Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTICS TASK FORCE 2023 MEETING

September 27, 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
Ibrar Ahmed	ZS	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. We have a guest presenter joining us today, and I would like to thank him for participating. 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 going to 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 let us know if you are here, and 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?

David Butler
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Present.

Michael Berry
Thank you, Raj. Adi Gundlapalli?

Adi V. Gundlapalli
Good morning.

Michael Berry
Jim Jirjis? Summer Kahlon?

Summerpal Kahlon
I am here, good morning.

Michael Berry
Steven Lane?

Steven Lane
Good morning, I am here.

Michael Berry
Meg Marshall?

Meg Marshall
Good morning.

Michael Berry
Anna McCollister? Deven McGraw?

Deven McGraw
Good morning, everyone.

Michael Berry
Ketan Mehta? Justin Neal?

Justin Neal
Good morning, everyone.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
I am here, good morning.

Michael Berry
Hi, Eliel. Naresh Sundar Rajan is not able to join us today. Scott Robertson?

Scott Robertson
Good morning, I am here.

Michael Berry
Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

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

Afton Wagner
Good morning.

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

Opening Remarks (00:02:19)

Hans Buitendijk
Good morning, everybody. I appreciate everybody joining again, as well as those on the public side of the call, and for those who are joining first, you have every opportunity to participate in the chat, and for the task force members, make sure it is addressed to everyone, otherwise it will not get on the record, but everybody can participate in the chat throughout, and then, at the end, we will have any additional comments that you may want to make. We have a good agenda today. We are going to continue ramping up towards digital therapeutics, and Shelly will introduce that in a moment further, and then we are going to go back to recommendations and try to get more from draft mode to the green so they can start to move into the Word document, so that is going to take up the rest of the time for today. So, with that, I will pass it to Shelly and get us started.

Shelly Spiro
Thank you, Hans, and welcome, everyone. I just want to thank the ONC team for putting everything together for us and keeping us on track. We have a lot of recommendations coming in that Hans has just done an excellent job of getting into the spreadsheet, and now we are beginning to move that into a Word document so that we can present it to the HITAC. So, with that, we can go to the next slide. I would like to introduce

our speaker today, and I apologize if I mess up your name. It is Ibrar Ahmed, software and enterprise architect manager, ZS. I will turn it over to you, Ibrar.

Topic 3 Guest Presentation on Digital Therapeutics (00:04:24)

Ibrar Ahmed

Thank you. Hello, everyone. The name was absolutely correct. I work for an organization called ZS Associates. I will give you a quick introduction to digital therapeutics. Most of you already know, but I just wanted to make sure everyone is on the same page with respect to the definition, and then, I will share the needs from manufacturers, a lot of who we work with. I will give you a brief description of who we are and then introduce DTx, then look at considerations for standards as we develop standards for pharmacy interoperability and interoperability with other stakeholders. We have created a generalized view. It is not comprehensive, it does not account for each and every scenario, but it accounts for the most high-impact, high-need scenarios. So, we will look at the PDT ecosystem, and then we will discuss some of the things we have heard from our manufacturer clients. Without further ado, go to the next slide.

I am a software engineer and enterprise architecture manager for an organization called ZS Associates, as I mentioned. ZS is a global management consulting firm, and we have been heavily investing our time, energy, and leading DTx growth for our clients with a team of experts that we have in house. Some of the work we have done is product managing a number of PDT initiatives that are either ready to be released or are in the clinical evidence phase. We have implemented a SAMD, software as a medical device, COVID-19 solution led by our SAMD factory, which is ISO 13485 certified. Overall, we are both a business consulting firm and we have strong expertise in business technology, and that is what we leverage to support our customers and stakeholders, who range from biopharma, med tech, health tech, payers, providers, and retail health clients. One status I am particularly excited about is in one of our most successful programs, we have impacted the lives of 5 million plus individuals. So, this was a quick overview. I am happy to chat afterwards if you have any additional questions. Next slide, please.

I want to give you a very brief introduction to what DTx is. DTx is a software product that delivers evidence-based intervention. It is different than digital health. It can be broadly considered digital health, but digital health is not necessarily required to be evidence based. Its primary purpose is to engage consumers and stakeholders like ACPs for lifestyle, wellness, and health-related purposes. Some examples are fitness trackers, step trackers, telehealth, HIT solutions deployed in the hospital, and other user-facing technologies. On the other hand, digital medicine and digital therapeutics are regulated solutions that are based on clinical evidence. The definition of digital medicine here is evidence-based software and/or hardware products that measure and/or intervene in the service of human health. These definitions are taken from the DTx Alliance and Digital Medicine Society. Some examples of products that fall into this category are digital diagnostics, digital biomarkers, electronic clinical outcomes, and so forth, as well as remote patient monitoring.

Now, of course, the topic of our discussion, digital therapeutics, is a kind of digital medicine, but more focused around creating evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease. Again, I am going to highlight the importance of clinical evidence and real-world outcomes of these products. These, as well as digital medicine products, are reviewed and cleared or certified by regulatory bodies, and these solutions are apps with different mobile web form factors that treat or manage diseases or improve a health function. As I mentioned, digital medicine and digital therapeutics are both software as a medical device. Next slide, please.

So, I will get a little bit deeper into DTx. As we are considering standardization of workflow interoperability within pharmacy ecosystems, we need to understand that DTx can take many forms. It can be a standalone used as a medical intervention, it can be a companion, meaning a patient can just use the therapy app to have interventions in the quest to improve their condition and manage or treat a disease, but it also can be a part of a companion combo product, which can include a drug plus digital therapeutics combined. It can be for a physical therapy or drug, or it could also be part of an RPM, not necessarily an RPM, but part of or deployed within an RPM to deliver intervention or actively collect patient data important to providers.

These different forms lead to certain challenges as we think about standardizing workflow and data while allowing **[inaudible] [00:11:12]** to select treatment, prescribe, and then stakeholders filling prescriptions and including benefit verification. For example, because of these variations, a DTx can be over the counter or prescribed. It can be purely medical or procedural. It can be purely patient-led, where a patient somehow knows about it, researches it, or is interested in it and seeks it out, especially in the case of OTC, or it can be inclusive of a provider where the provider is helping to make decisions around the use of these. The different distribution channels include drugs, which we know mostly come through pharmacies, whether specialty or retail, but because of the technologies that are involved with digital therapeutics, there are so many ways to distribute them. We will discuss some of these in the ecosystem in a later slide. Next slide, please.

Shelly Spiro
Just to let you know, you have two minutes left.

Ibrar Ahmed
Oh, interesting. Okay, I thought I had a total of 20 minutes, but no worries. I can quickly go through it. One of the things to notice is that drugs have different data elements and data fields, whereas digital therapeutics have nuances to them, such as product identifier. Where is the product identifier that helps identify a particular DTx? That information is different in digital therapies compared to drugs. Do medication strength and quantity really apply to PDTs, or do we need to repurpose these fields that already exist for drugs? Substitutions: DTx is new. There is not a lot available there. There are not a lot of substitutions around it. All of these need to be considered, but first, we need to look at whether existing fields can be applied. If not, we need to explore additional fields or additional standards. NCPDP is a good place to start, but of course, there is more work to be done. Next slide, please.

So, this is a quick overview of the PDT, prescription digital therapy, ecosystem. We have PCPs prescribing it two different ways, electronic prescription through an e-prescription provider, which goes into digital, original, or specialty pharmacies, or even fax, phone, or online. As I mentioned, there are so many other channels, even online form and fax. They are similar to what we have today in terms of drugs, but where it gets interesting is when the verification happens for medication, it needs to be fulfilled, and when it is fulfilled, it is typically done by a manufacturer who activates the product for a patient.

The patient goes and downloads the app, activates it, and then starts using it, and from there, additional data is generated that a lot of ACPs or clinicians are interested in to get better insights about the patient.

The lines in orange are the areas where most of the needs are for standardization, workflow, and data because that is where a lot of the difference is coming. The ones that are blue are either existing standards like HL7 FHIR, in terms of the **[inaudible] [00:14:42]** integration that exists, or ones where manufacturers have the ability to use their own infrastructure and technology. Next slide, please.

I will take a few seconds just to highlight some of the needs that we have heard. There is a need to define DTx data more clearly and have a standard for it. For EHR integration, we have heard from ACPs a lot that to reduce their burden, the prescription has to be from within EHRs. For the fulfillment of prescription, there are data exchanges that need to happen between the pharmacies and the manufacturer and so forth. We need to have some standards and guidelines for it. Again, NCPDP is a good place to start. They have existing standards. I know they have a task force to expand on it. So, those are good places to start, but again, the need is there right now. There is a lot of demand and a lot of need, there are good promises for high patient impact, but again, work has to be done to standardize workflow and data.

Lastly, we have heard from our customers that we should consider using **[inaudible] [00:16:10]** claims, using medical benefits versus pharmacy benefits, comparing it to things like continuous glucose monitoring, where there is a precedence to leveraging medical benefits to educate. That is all I have. I wanted to share the perspective of our customers. Thank you so much for listening to me. If you have any further questions, feel free to email, and of course, we can chat in this webinar as well.

Shelly Spiro
Ibrar, thank you, and I apologize for the miscommunication. We usually give our speakers about five minutes, and we did start early, so I am glad you were able to get through all your slides. My apologies for that miscommunication.

Ibrar Ahmed
No worries, thank you so much.

Shelly Spiro
We do want to open up the discussion to our task force members, and I want to remind our attendees to please go ahead and put your comments in the chat as well. Any questions from the task force? Hans?

Hans Buitendijk
Good morning, and thank you for your update and background there. I really appreciated that. As you started to go into some of the connectivity that is needed where some standards organizations may fit or not, at this point in time, is there a community that is already active to identify those gaps and start to work with those organizations to close those gaps, or is that work that still needs to start and a community that would still have to form to help move that forward? Where are you in the progression of addressing those gaps?

Ibrar Ahmed
I have to admit that I am not as involved in those communities, but there are certain communities that are starting to think about it and at least lay out the requirements and the needs. DTx Alliance is one, Digital Medicine Society is another one, and the NCPDP task force is a third. So, there are certain initiatives that have started. Again, I still cannot stress enough the need for standardization and acceleration that is needed

because what happens is the growth of technology is rapid. There has been optimization in gathering digital evidence, so, compared to a drug that takes years to gather evidence, digital therapeutics requires much less, not necessarily a few days or a few weeks, maybe a month or a year, but it is relatively less. The rapid growth of technology and the constraints that we have get compounded. All the initiatives that we have are great initiatives, but we need to accelerate that, in my opinion.

Shelly Spiro
Ibrar, thank you. My question is there are, especially through the FDA, some requirements on digital therapeutics, including clinical decision support algorithms, use of artificial intelligence, and other areas. Can you comment on what that means in terms of assuring that there are some standardized processes for patient safety, population bias, and some of those areas?

Ibrar Ahmed
I will try my best to answer that question from our observations in working with our customers. I am not going to claim that we have thoroughly evaluated each and every directive from the FDA, but as we work with our customers, we have looked at specific directives and unpacked that. With CDS, there have been a few notable discussions around it from FDA and some guidelines around it. Typically, clinical decision supports are not necessarily considered digital therapeutics. It is definitely digital medicine for sure…well, not necessarily. There are some criteria to meet to classify CDS as digital medicine. Some do not have to. For instance, if a solution is relying heavily on or sharing insights with an ACP, but letting clinicians make decisions, the clinical decision support is essentially supporting the clinician. That does not have to be a digital medicine and does not have the same risk classification.

And then, you mentioned AI. AI is interesting because it has the ability to learn continuously. One of the things we have understood as we have worked with our customers is to say when we build an AI algorithm to integrate into digital therapeutics or digital medicine, we ensure its explicability, which is difficult. It is not easy. The way these technologies work, it is not easy to draw up explicability about how certain decisions are made. We recommend that our customers spend a lot of resources in mapping the data that was used to make certain predictions or come to certain conclusions, but once the decisions are made from the algorithm, it should be looped back to see what data contributed to it, creating the explicability. So, that is one important thing.

Another important point that we have been stressing to our customers is you can **[inaudible] [00:22:00]** AI predicts, feed the prediction back to retraining of the algorithm automatically. We recommend that our customers not do that for the time being, given that when that happens, the AI model changes, and every change will have to be reviewed for risks. So, those are some of the strategies we have been taking to ensure that we still leverage the strong technologies that impact patient lives and human lives, yet we safeguard them by being a little defensive in areas where it can cause safety issues. So, we have been encouraging our customers to behave that way. I hope that answers your question.

Shelly Spiro
Yes, that was great, thank you. Pooja?

Pooja Babbrah

Thanks for this presentation. It was very helpful. There are a couple of things. As a task force, we have to come up with recommendations for ONC, and we are starting to do some work around this as well with DTA. When I think about what you said earlier with the prescribing, there are already standards in place and all of that, so it would seem like with a recommendation for ONC around digital therapeutics, there should not be any difference in terms of being able to prescribe these digital therapeutics if they are in the EHR workflow. I guess a question to you is from a task force standpoint, should the recommendations that we are thinking about go more toward collecting this patient data and doing that? Are some of the gaps that you identified covered under the medical benefit? If you had a wish list, what would be your wish list for recommendations to move these therapies forward?

Ibrar Ahmed

So, I do agree there are standards that exist to prescribe electronically. I have worked with FS3 customers directly who have not figured out what is the most scalable, least frictional approach to integrating the prescription of their product within an EHR. By no means am I saying they should significantly change the interoperability standards. The standard needs to account for some of the key differences. For example, in a PDP, when you transmit drug data using NCPDP standards or other standards, you are sending certain data, some of which might not be applicable to PDTs, and you may not be collecting certain data that may be applicable to PDTs.

One example was in the slides. The PDTs depend on a patient's device. What should be the device's minimum requirements? What should be the versions of those operating systems? There may be fields existing within those standards that can be repurposed or added. My recommendation would be to look at these standards and the fields that the standards expose to systems that are interoperating and explore which of these can be reused and repurposed, which ones we need to add additional fields for, and what the guidelines are if you want to repurpose them, strong guidelines so most providers, pharmacies, and manufacturers use the same standards so, when they send the data, everyone is reading it in the same way and there is no reason for confusion or issues like that.

If you really asked me my wish, it would be to standardize the way the EHRs embed or integrate new technologies with respect to PDTs. There is a bit of a gap there about getting that into a PDT once it is manufactured. To me, that is a lower priority, but there is a bigger pain point once… Somebody asked what the role of the pharmacist is. The pharmacist's role is very important. We have heard from a lot of our customers, our patients who we have done primary search with, that they are very comfortable with talking to pharmacists. They have a good relationship with them, especially in the case of specialty pharmacists, so they are very important stakeholders in training patients, educating them, and guiding them through concerns that they may have.

Basically, clinicians are one group of stakeholders, and pharmacists are another. They have these existing connections and infrastructure to do benefit verification, so that can be beneficial, but looping all of that back, once benefits have been verified, how does the manufacturer get the data and activate the patient's therapy? That is an area that we need to spend some time figuring out and standardizing. Different organizations do it in different ways. There have to be some standards so that, again, for pharmacies, it is easier to scale the data exchange standard with less confusion and fewer issues. That would be another area of interest.

Shelly Spiro

Thank you. We have had a lot of discussion in the chat. Go ahead, Hans.

Hans Buitendijk

I would like to follow up on the last point that you made on some of the primary topics. I am trying to tease it out a little bit more based on a comment I made in the chat as well. There is the prescribing part and the resulting part, in a way, and it seems that in that area, there are a variety of standards available. It might be more of a configurations question to ensure that systems can manage that, but then, there are the other interactions between the digital therapeutic device and the variety of environments.

I am trying to understand the key areas you are looking at in that space where you may need more information from an EHR. I am just going to go through something. Is there anything that, once it has been ordered, there is now a need to interact for these devices to get information from the EHR to provide better context? Is there more information that is needed back in addition to the actual results themselves? Is there other information that may be needed to interact with the pharmacy system? I am trying to get a high-level, general sense of where those interactions are and where you think the biggest pain points are to move this forward beyond prescribing and getting a result back.

Ibrar Ahmed

With eligibility benefits, reimbursement is a big pain point for incentivizing manufacturers to continue to innovate. This is why a comment from one of our customers asked if we should explore a medical benefit versus a pharmacy benefit. I have been in some of these webinars, and I have heard the strong case to commit to pharmacy benefits. That is one aspect of it from a pharmacy standpoint. From a patient STP standpoint, some work needs to happen to have a circular way to optimize and improve. So, data is being collected, it goes into an EHR, and then, based on that EHR, how do you change the patient's treatment regimen? In general, a lot of these therapies are not necessarily…

Let's say you go to therapy twice a week, and data is collected, vitals or whatever the endpoint is that the therapy is trying to influence, but given the current setup, it is not very easy to change treatment regimens right away given the flow of data that needs to happen, but also the accountability of what data is being used to come to that conclusion. Who needs to see this data to say, "Okay, the patient has been on this therapy, now we need to update the therapy because we are seeing improvement or not"? Being able to have that flexibility or configurability in terms of the treatment regimen in the prescription itself or in the fulfillment space would be beneficial, but I feel like a lot of that also comes down to the manufacturers. Manufacturing needs to be able to have that configurability, and it has to be evidence-driven. They cannot just say, "Oh yes, I can give you a technical solution." Technical solutions are easy compared to evidence. So, it has to be evidence-driven that if I change the treatment six months down the road, I can make it feasible without causing any concern to patient safety. Those would be my areas other than the no-brainers.

Hans Buitendijk

Thank you.

Ibrar Ahmed

Somebody just mentioned that it would be helpful for pharmacists to view changes in therapy based on tension monitoring of DTx. I agree with that. I think it is an important piece. In fact, we have also heard from pharmacists that while they are not clinicians, patients come to them and say, "I still have a headache. When will that go away?" Having data-driven training for pharmacists is very beneficial. Of course, they cannot consult, they cannot say, "Oh, go take this medication," but they can be empathetic and share their perspective from that lens. That would be beneficial.

Shelly Spiro

Thank you, Ibrar. Any other comments from our task force? If not, we are going to move on to our Topic 1 and Topic 2 recommendations. Thank you so much, Ibrar. You are more than welcome to stay on if you would like. We will go ahead and continue with our work. I will turn it over to Hans.

Topic 1 and 2: Review of Recommendations (00:33:22)

Hans Buitendijk

Thank you, I really appreciate it. So, we are going to go look at the recommendations to date and continue the progress we made in reviewing them. If you can put up the spreadsheet, we will pick it up with Topic 1. Along the way, based on the discussion that we just had around digital therapeutics and some of the other ones on specialty therapeutics, if you have any suggestions for recommendations, please add them to the Topic 3 recommendation tab. Let's start at E2. You will see that we have started to put text in green.

Just as a brief reminder, everything that is starting to shift today to green as well is going to be moved into the Word document, where we are going to progress our editing and organizing to make it flow better and connect further, and that could also yield some updates there, but green indicates that we effectively have general agreement that this is an appropriate recommendation and rationale to go in and that we are moving it out of the spreadsheet phase and into the Word document phase. What we wanted to do today is check up on the progress made with a couple of follow-ups that we had in the recommendation that are not yet green in the first couple rows, and then we are going to continue reviewing the rest and try to get as many as possible flipped over.

Steven Eichner

Hans, can you zoom in a little bit?

Hans Buitendijk

Sorry, I am not presenting, so if somebody else could enlarge it a little bit, that would be great.

Steven Eichner

Sorry for interrupting.

Hans Buitendijk

No worries. Any other questions up front before we jump in? Okeydoke. There we go. Is that better, Ike?

Steven Eichner

Yes, sir.

Hans Buitendijk

All right. So, in the first one, I am going to be looking on my screen at a slightly larger spreadsheet. I am not going to be able to follow hands up exactly or not, so, Shelly, keep me honest if I miss somebody.

Shelly Spiro

I will.

Hans Buitendijk

So, in the first one, we have R2, a couple of updates that were highlighted in red. I was going to look a little bit further at that and wanted to check in. Ike, any updates or additional ones that you were thinking of or that you think we have ready for review?

Steven Eichner

I think we did them. There is a minor typo. "May prescribe" should probably have a space in it.

Hans Buitendijk

Okay. So, let's look at this. What we have right now is "Recommend that ONC work with pharmacies, pharmacists, and public health organizations, including CDC and STLTs, to provide education, awareness, and, where needed, further policy guidance to pharmacies/pharmacists regarding submission of case reports, immunization, laboratory results reporting, syndromic surveillance reporting, and other data collected by public health agencies, as well as capabilities already available, opportunities, and need for bidirectional exchange between public health organizations, pharmacies, and pharmacists. This should include addressing supporting standards available to report this information to comply with current reporting requirements and mechanisms and capabilities for pharmacies and pharmacists to access public health information."

Any further thoughts on that, or do we feel that we have the recommendation reasonably nailed down to move it into the Word document? Any comments or questions on that? As you go through, looking at the rationale, are there any further thoughts to be modified or added there, or do we think that we have that also? I am not sure whether that one is fully visible. That is always the hard part.

Shelly Spiro

Do you want to scroll down a little bit?

Hans Buitendijk

There is more.

Shelly Spiro

Don't you have to click on it?

Hans Buitendijk

Double-click on it, try to edit it, and you will get the rest, and then we can look at the other ones more easily as well.

Shelly Spiro

That is better. Scott has a question. Scott?

Scott Robertson

It moved. I have to find it again. In the rationale, the second sentence may be convoluted. "There is a need for pharmacies and pharmacists to understand reporting requirements…" Sorry, I lost it. If I find it again, I will raise my hand.

Shelly Spiro
Is it where she has it highlighted?

Scott Robertson
No. There was a problem about sharing data…maybe up in the green. Can you scroll up into the green just for a second? It should be done.

Hans Buitendijk
Scott, if it is in the green, I would suggest that you make a note separately. If we need to catch a sentence that did not roll very well, we can do that.

Scott Robertson
No, it is not in there. I lost it when the things shifted. I will look for it, and if I find it, I will raise my hand again.

Hans Buitendijk
Okeydoke, thank you. Anybody else?

Scott Robertson
Nope, go ahead.

Hans Buitendijk
Okay. Then, for now, we are going to take the red out and turn that green. Let's go to R3, then.

Steven Eichner
Actually, I have one last thing on R2. We should put "public health agencies," not "organizations."

Hans Buitendijk
Okeydoke. Let's make that as a general note, and then we can use "PHA" as an abbreviation where needed as well. Is that fair?

Steven Eichner
Absolutely, thank you for that.

Hans Buitendijk
Okay, we will make that as a general added note. Thank you. Let's go to R3. "Recommend that ONC initiate a collaborative initiative with the patient, caregiver, pharmacy, pharmacist, other providers, and public health agencies, including CDC and STLTs, to prioritize use cases focusing on bidirectional data sharing and/or exchange among pharmacies, pharmacists, and other providers to patients' medical records held by each entity as part of the care team under emergency use interventions as well as during normal operation. Within established privacy policies and patient consent directives, patients should have expanded access to disclosure information from what is in practice today, including disclosures for PTO to

improve accountability regarding exchange." That update should have hopefully addressed Alexis's comment as well, so, particularly from Alexis, I am interested to know if we caught it in that part or not quite yet.

Alexis Snyder
I am trying to reread it and absorb it. I am not seeing what my comment was originally to be able to answer your question. Right now, it sounds okay, but I will look at it again.

Hans Buitendijk
Your original comment is…

Alexis Snyder
"Adding patients and caregivers"?

Hans Buitendijk
Yes, and I think that was D7, if I am not mistaken. We can look up where exactly it was.

Alexis Snyder
I think it looks okay for now. If I see something else, I will let you know.

Hans Buitendijk
Okeydoke. And then, I see Deven's comment about PTO. Do we have a typo? Should it be "TPO"? Should it be "treatment payment operations"? Which direction does it go in?

Deven McGraw
I have never seen it abbreviated as "PTO" before because that says "patent and trademark office" to me, but I think as long as we spell it out, it does not matter.

Steven Lane
And "paid time off" to others. "TPO" is usually what people use.

Hans Buitendijk
Okeydoke. I got that one.

Deven McGraw
We should spell it out.

Hans Buitendijk
Yes, I just spelled it out, and we can reference that later accordingly. So, Alexis, we will keep your question there for now and come back if we missed something. The next part of the recommendation is "Access by public health agencies, including STLTs and CDC, to patient health records maintained by pharmacies and pharmacists and for pharmacies and pharmacists to access relevant public health data for their patient populations. Overall, identify the appropriate relevant data sets, such as those captured during Pharmacist eCare Plan, in communication with payers for these use cases to ensure the correct and necessary data is shared for the use case at hand." There is a typo there that we will catch. Any other comments on the

recommendation, considering that there is still a little bit of fine-tuning on the sentence flow and we may have to chop up one or two sentences? Is there anything on the rationale as you move into that part to make sure? I am not seeing any hands.

Steven Eichner
This is Ike. I just want to make sure we are clear on looking at the disclosure components. If we can, we want to take a step forward in disclosure information for patients, not stay at the status quo.

Hans Buitendijk
Do you feel that the statement that says "including disclosures for TPO to improve accountability regarding exchange" is sufficient, Ike, or do you feel that more needs to be stated?

Steven Eichner
I think we are good. I just want to make sure that **[inaudible] [00:44:30]** with the rest of the folks that people understand what our goal is in general.

Hans Buitendijk
Okay. In that context, is there anybody else? Scott, I see you have your hand raised.

Scott Robertson
In the R3 rationale, there is a parenthetical in the second line, "this is not necessarily all the medication a patient has." I wonder if that is referring to prescriptions from other pharmacists, other pharmacies, or drugs to be dispensed, or if the patient has been recently discharged and has a series of medications that are pertinent.

Hans Buitendijk
Are you suggesting that we should say "access to the patient's pertinent medication list" rather than "complete," and then we can strike…?

Scott Robertson
Or possibly beyond what that pharmacy has.

Steven Eichner
I think a complicator is that the medication list in an EHR does not always reflect all medications that the patient has or that the owner of the EHR record is even aware of. In other words, something got stuck in a patient note because there was no place to put it in the medication list.

Scott Robertson
I see what it is trying to say. Afton has a decent thing in the chat, "all medications that are pertinent to the…"

Hans Buitendijk
I just made a brief update there, if you can close the cell and open it back up again. What I changed it to is "Pharmacists need access to the patient's pertinent medication list, particularly medication beyond the immediate knowledge of the pharmacist," and then continue. Can we put something like that and wordsmith it further, and does that sync with Afton's note as well?

Scott Robertson
I will look at further wordsmithing because we have a lot to go through.

Hans Buitendijk
Okay, so, you can look at that, and then, Afton, are we heading in the right direction and can work on this further?

Afton Wagner
Yes, I think so. I was just trying to point out that to see any medication possible is the best scenario for a pharmacist so we can make sure there are no drug interactions with anything we are adding or taking away, so anything we can get is good information, and Scott, I am happy to work with you if you want me to help wordsmith.

Scott Robertson
Okay.

Hans Buitendijk
I am marking it up for Scott and Afton to double-check the second sentence, and then we can move that along. Other than that, are there any other comments that we need to address before we then can turn it green as soon as we have Scott and Afton's feedback? I do not see any hands. All right, then we go on to the next part. We are going to go E3. There were a couple of updates on R10, "Recommend that ONC collaborate with CMS." Anna, Pooja, and Ike were going to provide some updates. Is this currently reflective of some follow-ups that you may have done?

Pooja Babbrah
I have not gotten together with anyone, but I do not know if we even had that scheduled yet. I apologize.

Steven Eichner
This is Ike. I went in and made some recommendations in red in the current draft.

Hans Buitendijk
Okay. So, maybe we will skip this one to give Pooja the chance to review further as well. I think Anna is traveling at the moment, so she might not be able to look at it. As soon as you are done, then we can move that forward and review it next time.

Pooja Babbrah
I just quickly reviewed what Ike wrote. I am actually good with that. I think what he wrote makes sense.

Hans Buitendijk
Okay. Any other comments? Then it sounds like we can move this one to green and adjust the colors otherwise. Great. Let's look at R11, then. "Recommend that ONC work with CMS, STLTs, and other relevant agencies to develop an incentive structure so that prescribing providers and patients can be accurately informed at the point of care with information regarding the availability of prescribed/recommended medication intervention at the pharmacy selected by the patient and the prescription has been

sent/referred." I think we have a bit of a long sentence there that we need to work through. I am not sure whether Christian, Anna, Afton, and Alexis had a further chance to look through this as well and that it might still be part of the review to split it up and make it a little bit easier.

Shelly Spiro
Afton?

Afton Wagner
We have a meeting scheduled this afternoon at 2:00 to look at it. I know Anna is out right now, but we were just going to take a look at it. In looking at this, I do not see any huge issues with it. I was getting caught up over the fact that I know that a pharmacist's inventory changes a lot, and I guess I was just trying to look at it from the prescriber's perspective and the perspective of the patient at the point of prescribing. Let's say a provider pings the pharmacy and says, "Do you have this in stock?", and right at that moment, they do not, but they can order it the next day and have it in there. That is why I was saying we should focus on a use case for urgent medications because then we can find where the drug is if the patient needs to pick it up in the next hour or two, like an antibiotic that they want to get on right away, but if it is something that can wait for another day or so, how would the prescriber respond? Would they be responsible for pinging another pharmacy to find out when, in fact, the original pharmacy could just get it in 24 hours?

I was just thinking through the different scenarios that could come up from that and trying to make it a little bit more nuanced in what we could actually do because if someone was talking about how a hospital does this today in community pharmacies, you are getting people that come in and out all the time, patients picking up medications, leaving the pharmacy, coming in, and getting it off the shelf for somebody. So, there are a lot of ways that it could and could not work. I just wanted to make sure there were not any unrealistic expectations from the patient at the point of prescribing if they go in and it is not in stock because it was dispensed that day or something. Things change so frequently. I think that is just where Christian and I were coming from with our concerns, but if we wanted to study this in this recommendation, I am okay with a workshop just to see how this would work. I just do not know if it would be super accurate all the time. Those are just my thoughts on it, and I am open to discussion or thinking about how to rework this.

Hans Buitendijk
You did indicate that this group is going to be meeting this afternoon.

Afton Wagner
Yes, we are.

Hans Buitendijk
So, as you follow up there, you might have an updated statement from that, and we will pick it up next week again to see where we are at.

Afton Wagner
Sounds good.

Shelly Spiro
Alexis?

Alexis Snyder

Sorry, I forgot to unmute. We are going to talk about it as a small group after this meeting, but as I brought up last meeting, it goes beyond what is in stock currently. It goes to whether or not it can even be ordered, and whether there is a shortage on that drug, and you may need to switch to a different dose or a different drug altogether, so I think we are missing all of that here, but we can discuss that as a group later.

Hans Buitendijk

It would be great if you could review that and see how it could be worked in, either inside the one recommendation or by splitting it up. Ike, I think you had your hand up.

Steven Eichner

I just wanted to claim the responsibility for making the suggested changes in red in case anyone was curious about where they came from, and I had intentionally used information regarding the availability rather than trying to come up with a definitive of "Yes, it is in stock, no, it is not." I imagine that could be very complex across a pharmacy network where, yes, there are large players that may have a consolidated inventory system, like the Walgreens and CVSs of the world, but thinking about the independents and smaller pharmacies that may not be as connected in, I could envision that it would be rather complicated to have a real-time, accurate inventory, so a good compromise might be information regarding the availability in some cases, "Yes, this is in stock, this can be ordered," etc.

Shelly Spiro

Hans, David Butler posted a question, and I do not know if he wants to speak on this, but there was an overall question on the difference between "pharmacist" and "pharmacy." David, do you want to speak to it, or do you want me to read the chat?

David Butler

The chat will probably cover most of what I am thinking of, but I think it is important to address it, so, thank you for the time. If I might sidestep for just a second to the comment on Ike's concern about the independent pharmacy, one thing that occurs to me is that most of the independents utilize systems that are provided by the pharmaceutical supplier companies, the McKessons and the like, so they typically do have networks that can tell them which products are available in the local distribution center, when they can receive them, and things like that, so I think there is backup in that regard that would give them access to that information for inventory.

Hans Buitendijk

If I am reading this comment correctly, you would suggest that we not refer to "pharmacies and pharmacists," but that we stick with "pharmacists" unless there is a really good reason to have the pharmacy called out as an organization.

David Butler

Exactly, and to correct some of what I had in there, the pharmacist is responsible for all the patient care information data, not the pharmacy, so I think we are implicating the wrong individuals or wrong entities if we combine the two. Plus, it is the pharmacist who is the practitioner, and to me, that is where we are trying to focus, so it should be the pharmacist who receives the information, not the pharmacy.

Hans Buitendijk

If the topic goes along inventory and otherwise, more of the operational topics, then would you be okay with using the term "pharmacy" so that we can figure out where to include it and where not to?

David Butler

For purposes of storage and security and such, absolutely. If the inventory has an effect on patient care, then it is the pharmacist who has the responsibility.

Hans Buitendijk

So, we will look at the recommendations, and please help us with that as we go through to make sure when to include just one, both, or the other.

David Butler

I will be glad to do it. In regard to that, there is one other expansion, because we were talking previously about the fact that there are pharmacists, and then there are other providers. Quite often, because of the uniqueness of pharmacy in this role, the pharmacist is sometimes the dispenser, but it is also sometimes the other provider because a pharmacist can administer, as we are seeing with immunizations, and so, they can participate on the provider side in roles that make them either also the dispenser or that may be separate from the dispenser. So, we are going to have to be careful about where we place the pharmacist in these categorization.

Hans Buitendijk

That is a fair point, and as part of the description overall, the terminology that we are trying to use should stick within the terminology of 21st Century CURES Act and otherwise. We need to clarify that when we say "pharmacist," we are meant to be inclusive of the variety of all the authorities that they have, and "other providers" covers everybody else that is not also otherwise a pharmacist. We should try to see how we can work that.

Shelly Spiro

Ultimately, you cannot have a pharmacy without a pharmacist, so I see David's point. It looks like Steven has his hand up.

Steven Lane

I just want to build on David's point and take issue with a small piece of it. Insofar as possible, I think we should try to track the way we approach pharmacists and pharmacies in the same way we approach physicians, other licensed providers, and the facilities in which they work, such as clinics, hospitals, etc. I am not sure it is accurate to say that the pharmacist is the individual with legal authority over all information any more than you would say that about a physician. I work in a clinic inside a health system. Each entity has legal authority based on how the rules are structured and how the IT systems are managed, etc. So, I love the idea of being very specific in our use of the term "pharmacist," that they are a provider, they are licensed, we are discussing supporting them being able to be a part of the care team like any other provider, and I do not think that we should start a whole new way of thinking about pharmacists and pharmacies, but it should track very much to how we refer to physicians and the facilities in which they work.

Hans Buitendijk

Great point, and as we try to define it better as part of the document, we should make sure that is clear enough, knowing that this is also an area with some gray zones in between. Summer?

Summerpal Kahlon

Thanks, Hans. Actually, Steven just said a lot of what I would have said a moment ago, so I agree completely with what he said. The only last thing I will add is I do think it is important to distinguish “pharmacist” from “pharmacy,” particularly in terms of the recommendations here. A lot of what we are ultimately recommending in terms of standard adoption and certification falls more under the pharmacy as an entity, similar to the comments earlier about a medical office or hospital being oftentimes the responsible party to incorporate and adopt a standard as opposed to the individual clinician on site. I would only suggest that as we ensure that we are being particular about that language, particularly “pharmacist” versus “pharmacy,” any point at which it becomes a recommendation for ONC to encourage adoption or certification of some kind of standard should really be at the level of the pharmacy organization as opposed to the individual pharmacist.

Hans Buitendijk

So, that goes back to being careful about two things. One is when to use “pharmacist,” “pharmacies,” or both, but it also sounds like we should never use “pharmacy/pharmacist.” We should always address them separately if both need to be involved in the recommendation or one or the other. Any other comments at this point in time?

Steven Lane

Sorry, Hans. To Pooja’s question of if pharmacists are covered under “providers,” it depends on whose definition you are looking at. We have been through this before. There is a CMS definition of providers, there is an information-blocking definition of providers, and there seems to be some mismatch between them. I think Shelly, Deven, and others know more detail on this, but I do not think there is one single clear answer that we can hang our hat on.

Hans Buitendijk

Which makes it a little challenging for us in how we are going to phrase this.

Deven McGraw

Thanks, Steven. I appreciate that.

Hans Buitendijk

Okeydoke. Let’s move on, then. So, we will get more information from the team on R11, and also in the context of this. Let’s look at R12. We had indicated last time that R12 is out of scope as currently written, and therefore, unless somebody has another way of phrasing this, we are going to put it on the out-of-scope list. Does anybody have anything they are working on to be aware of? Otherwise, we are going to mark this as out of scope. I am not seeing or hearing any comments, so it is out of scope at this point in time.

David Butler

Sorry, I had my mute button on. I think this is the one that I was supposed to take a look at, and I thought I made changes to it in the spreadsheet. I know I did, so I am not sure if you are… Is this the one, or is there a different one? I get lost in these cells.

Hans Buitendijk
There is a different one where you were called out to provide a rewording, and I am just trying to go down to see where that was.

Steven Eichner
Maybe it was the metrics one, Hans. I think that is R6.

David Butler
Yes, that one as well, but this one was put in with regard to PBMs, their coverage, and the formulary changes, and I think Alexis may have…

Hans Buitendijk
David, can we follow up on this? I am not seeing some of the red marks there, and I just want to double check with an old version to make sure we got the right place, so we will follow up on this one specifically to make sure we did not miss out because there was definitely one where you were going to try to phrase something in a way that would make it in scope, and it might have been that we are just not quite seeing the change and the red line.

Alexis Snyder
This is Alexis. I just heard my name, but I think you were referencing Anna.

David Butler
That may well be. Sorry.

Hans Buitendijk
Okay, we will come back to R12, and we already made R13 and 14 green. We know that they are going to be further aligned with some of the other comments that were made to line them up better, which means we are going to go to the next spot, and this is where we left off and have not looked at before. We are now looking at R15 and R7. R15 indicates, "Recommend that ONC recognize interactions between pharmacists and other providers as a critical component," though I think we have one word too many, and I will chop that, "of trusted exchange frameworks' treatment exchange purpose and address the barriers and encourage education for pharmacies and pharmacists to join the TEF as it is operationalized. This should address both the ability for pharmacists to query other providers and other providers querying pharmacies for patient data." Any thoughts or comments, recognizing that we still have this work of "pharmacies" and "pharmacists," particularly in this one, where we are going back and forth?

Shelly Spiro
Ike?

Steven Eichner
I have a friendly amendment. I think it should probably be "ONC work with the RCE" in that space.

Hans Buitendijk

Okeydoke, we will work that in because yes, it is both ONC and RCE, so we will work that in and make that comment. Thank you.

Shelly Spiro

David?

David Butler

Maybe I am getting a little too picky here, but it seems to me that when we use the term “other providers,” it should be “any provider.” Rather than using the term “other,” it seems like it would be more specific. We really want it to be any provider the pharmacist could interact with. It just seems more exact in terminology to me.

Hans Buitendijk

Would it be “any other provider”?

David Butler

I think it would just be “any provider,” a pharmacist interacting with any provider.

Hans Buitendijk

Let’s mark that for a moment to make sure. We talk about pharmacists and other providers who are not pharmacists, but here, you are saying it is pharmacists and any provider, which could be other pharmacists and other providers.

David Butler

Yes.

Hans Buitendijk

Got it. Any concerns if we do that? We may still have to further tweak that, but I will mark it as “any” and strike through “other,” but we need to look at that further with the rest.

Steven Eichner

Hans, this is Steve. At the wordsmithing level, it should probably be “a pharmacist and any other provider” or something in that space because, as Deven pointed out, a pharmacist that is not the first pharmacist is another provider.

Hans Buitendijk

Right. That is where we need to make sure we got it straight in our definition.

David Butler

My concern is that from a relational viewpoint, “other” is not a global term. It does not cover the full set of providers, where “any provider” would be the full set of providers.

Hans Buitendijk

Yes, in that particular context, and Ike agrees. We have to go through everything here to make sure that in all the recommendations, we use “other providers,” “any providers,” “pharmacists,” and “pharmacies” correctly because of the overlapping terms that we have as they are being used.

Steven Eichner
And it may not be every other provider of other types. I cannot say for sure one way or the other whether with durable medical equipment or some other esoteric provider type that there may not be a direct connection. I do not know.

David Butler
That is a good point. Should it be “healthcare provider”?

Hans Buitendijk
I thought “healthcare provider” was implied in “provider.”

David Butler
Then, from my viewpoint, that covers Steven’s comment. Thanks.

Shelly Spiro
Pooja?

Pooja Babbrah
In the rationale in R15, I notice there is some red text that was put in, “where they are part of the test-to-treat process,” and I know we are specifically referring to public health emergencies. I am just wondering if that is going to limit us if, in a future public health emergency, it goes beyond test and treat. I do not know if we need that specifically.

Steven Lane
I agree, Pooja. I do not think we want to artificially limit ourselves.

Hans Buitendijk
So, you would suggest striking that?

Pooja Babbrah
Yes, strike what is in red, because it should just be part of emergencies, interventions, and normal operations.

Hans Buitendijk
Okay, I just struck it, so if you do a refresh of the cell, you should see that. Thank you. Any other comments, or do we feel that with all the general wordsmithing we need to do, we are okay with this recommendation and rationale, move it into the Word document as green, and work it from there? I am not hearing or seeing anybody else. R16, “Recommend that ONC recognizes the pharmacist-public health interactions and reporting as a critical component of TEF’s public exchange purpose and address the barriers to consistent standardized data elements and formats across the public health community, including CDC and STLTs, considering reported framework such as APL’s case reporting approach. This not only applies to pharmacy

interoperability, but all reporting to public health by all providers." Any comments, thoughts, or adjustments? I am not hearing or seeing anything. Oh, Summer?

Summerpal Kahlon

Thanks, Hans. My only comment is that generically using the term "public health" or "public health agency" is very, very broad. There are a lot of components in a public health agency, some of which can be very different. There are clinical components, emergency management components, and more routine surveillance components, so I do not know how much it is worth doing here, but it seems like we ought to be a little bit more specific about what we mean by "public health" and what that level of engagement is.

Hans Buitendijk

Where would you tie that further to a specific subset of public health in that sense?

Summerpal Kahlon

The first one would be public health departments, where there may be clinical services that are offered, maybe coordinating vaccines, for example, or medications for treatment of certain conditions, sexually transmitted diseases, and other outbreak sorts of things. I think that might be one component, and more routine surveillance would be a different component of public health reporting data. Immunization registries come to mind there, as well as condition reporting, disease registries, and that kind of thing. I am open to more comments here, especially from those that are deeper in the public health community, but I think there are a lot of facets to public health organizations that probably represent more nuance than what is here.

Steven Eichner

I would agree that that is true. For the purposes of the recommendation, I think we probably want to be a little bit broad, perhaps calling attention to some as examples, but not necessarily limiting. I also just noticed that we probably need to correct the APHL line a little bit, but that is more editorial than anything else.

Hans Buitendijk

What we could put in the last sentence is "This not only applies to pharmacy interoperability, but all reporting to public health by all providers and public health agencies." That might help clarify it in that context, where we are talking about the agencies. Does that help?

Steven Eichner

Yes.

Summerpal Kahlon

Maybe it is a combination of the terms "public health departments," which are more local, typically at the county and state level, and "agencies," like CDC, which is more federal.

Steven Eichner

Using the term "public health agency" is inclusive of both. As an example, in Texas, there are some local health entities that are not local health departments because a local health department is required under state law to provide a certain set of services. Some of them do not, so they are local health entities, but they indeed are engaged in surveillance and healthcare delivery services, but they are not providing some things like health department restaurant inspections and some other things, so they do not meet the state definition of a health department.

Hans Buitendijk

So, do we need to include both terms?

Steven Eichner

“Agencies” is sufficient.

Hans Buitendijk

Okay, that would cover both sufficiently. Summer, are you okay with that?

Summerpal Kahlon

Yes and no. I see the point. Earlier on, I think we talked about public health emergencies and the idea of being able to coordinate something like a COVID outbreak, which, to me, is a very different use case than coordinating routine surveillance and management of communicable diseases, so maybe that is the way to parse it, as emergency management versus routine surveillance and management.

Hans Buitendijk

In the conversations and discussions, I think we see that many of the recommendations that are appropriate for emergency use interventions are actually also appropriate for normal operations because of the general expansion of the pharmacist’s role that is not limited to only at time of emergency, but also in normal operation, so it may not be as wide, but effectively, that interoperability we are looking for still remains a similar need, unless we can call it out as something specific and unique to emergency use intervention that goes above and beyond what you otherwise need.

Shelly Spiro

Just as a reminder, we have four minutes before public comment. Alexis?

Alexis Snyder

By rereading this one, maybe at the end, although it is in the rationale as “reporting to public health by all providers,” I thought adding something at the end of that about patient consent… Again, it is in the rationale with patient consent directives, but I think it is important at the end of the actual recommendation so we are not just saying that at any time, without consent from patients, you can share the information.

Steven Eichner

For public health reporting, under HIPAA, public health is authorized and providers are authorized to report data to public health without patient authorization.

Alexis Snyder

In some cases. I do not think that is true 100% of the time.

Tricia Lee Rolle

Just for public health purposes, there is specific wording in there. I do not think it delineates too much. Sorry, go ahead, Hans.

Hans Buitendijk

I just typed something in that might be able to address both if you refresh the cell. "Within privacy policies and patient consent directives, and they apply where they are not necessary, but that it is within the authority of what can be shared or not, however established." Would that help, Ike? It still provides the widespread access within public health based on privacy policies and general policies, but where they exist, they are in play as well.

Steven Eichner

We have not seen the revised text yet.

Alexis Snyder

I was going to say the same, that I cannot see it, but again, my thought is that if it is in the rationale, it needs to be part of the recommendation, so just throw in the same exact thing at the end, something like "in coordination with patient consent directives as warranted." Otherwise, it should not be in the rationale, either, and my point is that as people read recommendations, they do not always read rationales, and it is important that it is there.

Shelly Spiro

Excel team, can you refresh the screen, please?

Hans Buitendijk

Close the cell and go back in again.

Steven Eichner

As a placeholder, I will take care of it after we get offline, a minor change regarding APHL case reporting, just as wordsmithing because this is really case reporting. It does not necessarily belong to APHL as the ones that are currently performing that service.

Hans Buitendijk

I refreshed it on my side again. If you can refresh again, maybe that works this time around. It is interesting that it was not showing. While that is being done, do we believe that with this adjustment, which we need to see a little bit better… Interesting. We have to fix that. I put something in.

Tricia Lee Rolle

There might be other individuals clicked into the cell, so maybe if others come out, it will work.

Steven Eichner

I have a friendly administrative request. Can we consider moving all the recommendations into a different worksheet in a single column and putting each recommendation in a single cell? I was having a hard time.

Shelly Spiro

Yes, we are in the process of doing that, Ike. I do want to stop the conversation now. We are ready for public comment.

Hans Buitendijk
I have one last question very quickly, if I can. No, actually, I will do it after the public comment to confirm something, and maybe it will refresh better.

Public Comment (01:19:24)

Michael Berry
All right, thank you, Hans and 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 just for a moment to see if any members of the public would like to make a comment. I am not seeing any hands raised yet, so I will turn it back to our cochairs. Thank you.

Hans Buitendijk
All right, thank you. Let's go back to 16. Maybe that time was sufficient for the system to catch up to ensure that it made it. Oh, it disappeared in mine. We will have to apply it separately because I think somebody else must have been in that cell, making updates, and overwrote that. Let's skip that for a moment so we can try to fix it. Let's look at 17 and come back to 16 in a moment because, for some reason, it did not hold. "Recommend that ONC collaborates with the pharmacies and other providers, including their HIT suppliers, appropriate reporting mechanisms directly from pharmacies to care team members and vice versa, i.e., push messaging rather than solely relying on respective queries for information." Deven, you had a comment that we might be missing something. I am not sure whether that was sufficiently addressed.

Deven McGraw
There is no verb in that sentence! I do not understand what we are asking for here. So, we want to ONC to collaborate to establish appropriate reporting mechanisms directly from the pharmacy?

Hans Buitendijk
Yes.

Deven McGraw
Okay. There is a verb missing. I just did not know what we were asking.

Hans Buitendijk
Now I know where you were looking. I did not get that. Sorry about that.

Deven McGraw
That is okay.

Hans Buitendijk
But with that taken care of, is that clarifying and in line with what we were thinking?

Deven McGraw
So, it is "to establish appropriate reporting mechanisms."

Hans Buitendijk

Let's see if you can refresh that cell. I just updated that.

Steven Eichner

This is Ike. I do think it is important to say what is being reported. Are we reporting things about prescription status? What is being reported or exchanged here?

Hans Buitendijk

I think it is the information of interest. It goes to our use case in Topic 2 of bidirectional exchange of relevant clinical data or otherwise that we shared.

Steven Eichner

So, it might be good to say "clinical data" or something, "appropriate push of clinical data" or something in that space, so there is clarity about what is being reported.

Hans Buitendijk

Fair point, so that as they become available, lab tests or otherwise that are done that are immediately of interest can be pushed back, rather than sitting and waiting for a query.

Steven Eichner

Again, for clarity, is that supposed to be bidirectional?

Hans Buitendijk

Yes, and vice versa.

Steven Eichner

Okay. I guess I am a little confused what would get pushed automatically or automagically to the pharmacist and what would be the action causing that data to be pushed.

Hans Buitendijk

I think that is what would be worked out to refine that further, but it would address the question of as data becomes available, either from the pharmacist, the pharmacy, or other care team members, what information needs to be immediately pushed and what can wait for query. I think that needs to be established. I do not think we have the answer of exactly what data that is, other than that clinical data being generated needs to be able to find its way to the other parties in a timely fashion.

Steven Eichner

Right. So, again, as a friendly amendment, I think the other piece is that trigger conditions are also part of this conversation.

Hans Buitendijk

That is a fair point, and it can be clarified there that that is part of reporting mechanisms, including the trigger mechanisms, the actual data, and the timing thereof. Any other comments? I see that even though I have been typing things and refreshing, they do not quite pop up, so we have a little bit of a snag there.

Steven Lane

Actually, Hans, it may be that someone else got into the field before you did, and therefore, anything you try to type in would be lost, so if anybody else is in the field, they should get out so you can manage it.

Hans Buitendijk

I am not sure who is currently in control of the display version. Stay out for a moment. I will make one other comment here, "add trigger events," and we will probably want to change "vice versa" to "bidirectional" to maintain consistency there. Let me hit enter and see whether, at this point in time, if you refresh and open it up, you can see it.

Steven Eichner

It may very well be that different trigger events may be relevant to different providers. I could envision a trigger event of a new prescription, which would trigger a bunch of other data being sent from the prescribing provider, where looking at a lab test result from a pharmacy-based test could get sent, that test result being available.

Hans Buitendijk

Right, and I think it needs to be worked out that it is the intent, not that we have the answer today.

Steven Eichner

No, I do not think so, just that it is one minor example that is not well thought out.

Shelly Spiro

Ike, I think the use case is ADT information, admission/discharge/transfer. That is one of the use cases that has been brought up.

Hans Buitendijk

It is one of the ones where push messages are of interest. In the other one that was bought up, lab results become available, and how do we make sure that it was particularly from pharmacists to other providers on the care team? How do we make sure that they get back as quickly as possible while you wait for a query to pick them up or whatever?

Steven Eichner

Right, or I could envision, as I mentioned earlier, a trigger event of writing a script, and a condition of the script is getting the relevant information coming along.

Hans Buitendijk

Yes. We are getting close to the top of the hour.

Shelly Spiro

Pooja has a question.

Pooja Babbrah

Just to comment on that same one, can we put in the two examples we just talked about, the ADT and the lab result? I think that would be helpful for definition.

Hans Buitendijk
That also nicely shows both directions.

David Butler
If I could add one other one that is a good example that the pharmacist always needs, it is just knowing the diagnosis that the prescription was for.

Steven Lane
That is critical. Sometimes, though, it is an indication, and they do not use formal ICD diagnosis terms, right?

Shelly Spiro
Correct.

David Butler
Exactly.

Steven Lane
It could be one, the other, or both.

Hans Buitendijk
Okay. We are about to wrap up, but do we have enough? We have a little bit of follow-up to do because on R16, we could not quite see the edition and the recommendation, but the intent is to add what Alexis suggested, to clarify within privacy policies and patient consent directives explicitly and copy that over. Do we feel that both R16 and R17 can be made green, that we will follow up on that, and that any further wordsmithing will be done in the Word document rather than here, where we have gone far enough? Any objections to that? I do not see or hear anybody, so we will go with that. That means we got as far as R17, and we will pick it up with R18 next time around. Shelly, back to you.

Task Force Work Planning (01:28:22)

Shelly Spiro
Okay. Thank you, everyone. We have one minute left. We are going to start our fourth topic on October 4th, and that means we have four more meetings until we are done. On October 19th, we have to provide a task force update to the HITAC, and then, of course, our final recommendations will be November 9th. Thank you, everyone. Thank you, Excel team, Mike, Tricia Lee, and others. We really appreciate all your support.

Hans Buitendijk
Thank you.

Adjourn (01:28:59)