ONC HealthIT ADVISORY COMMITTEE

Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTICS TASK FORCE 2023 MEETING

September 20, 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
Stephanie Garcia	Office of the National Coordinator for Health Information Technology	Presenter
Mark Dunnenberger	NorthShore University Health System	Presenter

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

Michael Berry
Good morning, everyone, and welcome to the Pharmacy Interoperability and Emerging Therapeutics Taskforce. I am Mike Berry with ONC, and we are glad that you could join us. We have two guest presenters joining us today, and I would like to thank them for participating in this meeting. This taskforce is open to the public, and your comments are welcome in Zoom chat throughout the meeting or during the public comment period that will be held around 11:50 Eastern Time this morning. I would like to begin rollcall of our taskforce members, so when I call your name, please let us know if you are here. I will start 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?

Chris Blackley
Good morning.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
David Butler? Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Adi Gundlapalli?

Adi V. Gundlapalli
Good morning.

Michael Berry
Jim Jirjis? Summer Kahlon? Steven Lane?

Steven Lane
Good morning.

Michael Berry
Meg Marshall? Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Deven McGraw is not able to join us today. Ketan Mehta? Justin Neal is also not able to join us today. Eliel Oliveira?

Eliel Oliveira
I am here, good morning.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Scott Robertson? Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Christian Tadrus?

Christian Tadrus
Good morning.

Michael Berry
Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Afton Wagner?

Afton Wagner
Good morning.

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

Opening Remarks (00:02:18)

Shelly Spiro
Hans, I think you are first.

Hans Buitendijk
Good morning, everybody. I appreciate everybody joining us. As Shelly reminded us, this is the 11th meeting already. We have a few more to go. Today, we are going to look at Task 3, which Shelly will introduce in a moment, and after that, we are going to go back to Task 1 and continue where we picked up. We are going to highlight a few of the updates that were made to make sure we caught them, and then we are going to continue where we left off with the review and go as far as we can. So, today is very much about focusing on finalizing the recommendations as much as possible, so we are looking forward to discussion and clarifications, and please continue to make comments, thoughts, and suggestions in the chat that we can further blend into the spreadsheet.

After this week, particularly in Topic 1, we hope that we can close that down, if not Topic 2 as well, in terms of working on it in the spreadsheet, and then we are going to shift over to document format. So, depending on where we are at the end of this week, we will begin to edit and finalize in a Google or Word document to make that a little bit easier. So, that is where we are at. Shelly, it is all yours to take us into the first agenda topic.

Shelly Spiro
Thank you. I also want to thank Hans and the ONC team for covering for me on the last call. I appreciate it. I was glad things went as well as they could, and thank you, Hans, for going over the agenda. We have two presenters today, Stephanie Garcia, who is with the branch chief at ONC, and Mark Dunnenberger, the Assistant Vice President of Personalized Medicine and Pharmacogenomics at North Shore University Health Systems. To the presenters, we ask that you keep it to five minutes because we want to have time to make sure that we answer questions from the taskforce members. Welcome to our public attendees. Just to remind you, we will stop at 11:50 for public comment, with which Mike will help us, so if you want your voice to be heard, you are more than welcome to comment. To those of you who are attendees and also to the panelists, please put your comments in the chat. They are captured as part of public comment, so we encourage you to do that, and with that, I think we will move to Stephanie's presentation. Thank you, Stephanie.

Task 3 Guest Presentations (00:05:40)

Stephanie Garcia
Hello. Can you hear me? All right, awesome. Thank you so much for the opportunity to present during today's taskforce meeting. My name is Stephanie Garcia, and I am a branch chief within the Networks and Scalability Division of the Office of Technology at ONC. Today, I am presenting an overview of the Sync for Genes Project. Next slide, please. So, we will start with an overview of Sync for Genes, its five phases, and the premise for the work conducted. Then, I will give a brief description of the outcomes and opportunities that resulted from the most recent phase, and lastly, I will give an overview of the resource guide that was created to capture and present all the information across phases in one place. Next slide.

Sync for Genes launched in 2017 as a collaboration between NIH and ONC to help deliver on the goals of the Precision Medicine Initiative and NIH's All of Us research program. Sync for Genes was meant to be the first step toward integrating clinical genomics into the point of care to support the rise of genomic testing and the improved ability to study genomics and apply those findings to the improvement of health. The Sync for Genes mission was to standardize the sharing of genomic information among laboratories, providers, patients, and researchers, and over the course of five phases, the project advanced the development and use of industry-supported standards for the sharing and integration of genomic information in a consistent and usable way by primarily encouraging the use of HL7 FHIR for genomic data exchange. Next slide.

So, on this slide, you can see very top-level results from each phase. I will just pause for a brief moment, since I was speaking to the previous slide. Next slide, please. So, as the work started, we saw everything from interoperability challenges, the need for data partners to create unique interfaces for data exchange, to the complexities that genomics introduces that some standards cannot quite support yet, such as the need to share large data files that can be parsed. So, ONC understood that cutting-edge work like this,

work that happens at the intersection of health IT, genomics, science, healthcare, and research, is a greenfield, and that there could be incremental progress made by conducting short-term successive phases, each with small-scale pilot demonstrations or testing.

So, the project continued and picked up speed, with the goal of each subsequent phase being informed by the previous phase's findings and work. By focusing on these key areas, strategic development and adoption of genomic standards, support and coordination for implementers, targeted education and training on the use of standards and solutions, and again, a phased approach to make progress on larger industry challenges, the Sync for Genes Project paved the way for work to continue that supports efficient and effective genomic sharing, ultimately to improve patient care. Next slide, please.

Now, we are moving on to Phase 5. Next slide. So, for Phase 5, Children's Hospital LA and LMU developed a proof of concept for genomic clinical decision support. They successfully demonstrated that an app could retrieve patient genetic test results using the Global Alliance for Genomics and Health, or GA4GH, variant representation specification and the GA4GH annotation specification for results. The results were then delivered to the test provider using HL7 FHIR. The demonstration highlighted the ability to ask GA4GH specifications to represent genomic data and knowledge, the degree of harmonization between the GA4GH specification and HL7 FHIR, and the use of the emerging technology called Operation that makes FHIR APIs more convenient to use. But to learn more about the details of the work, I encourage the taskforce members to review the Phase 5 final report that is published on HealthIT.gov. Next slide, please.

So, the outcomes of Sync for Genes Phase 5 were informed by a panel and the demonstration project. The recommendations include the following. First, there are obvious gaps in standards and technology that are needed, but the recommendation is to continue developing or expanding existing standards rather than developing new standards. Second, there is a need for standards-based content, such as the description of genomic variations, and the annotation data that describes knowledge regarding the effect that variations may have. So, while there are knowledge bases that can present information about simple variations in a discrete format, complex variations are more difficult to present in a computable form. Currently, the annotations, such as the description of lab results, are typically presented in unstructured text, making them difficult to use by clinical decision support.

Third, it is well known that adoption of standards for genomics is difficult given the needed resources and technical expertise that is needed for implementation, and therefore, a finding was suggested to develop a testing environment, such as a sandbox, that could support implementers before installation and yield best practices to lower barriers to adoption. Fourth, the infrastructure that is needed to support the large volumes of data that result from genomic tests and studies is large, as is the need to support the complexity of genomic data and systems that would provide up-to-date interpretations for genomic variations.

Fifth, the use of complex genomic data by providers and patients could be supported by CDS, although robust training is needed. The quality of CDS depends largely on computable knowledge being available. Lastly, as we all know, genomics is a relatively new field, and there is much education needed on several fronts, as well as standardized representation, exchange, and use of genomic data and knowledge. I know my time is just about up, so I am going to skip to the next slide, please, and quickly highlight this toolkit that was developed for the Sync for Genes Project. It includes all the resources across phases. I have

highlighted core resources here that were most critical to the success of the project. Last slide, please. Thank you.

Shelly Spiro
Thank you, Stephanie. I appreciate you sticking to time. We did start just a few minutes early, so I did give you another minute. Next, we are going to hear from Mark. Mark, you are on for five minutes, please.

Mark Dunnenberger
Great. Thanks for the invitation to speak. It is a pleasure to speak about pharmacogenomics. Go to the next slide. My comments are limited to germline pharmacogenomics. I am not talking about somatic, tumor, or cancer genetics, but specifically about germline pharmacogenomics. In germline pharmacogenomics, there is an interpretation process that needs to occur. Whether this happens at the bedside or at the laboratory, there are multiple levels of information that need to be communicated to impact clinical care. The first two, haplotype and diplotype, are laboratory-based values. A phenotype is something that is easily described, such as a 2D64 metabolizer, and then, a therapeutic recommendation is what you need to do when you have this genetic result paired with the drug.

There are international organizations that create therapeutic recommendations, such as CPIC, the Clinical Pharmacogenomics Implementation Consortium. Those are widely available via API, so we are good there. For phenotypes, CPIC has gone through and standardized the nomenclature for pharmacokinetic-related genetic variants, but not pharmacodynamics. There is not a lot of information in that space, but that is going to be a problem heading into the future. These phenotypes are supported by LOINC codes, so they can be communicated pretty easily. One major problem we have here is there is not agreement, though. Not all labs use these standards for the translation from diplotype to phenotype, so that creates a problem where, as a clinician, I need to know the diplotype information that was used to derive the phenotype because I may disagree with that.

So, for diplotypes in pharmacogenomics, we use this thing called a star allele, and you can see it represented on this page as Star 1/Star 1 or Star 1/Star 2, etc. If we go to the next slide, I will tell you the secret about star alleles. So, Star 1 denotes a default reference allele, meaning if I do not find any changes for what I am looking at, I am going to call an allele a Star 1. All of the other star alleles just represent one or multiple variants in the order that they were found, but because Star 1 is a diagnosis of exclusion, I need to know the metadata around the test to be able to make sense of that Star 1 because I could test the same person at multiple labs, and if they tested different variants, I will get different call. The patient could be a Star 1 at one lab and a Star 47 at another, but actually, both of them are correct based off of their test.

We do not have good standards for communicating this metadata. This becomes important because typically, a Star 1/Star 1 is a normal metabolizer, and if the patient had a variant that was not interrogated but maybe had low function, they could be a poor metabolizer and I am going to make an incorrect therapeutic recommendation for that patient. Go to the next slide. We can advance all the way through the slides so I can show you.

One other problem I have is there are a lot of ways that a lab could report out the same information. So, we integrate with five different labs at my institution, and for one pharmacogenomic result, CYP2D6 Star 1/Star 10, I have it described 25 different ways in my medical record. I need all 25 of these to match up and mean

the same thing. I have the time and resources to do this, but an average health system and an average HIT department is not going to have the time and energy to aggregate this. There are thousands of combinations for CYP2D6, and this is just one combination I am seeing 25 different times, so having some standards around how things have to be reported would be huge, as would having those adopted. Go to the next slide.

Finally, the last thing that needs to be conquered is better communication between health systems and pharmacies. We need to use these genetic results in a number of different places, and the genetics may come from non-pharmacogenomic testing and other disease testing happening in a health system. How do we get that to the community pharmacies? Nobody has solved this yet. One of the big issues here is not a standards issue, but a value proposition issue that the field has to solve. With that, I will stop, and I will give Shelly back 15 seconds.

Shelly Spiro
Thank you so much. I appreciate it, Mark. That was great, and we appreciate you. We have two minutes extra. We will be having a discussion until 10 minutes after the hour, so we have 32 minutes for discussion. Pooja, I think you are up first.

Pooja Babbrah
Thank you to the speakers. This was great information. It is exciting to see especially Sync for Genes, but from a pharmacy perspective, I think the PGx is relevant for having that information within the pharmacy workflow. I know NCPDP has just recently put out a whitepaper, which I put into the chat, about how we should be thinking about potentially standardizing some of the information that is coming back from the lab and make it accessible to pharmacies, so I just wanted to point that out. I think it is definitely work the taskforce members looking at that as well as we start to think about recommendations.

Shelly Spiro
Thank you, Pooja. Anyone else? Christian?

Christian Tadrus
Thanks, Shelly. I just have a comment on the different labs reporting different…well, even the same result in different ways and that standardization process. I certainly agree that needs to happen because we need a universal translator scenario. Where would that best occur? Is that something that needs to be addressed through multiple SDO working groups? It seems like that has a lot of clinical subject matter expertise from the guidance entities, but also the so-called lightweights of that aspect of standardization of that data and the exchange process for information exchange and interpretation from these IT systems. How do you put that together? I guess the question is where would this all apply? Where could that work be done?

Shelly Spiro
Is that to Stephanie or to Mark, Christian?

Christian Tadrus
Maybe it is just a suggestion for Mark. How do you see that playing out? That is a huge group of labs, clinicians, guidance entities, and staff to pull together to try to standardize that. What does that look like from your perspective?

Mark Dunnenberger
I think the short answer is a number of stakeholders going to ABB or some other laboratory reporting organization and either collaborating with them to come up with the standards for how we should do that or expressing a strong need for this to happen to have better adoption of genetic testing. Because of the way lab reports work, I do not think it is something that a pharmacy group could put out a standard for. I think they need to be stakeholders in the use of a standard.

Shelly Spiro
As a follow-up on that to Stephanie, in your slide deck, you talked about this type of standardization. Do you have any comments on some of the issues that Mark had brought up?

Stephanie Garcia
I think the clinical standardization as a representation of the actual result would best be left to a body that has a majority of clinicians represented. I could speak mostly to the standards development organization point perspective. At that point, it is a matter of being able to transport the information in a standardized way. We were able to successfully demonstrated in an HL7 connectathon the ability to parse out different parts of the genetic test reports, and then demonstrate how to send that using FHIR and also demonstrating not just a simple report format, but basically embedding test results within the report. But as far as the standardization of the actual annotation or clinical interpretation of the results, I unfortunately cannot speak on that front.

Shelly Spiro
Thank you, Stephanie. Alexis? Sorry, Anna?

Anna McCollister
We both start with an A.

Shelly Spiro
I have that problem. Sorry about that.

Anna McCollister
That is okay. I have five kids. I am used to answering to anything. At the risk of seeming dense, part of my question is do we need to make it this complicated? I understand genomics a bit, I understand pharmacogenomics, and I understand a bit about data and data standardization, and I realize that all of this is incredibly complex, but as somebody who takes 14 different medications, which I believe is the current count, for some of which pharmacogenomics are important, I have had two different PGx tests, which have been helpful. It is difficult to understand because nobody really talks about it, but when you look at the report, it says CYP2D6, poor metabolizer, rapid metabolizer, or whatever, it seems like a relatively straightforward call if you could just put those two fields into a standardized format.

Again, I do not understand enough about the complexities to get it at Star 1 or Star 2 and how one person could be both a Star 1 and a Star 42, so I am sure there is a lot that is completely going over my head, and it probably seems simpler to me than it actual is, but I am wondering if we really need that level of complexity within the data or if the information that comes during the report about a specific gene and whether or not you are a fast, slow, or normal metabolizer would be sufficient.

Mark Dunnenberger
I would love for it to be sufficient. You could give that information as long as you also gave the method that you used to translate the actual laboratory result into that phenotype call because there is disagreement. Some commercial labs will report some diplotypes as ultra-rapid if you go to Lab A and normal metabolizer if you go to Lab B, so because I cannot trust that label and I do not know how you got there, I need to understand the diplotype underneath it and what was tested to come up with that diplotype because you start to get big differences based on a patient's race and ethnicity as to which variants you may or may not see, and if your test does not cover the variants seen in your population, you are going to erroneously give me a laboratory result that says they are a Star 1/Star 1, which translates to a normal metabolizer, when, in fact, they are going to be something else, maybe a Star 41/41, which would make them a poor metabolizer for a given gene.

So, you have two different problems. One is there is not an agreement among all labs to use the same translation from the raw laboratory result to a phenotype. Therefore, I want to know the raw laboratory result and to make sense of it. Because we use a diagnostic exclusion to assign the most common star allele, I need to know the metadata behind it. That is just the complexity of what is going on there. I wish you could just take a phenotype and move forward, but that is not where we are at today.

Anna McCollister
So, it just sounds like we have not really… If I am hearing what you are saying correctly, it gets into not really polygenic risk scores, but polygenic pharmacogenomic scores.

Mark Dunnenberger
We are still thinking about one gene, and I caution you that we just do not know enough today. What we know today are the low-hanging fruits where big bins of phenotypes work. Where we are headed in the future is going to be basically genotype substrate-specific recommendations where you are not always the same phenotype for a given enzyme across any substrate. You are going to have individual substrates or different drugs where you will be a normal metabolizer for one and a poor metabolizer for the other as you think about the protein changes inside of the enzyme based on the genetic variation. It is only going to get more complicated in the future. Right now, we are at the easy part of pharmacogenomics.

Shelly Spiro
Thank you. David?

David Butler
Thank you. I am going to pack a lot of history, among other things, into this premise before asking the question, but my premise is the fact that most of the clinical trials that have been done historically have been on populations that were assumed to be homogeneous, but as we know, those were just bell-shaped curves with a couple of standard deviations, and the drug therapy was said to work in that population or not. We know clearly now that we can be much more personal identifying each drug to the gene that would be applicable with regard to the dosing, the adverse effects, the potential types of allergies, and such like that, but if we do develop all of this nomenclature so that we do get the stars worked out, or aligned, if you will forgive me, then we will end up with a set of data from the clinical trials historically that is still very vague and nebulous.

Having worked on some of the groups dealing with adverse effects and worried about the fact that every one of our hospitals and every one of our community practitioners still asks the patient only if they have allergies, not if they have ever had an adverse event, we do not really have all of the data and we do not have a standard set for the clinical impact of drugs being used on a particular gene, so I am concerned that we may end up with an appropriate standardization on the genes, but we have nothing to tie it to on which drug within a drug class is the one that is actually going to affect that specific patient.

To my question, as this develops, do you see that as we improve the gene standardization and the specification per patient with the impact of the drug that we can further refine the drug adverse event standardization, which will lead us to improving the data capture when patients are admitted to the hospital or seen by a physician so that the pharmacist will know when this patient comes in to monitor for a specific adverse event or drug interaction that may occur, or if the dose is right, or all the things that we will be able to do? So, I am afraid we are going to get to a wonderful standardization structure, and then the other half of what is needed will still not be there. Could you comment on that? Maybe that is just something for the group to discuss.

Mark Dunnenberger
I can make a couple of quick comments on that front. One is that pharmacogenomics is not a panacea for getting rid of adverse drug effects. Knowing somebody's genetics is not going to solve all of the problems that are out there. There are a number of other OMIG things that we have to deal with, and then you have the whole environment as well. The microbiome plays a huge role in what your drug exposures are going to be.

What we know today, again, is the easily identifiable stuff where big sections of that bell curve have the genotypes and phenotypes that we care about, and we have been exposed to the drugs and can see them. We know going forward that if we can test more people for genetics, use that data more, and have it embedded in the record, if you parallel that with what I think you really want, which is better standardized reporting of adverse drug events, if you take a better genomic data set and a better adverse drug data set, you can begin to do new discovery work and really drive understanding of how genetics affect drug response, but you need both of them together. I think it is actually going to be easier to do the standardization on the genetic side than the adverse drug event side, but both of them together would be a pretty powerful tool.

Shelly Spiro
Great, thank you. Stephanie or Matthew, do you have any comments you would like to make on what David brought up? Okay, Scott?

Scott Robertson
Building on David and Mark's discussion just now and a comment that Christian put in the chat, I am looking at how to go about addressing this. I do not know if there is an organization that might take on the responsibility of taking on something similar LOINC, which is built so things can change, so there are multiple axes it tracks in terms of describing the sequence and variation, but also, you need to potentially know the methodology used or the nature of the descriptor. If there was an organization that could take on that kind of responsibility or an organization like that could be developed, that would seem to be a good

way to start moving forward toward something that could be recognized across the board, work against it, and tie into clinical decision support. So, making this into a question for you, Mark, do you know of any groups that are looking into such ideas at present or that should be either included or consulted in terms of that type of standardization of the tests?

Mark Dunnenberger
I will make a couple quick comments. Somebody asked in the chat if CPIC would do that. I do not believe it is in the purview of CPIC to solve that problem. One major challenge that we have now is the value proposition for pharmacogenomics as it stands today in a population approach is not great enough to create resources, standards, and organizations on its own. That is just not how medicine works today and is not how we have set out the value proposition for pharmacogenomics. You cannot find it in the literature. So, what pharmacogenomics is really focused on is how we use existing frameworks, and all of the problems you described, Scott, are problems for genetics in general, which is why I was able to work with Sync for Genes on one of the phases, thinking just broadly about genomic data and putting pharmacogenomics in there as a use case. It is a slightly different use case, but that is where pharmacogenomics is going to be successful, is when we can work with other genomic standards, and there are groups working on that today like ClinGen and others like it, but we have a long way to go.

Scott Robertson
It would not be very useful if pharmacogenomics ended up using something different, potentially incompatible to the rest of the genomics work. Thank you.

Shelly Spiro
Thank you. Hans and Jim, we have three minutes left, so, go ahead, Hans.

Hans Buitendijk
Thank you, Shelly, and thank you, Mark, Stephanie, and Matthew for the discussion and presentation so far. I am going to put this a little more strongly than intended, perhaps, to see what kind of recommendations we could make. I understand that a lot of progress has been made, is being made, and yet still needs to be made before we get to a point where we could say if you look at some of the areas where ONC typically gets involved, like certification programs, working with CMS or others to provide incentives to spur adoption, there are capabilities out there that are underutilized and need to have a push, recognition, or otherwise to move forward. That is where I am trying to get a better understanding.

Beyond the role that ONC currently has, and they are engaged, they are in facilitating roles or participating roles already, what do you see at this stage of the progression where ONC, in collaboration with other agencies, could help advance and remove a bottleneck that is currently in place, or do we see that it is still very much on the clinical community and environmental standards community to build up the toolkit before we get to the point where we can say that now there is wider adoption opportunity, it is not happening, and we need to figure out how ONC and others can help move that along? What is your thought in that regard, where are we at, and what could we ask or suggest to ONC to particularly pay attention to?

Mark Dunnenberger
We are in a world today where Medicare pays for pharmacogenomic testing and most max for specific conditions. If this is done correctly, one pharmacogenomic test will have lifetime value for that patient.

Through a standard mechanism, I currently cannot get enough information about that test to ensure that I am maximizing the value in patient care of those test results. ONC and collaborators need to work on HL7 FHIR-based standards to communicate that metadata around a test in an efficient process where I can take a test result or a lab report and get a full understanding of what happened so I can maximize the value to the patient.

Hans Buitendijk
Thank you. In that context, I am curious about the work that is happening in CodeX, a clinical genomics workgroup with HL7 and NCPDP. Is that in need of additional activity by ONC, or is it just helping make sure that it keeps on moving along because it takes time? I understand the need to get to that point. What I am trying to figure out is where the gap is and what we still need to do to move that along faster or better.

Mark Dunnenberger
I will defer to Stephanie.

Shelly Spiro
Stephanie or Matthew?

Stephanie Garcia
Hearing your recommendations on how to move projects with Sync for Genes, which is very valuable, and making sure that those programs continue, at this point, I cannot really speak to what the future of Sync for Genes is. What I would say is, as I mentioned in the presentation, Sync for Genes is really meant to be the start, as you might have alluded to, Hans, the instigator, or the catalyst to work that might not be done, so there are additional ideas that are brought to ONC for pilot testing and ways to support the adoption, but we really need to hear those recommendations from this group. I think that would be very valuable.

Shelly Spiro
Hans, we are two minutes over our time and have gone into the recommendations. Ike has a question. How do you want to move?

Hans Buitendijk
I would say to wrap up with Ike and go from there.

Shelly Spiro
Sounds good. Ike?

Steven Eichner
I will make this as quick as I can. I know there is a lot of data volume associated with genetic information. Is there a suggestion about a recommendation that we could make to ONC regarding how volume might be managed so we are not ending up with 22 different copies of the same data across 22 different pharmacies or other providers? That just seems to be an awful lot of unnecessary duplicative storage and transmission. Is there something we could do to recommend a more efficient way of storing that data while still making it accessible to those who need it?

Mark Dunnenberger

In clinical practice today, by the time the data gets to a healthcare system, there are not a lot of data points. If you want to visualize it, maybe 30 rows and six columns in an Excel spreadsheet would give you enough to be able to describe what you need. In the genomics space writ large, yes, that is huge data, but by the time it gets out of the laboratory, it has been distilled down enough that big data today is not a problem. I could imagine it might be at some point in the future, but that is a problem bigger than pharmacogenomics alone.

Steven Eichner
Just as a quick follow-up, would it be fair to say that the included recommendation might include the exchange of genomic data critical for clinical decision making, sidestepping that you necessarily need the entire stack of all the background data?

Mark Dunnenberger
Yes, I would include that in your recommendation in the scope that you are referring to.

Steven Eichner
Thank you.

Shelly Spiro
Okay, Hans, I will turn it back over to you now to go over the recommendations, and we can pull up the spreadsheet.

Task 1 Review of Recommendations (00:43:28)

Hans Buitendijk
Thank you, Mark and Stephanie, for the discussion, and we will move into the next topic. I really appreciate that. Throughout the conversation, if there are additional thoughts or recommendations, please put them in the chat so we can pick them up. That means we are going to go back to the spreadsheet. We are going to go to Topic 1. If we can, we are going to look mostly at Columns D, E, and F on the screen as best as possible. You may need to look up your local copy, but primarily, we will look at D and E, and we will use F for some comments that we make along the way to make sure that we are capturing some thoughts. As a little recap of what happened since last week and what you see right now, you will see in Column E that the column header disappeared for the final recommendation, and we will fix that, but we marked all the recommendations.

On this page, we are up to 23. We got from R1 through R9 last week. There were a couple areas that we needed to make sure were included and followed up on. If you look at the first cell, E2, there are two particular follow-ups. In one, we have a question for Ike to look at R2 to see if any additional refinements are to be made. In R3, Alexis, we had a little challenge to find the comments that you made. We made an additional update to that same one. I want to make sure the comment in R3, where we merged the three bullets into two, captured the consent and disclosure aspects efficiently. Look at that specifically, and then, generally, though we are not going to run through it today, run through and make sure there are additional updates if you have any further thoughts on the refinement at this point.

When we look at the next row, Row 3, what you see is that Anna had the opportunity to put a number of different comments in that we have not reviewed together. They are now marked as R10 through R14 in

this regard. The red is to clarify where there are differences from what Anna has put into the draft recommendation, and as it is being put into the draft final recommendation, there are some suggestions for adjustments there. They look substantial, but they are actually trying to condense some of the information and try to make sure that it is captured. Anna, particularly from your perspective, I want to see that we make sure we did not lose anything in the process.

We are going to come back to R10 through R14 in a moment because that is where we want to pick it up and run through with everybody to see whether there is general agreement that these are recommendations that we want to move forward and finalize or whether there are some we need to have further discussion around. In a moment, we are going to come back to R10, and then, in the next row, Rows 4 and 5, there are the remainder of the recommendations we talked about last week, where further additions or clarifications have been made. The question there is if we caught that or if we missed anything. Particularly, in E5, there is a question for Ike of whether the updated recommendation addressed the concerns that he recently raised or whether it missed them. So, those are the particular updates since last week, so have a look at those as soon as you can so that we can round that out. Today, we are going to pick it up with R10 a couple rows back, and then we will pick it up with the rest in Row 6. Before jumping into that, are there any general comments?

Shelly Spiro
Anna, you have a comment.

Anna McCollister
I just want to make sure I am following correctly. You took a look at my recommendations, and I want to know what it is I need to do to make sure that…

Hans Buitendijk
Okay. For example, particularly in the first two that are now in Column E, R10 and R11, I started with the recommendation that you had for both, but then, as I was going through, I was trying to streamline a little bit more to put them in the context of our overall recommendations. Particularly with R10 and R11, did anything get lost in the recommendation you were trying to make? I am trying to streamline that a little bit. I might have gone too far with that, and I want to make sure I did not, so anything you have there would be absolutely welcome.

Anna McCollister
Okay, I will take a look. Thank you.

Shelly Spiro
If I can, Hans, I think it is important that everybody realizes what we are trying to do. We have comments in the different topics, and what we are trying to do is harmonize those into recommendations, not necessarily by topic, but especially in public comments, a lot of those topics are duplicated in other topics, and Hans has done a great job of trying to consolidate them into recommendations that we can move together because we know there is some cross-pollination between the different recommendations in the different topics, if that makes sense.

Hans Buitendijk

Additionally, in this particular context, I was trying to transform some of the personal perspectives you brought to that, Anna, into a more neutral perspective overall to represent the taskforce's perspective. Particularly in No. 1, you will see the word "I" changed to describe it differently without trying to change the intent behind that. That is why there are more changes there. I did not do that in other ones because that was not there.

Anna McCollister
That makes perfect sense. So, I am guessing you took out the emojis.

Hans Buitendijk
I was trying to stay emoji-free there. All right, let's start with that. R10 through R14 are all from Anna. The first one is "Recommend that ONC require any informational element that is involved in determining which drugs get covered with or without a prior authorization and what cost is captured and accessible to pharmacies, pharmacists, other providers, and patients." So, it requires any informational element that is involved in the determination to be captured and accessible to pharmacies, pharmacists, and other providers, and then it provides a rationale behind that. That was clearly part of the conversation, that we want to find ways that such data can become available as the standard coursing matter. I think we need to do a little bit more tweaking, but are there any comments, questions, or concerns with carrying this forward, other than fine-tuning and clarifying?

Anna McCollister
I am happy to give clarification or provide some of the rationale, if that would be helpful.

Hans Buitendijk
This would not be specific to public health, but generally for pharmacies, pharmacists, and providers. Is that accurate, Anna?

Anna McCollister
Yes, and this is really driven by a frustration I had shared previously about a health plan that required only one specific NCD code to be covered, but nobody involved in the decision-making process knew anything about that, including my physician, the pharmacies, and the PBM. Only the health plan knew it. It was discovered accidentally that that was the secret sauce to why I suddenly needed prior authorization for a medication I had taken for 20 years.

Hans Buitendijk
I will make that note for us here at the end, that we need to make sure it is not tagged as specific to public health, but across the board. I will mark it as specific.

Shelly Spiro
Pooja?

Pooja Babbrah
I definitely like this recommendation. I am trying to figure out how to make it a little clearer. Today, in the e-prescribing workflow in an EHR, if the drug is covered under the pharmacy benefit, there is information that is flowing through the formulary and benefit file as well as the real-time benefit check where there is a flag

that says a prior auth is required for this drug, and then, again, through the EHR, if the drug is covered under the pharmacy benefit, the doctor could electronically ping the PBM, and they would bring back the questions that the provider would need to answer to get that prior authorization. So, I am just wondering if we need to change this recommendation a little bit. I am not sure if we are talking about certifying that workflow, which I think makes sense.

The other thing is that today, a pharmacist could technically do the prior authorization electronically as well if the health plan allows them to do that. I am just trying to understand if there is something within the scope of ONC. Do we make this more certification-related? Do we expand it for specialty? I am just struggling a little bit with this, but I do agree that we need something around this. And then, the final thing I will say is I think we are confusing prior auth with price transparency, and I wonder if we need to separate them out into two separate recommendations.

Anna McCollister
This is driven from my personal use case. So, everybody, including the pharmacist and doctor, saw that this medication required a prior authorization, but the reality was that it would not if you had the right NCD code, and nobody knew that, except for the health plan, until I accidentally discovered it. Again, this is a medication I had taken forever, and suddenly, it required prior auth. So, the health plan made a decision they just had not communicated. NCD codes are structured, understood, and exchanged, and that would have been a very simple piece of information to provide.

I did not specifically list NCD codes, and maybe that would be a solution because to me, it felt like a very arbitrary thing, and rather than speaking to one specific, arbitrary thing that happened to impact me, just stating that there is some sort of a decision filter that that data about whatever that decision filter is has to be communicated. So, I have no doubt that this is not particularly clearly articulated, but I was not quite sure how to do that without being too prescriptive in such a way that would still make it possible for there to be relevant data that is not shared, if that makes any sense.

Pooja Babbrah
It does.

Hans Buitendijk
Pooja, you might have some suggestions for updates, and then you and Anna could see whether that balances the two perspectives there.

Pooja Babbrah
Yes, absolutely.

Shelly Spiro
Also, Hans, because we are putting recommendations in public health, we might need to make sure that this applies to public health.

Hans Buitendijk
I agree, so when we put it in the final, we would not point back to this particular topic, we would point to the general topic at hand.

Shelly Spiro
Thank you.

Hans Buitendijk
Just looking at the time, we have a bunch to go through. I want to make sure we primarily focus on the questions. Are we generally in sync to move forward with the recommendations, or do we believe that it falls outside and we can have some offline refinement as well? For this one, it sounds like we would like to move forward with it, but it needs to be further updated to clarify and provide context, and maybe split into two. I also put in a clarification there that some questions might come up with real-time benefits and prescription benefits. What is the right time, and is this doing anything additive to that that we can highlight as well, or is this more advancing what we have? Scott, and then Ike.

Scott Robertson
I am going to be short because they are going to revise this. I just see this as being focused on the payer/PBM being required to provide this information. When I first read it, I was thinking that everybody has to be able to have access to the appropriate information, so maybe just make sure that gets focus when you do the rewrite. I will just leave it there, for time.

Hans Buitendijk
Thank you. Ike?

Steven Eichner
In the same direction, I think the purpose is great, but I think the language around the recommendation might be updated a little bit because requiring any informational element involved in determining which drugs are covered without a prior authorization is not really what we are asking. What I think we are asking is that the PBMs provide any of the information necessary if a prior authorization is required to be submitted electronically, if that makes any sense.

Hans Buitendijk
Pooja, does it resonate with you that that would better clarify the direction for this recommendation?

Pooja Babbrah
Yes, I think so. I need to look at the language a little bit, but yes.

Steven Eichner
I think the focus of the recommendation is on whether a drug needs prior authorization or not, and if so, what information is required to be communicated from the PBM to the pharmacist and the provider, not the determination of whether a drug needs prior auth or not by the PBM itself. In other words, that is more of an upstream decision than “Hey, this drug is prior auth, here is what you need; this drug is not prior auth, and you do not need it.”

Anna McCollister
In this case, the PBM did not even have the information. It was just the health plan.

Hans Buitendijk
All right. Ike, do you want to look at it when Pooja and Anna have an update to double-check that it fits better?

Steven Eichner
I am happy to do so.

Hans Buitendijk
Okeydoke, then I will have three names behind this to further clarify, and they are Anna, Pooja, and Ike. The next one is R11. "Recommend that ONC work with CMS and other relevant agencies to develop an incentive structure so that prescribing providers can patients can be accurately informed at the point of care whether a prescribed recommended medication intervention is available at the pharmacy to which the patient medication has been sent/referred. This should include data on the status of drug supplies, medication availability, and detailed tracking data on shipments for medication with all actors in process, including pharmacies, ordering providers, patients, and public health emergency systems. We suggest that a cross-sectional workshop with a focus on the patient and ordering provider go through a use case model to further inform the necessary capabilities and gaps."

Shelly Spiro
Anna, maybe we should use your use case.

Anna McCollister
I am happy to… I have several use cases for that one.

Shelly Spiro
It might be helpful to write them up so that we can use them.

Anna McCollister
Well, I think they are in there somewhere. I provide it in the rationale and the copy that I wrote as well. I put some of the use cases there.

Hans Buitendijk
So, I have two questions there, then. Anna, did that reflect the second recommendation sufficiently a the way that adjusted that, or does that miss anything there?

Anna McCollister
I will have to go through and read it again. I think you got it. I do not remember recommending a taskforce, but that seemed like a reasonable approach, if that is necessary. It seems to me like all the data around inventory is already there, just in other systems, and I think it should be incorporated into the system that is available. If UPS can have the tracking information, the distributor has information about their inventory and shipping, etc., then why not make that data available?

Hans Buitendijk
Yes, there was an additional comment that triggered the inclusion of that note on the workshop, so that discussion note is where it came from.

Anna McCollister
Okay.

Hans Buitendijk
Does anybody have questions? Christian?

Christian Tadrus
On this topic of inventory visibility, we have that example of the public health scenario with regard to public access and availability of vaccinations of COVID-19. I can speak from experience that it is an incredibly burdensome system to manage, on a daily basis especially, and I was just trying to keep it within real time being defined as around 24 hours. Inventory levels in any given part of the supply chain vary from minute to minute to hours, and it is just an incredibly complex request, even if it is well intentioned. I have some heartburn over this as a broad expectation. I think there are some use cases where it may make sense and are driven by urgency and means that are not just raw inventory numbers because of the risk of misinterpretation and the high likelihood of it devolving into a steerage scenario, which I do not think is appropriate.

This is really one of those things where it is always a "it just depends," and I do not envision an environment in the near term for sure, and maybe not even in the long term, given the pressures on the supply chain, some of the economics that are impacting real-time inventory levels and long-term storage of stuff, that this does not become problematic and misinforming in nature. That is my ultimate concern with this recommendation, not that the intention of reducing time to delivery… I just think that we need to dial this down into when timeliness of medication in hand is urgent. That should be where that comes from, ultimately.

Hans Buitendijk
Thank you, Christian. On that part, I would like to ask if you can review that further and make some suggestions on how to adjust the wording to better reflect that and strike that balance where we can. That would be great. I am going to go to Afton, and then we might have a couple additional follow-ups on this recommendation to be made. Afton, go ahead.

Afton Wagner
Thanks, Hans. I do not want to reiterate all of what Christian just said, but when you have seen inventory in one minute, it could change in the very next, so I agree with everything, and he just hit the nail on the head with what I was thinking. Could we focus this more on acute situations where patients immediately need medications and then maybe try to build on that if we can? It would be very difficult to know the inventory that day, as things change from minute to minute and hour and hour, so let's take a closer look at this and figure out what is doable and what might not be. I would hate to send a patient to a pharmacy saying that it is available, and it gets dispensed or put on hold for somebody else and causes more confusion, especially if they are told at the point of prescribing that it will be there. We already see that a lot. At the start of e-prescribing, when I was still a student, it was still new, and the patient got e-prescribed, and the medication was not there at the pharmacy, and it added to a lot of confusion, so I want to try to avoid that.

Hans Buitendijk
Thank you. Anna?

Anna McCollister
I am going to push back on some of those points, and again, not speaking about this with any degree of expertise in how inventory reporting systems work, I interact a lot with Amazon, and they seem to have a pretty accurate ability to understand where things are, as do other online retailers and shopping environments, including Amazon's pharmacy, about where things are, when it is being shipped, and how much the inventory is, etc. That is something that can happen in certain circumstances. If there are reasons why that cannot happen in a more distributed model with different actors and different companies involved, that might be something to explore, but it is not just an issue of urgency for a specific med, it is about what the workload is.

Again, take 14 different meds, use three different medical devices… I have to manage all of that inventory, and I have to keep on top of it, and PBMs are now restricting access to supply until you are pretty much almost out of it, so any change, any supply shortage, if the pharmacy says that it is ordered and will come in tomorrow, and it does not come in that day, the next, or the next, all of the burden for tracking that down and trying to find out where things are falls on me. Again, if you multiply that by 14, plus three medical devices, that is a lot of time and effort. I do this. Somebody like my mother cannot. So, it is not just an issue of urgency, it is an issue of burden, and this is really about coming up with the informational elements that can reduce the burden to make it possible for individuals to stay healthy and to avoid getting sick.

Hans Buitendijk
Can I ask that perhaps Richard, Afton, and Anna, and maybe Alexis as well, depending on the next comment, follow up offline between now and the next meeting to see whether there is language that can provide a balance between the two, the need of timely information in certain circumstances balancing with some of the questions that Richard and Afton are raising? Would you be able to get together as a small group to address that?

Anna McCollister
Sure. Could you just say who that was?

Hans Buitendijk
That would be you, Afton, Richard, and Alexis, depending on her comment.

Afton Wagner
Was it Christian? I think it was Christian.

Hans Buitendijk
Sure, it was Christian. Sorry, my bad.

Christian Tadrus
I am being voluntold to step up. I will do it. I still have R6 to finish, but I will do that, too.

Hans Buitendijk

It is only one more… Alexis?

Alexis Snyder
I think Anna made my point at the end when she talked about burden, so of course I am all for avoiding patient confusion, but also lowering burden. I think I had brought this up in a use case that is also embedded somewhere in the document at this point as well. I think this also leads us back to the point I had made in the past about somebody championing this whole process through from beginning to end, whether it is a pharmacist taking that lead or someone on the provider end taking it to reduce patient burden, because it is not just point of inventory in retail pharmacy, it is also supply, and when there is not supply and you cannot get it anywhere locally, then the burden is to get a new prescription, to make shared decision making about a different prescription, a different dose, who has what dose available at what pharmacy and when, and that all takes hours and hours of time, which we all know then leads to poor outcomes when patients are not taking their medication. I am also happy to be included in that small group offline, as you mentioned.

Hans Buitendijk
Great, thank you. If someone could then take a lead in pulling that together and reaching out to do that, that would be great.

Shelly Spiro
Can I ask Alexis a question, and Anna too? Do you have a case manager on your beneficiary side, your health plan side, that helps coordinate any of this?

Anna McCollister
They are useless.

Shelly Spiro
Useless? Okay, thank you.

Alexis Snyder
Some of the use case I am referring to is for myself, and in that case, no, but my daughter, who is a complex patient, takes multiple medications, and has about 14 physicians, does have a complex care program and a complex care physician that she works with, but this is not something that they take a lead on.

Shelly Spiro
Thank you. Sorry, Jim.

Hans Buitendijk
Jim, you are next, and then we are going to go on to R12.

Jim Jirjis
I just wanted to support the recent comments about inventory. I do not mean to state it roughly, but we should not just avoid it because it is hard. In the hospital space, non-med supplies are difficult with power levels, etc., but just focusing on emergent use seems wrong to me. Like people have said, Amazon and others have figured it out. From my perspective, I would start with understanding inventory and then educating the patients about how it changes. I would not support avoiding it right now.

Hans Buitendijk
Thank you. Regarding the general comment on emergent versus public health versus normal operations, with a number of these, like the prior one, as we are moving them into the document, we are going to make sure they are reflective of more general purpose or very specifically, and this one also looks like a general topic, not only an emergent one, but let's see how the subgroup is going to further refine that recommendation. Okay, let's look at the next one. "Recommend that ONC require any intent to change a health plan's drug formulary should be declared ahead of time, with that information being shared with the patient's pharmacist and the provider." This might get challenging because I am not sure whether that is in the purview of what ONC can do, so I think we need to think here about what the intent really is and what ONC could do. Is this something they can work on with somebody else, or is it out of scope of what we can achieve in this taskforce? That is not to say that this is not a challenge and a need, but it might be on the edge of our scope, if not beyond. Anna, if you could clarify the intent a little bit more, that would be great.

Shelly Spiro
Is that R12?

Hans Buitendijk
R12 is what we are looking at.

Anna McCollister
This may be outside of ONC's jurisdiction, frankly, but one of the things that is a constant frustration for me is that formularies change by surprise, and all of a sudden, a drug you have taken forever gets voted off the formulary, and even though you are almost out of it, you have no notification to actually get prior authorization ahead of time, so then you have to begin the process of prior authorization, denials, appeals, etc., meaning that in several cases, I have had to go months without getting access to medication because the only way that I can appeal as a patient is to literally write a letter to the health plan, who will not speak to me, and/or get my physician to do it in a couple of cases. I have dossiers of clinical studies that document the benefits of particular medications that I have submitted in various appeals that I have provided to my physician.

All of that stuff can be done, it is absurd that it has to be done, but there is no notification whatsoever that there is an anticipated formulary change. It just happens, and again, because PBMs are now limiting the amount of inventory for each medication that you can have for individuals, you have this just-in-time inventory rationale for medication access. If that is the case and you are trying to refill your meds, and they suddenly decide to take it out of the formulary without any notification, then your script has to be dealt with.

Hans Buitendijk
Can we perhaps use this as one of the use cases for patient engagement as a topic that is part of that general scope? That is where it is explored in the priorities and what kind of interoperability requirements should be established, rather than having a recommendation at this point.

Shelly Spiro
Hans, let Tricia Lee comment on this. Go ahead, Tricia Lee.

Tricia Lee Rolle
Thank you, I was trying to get off of mute. Thank you for bringing this area up. This is out of scope as currently written. There might be ways to redo this with focusing on the clinical capabilities, but I really cannot give that direction. Intent to change is not a space for ONC, and we do not have any jurisdiction over what policies the health plan or PBMs might have. There is more work to do to flesh out where the technical components might be, but right now, R12 is out of scope as written. Thank you.

Hans Buitendijk
Okeydoke, thank you, Tricia Lee.

Shelly Spiro
Just as a reminder, Hans, we have two minutes until public comment.

Hans Buitendijk
Unless there is something to reconsider, then we will have to drop this one, but Anna, you may have some thoughts on how to rephrase it.

David Butler
This is David Butler. That is exactly what I was thinking, just a way to possibly rephrase this. The formularies today are not interoperable in the sense that when the PBM is updating a formulary, that information should be viewable by patients before they begin selecting CMS Medicare plans, and therefore, just making formulary updates available at the time of Medicare plan selection at the end of each year is important for that patient to be able to know which plans to choose. I could see where we need the plan and the coverage to be part of the record for that patient's pharmacy record so that they could view all of that as possibilities, and could even browse and explore so that they could pick the right plans. I am digressing a little bit here, but just to add to this, most PBMs are now moving toward a device formulary to go with the drugs in the pharmacies, so the insulin pump and the insulin sensor should be part of that same formulary.

Hans Buitendijk
David, perhaps you might have an opportunity to provide the suggested rephrasing that would bring it into scope.

David Butler
Okay, thanks.

Hans Buitendijk
That would be great. I will put your name behind that. Otherwise, if that does not work, then we will unfortunately have to drop this recommendation for now.

Shelly Spiro
I think it is time for public comment, Hans.

Hans Buitendijk
Looking at the clock, let's go there, and then we will come back with R13, time permitting.

Public Comment (01:19:40)

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 when called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if any members of the public want to make a comment. I am not seeing any hands raised yet, so I will turn it back to our cochairs.

Hans Buitendijk
All right, thank you. That means we are going to continue with 13, and in 13, we are stating, "Recommend that ONC require pharmacy apps/portals provide specific information about why medication has not been filled." Any thoughts or comments? Anna, any clarifications here?

Anna McCollister
Sure. So, if you go in through a pharmacy portal or app, they have these structured messages. It will say, "Medication refill pending, additional information required," but it does not say what additional information I required, or "Refill on hold, insurance issue," but it does not say what insurance issue. So, in order to be able to figure out exactly which problem I need to solve, I have to either go into a pharmacy or speak to a pharmacist. I have waited on hold for six hours trying to get through to my pharmacist when I was sick with COVID. The only way I was able to get the information I needed was to go into a pharmacy, which is not an ideal situation for anybody, and even then, I had to wait in line.

So, when you go into the pharmacy after you get one of these cryptic messages, they have some sort of a thing in their interface that has the very specific issue that is at hand, and they print out a piece of paper that tells you exactly what that is. So, that data exists in a structured way, and it is already in there, so why is it not shared with me so I can at least know which problem it is I have to solve and begin solving it, rather than waiting on hold for hours or going to the pharmacy to be able to get that information?

Hans Buitendijk
Maybe this is one that we want to combine. As ONC is considering a certification approach, this would be one of the capabilities that should be included in that consideration as what PMSes should provide in their engagement with patients. Is that a reasonable place to consider merging this with that topic?

Anna McCollister
In terms of patient engagement? What do you mean?

Hans Buitendijk
Right now, we have a general recommendation that ONC advance a certification approach for pharmacy management systems with proper funding and incentives, etc., and we enumerate a number of different use cases. By including this as one of the aspects of patient engagement where the patient is informed about this topic of information, that it could be picked up there, rather than in a separate recommendation.

Anna McCollister

I am not necessarily opposed to this, although I would not necessarily consider this patient engagement. It seems to me to be around what is needed to actually get medication to the patient as opposed to the patient engaging. It is about what I have to have to be able to get my medication. This data exists in the pharmacy, it is already structured, and they have it in their system. Why is that not shared with me so that I have the information I need to take action? I have to have that to stay healthy.

Hans Buitendijk
Maybe we could use it more generally in the pharmacy-patient interactions, of which there are a number of different ones. Any other comments? Scott, go ahead. You have your hand up.

Scott Robertson
Sorry, I could not get to the mute button. The pharmacies would be limited to passing along the information that is accepted. I can see an insurance issue. It could be a wide range of things, but some of them are rather arcane responses that may not be a whole lot better, although if it points to something the patient can deal with, then that is really very useful. Frankly, especially in the pharmacy with the six-hour wait, that is just an unbelievable situation, though not unbelievable that you experienced it. I do believe you experienced it. I say that just to point to the fact that nobody has done the due diligence of following up on it, which is really kind of crazy. Unless the pharmacies receive more specific information, they cannot provide anything more than they receive.

Anna McCollister
But they should provide the specific information that they have.

Scott Robertson
Yes. I think that they should provide something more specific than "an insurance issue." They probably have something more specific. It may not be terribly helpful because it is not always **[inaudible] [01:25:58]** the pharmacy, but the more you know, the more you know about the situation, and I can agree with that.

Shelly Spiro
I would like to also state that many times, pharmacies are put in the middle. They are not the payer, and they are not the prescriber. They do try to do the coordination as best as possible, but again, because of the lack of interoperable exchange with the payer and the provider in some cases, it becomes difficult, and the pharmacists are usually stuck in the middle, trying to help the patient, but too do not have the information that is available, so I just want to make that statement. Alexis, we have three more minutes.

Hans Buitendijk
I would like to see whether we can get through R13 and R14, which are in a similar kind of space.

Alexis Snyder
It can wait. We can move forward.

Hans Buitendijk
Okeydoke, thank you. Are there any other concerns with this generally? We might discuss placement. Any concerns with the R13 recommendation moving forward and clarifying beyond that? Do we hear any concerns there? If not, then the last one, R14, is "Recommend that ONC require pharmacy apps/portals to

facilitate two-way communication between pharmacy and patient." This might also be another one as we talk about certification approach. There are a variety of different topics to prioritize. This will be an example of a capability that would substantially benefit the interaction between a pharmacist and a patient. Anna, if we can, would you be okay if we put it in that context rather than as a separate, dedicated recommendation?

Anna McCollister
Sure, that is fine.

Hans Buitendijk
Okeydoke. Any other comments? Steven, I see you have your hand up.

Steven Lane
Hans, I think we have had many discussions about pharmacists wanting to be treated and enabled to function like any other member of the care team, and certainly, as a PCP, I am very familiar with bidirectional communications with my patients, and I think if pharmacists want to be members of the care team, endocrinologists do that, general surgeons do that, and if the pharmacists are going to be members of the care team, it does make sense that they would also support that bidirectional communication allowing patients tor each out to them with questions and get answers. I like this recommendation, regardless of how we contextualize it.

Hans Buitendijk
Thank you. In general, that is going to be around topics of the ability to share when you have the information available. You may not have it, and then there is nothing to share, but where you have it, how do we address the opportunity to then share it most efficiently with all involved, all with proper consent, authority, and those considerations? We are pretty much at the top of the hour, within about zero seconds, so we got through this section. Next time, we will pick it up with R15, which is a couple of rows down, so in the meantime, please review, make suggestions like you see in red, and for the particular groups that were identified, please take the opportunity to reach out to each other and identify an opportunity to enhance and advance the recommendations that were discussed. Great discussion and input from everybody. Shelly, the last word goes to you.

Anna McCollister
May I make a request that the Accel team help facilitate the one-off small-group discussions? Just from a scheduling perspective, it would make it easy.

Michael Berry
They cannot do that because it is not a public meeting.

Task Force Work Planning (01:30:10)

Shelly Spiro
Hans and I can help facilitate that, Alexis. I just want to remind everybody that next week, September 27th, we are going to continue on with Topic 3 and our recommendations. Thank you, everyone. Have a great day. Sorry we went over a minute, Mike and Excel team. Thank you for all your help.

Adjourn (01:30:34)