion, and I am going to turn this over to Hans.

Task Force Expectations on Recommendations (00:35:35)

Hans Buitendijk
All right. The next topic on the agenda is to talk a little bit about what our goal is in terms of a deliverable and how we are going to get there. Could you share the Word document? It has an initial sketch outline of what our recommendations document is going to look like. We will start with that, and then work back to how we are going to capture our information using a Google spreadsheet, but a number of us have been part of a number of these conversations before and others have not, so I just wanted to give a little bit of a sense of what it might look like in terms of the organization, what the elements are that can help us give an idea of what kind of recommendations, ideas, or otherwise we should consider, and what format it is going to end up in.

So, if you can scroll to the table of contents for a moment, that might highlight some of those areas. There are a number of different sections that we are going to be looking at to really provide the background to why the Task Force is formed, etc., then go into the charge that is there, and then we will go into a couple of different sections to introduce and provide more background where needed on some of the challenges that we have, and the mainstay is going to be around that recommendation. The rest of it is going to be mostly the roster and other information that we may have, plus, that might be an area where we have thoughts to be referred to another group, not for the Task Force to address, but something for others to pick up at some point in time for their consideration. So, if you go through to the next part, that is what we just talked about.

We will start to end up there, and if you gently keep on scrolling, we had just talked through that with the timeline. It will be recapped here to make sure our additional background is clear, but when we get to the recommendations, that is where you will see a particular style, which I think starts on the next page. This is what we are ultimately aiming for. These are strictly examples at this point in time from a couple of areas, so do not take these as something we have discussed and agreed to. They are not applicable to this per se, but we have the actual recommendation, where we want to be very specific about what we recommend that ONC can do, either by themselves or in cooperation with other agencies, departments, industry, or whatever the focus might be. As appropriate, sometimes the recommendations are very clear and speak for themselves, and other times, we need to have a rationale to understand why it is that we recommend this so we have an opportunity for that.

And then, we will just run through the different areas. They will be generally organized by the different topics that we will have, 1 through 4. In this case, this is a sample from the NPRM response, so, clearly, you will recognize the things like USCDI and C-CDA. We are going to be organizing it around the topics, and within that, some of the short- and long-term aspects of that. So, that is really the main content that we are working towards, and I think, then, if we can jump to the end for the final aspect of it, I think there were 65 or 67 recommendations there, and it is not necessary for us to have as many. We can have more or fewer. Whatever we end up with in the time available, that is what it will be. And then, we have a couple of appendixes. One of them is the roster, and we may have some references of thoughts for other groups.

So, basically, if you want to get a sense of what we are trying to aim for, that is what it is going to be, and then we can jump to the Google spreadsheet, where we can look at how we are going to capture the thoughts and ideas we are going to go through. There is the spreadsheet coming up. Everybody will receive an invitation to be able to review and edit this document, or this spreadsheet. It is a Google spreadsheet, so if you do not have an appropriate account that is recognized by Google, you will have to set one up. We know that some organizations do not allow access to Google spreadsheets, and others do. Typically, that means somebody needs to use their personal information to set it up, or you can create one for the specific purpose of just using it for this. Instructions will be sent out and made available for everybody so that this is our work area, and you will see four tabs at this point in time.

As we progress, we might find out and learn that we might need an additional one or that we need to add some columns to it, but this is the starting point to organize our work, and as you scroll from left to right, you start to see member recommendations. So far, we have the charge, member recommendation, justification for recommendation, and then any kind of discussion we have, and then it ends up with the final recommendation. So, as we go through, our progression is that as you have thoughts or ideas about draft

recommendations, you can start to enter them on each of these topics in any of the tabs. You do not need to wait for the week that we are there to start to put them in, but make sure that in, for example, Cell E2, you put in your name, either your initials or your first name, and then start to write down your thoughts. The more that you already have it in a recommendation format, great. Initially, it is not the most critical thing, just to make sure we have topics and thoughts that we start to gather, and then the justification as to why that is an important one to be picked up and considered.

As we go through the weeks and have presentations and discussions, you can immediately start to enter this as well, or you can hold onto it. You can use the chat. We are going to be capturing that as well, and then we will transpose that where appropriate also. One thing to keep in mind with Google is that if three people are trying to edit E2 at one point in time, one will win. I am not sure who, but somebody will win, and the other edits will disappear for a moment and have to be reentered. So, typically, during the meeting itself, we want to be cautious that there are not too many different people active in these recommendations, but in between meetings, the probability of that happening is not that high. So, keep that in mind. Do not be surprised if that happens at some point, that you have to reenter that. That is unfortunately what spreadsheets do not allow for yet. I think those are the main topics on how we go about it.

When we get to the end, we will start to translate them into final recommendations, then primarily, Shelly and myself, with the ONC team, are going to be editing that column. We are looking for suggestions on wordsmithing at that point in time. In another one, we used Column K, but Columns I and J can be used by others to make suggestions for recalibration, but primarily, Shelly and myself will be the key editors of that to make sure that we capture what is there and that we can get to that consensus level that we are looking for. My last comment there is that we are referencing consensus, not voting. We are not going to have a formal vote or anything like that on every recommendation, but we will sense the level of consensus. If we have a clear consensus on a recommendation rationale, we will land there. If there is a variation in perspective and we feel that it is still relevant to get that across and have a recommendation that might, as a result, be more general to consider that recommendations, we will aim for that as well.

If we cannot get alignment of enough people or there is a strong objection to something and we cannot find that balance, then it is going to be one of those topics that is going to sit on the sidelines because we do like to get to a point where we can say to the HITAC Task Force and subsequently HITAC overall that this is a set of recommendations that we all can feel comfortable about. We might not all agree with the exact aspects of it, and that always will be a challenge, but at least we have a good sense of providing ONC recommendations and guidance on where to move, and there is an opportunity as that is being implemented as well to further refine that. So, I am going to stop there for a moment and see, Shelly, Tricia, or Mike, whether there is anything else on this process that you would like to add or clarify, and then we will see if there are any questions about this.

Shelly Spiro
I do not have anything. Hans, you did a great job with the update. Anyone else from ONC?

Tricia Lee Rolle
I will just mention that we are a little bit on trial and error, so we will see how things go as we are documenting, and if we need to adapt the template, then we can, so we will work with what we have for now, and we will also take feedback if there are better ways to capture this information from you all.

Hans Buitendijk
I would like to underscore that trial-and-error piece, and iteration is our mantra as we work through this, so we want to fit this group on how best we can do that.

Shelly Spiro
Please look at the chat. Steven put in his experience on leading some of these Task Forces and some advice on what you do if you are locked out, but more information will be coming from ONC staff for the panelists on what we will be doing on entering information into the Google doc. Does anybody have anything else? Any questions about this portion?

Hans Buitendijk
There is a clarification that Steven notes. Just for the sake of example, you see right now on the screen that it is gray and a little purple around it. I am actually the one that is typing "test string" right now, so that is what you would see if somebody else is already in there, and therefore, if you then try and go in there, it is not going to fly, and I just got out of it, and you can see that it is blank again. That is what we have to keep in mind. Someone is sitting in the purple field right now, and now I just moved, so that is what you will start to see to help indicate whether you should wait a moment or if it is ready for you to jump in. Thank you, Steven.

Shelly Spiro
It looks like Anna has joined us. Anna, do you want to introduce yourself?

Anna McCollister
I am Anna McCollister, a member of HITAC. I am not sure what other introductions you guys provided, but I am an independent consultant focused on data, data use, governance, and patient engagement.

Shelly Spiro
Thank you, Anna, and thanks for joining us. Any other questions before we move on? If not, let's go ahead and move on.

Hans Buitendijk
Shelly, I think it is on to you, starting with the deep dive.

SHORT-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities (00:48:00)

Shelly Spiro
Yes. So, we are going to take our remaining time before our public comment, for which we have to end at 11:50 to have the public comment, and if there are not any public comments, then we will continue our discussion until the very end, and let's go to the next slide. So, as we said before, this is our first task, for which we will have a discussion on June 21st and June 28th, and our first topic is public health, emergency use authorization, and prescribing authorities. Many of you know what has happened with COVID that triggered a lot of these issues, as we needed to have information come to pharmacies, which are one of the largest immunizers in the united states, so we found a lot of gaps and issues, and what we are going

to try to do is to consolidate those gaps, so our short-term goal is to identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions, so we have a great use case with COVID-19, the use of the test-to-treat types of programs.

There has been a lot of work done with NCPDP on this particular aspect, and other work that has been done, such as long-term post-acute care, hospitals, and in the community settings and ambulatory settings, in relationship to COVID, so be thinking about that as we go into this discussion. We want to be able to identify critical standards and data needs, so keep that in mind as we go through this discussion today. And then, are there actions that ONC can take to enable data exchange to support public health emergency use cases, for example, the test-to-treat in COVID treatment and prescribing? Let's keep that in mind.

So, our subject matter experts that will be coming in next week will begin to discuss what has currently taken place and what those gaps are, and that is what we want to focus on. We want to focus on those gaps and how we can leverage health IT to improve that. We also have a gap with two of our healthcare partners, the hospitals and the medication offices, that use certified health IT, but others do not. Also, there are the issues that are arising with public health as they are increasing their capability of exchanging data and what the CDC is doing. Those are the areas we really want to focus on. And then, in Meetings 3 and 4, which will take place after, we will begin to look at the long-term recommendations.

So, remember, today, we just want to focus on the short term and be thinking about our long-term recommendations. At this time, I want to open it up for discussion, and the reason we did not have our subject matter experts come today is because there is a lot of information we are giving to our panelists now, and we really wanted to give you the opportunity to see how the engagement works within this particular Task Force, since we have several new people who have not been involved in the process, so we want to give you the opportunity to now talk about and focus on our short-term tasks, okay? So, let's open it up. I am looking for raised hands, and I see Pooja. You are up first.

Pooja Babbrah
Thanks, Shelly. So, I put this in the chat, but just to clarify for everyone, the work done at NCPDP was to allow for billing. I would love to hear from some of the folks who are actually in the pharmacies to better understand, but I think one of the data gaps was being able to access patient records. So, as an example, in Arizona, we have a drive-through for COVID vaccines, so I got my first COVID vaccine in the drive-through in the stadium in Arizona, but then I got my second one at CVS. I had to carry my little card, so, as a pharmacist, being able to access my patient record to know that I received that first vaccination would be really important, so that is just one example of a data gap that I have heard through work at NCPDP that we are doing. So, I would love to hear from others around that as well.

Shelly Spiro
Anyone else? It looks like Hans.

Hans Buitendijk
I want to add to Pooja's comment for a moment. There was a little bit of conversation with Adi Gundlapalli from CDC. One of the things in that context that he particularly raised around medications was, not only as part of vaccinations, but medications and therapies being provided that are relevant to the emergency situation, and where those treatments are not being built, one cannot necessarily easily get the information

in public health or otherwise. They are not necessarily immunizations and not necessarily built for it, and therefore, the sources of getting to that information are limited, so I think that ties into your comment on the patient record. Depending on the context, there might be a variety of different elements that are currently not flowing to public health or to other parties because normally, they do not need to be exchanged at that point in time.

Shelly Spiro
Thank you, Hans. Ike, since you did not introduce yourself, do you want to go ahead and do that?

Steven Eichner
Absolutely, thank you. My name is Steve Eichner, and I am the health IT lead at the Texas Department of State Health Services and have been a HITAC member involved in working on health information exchange issues at the national and state level for a bunch of years. One of the challenges we saw, especially early on in COVID-19, from a public health perspective is that a number of folks that were administering immunizations did not have technology that was capable of sending data to public health. While we had a good set of tools in place to receive information in certified formats or formats that supported certified technology, there were a number of providers that simply did not have the capability to send data in any kind of format, and that created a substantial gap and delay and created a real burden on providers for doing manual entry.

We have a web portal that is available for folks to use, and it worked well for 10 or 15, 20 or 30, or 40 or 50, but when you are looking at hundreds of immunizations a day, it becomes really problematic for some staff to be able to do that on a repeated basis to get the information into the system so that Pooja's pharmacist can pull it back down on the other side. I think also looking at what we can do about making it easier for facilitating pharmacies to order medications electronically or track the ordering is also probably another gap in reporting that information. Again, depending upon what the distribution mechanism is, from a situational awareness perspective, understanding what pharmacies have what resources at what time is also a vital piece of information.

Shelly Spiro
Thank you, Ike. Pooja?

Pooja Babbrah
This also brings up what Steven had mentioned in the chat about information blocking, and this makes me wonder if, as pharmacists, they are covered as providers, what is the impact of the information-blocking rule? Because that is sharing of data between vendors, I wonder if that plays into this as well, so I think we need to have a better understanding of how that ties into all these data-sharing pieces.

Shelly Spiro
Afton?

Afton Wagner
Hans had mentioned something that resonated with me about medications and potentially needing information that we traditionally did not always need in the pharmacies. Think about Paxlovid. We had this emergency use authorization last July where pharmacists were able to directly prescribe it, but we needed

information in a timely manner because you need to prescribe it within five days after symptoms begin, so we needed health records less than 12 months old, and that needed laboratory tests to check for kidney and liver functions, and we needed a list of all medications that patients were taking, including any over-the-counter medications to screen for any drug interactions. So, with that in mind, it is not just as easy to walk into a pharmacy and have access to new and emerging treatments that pharmacists are able to prescribe under emergency use authorization, so thinking about how to get that done and how to quickly get that done will be important.

Shelly Spiro
Chris?

Chris Blackley
Good morning, thank you. I will turn on the camera here. I think I am reinforcing some of the things that were mentioned already, but we played a role with the state of New York in rolling out vaccination test-and-treat for COVID with about 600 pharmacies, as well as across other states. There were specific challenges that were extremely difficult to overcome, particularly in a quick period of time, and the point about health information reporting was one of the biggest challenges. There is a regulatory impediment that then creates concern and risk around the pharmacist being compliant, and therefore, they do not touch it if they feel like they run the risk of not being compliant with those requirements, and so, providing any sort of standardization or ability to onboard, ability to accelerate and scale workflow within the pharmacy. And then, another one is the credentialing and authentication as well. When you are working across different systems, the ability to manage different systems as a pharmacist makes it very difficult.

So, I think all of those are very relevant, and you end up with a behavioral response that makes it so that they will not even get close to it if they fear losing their license because of it. Another one is discoverability of access to when there are vaccinations or treatment. I think that is another significant gap that affects both a pharmacist's ability to provide care and a patient's ability to discover it and get access. The last one is not particularly sexy, but it is also a significant barrier when you have a system that is overwhelmed. One of the biggest challenges we had was enabling scheduling, so, to the extent that there is any sort of data publishing discoverability or interoperability that allows you to affect the scheduling capability for both the patient and the pharmacist, that was one of the biggest technical barriers that most pharmacists had because they way that they provided care up until that point in time did not require it. And so, those were some of the areas where we experienced significant challenges in just getting a pharmacist capable of being to provide those services to test and treat.

Shelly Spiro
Thank you, Chris. That was great. David?

David Butler
One of the things that I think needs to be added to these discussions and all these excellent comments is the recognition of what I call lifetime health information. We have reached a stage where we have the platforms, we have the software, both what we have today and even new software that is being developed, new ways of retrieving and storing information, that now allows us to really do lifetime health information, and we need to look at the interoperability of that.

I think the vaccinations and what we have seen with COVID and dealing with public health needs us to recognize the fact that a patient can remember where they got their other drugs filled 30 days ago or 90 days ago, and they can go back to that same place, but when we are talking months or years of time, they do not remember where they went to, and when we hold these multiple events in multiple locations, we lose a lot of information over not just a short time period, but over a lifetime, basically, and understanding where patients stand with regard to their vaccination schedules is something that should be important to a pharmacist to be able to counsel a patient when they come in. "Do you know that you have not had your latest tetanus, and it has been that long? You did not receive this as a child because you came through some procedure or some public situation where you did not obtain it, but you still need to get it." Those kinds of things are little cracks that fall through, and I think they are cracks that are becoming larger and larger, and we need to recognize the need to consider lifetime health information in interoperability.

Shelly Spiro

Thank you, David. I am going to take the cochair's prerogative at this particular point and give you my personal experience. I am going to share some of my personal health information with you, which is my prerogative as an individual, but give you the case scenario of what it is like in real life when it does work. So, I think that this will be an important part. I also want to respond to what David said. We talk about medication reconciliation, but we do not talk about immunization reconciliation, and that is a very, very important part of public health, that as patients, we have to begin to know when our immunizations are due and reconcile that because there are different timing issues, and we have not done as good a job as we should in making sure that we can do immunization reconciliations and that information is shared, as David has brought forward, on the historic perspective of the type of data that we are actually storing. Pharmacies do store data, but it is more difficult for us to share between pharmacies and between that data, and that is another potential gap.

So, to my personal story, I would like to tell you what happened to me when I actually tested positive for COVID. I was able to do a home test, I was able to test, and the first time I took it, it was negative. The next time I took it, because we had a family event and were all exposed, later on, I had a very positive test, which I did report to the CDC within my application. I had all my immunizations up to date at that particular time. I did a telehealth visit with my provider through an MCO, a managed care organization, that I am a part of. I do have a personal health record that gives me access to all my information, including a number of labs, and as a pharmacist, I was very in tune as to what I needed to do, so at my telehealth visit, my practitioner was able to let me know that they also had access to my personal health record, they could see the labs I had taken a few months earlier, so I had all my active labs in place, and that prescriber was actually able to prescribe Paxlovid for me, and I was able to pick it up at the pharmacy and start the therapy, I was able to communicate with my primary care provider that I did test positive, and then I had a telehealth visit, I was able to send a note to my primary care provider, and they also did follow up with me to make sure that I was okay and that I was symptom-free after my amount of taking the Paxlovid.

So, there are situations where it does work. I think the gap in that particular scenario was that I was not sure that my local public health department was aware of what happened to me, so that is a potential problem: Who is responsible for actually sharing that particular information? But, I thought I would give you a use case scenario of something that does mostly work, and that really helps us identify the gaps in these processes, which is what we want to look at. Now, I could have gone directly to my pharmacy and had them prescribe the Paxlovid for me, so there were several options that were available. I know we had talked

about scheduling, and what COVID brought to pharmacies was that increase in the ability use automation to schedule the vaccinations, and I do want to say there are many gaps that occur in the long-term and post-acute care setting that I think we really need to address. Those connectivities are not there, but we do have a subject matter expert coming in on that portion to show what actually happened and how the pharmacies came together to share that information in that unique setting. So, it looks like Pooja has a question or comment.

Pooja Babbrah
Yes, just a comment. I wanted to address Steven's comment about the AMA, and I think that is definitely an important concern. We talk a lot about this at the NCPDP as we are starting to take on more of the care coordination use cases and pharmacists being able to do clinical services. I support bringing in the AMA. I know there is a lot of concern about that, and that is something that is definitely an industry concern, but I want to make sure we do bring in the AMA. We need to be focused on the exchange of data because there are states where pharmacists are absolutely given this permission from the state perspective, so I want to make sure that under this Task Force, we are focused on the data exchange to support, especially in those areas where pharmacists can do this work, so that is just one thing to note.

There is one other thing I was thinking of, and Shelly, thank you for sharing your experience with COVID. I think a lot of us probably had very similar experiences, but the other thing I wanted to note that we talk about a lot at NCPDP as we are talking about the sharing of data in public health emergencies is the opioid crisis, though I know it is hard to bring in a couple use cases. In the Task Force, we do mention PDMPs. Of course, COVID is not past us completely, but that is another one where, as we are thinking about data exchange, opioids are the other public health emergency use case that we want to be thinking about as we are thinking about the data exchange in this conversation.

Shelly Spiro
It looks like we have quite a few chats coming in. Steven, I know you had quite a few chats and some great comments, and just as a reminder, the chats will be part of the public record, so continue to put those comments in. Anyone else? I do not want to go through and read these questions, but I will call upon you. Steven Lane, I know you had some concerns. I wonder if you could just expand on your comments in the chat.

Steven Lane
Thanks, Shelly. I actually will always raise my hand if I feel like I need to supplement my chat with verbal comment, but thank you, Pooja, for calling some of that out. As a practicing physician, I am well aware of the concerns of my colleagues, and I hear it all the time. "Oh my God, how can we let pharmacists order tests and prescribe medications? Do they have the training?" I think it is important that we bring those concerns over and consider them, especially as we are making recommendations regarding federal policy.

I am personally of the opinion that everyone should work to the top of their license and training. I trained with and worked beside incredible pharmacists and clinical pharmacists over the course of my career, and I have a pretty good feeling about what we can do together working as a team. I think the more that we have true nationwide interoperability of health data, the more that we can rely on pharmacists to access all of the available data to inform decision making and then contribute that data back to all other members of

the care team and all of the providers who might touch a patient, the more confident we can be that the care provided will be safe and effective. Thanks for the opportunity to just add that, Shelly.

Shelly Spiro
I appreciate that, Steven, because some of the things that I hear out in the community… Just to let you know, the Pharmacy HIT Collaborative is in our 13th year, but it was really formed to ensure that pharmacists that provide clinical services are integrated into the national health IT infrastructure and how we can leverage standards to actually do that. I think what is important on what Steven has said as we move through with TEFCA and start to put some more structure into health information exchange is what I hear from smaller providers and smaller system vendors who cannot afford to connect to a health information exchange.

It is an affordability issue to some of the smaller vendors that are out there, and this then becomes an issue of how, in our test-to-treat and treating using medications such as Paxlovid, it would be difficult for some of those pharmacies to have access to the clinical data that they need in order to prescribe and/or dispense that particular medication, and I think that is the key to what we have to do from an interoperability standpoint. Pharmacy system vendors have to voluntarily meet the requirements for certification, and this comes back in: What does that mean as we move forward with public health? I am so glad that Chris, who is up next, can expand on some of those comments.

Chris Blackley
Yes, thank you. I have a question more than anything else. You made a very good point just now around the financial viability of not just the technical vendors, but also the pharmacists who generally pay for those. In the scope of this conversation and the Task Force, what are the boundaries of recommendations? Is it specifically limited to technical standards, or is it within the bounds of the charter to make recommendations for experts? How do we address the financial barriers to being able to use those standards?

Shelly Spiro
Well, Tricia Lee, if you are still on, can you respond to that question?

Tricia Lee Rolle
Thank you, Chris, for the clarifying question. We are welcome to accept recommendations back to us. I think what bounds those recommendations is an understanding of where and how ONC functions, and so, for example, you can make a recommendation that we need to go to the moon and launch a rocket, but we do not do space exploration, but yes, I think it is certainly within the realm to have us consider, where we do work with other federal partners, we work with CMS, FDA, and others, if there are points to be made around us engaging in work that is helping to support the adoption or use of certain health IT standards. I think that is certainly in scope, along the lines of the task. Developing business models is not something that we really get into, but hopefully that helps answer your question.

Chris Blackley
Thank you.

Hans Buitendijk

Tricia, on that clarification, I think under Topic 1 is where, David or Chris, if you have particular suggestions on what ONC could do, it sounds like it would allow for something we can take to enable exchange. That might be an enabler to make it happen and to consider, if not its own, with somebody else.

Shelly Spiro
Great. I saw another hand, but it disappeared. Steven, I know you brought up other providers, and this is probably one of our larger issues, like dentists, nutritionists, social services, and others that are part of the care team that might not have the requirement of certified EHRs to actually exchange health information, and so, I think that these are issues where pharmacy definitely falls into that category, along with others, like long-term post-acute care and rehab. All of these are connectivity issues that we hope we will eventually address. Again, this is not our focus, but you can see how our pharmacy is not connected, so we have to think about how that relates to other members of the healthcare team that it can also affect. I think ONC might learn a lot from our discussions that could be related to other practice settings and other healthcare providers who are part of the care team. Ike, I think you had your hand raised.

Steven Eichner
Yes, I did, thank you. I just wanted to make this workgroup aware of recommendations that were presented to HITAC last week that included some information about the impact of certification of EHRs and potentially looking at what constitutes a fully certified EHR versus modular or specialty certification in that space. There are some tradeoffs that need to get addressed that if you limit certification to a particular functionality, you may be missing things that you need later on, but it is an approach that can be discussed and considered.

Shelly Spiro
Great, thank you, Ike. Mike, I think we are getting very close and are right on time for our public comment.

Public Comment (01:18:04)

Michael Berry
Yes, great. We are happy to open up our meeting for 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. So, let's pause just for a moment to see if any members of the public raise their hand. Not seeing any hands raised yet, I will turn it back to our cochairs.

Shelly Spiro
Well, thank you. I know we have several folks who are not part of the panelists, so if you are, just put your chats in there if you do not want to speak on the phone, thank you. So, let's go back to our discussion for a few more minutes before we close the meeting down. Does anyone want to add additional comments, especially on what Ike just talked about, in relationship to what the last Task Force did as part of the HTI-1 recommendations?

Hans Buitendijk
Shelly, I think in the chat, there are a couple of different comments around the use of networks, not only looking at the pharmacists per se, but, in the process of describing, dentists and other areas that have interest as well because they are involved in the pharmacy medication-prescribing process, so I think there

are a couple other comments that we can pick up for notes as well. I am looking at Scott, Deven, and Steven. Is there any additional background you want to provide to that? Deven, go ahead.

Deven McGraw
I cannot speak to what the experience may have been for pharmacists, but in hearing some of the commentary, it did not surprise me that even pharmacists who have, under applicable law, the ability to prescribe or treat patients in some way, shape, or form often do not have their queries for data recognized when they are treating patients because they are not necessarily seen, either from a network rules perspective, which is probably less common, but in terms of other participants releasing data to them, it seems nontraditional and questions get raised. We have experienced it in the lab context, and it would not surprise me if that happened with pharmacy, and maybe with dentists as well, where there are these "You are concerned about the mouth, why do you need the rest of this data?" sets of questions.

Hans Buitendijk
Right. I think that is a good point, Deven. At a minimum, clarification of what is permissible, if not desirable, would be helpful in that space.

Deven McGraw
Yes, and in terms of ONC's authority, there is this bucket of standardization issues that have come up periodically on the call, but there are also the information-blocking rule policies. Thanks.

Shelly Spiro
Scott?

Scott Robertson
Yes. My comment is really in terms of coming from an integrated care environment, where access to information is sort of an expectation and done just as a matter of course. It is extremely important and very useful to have pharmacists as providers of care, but other care providers having appropriate access… On that comment a moment ago of "You are a dentist, why do you need this?", there are times you need to know about cardiac issues or medications that are being used. While not everybody needs to know everything, it is hard to really know where to cut things off because there can be interplay between medications, between diagnosis and treatment, and all of that, so I am really a supporter of greater access, but we should understand that there may be needs for some limitations, though we should promote it whenever possible.

Shelly Spiro
Hans?

Hans Buitendijk
I think Ketan's hand is up.

Ketan Mehta
Hi. I am a pharmacy software vendor. Obviously, I am in the middle of all these things, so I may ask a couple of questions which are going through my mind. First of all, is this only related to the data being sent for medications being used during the emergency rule, for example, the vaccinations? I heard comments

about needing to know about heart conditions and that kind of stuff. The reason why I ask this is because there have been multiple scenarios where, first of all, there are 50 states, so there are 50 different formats, which is fine. We go through vendors and we make sure that the data is being submitted. But then, there are questions being asked about if we have consent or not from the patient, so we have to rely on the fact that the pharmacy has taken this consent, so then we take other additional precautions on signature pads or text messages to say, "Hey, we need this consent so that way, we can release the data."

So, if this is only related to the emergency use, then yes, we have a limited scope. During COVID, we just started submitting all vaccinations, but if there is more beyond that, which it looks like there is, I do not know if that is a standard format, if that is one clearinghouse versus 50 and that is one standard method. I know it is a big topic, but I will just pause there because we are in between all of this.

Shelly Spiro
I will try to respond first before we go to Scott, but I agree with you, but there are other things that public health is looking at, such as antibiotic stewardship. We are looking at other areas with the opioid use disorder and other chronic conditions, like hypertension, that CDC and public health might be interested in, especially as we go into looking at health disparities and health inequity issues occurring. I think this is just the beginning. It is a good use case to figure this information out, but there are a lot of public health issues, and who knows when the next pandemic or epidemic might be coming? So, I think that it is a good use case, but I think that there are other areas that we need to consider, and if we come up with a good process, we will be able to handle any type of medication issues that need to be distributed throughout the care team and public health. Scott?

Hans Buitendijk
Before we go to Scott, just one additional comment. Part of it is that today's topic is, indeed, more around emergency public health, but perhaps in Topic 2 or 3, there are opportunities to address some of Ketan's questions or areas of concern as well. Variability across jurisdiction is always an interesting topic of ours as well, so I think there are some questions there on whatever we do, how we can make sure it is as consistent as possible when we communicate with public health, be it for emergencies or not, and generally that we communicate as consistently as possible. We will probably have a couple more opportunities as the weeks unfold.

Shelly Spiro
We have two minutes left. Scott?

Scott Robertson
For everything terrible that happened during COVID, it did provide **[inaudible] [01:26:16]** such as the emergency use authorization, the time that we were able to actually accelerate things that would have taken many, many years to come into being, such as further access of information and greater sharing of information and finding out what was good and bad about our existing systems. What still has to be recognized as the emergency use authorization plays out and comes to an end is that if pharmacists are prescribers, they have all the responsibilities of a provider. You do not just get to take on some additional capabilities without taking on responsibility as well.

I want to keep that in mind. We are not trying to carve out something special for pharmacists. These are responsibilities for everybody that is going to access or contribute information. In terms of different regulations in the states, that has been a problem for a long time. The idea of model legislation can sometimes help, and for the example of PDMPs, there are standards that exist, but they are just not in the same place in all the states. States have added complications in terms of different levels of funding available, so the best we can do is provide recommendations for a target that everybody can work toward in those regards.

Shelly Spiro
Thank you, Scott. I think that is our last comment. We are at the top of the hour, so I will turn it back over to Mike. I want to thank everyone for all their great comments and chats, and thank you all for moving forward. These are the dates of our upcoming meetings. Again, we have a call next week. Thank you, Mike. Is there anything else I need to say?

Michael Berry
I just want to remind everybody that the link to the worksheet that we displayed today will be sent out later today, if you have not already received it, and there was one other thing, but it went out of my mind, so it must not be too important. Otherwise, we will see you next Wednesday. Thank you so much for joining us.

Shelly Spiro
Thank you everyone. Have a great day.

Hans Buitendijk
Thank you.

Adjourn (01:28:54)