ONC | HealthIT ADVISORY COMMITTEE

Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTICS TASK FORCE 2023 MEETING

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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
Phillip Lettrich	Vela	Presenter

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

Mike Berry
Good morning, everyone. Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force. I am Mike Berry with ONC, and we are always glad when you can join us. This task force meeting is open to the public, and your comments are welcome in the Zoom chat throughout the meeting, or during the public comment period that is scheduled around 11:50 Eastern Time this morning. I would like to begin roll call of our task force members. When I call your name, please let us know that you are here. I will start with the co-chairs. Hans Buitendijk.

Hans Buitendijk
Good morning.

Mike Berry
Shelly Spiro.

Shelly Spiro
Good morning, everyone.

Mike Berry
Pooja Babbrah

Pooja Babbrah
Good morning.

Mike Berry
Chris Blackley.

Chris Blackley
Good morning, everybody.

Mike Berry
Shila Blend. David Butler.

David Butler
Present.

Mike Berry
Steve Eichner.

Shila Blend
Good morning.

Steve Eichner
Good morning, this is Steve.

Mike Berry
Thank you, Steve. Raj Godavarthi. Adi Gundlapalli.

Adi Gundlapalli
Good morning.

Mike Berry
Jim Jirjis.

Jim Jirjis
Present.

Mike Berry
Summer Kahlan. Steven Lane. Meg Marshall.

Meg Marshall
Hi, good morning.

Mike Berry
Anna McCollister.

Anna McCollister
Good morning.

Mike Berry
Deven McGraw is not able to join us today. Ketan Mehta.

Ketan Mehta
Good morning.

Mike Berry
Justin Neal. Eliel Oliveira. Naresh Sundar Rajan. Scott Robertson.

Scott Robertson
Good morning.

Mike Berry
Alexis Snyder.

Alexis Snyder
Good morning.

Mike Berry
Fil Southerland. Christian Tadrus.

Christian Tadrus
Good morning.

Mike Berry
Sheryl Turney.

Sheryl Turney
Good morning.

Mike Berry
And Afton Wagner.

Afton Wagner
Good morning.

Mike Berry
Good morning, everyone, and thank you. Please join me in welcoming Hans and Shelly for their opening remarks.

Opening Remarks (00:02:15)

Shelly Spiro
Good morning, everyone. Thank you. This is our agenda for today. We are at the last session for Topic 2, so we will start out with the agenda. But Hans if you want to also do an opening remark.

Hans Buitendijk
All right, good morning. Thanks, everybody, for joining. As Shelly indicated, we are today going to explore the last topic of Task 2, as well as go through the agenda in a moment by looking back at the B and C, and any other recommendations as well. Looking forward to a good discussion today and seeing whether we can round out everything around Task 2 to get us to beginning to draft and finalize recommendations. So, thank you very much.

Shelly Spiro
We also have a guest presenter today, Hans.

Hans Buitendijk
Let us look at the agenda if you can. I am not sure if I am looking at the right screen. Yes. We are going to have a guest presentation after the review of Task 2b. Shelly will do introductions in a moment when we get to that point. Then we are going to go into a wider discussion on the presentation and any thoughts around that. We will have at the end, as usual, our public comments. Along the way, for those who have joined, and thank you for joining, you are able to put any comments along the way in the chat, as well, and everybody can respond to that for the panelists, as long as you use everyone in there, in the chat audience.

But you will not have the opportunity to provide some additional verbal comments until the end. But please do not hesitate to put your comments in. There is always good and lively debate as well. That all will be

captured as part of the notes and minutes. And then we will look at the steps ahead of us at the end for next week. With that, I think Shelly, unless there are any other agenda topics, to discuss?

Shelly Spiro
No. I think just advance the slides and let us start the meeting by going over Task 2 use cases.

Task 2b Use Case Review and 2c Recommendation Discussion (00:04:58)

Hans Buitendijk
All right. Again we are looking at Task 2 with a very long list of constituents that we are considering on how to improve interoperability with pharmacy and pharmacists in particular as well. If you go to the next slide, we are at Task 2d, and particularly that indicates what can ONC do to address drug inventory transparency for prescribers and consumers. That has come up in a number of different discussions over the last couple of weeks, and here today we will be able to dive a little bit deeper. That is the goal for today relative to Task 2, to discuss that further. With that, I think we can go to the next slide, and that means we are going to have a quick look at the Task 2b use case review and 2c recommendation discussions. And if you can switch to the slide there. We want to highlight a couple of different things in there and then go through them. There we go.

When you look at this tab, there are currently two tabs that you will have discovered and that have been referenced. There is the one that is open, TF Topic 2 recommendations. And next to it with a red bar that is Topic 2 discussion notes. That one that was just pointed at is the one that we were making comments into last week, organized it around questions, etc. And then between last week and now, and when you received homework and TF Topic 2 recommendations. If you go to the other tab, yes that one, we organized it a little bit according to the use cases that have come up and then identified based on the comments what are they trying to address in terms of the questions and topics that further were raised.

If you want to go to the left-hand side in Column A, and just gently scroll through, you will see that there is a general. That one is scrolling within the general comments that have been made across a number of different use cases. The next one is that there was a wide discussion around access to individual patient data, supporting testing through treatment process bidirectionally. Below that, a number of different examples before you jump to the next one, just to look at that list. There were a variety of different topics that could be considered individual use cases or they are a type of this use case effectively. If we need to split them up because there are some fundamental big topics in there for the final recommendations, we can do that. But generally, we were trying to see can the comments that we are going to have apply across those where these are example use cases in more detail. That repeats in some of the next ones.

You go to the next row 21, you will start to see that incorporating pharmacists into the care team was a big discussion, where aspects of care planning, event notification, and transitions of care came up and opportunities around that. When we look at patient engagement, there were a variety of different topics raised around availability, and inventory insight. We will surely come back to some of today. Patients informed when data is used and shared, so a number of different use cases in there, and a couple of notes that were made around that. There was a discussion on the use-case level of data-driven medication, and related population-level interventions, particularly identifying patients whose meta-list is not optimized. We want to look in a moment further at what kind of recommendations can we specifically make there beyond the use case definition.

Next one, pharmacy quality measures of clinical pharmacy services. A number of different topics around Task 2, as well as earlier that came up, and we are going to look at what else can we suggest there. The next one, more specifically around value-based care and quality measures. Public health was a use case generally that came up with a number of different things around reporting, having insight into public health information, and public health emergency data access at that point in time. And last one that came up, as well, is patient safety. There might be some other ones around pharmacy payer that in earlier discussions we talked about did not come up specifically. But anything beyond some of the prior auth notifications that were discussed where payers were a part of the parties to be notified or a specific interaction. But if there is anything else, there still might be something there.

We then for each one of those, I think you could stay in either one of them. We then split it up for each use case into the questions that we had. What is the short-term? What are the long-term opportunities that we have, which really reflected 2c? And within that, as we went back and forth. You particularly can see in some of the earlier use case topics there were a number of them around technologies and standards, and there was also a number around governance, collaboration, etc. We tried to group them a little bit together.

What you then see in the next column, D, and scroll back up, is where a number of aspects in that started to come up. We were talking about queries. We talked about push messaging. We talked about network database exchange. The reason for organizing it this way was in our current discussion today, and in any of the follow-ups that we are going to still have to do to get to recommendations, is help to use this to say did we forget about any key recommendation? Is there, for example, on this one, around either prescribing over-the-counter medication, etc., any of these more specific examples, of what sort of recommendations should we make around **[inaudible] [00:11:40]**? Is there anything unique around that? Or is the one that push **[inaudible] [00:11:44]** push messaging, is that really sufficient? Is that the key one?

Our goal is not to fill out every cell in Column E, but it is just to make sure that we have some triggers and thoughts that might remind us to say that, okay, yes, there is something here that we need to put in. We tried to capture everything from the discussion so far. We may have missed something or did not copy it totally correctly, so please look at that. And that is what we want to look at today to go through and see whether there is anything else that jumps out. If you have additional thoughts please drop them in as thoughts and suggestions for recommendations. The more you start to phrase it like a recommendation that we want ONC to do that would be great because then we can start to use that for Column F and then start to populate that shortly as well. Which is currently empty, but soon we are going to start to populate that. If you can scroll slightly to the left where we can see through Column E. That does the trick. Thank you. We want to go to the top.

And the first question overall is does this help? Is there anything else that we want to or need to clarify around the overall way that we organize the data? And then we want to start from top to bottom as far as we can get in the next 10 minutes to get started. And then we are asking everybody to add their additional recommendations and thoughts or updates to these as well, where they believe that it needs to be adjusted. You might disagree that we get those as well, so we can use that to finalize our recommendations. Does this help?

Shelly Spiro

I think Ike has a question.

Hans Buitendijk
Okay, go ahead.

Steven (Ike) Eichner
Thank you so much for doing this background work. I think it is really helpful. Two quick observations, 1.) I think for many of the elements there may be a set of non-technology policy considerations that may impact the various elements. I am not sure it does not do some good to break those out. Secondly, looking at the categorical pieces and thinking about public health in particular, there are some things we have talked about that are public health emergent specific kinds of activities, But public health provides a large number of roles, including in many states looking at distributing vaccines during non-emergency times as well.

I was wondering whether it might be good to kind of include a definition up front or from a scope perspective or what role in public health are we including in the public health block versus other things. That is one where we may see some cross-over into other spaces. It would be unfortunate for someone to think that they were looking for something in one place and think, "Oh, well we did not make any comments on it," but it is really in this other location.

Hans Buitendijk
On that last one particularly, Ike, is that their Topic 1 that we are very specifically focused on, emergent emergency situations, that is where a number of those topics and comments were made. We did not try to copy those into this construct, because this was more around use cases. Those overlaps, and where they are tied together, we need to make sure we do that. That is why you might not see some of the comments that were made in discussions as they were already in Topic 1. Regarding the first comment around policies that are specific to technologies, very specific to technologies –

Steven (Ike) Eichner
Sorry for interrupting. Actually, I was looking at policies that were not technology-related. For example, looking at including pharmacists as a provider type. Yes, there may be actions necessary at the federal level to include them as a provider type. That is not technology-specific. That is just as a matter of function there may be similar things at the state level that need to occur as well. I think there are a whole series of those kind of policy pieces that are technology-agnostic and do not necessarily have anything to do with data exchange or technology. It is just a fundamental underlying component.

Hans Buitendijk
If I hear you correctly, that was the intent of the governance collaboration policy, but as an example, and as Steven Lane might react to that whether it is appropriate or not. But if we were to put Steven's first comment, it is imperative for safety, it is not specific to any technology if we move that to the governance collaboration policy because it is an overarching comment there. Would that be a good example of where it would help to organize that a little bit further and better?

Steven (Ike) Eichner
I think so.

Steven Lane
I certainly have no objection to that.

Hans Buitendijk
Okay, why do we not move that? That is a good example of helping organize them accordingly.

Steven (Ike) Eichner
My objective here is to help make it navigable and not lose information or constrain.

Hans Buitendijk
That is helpful, thank you. I see that Summer, you have your hand up.

Summerpal Kahlon
Yes, thanks, Hans. A couple of things actually, the main thing I wanted to mention relates to the value-based care piece and the data exchange for fills and handwritten actually the prior comment just made me think of something on the public health side. But focusing on the value-based care, I think a lot of what we have discussed so far has really been about data exchange between the patient and provider. As it relates to closing certain quality measure gaps, and that tying into accountable care alternative payment model arrangements, it may be worth talking for a moment about how we get fill data from the pharmacy to the health plan because that is really where the metrics and scoring occur. That data is useful at a provider site in managing a population and in managing risk.

But in terms of actually being able to close a gap, so to speak, on the health plan side, a number of the medications that are filled to meet quality measures are cash-pay meds. Getting the fill data over where there is not necessarily a claim, or even considering some of the newer pharmacy models where they are direct to consumer and they are not running through insurance, so to speak. Again, there may be a gap in that data getting back to the health plan to appropriately fill gaps and report quality. So, may be worth talking about that for a minute. And then I will hang on with my second question so it does not blur this question.

Shelly Spiro
Hans, if I can.

Hans Buitendijk
Go for it.

Shelly Spiro
Summer, those are really good points. I think the issue is, especially from a pharmacist's standpoint, just filling a prescription does not necessarily mean it is adherent. It is a tool to see that there are additional questions that need to be answered once the fill information is there. The problem that we have in getting fill status, and even fill status to providers and or payers, is an issue of connectivity and sharing that particular information.

We did add fill status to the USCDI. The problem comes in on the fill status, it is still an optional field for the ePrescribing or the script standard. So, that information does not always get transmitted in a bidirectional

way. We have a lot of problems with the ePrescribing standard and the adoption of bidirectional exchange of information using the standards such as fill status. That could be a potential problem.

Hans Buitendijk
And what would be particularly a suggestion or recommendation to advance sharing fill data with payers? What would some of the recommendations be?

Shelly Spiro
Making that a mandatory requirement as part of the certification process for ePrescribing.

Hans Buitendijk
Certification of whom?

Shelly Spiro
The certification of EHRs because ePrescribing is part of the ONC certification process for the prescribers.

Hans Buitendijk
So, it is solely on the provider side or is there also on the pharmacy side information that needs to be shared with **[inaudible – crosstalk] [00:21:20]**?

Shelly Spiro
It has to be turned on on the prescriber side to receive the notification of fill status. Now, if we advance it to payers that is going to be another issue. And maybe this is a discussion for those, you know, later on as we go through this again, that we bring this up.

Hans Buitendijk
What would be helpful is to understand is where do we have a gap, or do we have standards that are not implemented. Do we have policies that need to reinforce that? Is it only the prescriber? Is it the pharmacist, as well? What needs to happen on the payer side to ensure that the flow is fully addressed? Not only one side of the equation when we talk interoperabilities. Any thoughts as to where are those gaps? Do we need better, more standards? Do we need certification, and if we need certification, who **[inaudible – crosstalk] [00:22:17]** adheres to it?

Shelly Spiro
I think the standards are there. Let us go to Pooja. She might have something.

Pooja Babbrah
Yes, I agree with that. We do have standards for this, and maybe this ends up being a smaller group. The standards between the pharmacy and the EHR exist. To Shelly's point, you have to turn that on. I also know that in some states, fill data is uploaded to HIEs, there are also the PDMPs, where in some states the pharmacies are uploading just controlled substances. In other states, they are asking for everything to be uploaded. So, there is a lot of data that is being uploaded to different places. I think the real issue comes down to whether or not the data is being accessed for the things we want it to be accessed for if we want it for quality measures, things like that. So, I think a look at where, how all the data is flowing today. But we

definitely have the standards. I think it is just a matter of access to the data. That is kind of how I am looking at it.

Hans Buitendijk
Yes, and one clarification there, and it might be you, Pooja, and Summer. Summer in the notes indicates that it is from the pharmacy to the health plan. I am hearing Shelly talk about the prescriber to the health plan. We do not need to immediately discuss it right now, but in the notes if that can be clarified which are the parties that would need to adhere to or implement those capabilities that ONC might be able to help out with. Christian?

Christian Tadrus
Thanks, Hans. I just put a comment in the chat. What I was going to say is, and it is the last thing you just talked about, which is really who needs access to fill history, so to speak? It makes a lot of sense for the providers involved in patient care to ensure that as part of the care process in a value-based arrangement and for some payers to have access to it. But there are often multiple payers that are paying the overall cost of care, whether that is patient out of pocket, whether that is a secondary or an alternative payer source.

So, we want to dial that in as what that recommendation looks like, is who needs which pieces. How do we reduce the multiple transaction counts that might have to come when multiple "payers" might be involved? And how much of the broader information exchange is necessary for any given particular payer in the arrangement? So, just some nuances to tease out as you guys mentioned. I just wanted to put them on the book to talk about.

Hans Buitendijk
We got your note. That is great. We have three hands up. We need to start to shift to the next topic in a moment. Shelly, if we go until 11:00, I think we still are good to introduce. So, let us go. But Chris, go ahead. And then Afton. Some of you dropped your hands. I am still keeping in mind that you had your hand up.

Chris Blackley
Regarding the Rx fill transaction back to the prescriber, the barrier, I think it was already mentioned, but the transaction is not a required standard. It is not required to be transmitted. The consequence of that is that many of the pharmacy systems do not actually implement it because then the pharmacy also has to pay the fee to the switch provider to transmit it. So, you have a financial disincentive for transmitting a non-required transaction, and the pharmacy systems therefore do not all support it. So, making it a required element of the standard would be the solution, I think.

Hans Buitendijk
Thank you. And we will come back to Summer in a moment with the comments that he had. Afton, you had a comment?

Afton Wagner
Yes, I will be quick. Just to add to Christian's comments of things to take into consideration, obviously who needs the data and what data is shared. But can pharmacists receive it in a readable format, and also what is the priority that they would need to receive it in and be able to exchange it bi-directionally? So, just making

sure we are getting the right information and the most accurate information, and being able to, as other folks have said, get it back to the health plan. And echoing what Chris just mentioned too, is that is always a how-do-we-get-back-to-the-plan-in-an-economical-fashion?

Hans Buitendijk
Thank you, and also some good discussion in the chat around what data can be shared or not based on self-pay, or consent, or otherwise. Before then jumping into the next topic, Summer, if you have any additional comments based on the notes and discussion that we appreciate you started on who needs to get what. Any final comments before we jump to the next agenda topic?

Summerpal Kahlon
No, Hans. I shared some thoughts in the chat. I will leave it there for the sake of time. I think the biggest thing for me is we do not turn the provider into an intermediary here, trying to flow data to close gaps. I want to make sure that does not become the result of the standards that we end up endorsing here.

Hans Buitendijk
Okay, appreciate that. If you have any additional thoughts you want to drop into the spreadsheet to make that more clear and who we need to focus on for what aspect, that would be great.

Summerpal Kahlon
All right, sounds good. Thanks.

Hans Buitendijk
I think we will jump to Shelly to move on to Task 2d. After that end of discussion there, and time permitting, for today we will come back to the conversation here and progress that. Shelly?

Task 2d Introduction: What can ONC do to address drug inventory transparency for prescribers and consumers? (00:28:08)

Shelly Spiro
Great, thank you. If we could go back to the slide deck, I would appreciate it. We are now on Task 2 discussion. Go to the next slide. If we do not have that I will be glad to tell us what Task 2 is. If you go to the next slide, okay. So, Task 2 is what can ONC do to address drug inventory transparency for prescribers and consumers. I want to make it clear that this is under the category still of pharmacy-based clinical services and care coordination. We know that from a care standpoint that price transparency can be an issue, especially if you have a patient who cannot afford their medications. So, we want to look at it also not just from the physical aspect of getting price transparency, but really how does it address our patients in terms of, especially for those patients that might not be able to afford it or might not want to pay a copay or go through a prior authorization process. From a technology standpoint, having price transparency can be really important. I wanted to make it clear that we are not just talking about having price transparency, but we want to make sure we are bringing in the clinical aspect of what this means. So, let us go to the next slide.

Tricia Lee Rolle
I am sorry, Shelly. I need to interject.

Shelly Spiro
Sure.

Tricia Lee Rolle
I am not sure if you may have misspoken. We are not talking about price transparency here. It is the inventory transparency.

Shelly Spiro
Oh, thank you.

Tricia Lee Rolle
No problem. I know price transparency is on top of our minds.

Shelly Spiro
Yes, it is. Sorry about that. It is drug inventory transparency. Very similar, I apologize for misspeaking about that. For drug inventory transparency, this is an issue that some of our patient advocates brought up, but they might not have access to medications. I just wanted to remind everybody that we wanted to look at it from a clinical standpoint and a care coordination standpoint. Let us go to our next slide and to our speaker. Our speaker is Phil Lettrich with health policy and business development with Vela. So, Phil,
you are up next.

Guest Presentation (00:30:41)

Phil Lettrich
Okay, great. I appreciate you sharing the slides, and I will let you know when to advance. As a self-introduction, I am a pharmacist. I have a degree from Ohio Northern University and I maintain a current license. I have experience in and visibility across multiple perspectives of pharmacy and the industry, including 30 years across dispensing and retail, pharmacy benefit management systems, PBMs, drug database compendia where I currently am at First Databank, and then professional associations and standards development organizations.

So, if you want to change to the next slide, please. This topic has drawn me to present to you today, it relates to the interest in enabling communication of some version of medication inventory. In-stock status or medication availability to various parties in the healthcare ecosystem, which I will go through in a minute. The NCPDP standards development organization has been exploring and discussing this subject within a task group, which I serve as the task group leader. The task group is the pharmacy product locater task group. And this task group is within the NCPDP Work Group 11 ePrescribing & Related Transactions work group. The purpose is to investigate creating a technical solution for pharmacies to query pharmacies to locate products on behalf of patients. Participation in this group has been modest. Most often just a handful of participants.

And for transparency, the group is currently not meeting while some of the thoughts percolate and mature and task group participation and recruitment make some gains. I am going to dive in a little more into the progress of what the task group has accomplished so far. It includes the identification of stakeholders in

the communication of medication availability. Those stakeholders include pharmacies, prescribers, EHR systems, patients, payers, and suppliers, many of whom we have been talking about or hearing about just in these last few minutes.

Another advancement of the task group is the identification of multiple use cases. Those scenarios, for example, well, 1.) The way it started, which is the acute need for a medication out of stock with, say, inhalers, anaphylaxis medications, pain medications, those acute needs, the medication should be available to the patient at the earliest convenience. Other scenarios where it is just they do not stock the medication, will not stock the medication, or cannot get the medication. The one that comes up so often is Paxlovid when it was first marketed. It was available at a limited number of pharmacies, and specialty medications get **[inaudible] [00:33:34]** in that do not stock or will not stock kind of environment as well.

A pain point that is often heard as well is limited distribution drugs, where only certain pharmacies have the medication as determined and mandated by the manufacturer. Additionally, the task group has drafted proposed data fields and process flows for transactions to enable the communication of product availability. And finally, the task group has identified some out-of-scope topics to keep the topic clean and serve the function of delivering on the intent. So, out-of-scope includes things like the ownership of the patient by the pharmacy, the economic model, the method of the transmission of the original prescription, interrogation of benefit coverage, and the process after the response is received by the inquirer. These things have served us well to provide a foundation for the conversation and to guide us in the development of the draft transaction and fields that are needed to produce this answer to the question of is the product available.

To dig into the use cases a little bit deeper, while the purpose of the task group was initially identified as pharmacy-to-pharmacy interaction, as we discussed the usefulness and value of this content has been recognized in the discussions thereby leading to additional use cases. Again, number one was pharmacy to pharmacy, avoiding a phone call, finding the answer the quickest you can, and not tying people up in a manual process. But number two surfaced as a use case, which is prescriber to pharmacy, and this resonates well with what I am hearing in some of the conversations today. There is a lot of value in the prescriber knowing whether a pharmacy has the inventory to fill a prescription that he is prescribing.

Therefore several benefits would exist in knowing that. Satisfying the patient's expectations that the pharmacy will have this medication, the avoidance of patient inconvenience and therapy delay while the medication is being prescribed rather than being sought out after it is prescribed, the avoidance of going back and forth. The professionals are busy and if an electronic communication could answer a question of availability, that would be more efficient. We mentioned already, or I mentioned that Paxlovid was an example of do you have it or do you not have, as that was emerging as a standard therapy.

Unfortunately, drug shortages continue to be in the space. Whether it is an inhaler, a pain medication, or something else, the patient and prescriber would benefit from knowing whether or not they can get it at the store or pharmacy that they are attempting to get it from. And the consumer has also surfaced as an interested party. These may be obvious, but they are worth mentioning. The consumer has also surfaced as an interested party. These are maybe obvious, but they are worth mentioning. The consumer is well served because they would avoid unnecessary travel if they knew the drug was in stock. They would potentially avoid unnecessary exposures.

Another great example with the pandemic is do not go to a place where you cannot complete your transaction or get your medication. And the ongoing flu season, do not need to be exposed as well. Therefore also avoiding unnecessary delays in therapy if that medication is not available. The current task group status is that it is on hiatus and not meeting, but it is continuing to work in the background with some individuals. It is encouraging individual perspectives to mature and evaluate efforts to enable a transaction in its basic sense and what is the effort to build out development to support it. And ultimately the pursuit of mutually interested parties engaging in a pilot. There are several parameters that the task group has memorialized to guide efforts. They include the following. I think they are on the next slide, please. I will give you a 5 to 10 seconds to look at these. Think of these as foundational to our work in the task group, and what we anticipate, perhaps, being the guidance to delivering on a transaction that satisfies the inquiry of do you have this, can you fill this prescription or not.

And finally, next slide, please, is just a quick summary that says, "In summary, a transaction which communicates medication availability delivers benefits to the crew, to the patient, to the prescriber, and the pharmacy. Those include efficiency in healthcare delivery and operations, and improvements to patient experience and outcomes by mitigating the delay in therapies." This slide highlights those. And I am through in about five minutes. I will take questions.

Shelly Spiro
Thank you. Thank you so much, Phil. I did let you go a little bit longer. We get a little **[inaudible – crosstalk] [00:38:50]**.

Phil Lettrich
I appreciate it.

Shelly Spiro
So, thank you for that. We do have Anna. Do you have a question?

Task 2d Discussion (00:39:00)

Anna McCollister
Hi there, yeah. Thank you for this. As somebody who put a lot of the use cases into the document around this issue, this is one that has perplexed me for years that this is not data that is readily available given where we are in terms of data accessibility and data standardization. I have Type 1 diabetes, all the complications, and co-morbid diseases, so I take a lot of medications. And the amount of time it takes for me to manage my medication inventory is absurd. And it has gotten so much worse in recent years than it has ever been because the PBMs, insurance companies, and pharmacies, have all gone into just-in-time inventory management of their in-stock capabilities and for what PBMs are allowing patients to have. And that combined with certain classes of medications that now have shortages, it is very, very difficult and remarkably time-consuming to just get access to medications, even generic medications, let alone biologics, and I take several biologics.

This, to me, is a critical issue in terms of patient workload and the ability to actually be adherent. My mother is on Medicare and not well, and the amount of work she has to go through is absurd with Medicare Advantage. Why would we not just be able to get access or insight into the pharmacy's stock as opposed to whether or not they could fill a certain prescription? For instance, there are several medications that I

take that could be prescribed in different denominations. I could take two 15 milligrams or I could take one 30 milligram. If a pharmacy could fill one, but not the other, that is fine. But if my doctor writes for 30 milligrams, they have only got two 15 milligrams, then why would I not be able to see that my physician could then send it to the correct pharmacy, etc.?

As much information as possible needs to be provided to the patient. And I think the expectation should be there that ideally the patient would not have to manage that. But the reality is that the patient does have to manage that, and caregivers of patients have to manage all of this inventory control. Again, Paxlovid, I have had to try to source that a couple of times. It is not fun, but that is like a one-off. Doing this monthly across 15 different medications is a lot. I have waited on the phone on hold for hours countless numbers of times.

Shelly Spiro
Anna, this is Shelly. What recommendations would you recommend that ONC does to increase the pharmacy or pharmacist communication with the patient?

Anna McCollister
I think ONC should use its ability. There are data elements that could be made available to, and visible to patients, which would make it easier to coordinate with the pharmacist. I think we need to assume that the pharmacist is going to be super busy because a lot of the **[inaudible] [00:42:40]** injections of vaccines, they have got long lines. They have got people on hold. The pharmacy tech situation has not recovered from the Great Resignation. If I have to coordinate with a pharmacist, that is a minimum of an hour, whether that is on hold, me going to the pharmacy, whatever.

Providing specific information about medication inventory, specific denominations of medication inventory, and specific distributors or manufacturers. I had an issue where the PBM or the health plan was only covering one specific NCD code for a particular medication, but neither the provider nor the pharmacy, nobody in the process had any knowledge, even the PBM did not have knowledge of this until I got accidentally got it filled at a different pharmacy than I typically go to. So, that sort of information, anything that could be identified as a requirement or barrier or some sort of filter for what can be prescribed, should be included in the data there are is transmitted and collected and made available and visible to the patient.

Shelly Spiro
Thank you, Anna. Summer?

Summerpal Kahlon
Thanks, Shelly. I wanted to talk through a little bit as a group the standards and the workflow systems these standards plug into to solve the problem. I agree it would be very helpful as a prescriber to be able to use ePrescribing networks to be able to ping and say before I send this prescription, can you tell me if you have it in stock, or if not should I go to a different pharmacy and transmit the prescription there instead? It saves a lot of workflow efficiency. I think if we expand the use cases though, like we were just talking about patients wanting to be able to get that access. In the chat, there is back and forth about whether that should be the health plans and PBMs, for example, that make that available to their members. But also thinking about the public health emergency environment.

I am not entirely sure what the public health workflow system should be. Not only in the context of a pandemic like COVID, but also regional emergencies like after a hurricane or a fire, where services are disrupted but people still need to get access to their medications. I do not know what systems a public health agency or a public health leader would be accessing to help coordinate that. Especially because a lot of our standards are built for workflow systems like pharmacy management systems and EMRs. Maybe as a group, I would be curious to get everybody else's take on this, how do we construct a standard or a set of standards that accomplishes this goal, or a larger number of stakeholders than just provider to pharmacy?

Shelly Spiro
Along those lines, what would you recommend to ONC then as a recommendation? We know we have a problem. We know there might be some solutions. Would that be more like convening a task group? Or an educational session?

Summerpal Kahlon
I think, for me, Shelly, and I will just give my opinion, and I am curious to hear others. The script standard around ePrescribing makes a lot of sense for a prescriber in an EMR looking to get that information. I think for a patient, I think we would want to talk through the use case. Is it a one-off query, in which case maybe it is a proxy of the script where it is a patient making a query? But is it something that looks more like a registry where perhaps it is accessible through a health plan's website? A member can go in and search and say, "Is my prescription available at Pharmacy X?" And that kind of ties to the public health environment as well.

A lot of the interaction with public health is through registries, EMRs, and other systems sending data to registries as a single point of information access. I am just putting those out there. I do not know what the right solution is. That is where I want to talk through it with the group. But I think there are two paths there. Is it a transactional standard, Point A to Point But, and two workflow systems, or is it more of a registry-type standard that maybe leans into more of an HL7-type transaction, for example, that creates a single point of access?

Shelly Spiro
Interesting. Scott?

Scott Robertson
I have a couple of concerns about the inventory discussion. At times there is more than is there enough inventory to dispense a prescription. Yes, that is a primary point. I think the query would be useful, but there still might be other complications. I do not favor the idea of a registry in this regard because inventories change so dynamically. Keeping registries up to date is going to be extremely difficult. Now, this also means the converse of that is every query is some level of load on the pharmacy. If there is going to be hundreds, if not thousands, if not tens of thousands, depending on the local pharmacy ecosystem, how many pharmacies are in the area, and how many patients, that could become potentially burdensome as well.

I do want to say in terms of the patients getting it, I think it is a really good idea for the patients to be able to get, be able to determine at least do they have it in stock. But wide open access on a broad range of products concerns me a bit. I hate to say it, but if somebody is shopping around for which pharmacy they

want to steal from, and that is sort of out there, but I have a concern if it is not directed. Granted, you might want to find out do you have the 15s and do you have the 30s. But if you want to know all the drugs related to this, I do not think those larger queries … maybe it is just a matter of being a little more explicit on exactly what the real use cases are, as opposed to we are still being pretty general at this point. Thank you.

Shelly Spiro
Thank you, Scott. I am going to go to Phil. Anna and Alexis, if you will let Phil answer since he is our presenter? Maybe he might glean some information on this. Go ahead, Phil.

Phil Lettrich
Thanks very much. I wanted to respond to a couple of those things because the work group task group has had discussions on some of them. One is to say we expect it would be a crawl, walk, run kind of environment. Let us get the answers that are needed today and then mature them. And the most common answer that is asked is can you fill my prescription? And the most common method today is a phone call. Let us get that phone call set aside and let a real-time transaction ask the same thing that a phone call could ask. Can you fill my prescription? Now the answer could be yes. It could be no, or it could be no but I can get it. Now, the patient or the doctor is much more engrained and tied to the appropriateness of that pharmacy's ability to fill.

I think that Scott, you bring up a point that has certainly been discussed, which is I do not want to expose my inventory to my competitors, my criminal element, etc. Allowing an inventory on hydrocodone is not something that anyone wants to open up to, but maybe by inquirer type. I am a patient. I am a health plan. I am a physician. I am another pharmacy. Those are constraints that we have looked at that make sense in a public environment. I also want to say that it is always going to be a point-of-time query. Can you fill it, yes? Did you just come in after somebody who took all my inventory? That could happen. It is not a reserve system that we have been talking about. It is a can-you-fill-it. It is normally going to be 90% true when somebody shows up at the door. Or they may not show, so you do not want to reserve it.

Those are a couple of things that I wanted to mention that were tied to what folks were talking about. The registry does seem to be one of the highest hurdles where folks and I say folks, I mean corporations, do not want to aggregate the inventory they have on a third-party site. But they would be open in most cases to making an inquiry. In today's environment, it is all computerized. They can check do I have 30 tablets of Drug X, etc. And by the way, we have identified that those elements exist already in the script standard. So, that is not a new set of information. It is just a new transaction that uses similar information to answer the question because it is like a prescription. You are answering can you fill at this quantity, etc.? So, that is a positive for us as we have looked at what fields to use. Thanks for letting me interject, Shelly.

Shelly Spiro
Sure, Phil. Anna?

Anna McCollister
As I listen to some of these arguments or points, they may be valid, but part of my frustration with this, one of the reasons I put all of these use cases into the document last week is that this happens across all discussions around health policy. We need to begin with the point of what can we do from an informatics and ONC perspective to make it most likely that patients are going to be able to seamlessly, and easily

access the medication they need to stay healthy and to keep their disease from getting worse and to manage their care, rather than starting from the perspective of what is it possible for pharmacies to want or not want to share for whatever reason. We need to center everything we are thinking on what allegedly people care about, which is adherence and the ability to stay healthy. These medications and information about these medications are critical to an individual and the patient to be able to preserve and maintain their health.

Everything else should fall under that objective because all of this stuff that you raised may be incredibly valid, but the reality is that each of these points gets in the way of facilitating an individual's ability to care for themselves. If I am going to benefit from being able to tell if my pharmacy is able to fill a particular denomination of Concerta or generic Concerta and have the amount, and it be from a specific distributor, I should be able to get that information without having to call around to every pharmacy in the area, feeling like a drug seeker, and then letting my physician know which of those places he should send this controlled substance prescription to.

Literally, the amount of hours I have had to do to deal with that very specific scenario, means it is like an entire workweek of hours of trying to manage that specific scenario. And none of that gets considered. But all of the concerns about pharmacy inventory and pharmacy corporate concerns, or the desire to own a specific patient or whatever, that stuff gets concerned within discussions around these policy issues. The reality is we need to center them around what is going to make it possible for people to be healthy.

Shelly Spiro
Thank you. Alexis?

Alexis Snyder
First and foremost, hear, hear to everything that Anna just said. I think I presented this a few weeks ago with another use case as well, that people really do not stop and think about what should be a patient-centered problem here, and focusing on what needs to be done in the end so that patients have what they need to be their baseline of well or whatever that looks like for them. I do not think people realize how many hours of time it takes for patients and caregivers to get this sorted out and sometimes end up with no solution. So, thank you, Anna, for addressing that again, as well.

I wanted to bring up something we talked about. I had mentioned a use case a few weeks back. And then I think Scott had mentioned on one of our previous calls, thinking about things is not just sending a prescription to a pharmacy, but to a pharmacist or particular person who would act as your medical home, your pharmacy medical home person to see things through. I think part of this issue is not just where is it available and whether can I get it at that pharmacy. That does not always give us a picture. I presented a use case in the past with an injectable drug that comes in multiple doses and a pharmacy originally sending me a text update when it will be ready, as if they have it. And then finding out a day later they do not have it. And then them saying they have to spend hours of time on the phone trying to figure out when they can actually even order this or not. Is there a shortage for them even to be able to get the medication in?

It is not just who has it but does anybody actually have it, or is anybody actually able to even get this from the supplier? When that answer is no, and you cannot get this right now, it is not currently available in the U.S. because of shortages, then what? Then that becomes the patient's or caregiver's problem to sort out

what dose is available. What can be gotten? Now I need a new prescription from my provider. I may also need a new prior authorization. I need an exception from my insurance company. Why if I just got XYZ dose and a prior authorization for that, am I requesting a new prior authorization for a different dose? There are too many things and too many catch points that a patient and caregiver cannot be stuck in that middle managing. You can make all the phone calls in the world, but at the end of the day, you are not the one who is actually able to do these pieces and move these pieces forward.

My overall point is pushing, again, for better-coordinated care with the pharmacy medical home. It cannot just say it is the patient's problem, the caregiver's problem. It is the provider's problem. The provider says it is the pharmacy's problem. We need a way to fix this so things are not only real-time access to inventory and what we can actually get but also solutions. We cannot have people falling through the cracks and then having poor outcomes because of this issue.

Shelly Spiro
Thank you. Ike?

Steven (Ike) Eichner
Thank you. Looking back at the COVID-19 PHE, public health emergency, we did have direct experience looking at inventory management, inventory control, drug distribution, and accountability. Texas, like many other health departments, had received COVID-19 vaccine allocation from the federal government and had an inventory control system where providers, pharmacies, hospitals, etc., across the state, would order medications from DHS, the state health department, and we distributed them to the pharmacy. From an accountability standpoint, because there were requirements that all COVID-19 vaccine administrations had to be reported back to the state, we then received back information about how many of those vaccines actually got administered and when. That was part of the accountability piece in there.

One of the issues that emerged is that some of the larger hospital systems did not want us to allocate prescriptions or allocate medications not to specific facilities, but to the system, to their health system overall, and enable them to redistribute the medications within their system as they deemed it necessary and appropriate. That made it a little more difficult from an inventory control perspective or inventory management standpoint to understand exactly what vaccinations or what supplies were available in what location. That is another element of this broader puzzle, which is if you are looking at inventory management and inventory control, at what level are you really tracking that behavior?

Is it not just the pharmacy operated by your favorite grocery store, but is it the specific pharmacy that is around the corner at a particular address? So, again, that is another level of complexity that needs to be worked out. Now, as the other aside, we are all familiar with putting in refill requests with the pharmacy, picking up the phone, calling, entering a prescription number, and the auto-voice response says, "It'll be ready in two days." I am not sure if there are systems that are actually doing current inventory checks about what is actually in stock. I know that fairly frequently we go through it. Yes, it will be available in a day or two days or whatever. Lo and behold, two days later we get a note back saying we were unable to fill your supply, or we are doing a fill of 2 pills as opposed to 20.

I think there are some fundamental tools that are already in process. But I am not sure from an information system today, is inventory information being used to populate voice response systems? That might be an initial first step. Thanks.

Shelly Spiro
Ike, I think what you are saying is important in using the use case of what we saw with COVID. But you are talking about one or two drugs. What Anna and Alexis are bringing up are multiple drugs and multiple situations, which becomes a lot more complicated.

Steven (Ike) Eichner
Absolutely. Please, I was not looking at we solved it with COVID-19, and it is done. We can use that as the perfect model going forward. It is a building block and example as a one-off scenario with a very limited spectrum of drugs, COVID vaccines and some of the antivirals were what was the scope, But by no means does that mean it is immediately expandable to every medication out there. But it does give us some experience on which to build.

Shelly Spiro
And there were all sorts of problems with that, too.

Steven (Ike) Eichner
Yes.

Shelly Spiro
Major problems.

Steven (Ike) Eichner
Exactly. It is a foundation on which to build some lessons learned. Some things worked better than others. Some things really had some significant learning curves.

Shelly Spiro
I am hearing a recommendation that we need to define the process that would work for patients, pharmacies, providers, wholesalers, and others, is what I'm hearing as a recommendation. Still have not gotten to a recommendation of what would work but let us go to Hans.

Hans Buitendijk
I actually wanted to take your comments a little bit further there, because I am hearing as well through the discussion and the chat that there are potential opportunities in targeted queries, and targeted requests, to understand if there is a sufficient inventory, perhaps even reserve under certain conditions. Part of that is concerns were raised around whether the request is appropriate and authentic, or whether it is somebody trying to figure out where to go from a nefarious perspective. With those kinds of things, there are opportunities in the work group Phil highlighted some of the aspects of those kinds of questions. How do I authenticate that it is for a real prescription that is from a real prescriber, that the patient is authentic? That can be worked out in work groups like that, and that can advance. And there is already work in place.

But Phil also indicated if I heard it correctly, that the workgroup is on hiatus. To me, that starts to raise the question of not only the recommendation we need to do work here but also what can ONC do. Are there considerations or priorities or otherwise, that with some assistance from ONC, these kinds of efforts to figure this out can advance further? We have talked in prior discussions around should there be a community around pharmacy using the iData elements, etc., and prioritizing use case over time. Is forming that kind of community where all those aspects can be discussed, including this one, is that something where ONC can have a role in to help advance that, to move beyond where we currently are at, at a better pace? Or is this something the industry has to do on its own? I am curious for some reactions as we go through the conversation. What is it that ONC can do?

Shelly Spiro
On that line, would it be good to recommend maybe a playbook or a tool kit of some kind, 1). That identifies the problem. And is that something that we could possibly recommend to ONC? Let us go to Anna.

Anna McCollister
Part of the reason why I put these use cases specifically in there is for this particular provision. It is not just to vent via a workgroup, but to say there are data that is already collected that exists in one form or another that could be mandated to be shared and disclosed. It is like all of this inventory is now automated and shared in incredible detail about each point in the inventory process. That process has been perfected over time and put on steroids amidst COVID with all the inventory supplies across all the different sectors, not just healthcare. All of that data exists about where is it in transition. The point that I think about, you get a notification, clearly an automated notification, that the medication has been ordered and will be in tomorrow by 4:00 p.m. You have no idea if that is a real thing or if it is actually going to be in by 4:00 p.m. Chances are it is not going to be there, but you have been told by the pharmacy definitively that it will be there.

I have no insight and apparently the pharmacist has no insight as to whether or not that is a true reality based on what they say when I go to pick up the medication and it is there. All of the data exists. It is already collected by somebody. It just is not being made available and visible to either the pharmacy or the patient. Again, there is no one patient use-case scenario. I would really prefer to not have to manage this stuff. But for all of the data that needs to be accessed by anybody in the system, we should assume that patients will need access to data. Whether or not they have to is a different question. But if they do have to they should be able to.

Shelly Spiro
Scott?

Scott Robertson
Yes. Inventory management is electronically managed in most pharmacies and orders are done electronically. But it is not as robust as everybody thinks. DSCSA, the track and trace rules, have proven to be very complex to bring into reality. If a pharmacy does receive notice that products that were ordered are in this package, and this package has been shipped and is expected to arrive tomorrow, it is the same thing as you getting a notification from UPS that your package is going to be delivered today between 10:00 and 5:00. I have waited way past 5 way too many times. I do not mean this against what you are saying, Anna. They can only provide the information they have.

Now becomes the question should they tell the customer, the patient, that your medication will be ready at 4:00 tomorrow, or should it only be said your medication has actually been prepared and is ready and waiting for you? There is no good answer to that. And I am not quite sure if we could even do anything as far as recommendations in terms of that. It is just the standards support these things, or the standards could support these things with not much more added. But the reality is going to take a little longer to come into existence.

Sorry. Cold water thrown on all our good talk right now.

Shelly Spiro
No, I agree with you, Scott. It is a very complex issue. I know that Summer has put into the chat that maybe we should recommend convening a group of stakeholders to sort of flesh out in more detail this very complex topic of it is not just inventory or shortages. And if we look at it from a clinical and care coordination standpoint, as Anna and Alexis have brought forward, is the fact that we need to do a little bit more in thinking about the entire process, from prescribing all the way through the patient accessing the medications. I think this is an extremely complex topic. I do not think we have enough time to address it here. We still have eight more minutes left before we go into public comment. So, I will turn it over to Phil for his comment or question.

Phil Lettrich
I just wanted to add one thing that I did not put into the presentation. But the patients who are consumers, consumers are driving this. We certainly heard that from the perspective of the patient. But today if we order on Amazon, they will tell us if we are out of stock. Today if we order from a retailer who is going to mail us an article of clothing, they might say I have three left. Do you want them?

Shelly Spiro
Exactly.

Phil Lettrich
The expectations are building and the technology is working for somebody out there. It should transition to pharmacy as well. It is more complex perhaps because of doses and strengths, controlled substances, and all those things. But I think the consumer is driving that expectation because of their experience in the marketplace today, and they are the buyers. I wanted to add that in.

Anna McCollister
Exactly. If Amazon can correct the number of Diet Cokes that are in my cart for delivery based on their real-time inventory, and keep telling me you do not get 10, you only get 5, then we should be able to get that kind of data. The possibility is there. We are just not requiring it.

Shelly Spiro
Okay, any other comments? We have got 7 minutes left. So, I have got a couple of recommendations. Go ahead, whoever was wanting to speak.

Hans Buitendijk

I was just wondering, Shelly, whether we want to jump into some of the spreadsheet related to this. We have seen that Summer made a suggestion in the chat, and others close to that, that can update the spreadsheet. Is that there you want to go before public comments, or do you want to go to public comments?

Shelly Spiro
We have got six minutes. Let us go to the spreadsheet. In the meantime, Ike, you had your hand raised?

Steven (Ike) Eichner
Yes, one other thing. I think the other piece, backing up and supporting what Anna was saying earlier, this needs to be patient-centered and patient-focused as a component of providing information electronically to the patient without creating any additional burden on the patient to go out and seek information. As an example, potential workflow, okay, physician or other script writer generates a script, sends it electronically to the pharmacy, patient gets an electronic copy of the send. They get a copy of the acknowledgment of the receipt by the pharmacist or the confirmation that supplies are available to complete the fulfillment, the projected date of fulfilled script availability, and then a confirmation the script is then available and confirmation that it has been picked up. It is reflective of the same general concepts that the issuing prescriber is looking for, as is the pharmacy.

The patient should have the same information, again, without having any additional burden or going to 22 different pharmacy websites to find out what is available for that patient. It should be more of a collected, distributed search where I am saying I need to get my whatever it is refilled. Who has got it in stock, with a geographic proximity search to my location and my payer information and that kind of stuff? We do not want to have a system that creates additional work for patients.

Shelly Spiro
Totally agree. But I think maybe the start or recommendation might be that we might need to develop several use cases. If you have a drug that is a REMS drug or you need a prior authorization, there are so many issues that I think we need to begin to develop use cases on the different scenarios that cause access issues to the patients. That is apart from the connectivity that needs to take place between the prescriber, the pharmacy, the patient, and the payer. These are all very complex issues. Maybe the recommendation is to form a group that would begin to develop, whether that is NCPDP, HL7, or some other standards organization, or the pharmacy associations come up with a way to come up with these use cases, or the patient advocacy groups. I think we need to begin to identify this very complex issue from beginning to end. So, Hans, I will turn the spreadsheet over to you. We have three minutes.

Hans Buitendijk
Okay. When we go to the spreadsheet, a couple of thoughts and comments. One is that if you are interested, go all the way to the top. Actually, let us leave it here. There are a couple of comments that were made in here that if you have additional ones, all task group members can get into this directly if you see something that may not reflect the comment exactly as you made it, or it might have been made by somebody else. You can go in and make those fixes. As you can see, in red, you can make some additional comments as well, if you want to clarify that.

I believe there was a comment from Summer, cross-sectional group there. I think that came from the chat. When you look at this list, this is just captured during the meeting, are there other comments that jump out?

For example, the suggestions that were made by a variety of people is to look at the kind of data as Scott also indicated, to have the ability to look at and ask for availability of filling that particular prescription and possibly going further. That requires a community to come together. Can we widen the comment by Summer a little bit further on how can ONC get collaboration across standards organizations, the pharmacy community in general? How can we move that forward to do that? Can we be more specific, or is it just a general comment that we provide to ONC to help pull that together? Any thoughts in that regard? Because many of the comments that we have are around that part.

So, curious whether anybody has additional thoughts on how to get to a more specific recommendation if we can. Perhaps that might be offline as well. There are in Topic 1 some comments that are like this, but then relative to comment one. I think there are a couple of places where getting a community together to continuously prioritize use cases, which ones to focus on, identify what standards we have, and where they can be, where we need to fill gaps. Shelly referenced other guidance, or how-to, best practices information that can be created. But particularly, what kind of policies need to be advanced to help encourage everybody to participate?

Any additional thoughts there that somebody has? Again, please go directly to the spreadsheet, particularly after the meeting. At this point in time, I am not sure who is editing. But if you are trying to go in right now you might be locked out for the moment, or your update is not made.

Shelly Spiro
I think we are at public comment, Hans.

Hans Buitendijk
Okay. And then after the public comment, we will go back and look at the chat and see whether anything jumps out that we want to discuss further and see if we have an opportunity to move that forward. Mike, over to you.

Public Comment (01:20:15)

Mike Berry
All right, thank you, Hans. We are going to open up our meeting for public comment. If you 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 are on the phone only press *9 to raise your hand. Once called upon, press *6 to unmute and mute your line. Let us pause for a moment to see if any member of the public wants to raise their hand and make a comment. I am not seeing any hands raised at this point, so I will turn it back to our co-chairs. Thank you.

Hans Buitendijk
All right.

Shelly Spiro
Go ahead, Hans. Do you want to go back to the spreadsheet?

Hans Buitendijk

Yes, let us do that. I am just scrolling through the chat a little bit further. There are a variety of people who are indicating that there is a need for the group. so I think we have a general sense around that.

Shelly Spiro
Also, I think we need the develop of use cases because of the complexity of this issue. It is not as easy as just setting up an inventory. There are different scenarios that I think we need to bring forward. I think Rick Sage had put something in the chat about that.

Hans Buitendijk
Yes, and if you go up to perhaps the left-hand column, a little bit patient up to patient engagement. You are in the discussion notes. If you can jump to Topic 2 recommendations, and I will copy things over after the meeting as well. But if you look at patient engagement, started to have a couple of things in there that if you have ideas about the double question mark, what others to put in there. I think you already had a couple of them that we did not quite put in there. One of them wants to add there is that really you have the ability for a prescription to flesh it out more, for a prescription. Is there enough available to fill that? So, it is the filling part and the prescription part specifically to get the insight, not just general inventory. I think we need to clarify that, that we talked about.

Anna McCollister
Hans, are you asking for us to go in and fill in this information, or do you want us to attempt to write specific recommendations?

Hans Buitendijk
Both. If you have an example of a use case that falls within this that we need to consider, that would be helpful because that could be part of an initial, not prioritized, but an initial list. And then recommendations either specific to one of those or overall on how ONC can help advance that.

Anna McCollister
Okay, so in addition to the use cases. I put in a whole bunch last week.

Hans Buitendijk
Yes, and I think we need to go through it a little more. They were in a couple of different areas. If you want to double-check whether it is there, and we will double-check as well.

Anna McCollister
Okay.

Shelly Spiro
And I think use cases are important because we need to come up with a technology solution for this, the use cases become a very important piece for ensuring we can hit all the data points that are needed. Anna, anything you can do to actually flesh out the use cases, that would be extremely helpful from a patient advocacy standpoint.

Anna McCollister
Sure.

Shelly Spiro
Because we can apply the technology to that and find the gaps that we are missing in this entire process of access.

Anna McCollister
Absolutely.

Hans Buitendijk
Yes, and that is a good spot. We might find a couple that we need to put into other rows a little bit, but that is a good place, and we will get the carriage returns in there. Let us see, from the chat, and if anybody wants to jump to a specific one that they had for additional time, let me see that I can scroll correctly. We have the other one that jumped out is the ability for pharmacies to share information with health plans. Very clearly there is the aspect of self-pay in there, where if the health plan did not pay for it, it is not appropriate to share unless the patient does not mind. But are there other examples beyond that, where data sharing between the pharmacy and health plan, or prescribers, or prescribers for other providers, where we need to make sure, generally, not all the lists specifically, that there are concerns around data sharing as well, where the patient may want to indicate that it is not appropriate to share?

Shelly Spiro
I guess that is more of a question for Anna. Do you think that there is a patient consent issue in this, being a patient advocate?

Anna McCollister
Patient consent in terms of what, data sharing about specific …

Shelly Spiro
Yes, of who should know about the access issues. Do you find that?

Anna McCollister
I do not think so in this case. Most of the stuff that we are talking about is not necessarily, as it relates to inventory, that is like does this stuff exist in the pharmacy's inventory, and giving me the information I, my provider, or my caregiver needs to be able to do that. In terms of the specific prescription, I mean that information is being shared already anyway. So, I do not know that we would be considering introducing new privacy concerns unless I am missing something.

Shelly Spiro
Maybe Alexis has. Did you want to get in this conversation, Alexis?

Alexis Snyder
Yes. I had put something in the chat earlier about this and the disparities we might create along the way when we are talking about paying out of pocket and not being able to share that information. Or being able to, if you are paying out of pocket, saying that you do not want this shared with certain folks, including providers, not just your health plan. Versus somebody who does not have the financial ability to pay out of pocket and must use their insurance, Medicare, or Medicaid to cover their prescription, and not having that

same ability to consent or to block the data that is being sent to your provider or other, as far as a privacy concern. Because that is really not fair if somebody does not want that shared, but they have no choice but to use other means than out of pocket themselves. Then we are really creating an unfair disparity based on ability to pay.

Shelly Spiro
Thank you, Alexis. I also want to make a point about provider burden in this whole process. We know that we have a huge amount of patient burden. But if we flip it over to the provider and do not leverage the technology to make it easier and more automated, are we putting an undue burden on pharmacists and prescribers for this process? I mean we have all sorts of areas of relationship to reimbursement around this. I think we need to take that into consideration also. Not to come up with a process that would cause undue burden for any provider of these types of services by shifting it away from the patient.

Anna McCollister
A.) I think we need to focus more of our efforts on the individuals who are trying to get healthcare as opposed to the system more broadly speaking. Having said that, I have great empathy for all of my providers because of the amount of work they have to go through for all of this too. But I think the data elements that we are talking about if we make them more visible, transparent, and accessible, and this just inventory and like which NCD code does the health plan care to reimburse for this month. That will help the provider as well. I would love to not have to manage this stuff, but the reality is I do. So, just give me and my doctors the information we need to be able to do it.

Shelly Spiro
We only have one minute left. Alexis, I will let you talk. But first, the person who raised their hand on the attendee side, we already went through public comment. So, please put your comment in the chat. Alexis, I will give you the last word very quickly because we have to close the meeting down in a few seconds.

Alexis Snyder
Sure. Real quick, I was just going to say I do not think it is about completely shifting away from any patient or caregiver role in the process. It is about making it easier and being part of that team because, without the transparency and the solutions, it is a tremendous amount of time just because we cannot actually do these pieces, and we are stuck in the middle.

Shelly Spiro
Exactly. And that is where **[inaudible – crosstalk] [01:29:14]**.

Alexis Snyder
It would be helpful and time management for all involved. That is fine. But also, that said, we need to remember there are people who do not speak English, people who are not well-spoken, people who do not know how to access these things, and those folks can also not be stuck in the middle and manage this for themselves.

Shelly Spiro
I totally agree. That is where leveraging the technology might be helpful, hopefully in the future. With that, just last words, next meeting, which is next week, we will be starting Topic 3, identifying standards and

needs to support the prescribing and management of emerging therapies, including but not limited to specialty medications, digital therapies, and gene therapies. Hans, is there anything else you want to add before we close? We are a minute over.

Hans Buitendijk
No, not specifically on next week's tasks, but on prior. Do not hesitate to go into the spreadsheet. Also, look at the open placeholders for a number of participants on Topic 1. If you have additions, please add them in. If you have modifications to somebody else, please mark it up. That will be great. Thank you for everybody's discussion. Good conversation on inventory and looking forward to next week, as we shift to Task 3. Thank you.

Shelly Spiro
Thank you, everyone.

Alexis Snyder
Thank you.

Hans Buitendijk
Take care.

Adjourn (01:31:09)