Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) ANNUAL REPORT WORKGROUP MEETING

September 14, 2023, 1 – 2:30 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Medell Briggs-Malonson	**UCLA Health**	**Co-Chair**
Aaron Miri	**Baptist Health**	**Co-Chair**
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Jim Jirjis	HCA Healthcare	Member
Anna McCollister	Individual	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Michelle Murray	Office of the National Coordinator for Health Information Technology	Staff Lead

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

Michael Berry
Hello, everyone, and thank you for joining the HITAC Annual Report Workgroup. I am pleased to welcome our cochairs, Medell Briggs-Malonson and Aaron Miri, along with workgroup members Hans Buitendijk, Hannah Galvin, and Eliel Oliveira, and we are expecting that Jim Jirjis and Anna McCollister will also be joining us today. Public comments are welcomed, which can be typed in the Zoom chat or can be made verbally during the public comment period later in our meeting. I would like to turn our meeting over to Medell and Aaron for their opening remarks.

Opening Remarks, Meeting Schedules, and Next Steps (00:00:35)

Medell Briggs-Malonson
Wonderful. Thank you so much, Mike, for kicking us off, and it is great to be with everyone today. This is an additional meeting that we are having just because of all of the important content that we still need to review, so we are going to dive on in very quickly later on today so we can try to finish up the discussion of our crosswalk. Aaron?

Aaron Miri
Yes, ditto. Welcome to today's discussion. It should be fun. Let's get on into it and really knock this crosswalk out so we can really get into refining it afterwards. Let's go.

Medell Briggs-Malonson
Do you want to go over the meeting agenda?

Aaron Miri
Sure, I will start off. Obviously, we have our next steps here. We will go through the discussion of the draft crosswalk of topics for the annual report, go to public comment, and then adjourn for the next meeting. Next slide. So, we are here, already halfway through September, which is amazing, and we have a few more meetings to go. This is the fast and furious part of the workgroup, so we are looking forward to getting some good content, and then hopefully wrapping up by later this year. Next slide. All right, we have the 19th. We will be doing an update for the HITAC, and that will give us an update of what is going on there. As you know, we did cancel the meeting before that, which was supposed to be today, because we are starting to prepare for the November in-person, so the October and November updates for the HITAC will be busy, hopefully with approval in the late winter or early springtime. Next slide.

As next steps for development, we are going to develop a draft crosswalk of topics for all the gaps, opportunities, and activities, then we are going to present that draft crosswalk on the 19th of October, as I just said, and, of course, continue developing the crosswalk document during the fall to present an update to HITAC in November in person, if needed. In previous years, we have done that, so plan on it, but those will be good updates. Really, this is where we are going to need the help of the entire committee to pull feedback out of the HITAC to make sure that even the slightest question people have in their minds or the slightest feedback are captured, we respect that, and we look at those ideas and see where they belong. This is a multidisciplinary work effort, so sometimes people just need encouragement to speak up, and that is okay. All of us can help to get it there. Next slide.

All right, let's go to some of these draft crosswalk topics. So, obviously, we are going to be looking at some of the two additional target areas here, one with promoting and advancing health equity, which is very important, and of course, technology to support public health, as we saw recently with the pandemic and the ongoing prevalence of disease that we need to be able to measure, monitor, and maintain. We see interoperability, which is one of our original charges, privacy and security, which is near and dear to my heart, and, of course, patient access to information. Next slide. I think we are at the crosswalk section. Is that right, Medell?

Discussion of Draft Crosswalk of Topics for the HITAC Annual Report for FY23 (00:03:40)

Medell Briggs-Malonson
Sure, thanks, Aaron. I am happy to go over that. Let me talk about one of the things we did before we do bring up the crosswalk next. Before we go too far down, can we go back up to the top very quickly? I want to make sure the entire workgroup is aware of this legend because Michelle and team have actually put in a lot of effort in order to ensure that as we are walking through the crosswalk, we are notating all of our discussion as appropriately as possible. So, at the legend, where you see "key for edits," I just want to orient the entire workgroup to these revisions. You see that each one of the edits from our workgroups are now in a different color. Today, since it is September 14th, all of our comments are actually going to be notated in green, but I think there are two other very important pieces here. When the topic is in a blue box, those are the topics that we have already discussed, and when a topic is in a green box, those are the topics that we need to discuss today and likely in our next workgroup meeting, but we are going to try and see if we can get through many of them today.

Now, the reason why I am bringing this up is because as we go down and as you probably saw in reviewing these documents beforehand, there are some blues and greens that are mixed into each one of the various different target areas because sometimes we jumped ahead and started to talk about some of those topics, but I just wanted to make sure that everyone was oriented to this legend so that we can all follow it appropriately. Let's go on down to Page 3, and I believe that is where we will be starting. Great.

So, our first area that we left off last time with the workgroup was really centered around interoperability, supporting interoperability standards. In terms of the gap and the challenges, those are still blank, so that is something we can discuss, but the opportunities that were brought were exploring requirements for reference labs to meet USCDI standards, exploring requirements for pharmacies to provide NCD and RxNorm codes, and also exploring the requirements for LTAC providers to meet Meaningful Use standards. So, we want to open it up to the workgroup to see how we want to flesh this out a little bit, especially when it comes to the gaps and challenges, as well as any additional proposed recommended HITAC activities.

One other quick piece: Our charge as the Annual Report Workgroup is not only to take a look at all of these topics, but also to ask if this is something that we still want to include in this year's report, which will then be delivered to HITAC and then be submitted not only to Micky from ONC, but also to Congress. So, if we feel like we have talked about some of these topics in other areas, that is something for us to discuss as well. Why don't we open it up for discussion, especially centered around supporting interoperability standards? Any thoughts? Anna, there was a quick question. I believe that may be an error. It should be LTAC, long-term care centers. Michelle, I will ask for that, but I think that is what we are referring to there.

Anna McCollister

Thank you.

Medell Briggs-Malonson
Any thoughts about this?

Anna McCollister
I have one thought and question, though I am still orienting myself to this, but thank you for the review of the color-coding, etc. One of the things that I think really needs to be addressed for interoperability standards for future versions of USCDI is patient-generated health data of any kind, but I am specifically concerned and a bit frustrated that we do not have any home use medical device data incorporated into it, and to my understanding, the specifics of how that would work have not really been fleshed out, so before we can really incorporate that technical capability into USCDI, there needs to be a lot of thinking given to that. I saw a reference to that, but I do not really see the interoperability standards part. Maybe I am just confused.

Medell Briggs-Malonson
No, you are absolutely right. We actually do have an entire area, which we can hopefully get to today, specifically around patient-generated health data, and not only the workflows for both the providers and patients, but I think you bring up a really good point about making sure that that is part of our interoperability standards. So, that is on the list for us to discuss today, and maybe we can capture that concern right now, but also, when we get to that section, maybe we can go a little bit deeper into it as well.

Anna McCollister
Not to give it semantics and spreadsheet development, but I noticed it was in the patient access to information section, and that made less sense to me than the interoperability standards section. Again, I am not trying to split hairs. I do not know if that matters or not.

Medell Briggs-Malonson
No, you bring up a good point. When it was initially proposed, I think it was under patient access, but I think that is very important for us to discuss, primarily due to the fact that it is not just about giving patients access to their patient-generated health data, it is also ensuring that providers have appropriate access and that interoperability standard. It is one of those broad-reaching topics, I feel, and let's talk about where we think it is best to actually live in this report and even on this crosswalk. You bring up a very important piece there. Let's hold onto that, and let's hear some of the other pieces for interoperability, but I absolutely think we need to figure out where it is best for it to live in order to meet the needs and the standards that we know are going to be most effective for everyone involved: Patients, providers, as well as our overall larger systems. I see Hans's hand up first, and then Eliel's.

Hans Buitendijk
Thank you. I have a couple thoughts around interoperability, and those are based on where we are at, how far we have come, what still needs to be done, and what is holding it up. I am looking at those three bullets there. In the first and the third, as we are seeing with the pharmacy taskforce as well, the discussion is frequently around funding. It is not as much that the standards are not necessarily there, though we still have some standards work to do, but it is the ability to connect and have the IT that is capable of connecting

[inaudible] [00:11:04] be up to date with the latest capability, to be FHIR-enabled, or whatever. It is not as much about the standards.

What I am curious about is whether we should shift this a little bit in the direction of where ONC, working with others, whether it is CMS or other places that have payment program opportunities for those settings, whether it is LTPAC, pharmacy, or labs, that they have the ability to support that, and that that certification is being promoted if we think that is important, but that means that the program needs to be adjusted that enables them to certify to the componentry that is applicable to them, no more, no less. That seems to be coming up more and more as an area of friction than having the standards themselves.

Medell Briggs-Malonson
So, the full implementation of it all, and the financial support of certification.

Hans Buitendijk
Yes, financial incentives, budgets, and availability. At that point in time, if we believe there is value to certification of HIT on all sides of interoperability, which, after all, has a multiparticipant requirement, we are mostly focused on the EHRs to be certified, but not the other side. Frequently, the other side is the source, and we need to make sure that they send it or have it available in the right format. So, if you believe that certification is a helpful mechanism to do that, how can we get those other HITs to be certified as efficiently and as streamlined as possible? That also enables the providers in that community or other participants that use that to use that software to then connect with the networks nationally, locally, etc. That seems to be more where the rub is.

Medell Briggs-Malonson
Hans, I will just say I fully agree with you. In fact, I had a conversation with my teams last week about this exact piece, one looking at how best we serve patients as they transition between the acute care settings and some of our skilled nursing facilities and other facilities, and our systems are just not connected and there is not that level of interoperability, not only sometimes with the right data exchanges, but also to flag certain concerning pieces. So, for instance, if you have a patient with special needs, how do you ensure that those types of flagging mechanisms are also there so that we are sharing information that may occur on the acute care side or on the post-acute care side as well? This is really about ensuring that we are providing and also supporting those transitions of care most appropriately, but there have to be some incentives or requirements for that, so I absolutely agree with you on that. That is a really good point, and we would have to work with some of our other agencies in order to support that.

Aaron Miri
Also, there is an issue when it comes to availability of the right data to do so. We use so much of the claims data to understand what is going on, and that data is held closer to the vest by a lot of people, so I think to really get at the root of this issue, to what Hans is saying, there should be some element of consideration of if it falls into information blocking if people are unwilling to give claims data. I know that is a third rail to some degree, but at some point, that needs to be surfaced, saying claims data is as important as the clinical note itself, and we cannot do anything unless we know what is happening in the total course of care to be able to do the appropriate care gap closures and facilitate transitions of care appropriate. It is a major bugaboo.

Hans Buitendijk
If I may just follow up on that, the question is what the right lever is to get everybody to participate: The suppliers for those other settings, the settings themselves, etc. Information blocking is a pretty harsh lever when it is hard from a budget or other perspective to be able to implement the systems that are necessary to connect. So, there is an interest and a willingness, but how do we make it affordable and feasible for everybody to participate before we get too quickly into information blocking and say, "Hey, you should have been able to do that." That is a pretty hard step.

Medell Briggs-Malonson
So then, in summary, really making sure that we are partnering, or somehow, ONC has these different discussions with some of the other agencies, such as CMS in particular, so that we can ensure there is the appropriate support, whether it is infrastructure support, financial support, or other types of incentives to have the systems in place to allow for appropriate interoperability, and then, Aaron, to your point, if those systems are in place but there is still not the exchange of data, then that is another huge concern in itself.

Hans Buitendijk
Yes.

Medell Briggs-Malonson
Awesome. Thank you, Hans and Aaron, for both of your thoughts.

Aaron Miri
I think Eliel has a question now.

Medell Briggs-Malonson
Yes, Eliel is next.

Eliel Oliveira
Thank you for all those comments. I was going to suggest first, Medell and Aaron, that we split the requirements for LTPAC into another bucket in itself because I think in terms of identifying gaps and challenges in the proposed recommendations, it is a bit different than what I see for enforcing lab standards and medication standards to be followed. I hope that makes sense. So, that is one recommendation, that maybe we need to separate those two. In terms of exploring labs, reference standards and pharmacies, I think you all know the gap there, that we have CPT and ICD codes, and the key reason behind it is that if you do not use them, you are not necessarily getting paid. So, because there is a linkage to the reimbursement from payers, everybody follows those well, but for labs and medications, not so much.

In the case of labs specifically for these two, I am bringing it back to COVID. If we do not have everybody using the same data standards for labs and medications, we have the challenge then to be able to track effectively on a regional or national level. For instance, hospital systems usually have their labs within their facilities. Lab companies follow LOINC for the most part, but the hospital systems may come up with their own data nomenclature or metrics for specific labs, and that becomes a nightmare to harmonize. I focus specifically on that to give an example of the challenge because I have tried to deal with that before for PCORnet when we are trying to harmonize labs for a specific research project, and one of the health

systems that was providing to us had 15,000 labs. I am talking about the number of different labs they do within the organization.

We were trying to normalize maybe 10 of them to be able to utilize them for PCOR. One was, for instance, H1C. I cannot remember what the other ones, but there were 10 specific labs that we wanted to normalize. Just for H1C, we did a search within their lab system, and we had 300 different options of H1C labs that were created over time within their own organizations with different metrics and different names, but likely possibly the same lab anyways, and someone was going to have to sit down with the lab folks and the physicians to understand exactly what specific lab they meant in each case that aligns with that LOINC code for us to be able to normalize that to be able to utilize it. I even went about finding a solution that could do some normalization of those labs for that one organization, and it was very pricey. It was about $500,000.00 just to do that linkage of labs to LOINC codes for one organization, and it would not achieve 100% of them. They promised about 70%, if that.

If you think about that problem for one organization, then nationally, you probably cannot solve that because the cost of fixing it would be too high, but there is probably a need here to at least offer a strategy. What are the ones that we are going to try to enforce everybody to normalize first for labs and medications that are key priorities, and how do we go from there into guaranteeing that folks are now going to follow those standards? Again, if we are face with another health challenge and we are still at this stage, it affects research, but it also affects care if everybody is using their own codes on their own basis.

Anna McCollister
CMS has standards for labs and medications, so wouldn't they have some ability to require a specific type of standardized format? Just thinking jurisdictionally about which lever we can pull or not, I would think that might be helpful.

Medell Briggs-Malonson
Potentially for sure, Anna. Eliel, that was an astute observation of separating these two, and Anna, I would say you put out a possible solution there, and I was just going to ask the workgroup what one of our recommendations would be in order to try to ensure that we have the standardization. Anna, sorry, I missed the first organization that you mentioned when you first started talking. I just want to see what some of our recommendations would be, especially as we separate these two out, for additional HITAC activities. What are some thoughts from both of you all, or from the rest of the workgroup?

Anna McCollister
By the way, at any point, if I say something that is completely incorrect or sounds crazy, just let me know.

Medell Briggs-Malonson
Never that, never that.

Anna McCollister
I will just give that blanket statement about this and everything else. CMS's ability to pay providers, along with the original stimulus bill, provided the incentive for standardization and exchange of provider data. They are also paying for lab work and medication, so I would think that they would also have some pretty powerful levers to require standardization of the nomenclature or whatever we need to do to have

standardized and normalized exchangeable data. To me, that would seem to be an incredibly powerful lever that has worked for all the other stuff, but would not be able to **[inaudible] [00:22:59]**.

Medell Briggs-Malonson
Correct. Again, I just did not hear what you said initially. You are absolutely correct about some of the various different influence and jurisdiction from CMS, so maybe part of our proposed recommended HITAC activities would be to explore what CMS is doing in this space. Although a lot of this does also fall into ONC's jurisdiction as well, since we are talking about USCDI standards and some of that enforcement, we know about the strong partnerships between ONC and CMS in order to ensure that we are providing the best care and most efficient organizations possible, so yes, that absolutely has potential. Eliel?

Eliel Oliveira
I want to complement that. I agree with Anna that that is a good track, and maybe part of the recommendation here would be a workgroup or taskforce with HITAC where we basically have that umbrella to explore what CMS is doing and would hope to do here, but there is probably also a benefit in bringing other experts and holding listening sessions about how to best achieve that, and maybe even to define a strategy. I do not think this is something that would be easy to mandate without having a financial discussion because it is not a cheap thing to achieve, so that might be a strategy that needs to be devised. What are the first priority labs that we want everybody to standardize to, and how do we go through Phases 2 and 3? So, maybe in a design of a taskforce or workgroup, under that umbrella, we have these listening sessions and have a partnership with CMS or maybe even private payers and other specialists on labs. I know we have Clem in our group, and he probably has a lot to say about labs. Anyway, that is my suggestion here on some proposed activities to go forward.

Medell Briggs-Malonson
Excellent, thank you. This sounds great. And so, we do have some items in the chat as well, just for clarification. Let's keep moving on down to the next items. Can we move on to the next page? Excellent. All right, we had a very robust discussion last workgroup for the very first topic, but then we ended up here directly when it came to privacy of sensitive health data, consent, as well as lack of accounting of disclosures. I will cover this one, and then, Aaron, I will turn it on over to you for the next target area. So, to start off with privacy of sensitive health data, the gaps here are a lack of consensus on the key use cases, the definition of sensitive health data, and the path forward to support improved electronic patient consent. The challenge is that the ability to exchange interoperability consent directives across health IT systems is very limited. So, of course, we are charged with identifying the opportunities as well as our proposed HITAC activities to try to help to guide and address these challenges and opportunities. Does anyone want to kick us off? Hans, your hand is up.

Hans Buitendijk
Sure. I think the bigger challenge in managing consent is around what kind of infrastructure needs to be in place in combination with the standards, of which we already have a variety that are very fundamental to it and can be used, but how do we actually share that across different systems as the data moves? I think that is the space where we have not spent enough time. There has been some work done. ONC has done some funding through the LEAP Project in San Diego. There are efforts that Hannah is quite familiar with on what is happening. We can have tagging and other types of standards, but if we do not understand how the data needs to be evaluated every time that data is being asked to be shared or pushed to be shared

and how we make sure we constantly have the most recent privacy and patient consent rules available to us as they change over time, though hopefully not too much, that infrastructure will not be clear.

So, I think one of the reasons why we have not been moving as quickly on it is that it turns out that "just" tagging some data in the C-CDA document and letting it flow is actually not achieving what we want. We need to look at not only C-CDAs and FHIR, but Version 2 and NCPDP proprietary standards. Every means by which data can be shared and exchanged needs to be subject to being evaluated to determine if it can be shared or not, and I think that is the hardest part. Bits and pieces have been explored, but to make that happen, we have to have a collective approach to that that works at a national level, not just point to point in some areas, and there are initiatives going on, but they are relatively isolated, and they are not necessarily going to scale to a national level as a result.

Somehow, we need to identify how ONC can work with the right parties to explore what an actual infrastructure would look like in combination with the necessary standards that we can then collectively use so that we can have access to the latest consent rules from the patient, whatever the data source system is that is being asked to share data or that is ready to send some data to somebody who does not know whether they can.

Medell Briggs-Malonson
Yes, thank you, Hans. Aaron, I saw you come up. Do you have a quick response?

Aaron Miri
This harkens back to what we talked about with granular consent back in the day with ONC. I think it was around Blue Button and Blue Button 2, some of the efforts going on there, and the need to parse out and give people that granular consent, and I agree with Hans that transitions of care organization to organization or agency to agency do not follow you, so there is not really a standard there on how organizations transmit that. Also, given the new consent rules for research subjects that were just passed, how does that impact things here, and should we consider that, since that is breaking news?

Medell Briggs-Malonson
Absolutely, thank you for that. Eliel, we will go to you next, followed by Hannah, Anna, and then Medell after that.

Eliel Oliveira
I agree with Hans. Maybe the key opportunity here is on the architecture of how this could work because I think now, we do have the standards, whether through FHIR, USCDI, or other places. They are there, but we just have not actually put them to use because there is not a structure we could tap into at the national level. There have been some very interesting pilots done in California with MediCal for the Ask Me form, which is for substance use, and I am happy to share some details on that, but we can also hear about results from Californians directly.

I think a key point here might be trying to solve very specific, key problems for consent, because granular consent can get very tricky, as well as consent for different aspects as well, but we just need that infrastructure first so we can at least solve one use case and make it electronic to start with. In this case, it might be the opt-in for mental health data to be able to be shared, or it could even be a different use case,

like this one here that I personally like the best where we currently have a challenge, sharing of data with SDOH partners, whether it is clinical data or SDOH data. I feel like the opportunity is to narrow our focus onto a specific consent use case where we can then devise the infrastructure that would allow that and maybe make it possible to implement or test. If we go too deeply into the granular aspect, we may still be in a phase five years from now where we still do not have something that is functional.

Medell Briggs-Malonson
Great, thank you for all of that. I think we are all in agreement of diving deeply into that infrastructure and having those really focused use cases to ensure that exchange of the consents throughout. Hannah, you are up next.

Aaron Miri
You may be on mute, Hannah.

Medell Briggs-Malonson
Hannah, you may be double muted.

Eliel Oliveira
Yes, she is muted on Zoom.

Medell Briggs-Malonson
Yes, you are muted on the screen.

Hannah Galvin
How about now? Can you hear me now?

Medell Briggs-Malonson
Yes.

Hannah Galvin
All right, good. So, I have a few thoughts here. Shift, at least, has four use cases that we are working with right now around this, and one thing I have noticed is that we and ONC have been working on this for a decade now since DS4P came out, but the work is very segmented. There is a pilot here, there is a pilot there. There is nothing that is aligning all these pieces into a coordinated roadmap around how we get to an end goal of being able to implement this in a widespread way as opposed to one organization doing a pilot of granular consent or one connectathon doing a pilot with granular consent. So, the LEAP grant was great, and San Diego HIE did an excellent demo of what data segmentation and granular consent using FHIR standards would look like, but it was one pilot demonstration, and not incredibly scalable in and of itself.

So, how do we develop a roadmap to actually bring this to fruition from all of these scattered pilots? I think there are use cases where those have been defined, and some of those have been worked out in conjunction with the gravity project around social drivers of health. Some of the dependencies to bring this about include having semantic conceptual models of what these sensitive data elements would look like. SAMHSA is no longer keeping up their VSAC value sets, so one real deliverable that I think would be very

helpful is for ONC to work with partners to sponsor terminology value sets to be a steward or have another national partner to steward and maintain terminology value sets around sensitive data elements because that is a real dependency to doing any of this work, no matter what use case you are looking at, and has been a barrier to moving any of these use cases forward if you start to look at this from a roadmap perspective and not from a buckshot approach of multiple different pilots and throwing things at the wall and seeing if they stick.

I would guide us in our guidance of ONC to really try to look at how we put these together toward an end goal as opposed to the lots of different great work that is happening right now across the country. How do we start to organize that work? I will stop there. I know Anna has some comments as well.

Medell Briggs-Malonson
Thank you for that, Hannah. You actually hit on the thing that I was going to bring up, but the only thing I would add is the exact definition of true sensitive health data because it tends to change very often, and it is interesting how one organization may define some sensitive health data in one way, but other organizations define it in others, and so, I also had the idea of setting up a taskforce, as you mentioned, Hannah, whether that is solely within ONC or with other types of partner that we have seen from other efforts, such as the Gravity Project, Gender Harmony Project, and others, and really making sure we have a true definition of what sensitive health data is and what it can include. So, thank you for all of your different comments about the pilots in that. Anna, you are up next.

Anna McCollister
I have a number of thoughts related to this. Just for a tiny bit of context, my background is in public affairs and journalism. I got into health data stuff because I was frustrated with the limitations of randomized controlled trials. So, for me, all this data and the potential for using it for research and improving care was the thing that got me into being in glamorous meetings like this one. So, the work I am doing now is as a consultant working with companies to create trust and embed patient concerns in different forms of governance. Based off the research that I have done professionally and personally, my experience is that patients are less concerned about data elements than they are about data uses.

So, this does not apply to everyone, most patients that I have interacted with are cool with their data being used for research because they understand that research is important. They are less cool about sensitive data being used by clinicians for whom they may not think that data is appropriate, and they are really concerned about information being shared with insurance companies and, in some cases, pharma companies. So, when I have approached granular consent models with clients, we have chosen those categories rather than specific types of data because if you start getting into specific types of data, that is kind of a nightmare. I cannot even imagine what kind of informatics structures would be required to A). Allow that, and B). Make sure that it is consistent in an interoperable structure. So, those are broad thoughts related to that. There may be a different way of approaching it.

Secondly, knowing a tiny bit about informatics and how difficult it would be to be able to manage consent from one place to another with various types of data, etc., I feel like the most important next step that we can do is really around giving people information about who is accessing their data and for what because most of the time, data that is being used and accessed is for the benefit of the patient or may be for the benefit of the patient in terms of research and advancing the scientific understanding of it. It is scary to think

about all of your data floating out there if you do not really have a context of understanding about how it is being used, and as patients, we really have zero information about how our individual data is being used, so I feel like that is almost a first step as we try to figure out all of the consent stuff.

Medell Briggs-Malonson
Absolutely. Anna, those are all really wonderful points, and it was almost like you were automatically transitioning us into the next topic, which is truly lack of accounting of disclosures, how we are using health data, and how much transparency there is to patients, so thank you for all of those different points, and just for the sake of time, let's bring those thoughts and move on to the next topic if there is nothing right now on consent. I will take any last comments on consent, going once, twice, and three times. Hearing none, we will move on to the next one.

So, as Anna so nicely transitioned us, this was another topic of concern, lack of accounting of disclosures. Here, for the gap, today, patients have limited transparency into how their identified and deidentified health data are actually shared, so the challenge is with the growth, exchange, and expansion of purposes of use beyond treatment driven by national networks and TEFCA, it is important to balance increased transparency to consumers with the burden on healthcare organizations to provide an accounting of disclosures. Anna, what you were just mentioning about some of the various different categories of, say, the comfort level of exchange of protected data, this goes even beyond just our national networks with TEFCA. It is really just some the core element of how we exchange data and the importance of transparency to our patients of how we may utilize their data in different venues. This is all related, so let's open it up for discussion in terms of the opportunities and proposed recommendations that we can have. Hannah, your hand is up next.

Hannah Galvin
Thank you. I am all for this. I think that increasing the transparency of the data is really important. I do think that, just as we talk about granular segmentation and everything else, how this is done in the real world is really the crux of the matter. I even think about my own healthcare data and where it may go because you can consider one prescription, and it goes to the pharmacy benefits manager, to the pharmacy, and to the payer. Even if I had full transparency around that one prescription, where it goes, and everybody who looked at that one piece of data, that one element, I do not know what I would do with that as a patient. I do not know if I would know whether it was appropriate this particular person who looked at that piece of data to look at.

I think an important piece here is how do you not then burden the healthcare organizations or the system to provide the accounting of disclosures, have an understanding of how to not cause more confusion for people, or even trace that down. If somebody called me as their provider and asked, "Who is this person at the PBM who looked at my data?", I would have no idea who that is. That reflects the complexity of the system, and you have to start with the metadata on all of the employees in the system and who they are, so I think there is work behind this that needs to be done before we can even increase the internal transparency within the system of who all these people are who are interacting with the data before you can even open that up and help patients understand who everyone is. I am all for this, but I think it is much more complex than it is on paper here.

Medell Briggs-Malonson

Thank you, Hannah. In brief summary, what I am hearing is that we have to do our own internal evaluation of who the primary stakeholders are prior to even sharing with patients and just having that clarity of who they are and what their purpose is for some of that data.

Hannah Galvin
Yes, or what metadata we might need in order to be able to make that transparency effective. That is what I am saying.

Medell Briggs-Malonson
Absolutely. Thank you for those things. Anna?

Anna McCollister
I think of transparency around data use in two different tranches. One is at an individual level: Who is accessing my data, and for what? I completely agree with Hannah. That is a really easy thing to say, but incredibly complex to solve and to do, though I think it is doable. Not only figuring out what information that would be, but how to make it available in a way that makes sense is something that really needs to be thought through, and I think it is time for ONC to begin to prioritize that and begin the work needed to be able to make this possible. Secondly, I think perhaps an easier ask, which is one, again, that I have worked on with my professional clients to do, and I finally got a company to do it, is to be transparent at an institutional level about how different deidentified data is used. All of our healthcare data is being collected. HIPAA gives us "collected, aggregated, and sold or shared for research."

Again, my personal bias thing that landed me in places like this is frustration with RCTs. We have to have real-world evidence. This is critical and essential. We need research, but I want to know who is using it, and for what, and personally, I think it is incumbent upon all of us to encourage a better understanding of how this research benefits science, drives things forward, and improves regulatory decision making. So, I feel like having institutions in an aggregate manner be required to list out how the data has been used is a first-tier ask while we are trying to solve the other pieces. It is a much easier thing to track, and it should be something transparent, both for the understanding of individual patients of how their data is being utilized, but also the understanding of all of our parts about how our data is contributing to science and/or being used for things that we do not necessarily think are appropriate.

Medell Briggs-Malonson
Thank you, Anna, and before I jump to you, Jim, I want to make sure we have some proposed recommended HITAC activities just for us to put on paper, just for us to consider, so, again, Hannah, you are saying we should make sure we understand internally who is using that data and for what reason, and what additional metadata may be needed for increased patient transparency. Anna, what I am hearing from you as well is asking if there is a way we can help to encourage and recommend to ONC that all for healthcare organizations that collect data, there is a clear repository of what that data is used for, whether it is for research, quality improvement, or some other item, so it is very clear to patients how their deidentified health data may be used in other avenues.

Anna McCollister
I did an annual data use transparency and impact report with my consulting client, which is an annual report of "This is the way deidentified data was used by this company in calendar year 2022," and it is a pretty

impressive report, and patients have loved it and been impressed with it, but lacking that information, people are like, “Why is this company using my data? What are they doing it for?” When they saw it, they were excited.

Medell Briggs-Malonson
Thank you for that, that is clear. Jim, you are up next.

Jim Jirjis
I wanted to talk a little bit about scope as well. I agree with some of Anna’s points. When I was medical director of internal medicine at Vanderbilt, I was also the CMIO, and we were evaluating whether people were violating security by looking at other employees’ medical records. I took point on that project, and to Hannah’s point, what we found was how complex it was. We had a list of those who were employed who had encounters, and then we went through the audit log data to try to determine who all had touched the chart, and we ended up having to abandon it because there were so many… For example, someone went on lunch break, so their secretary looked at the chart because they were not answering the phones for an hour. To me, it seems like we need to understand just how granular we want to be because there are so many user IDs, and not all their roles are clear and transparent to patients.

If we are going to get that granular, have we had successful pilots that show that this is even doable without confusing patients? And then, do we have a good set of patients where we have done focus groups and surveys to understand what it is they are actually interested in so that we can design this around something much more focused initially? For every organization a patient has been at, if you try to say who has looked at their record, including third-party companies, and try to process that in a way that a patient can actually understand and either ignore and have no value, or worse, have all kinds of reactions to it that take enormous amounts of time for an organization to explain, “No, that person was on lunch…” Do you see what I am trying to say? So, to me, it seems easier stated, and I guess the question I have is how far have we gone with narrowing the focus and making it consumable?

Medell Briggs-Malonson
Those are all excellent points, and I strongly always believe that the patient should be centered, especially any time we are thinking about what the patients may need. We need to have their voice, and I do not know if anyone else on the workgroup knows if we have actually gone to patients and said, “Okay, if we are going to make this information more transparent to you, what is the information that really matters most?” So, that may also be part of the recommendation, scouring the ecosystem to see what it really is that patients want to know when it comes to the transparency of how their data is used, whether it is identified or deidentified data. Go ahead, Jim. Were you finishing up on that?

Jim Jirjis
I had one comment to one of Hans’s earlier points about the infrastructure and the architecture for consent. I know that healthcare data itself was messier, so it is often hard to look to other industries, but I wonder if there are other industries that have developed a successful architecture for something similar, and if maybe our recommendation might be to evaluate healthcare and non-healthcare approaches to infrastructure and architecture to support consent.

Medell Briggs-Malonson

Very good point, thank you for that. Hannah, we also see your comment. Equity and justice should also be centered. It is really important every single time that we center our patients and our communities, so I fully agree with you on that. Hans, I see your hand.

Hans Buitendijk
I just have a couple comments. I very much appreciate the comments that have been made around disclosure and consent. They are both hard topics. Granularity is hard for both the extent to which we understand what data is being used where and the intersection and interplay between the two where better awareness of how your data is being used may alleviate some of the challenges or concerns that people may have on actually sharing data. I think that is a constant interaction, but at the same point in time, it makes it hard to say whether solving one before the other would actually be the best approach because either way, we have both challenges right in front of us for an appropriate and important part of the population. In that sense, they are very similar.

There are privacy rules that are established by jurisdictions and, next to that, patient consent directives that are effectively doing that based on the individual patient. Those kinds of rules and how we manage them are a pressing need at this point in time that we do not have a good answer to. Also, on the disclosure side, having good information that is useful with the challenges that Jim highlighted on how we interpret that depending on the level of granularity is a hard challenge as well. I think these are two things that need to happen in parallel so they can both learn from each other, and one is going to inform the other, but I do not think either one is going to go down to zero or that is the only way in which it can be resolved. I think they are two equal challenges that we need to address together.

Medell Briggs-Malonson
The linkage of them is very clear, so thank you for all of those very insightful comments. So, due to time, we are going to continue to move on. I appreciate all the thoughts and recommendations about this. Aaron, I am going to turn it on over to you to go into some of our more recurring areas that we have to discuss as well.

Aaron Miri
Yes, absolutely. I see several that are optional, so we want to definitely go to interoperability, correct?

Medell Briggs-Malonson
Yes, please.

Aaron Miri
That is what I thought, all right. So, standards for patient matching: Obviously, this is an area that we have talked about at length. Eliel, I know you have a lot of feedback on this one. You have had it over the past few months and meetings. We need to fill out some recommended activities here. Again, the gap that is patient matching when sharing data needs to be improved, especially with vulnerable populations. The challenge is that patient-matching errors create inadvertent record creation and inadvertently merge records, and of course, efforts addressing patient matching should continue while ensuring solutions meet the needs of vulnerable populations. At the end of the day, this is a patient safety issue, and it really confuses and confounds me why we continue to have this lack of a national patient identifier, but that is neither here nor there. We have to come up with some solutions. So, I will open it up to the floor. Besides

saying we should create a UPI or something like that, what do we suggest here? Eliel, you are already first in line. Go for it.

Eliel Oliveira
I agree with you, Aaron, that going to the top of the desire here may not get us too far. You saw an announcement today from ARPAH about the meeting in the White House yesterday about trying to do better cancer research. I was in cancer research for about 10 years. I worked with NCI on the creation of CAB, which was an all-in-all solution for cancer research nationally, a $1 billion investment during the Clinton administration, and we did not get a lot of results there in interoperability across cancer centers throughout the country. One key aspect to me is this ability of linking records. We have so many national networks, and the CDC, FDA, and others are trying to connect the dots between claims data, clinical data, and other pieces of data, and there is just not an ability to do that.

The recommendation that I would have here is to start from the top and have a listening session from these key agencies, such as NCI and CDC. CDC has a lot of work going on there right now in terms of record linkage. I talked to Abby from the CDC, who is part of our HITAC group. With the group of representatives we have in our HITAC from the federal level, I think we will hear quite a bit of their struggle. I can tell you there is a lot of struggle from the FDA as well in trying to connect the dots between clinical and claims data because the Sentinel network is based on claims data only. So, that is the recommendation I would have, a listening session from the federal partners to address data linkage just within the ability to do surveillance and research, if you want to put in that bucket as well, because given the cancer focus federally, I think that would be very valuable.

Aaron Miri
Great points. Hans, you are up next.

Hans Buitendijk
I am wondering whether this should be addressing two parts, and that goes back to what Eliel has talked about today, but also in the past. We have the identifiable population, where we can share data on records with the patient's identifying information in there, but we need to have good patient matching, and we have the deidentified space, where the objective is to have as complete a record as possible so that where information and context of the complete individual record is relevant, we actually have the complete record, and that is hard when deidentified data is sourced from many different places that are not otherwise connected.

So, I think we have two problem spaces that we need to address. In the deidentified space, there are the concepts of tokenization, PPRL, etc. that are being explored all the way into the deidentified space so the PHI is being replaced with a token of sorts, and they can help link it together. There are some interesting opportunities and challenges around that on how to do it so that I can still actually match without knowing who the patient is, but still knowing that it is the same patient. I think those are two areas that we need to focus on: What can we do to better enable data to be matched in the identifiable space versus the deidentified? In the first one, which might be at an intersection there, what I think ONC can also do besides the listening sessions that Eliel is identifying, which I agree with, is state the role of TEFCA in here.

We are in a progression where there is an opportunity that the QHINs, with their record locator services among that combination of record locator services, have to learn how to better match and therefore effectively share, based on the matches and the information that we have put together across all the different parties, on who is actually the same patient and who is not. How do we interact it? I believe it is the same patient, I shared it with somebody else, they agreed with it, and now we start to say yes, that is the same record. How can we persist that learning across the QHINs so that we effectively end up with something that, while not perfect, because even in countries where there is a unique patient identifier, it is not perfect and there are still challenges there, but is a lot more perfect than what we have today?

I suggest we encourage ONC to particularly work with TEFCA and the QHINs on how their record locator services in combination can really advance the opportunity to get better record linkage and therefore effectively get to a more unique record. In turn, how can that be used to be part of feeding deidentified data stores where that information is used to get a more complete record on the public health side and otherwise, where that is relevant as well?

Aaron Miri
Great point, Hans. I do not know if every QHIN has adopted RLS as a standard yet or has said so, so that would be even more interesting. Is RLS a common, universal, adopted practice for every QHIN or not? TBD, I think.

Hans Buitendijk
That is an interesting part because certainly, at the onset of TEF, RLS was one of the key elements where there was a requirement to support that. I know that has been adjusted a little bit, but that still should be looked at to say that is where you have a tremendous opportunity where we are learning across all the providers and participants data that we are sharing, and we certainly want to do that for the right patient. So, we should take advantage of all that learning to then be able to put it together so it makes our matching easier and we know exactly where to go. In whatever flavor that advances, I think it behooves TEFCA to come through on that original promise of record locator services being an integral part of it to advance that. I agree with you, Aaron, that it is not totally quite where we thought it was going to be, but we should not let go of that opportunity because this is one of the areas where that can be tremendously helpful.

Aaron Miri
Very true. Great points. Medell, you are up next.

Medell Briggs-Malonson
Thank you, Aaron. We are now on the recurring topics, and thinking about some of the notes, we have had this as a topic in the last three annual reports, and I also agree with the listening session, but I think that was also recommended in our past annual report, but we have not had it yet. What I am thinking about is what we can do, even this year, in order to ensure that we are making progress? Because I think we continue to identify great ideas, solutions, and recommendations in order to push this topic along because we all completely agree that appropriate patient matching is critical for patient care, for patient safety, and for operational efficiency as well within all of our organizations.

So, my recommendation would be to really reflect on our past reports and past recommendations and start putting those into action, and maybe we can even do some of those this year, and then also continue to

build upon some of the focus on our most vulnerable populations because I still feel like that is a huge gap that we have within our country, knowing the various different needs of our diverse populations throughout, so whether part of the recommendation is taking a step back, and I hate to add another taskforce onto this, but once again, trying to understand more from our community perspective and patient perspective what is going to be most palatable to various different populations. As we know, what may work in one community when it comes to patient matching may not work in a different community, and I think it is very important for us to continue to gather insight so that as we create or have recommendations for effective patient matching, we are also taking into account the various different needs, as well as beliefs and preferences, of all of our various diverse populations throughout the country.

Aaron Miri
Great point, Medell, and given the fact that I believe the first QHIN-to-QHIN transactions should be done by the end of this year, maybe there is something to learn there too, for all the positives and opportunities. I would be willing to bet a steak dinner that there will be some patient-matching questions that come up as opportunities with that, so maybe that is an opportune time to convene a listening session or workgroup to think through that and ask what we learn from this QHIN-to-QHIN transaction and what we have the gaps on. I bet this is one of those items. Great points, Medell. Eliel, you are up next.

Eliel Oliveira
I like that as well, Medell, as well as the comments from Hans, because it leads me to think maybe there are two things here related to matching or record linkage. I think that may have been captured in a different place in the document previously, and might have been referencing that, and here, we are talking more about data exchange and linkage of care, but where it was coming from was the perspective that that is still challenging, having a patient ID may not get us there, but we need to define a standard. There are vendors out there that many of our agencies are utilizing for record linkage on that side that Hans was talking about, limited or deidentified data sets, that do not necessarily use identifiable information, and that requires some definition of standards because what happens right now is you look at N3C, one of the consortia for COVID research. They use a linkage method using limited data sets, and PCOR uses something as well, and then CDC is using something, and I think the FDA is considering a few things, but there is not a standard.

Everybody continues to do those linkages using PPRL on their own and are spending quite a bit of resources and money when what likely could happen is all these efforts could be using one specific standard where, whenever you link something, its link can be reused by others in that aspect of research and surveillance. So, it is a bit different than the care-related EHR/TEFCA linkage that we need to have there. I want to clarify that, and also add that my recommendation was to have a listening session with the federal partners, but also maybe with the vendors of those solutions that have been utilized to highlight how they work and what solutions and standards could be defined. I hope that helps a little bit, as we are likely talking about two different things here.

Aaron Miri
That is a good point. Those are two different listening sessions. We have done that in the past, where we have had different constituents come in and brief us, so I think that is a fair point. I do also know there are vendors that intersect, like the DOD and DHS, and do linking of data there. I like to think that healthcare is special, but it is not. You have the same challenges in the Department of Homeland Security or Department

of Defense, so maybe they have figured out how to crack the walnut in a way we have not yet thought about. That is a great point, Eliel.

Eliel Oliveira
To Medell's request, we have talked about this in so many reports. How do we get to something tangible? That is where I was trying to focus on that specific process of linkage to make sure that, at the end of next year, we actually have a definition of what that data should be like, listening to vendors that are providing those PPRL solutions and the agencies are in need of it. At the end of next year, we could actually have a solution that allows all these agencies to be able to leverage the same standard and not have to redo everything every time.

Aaron Miri
Anything else other than listening sessions that you guys have thought about? In the past, we have talked about biometric linkages and talking to NIST. In a previous committee a long time ago, either the policy committee or HITAC, we actually had agencies from Europe come in and tell us what they had done, so this has been a topic for quite a hot minute, so think about if there are other aspects that we could do. Jim, you are up.

Jim Jirjis
One question I had is since this has been a topic for some time and since the QHIN is getting ready to connect, do we know if ONC is already working on this standardization and alignment listening session, or is that knowable?

Aaron Miri
I have not heard. I do not know if Michelle or anybody could speak to that. If only we knew people at the CDC, Jim, who could maybe help us pull that together…

Jim Jirjis
Abby is actually on my team, and she mentioned she is very eager to participate, but I think there has been a lot of rich collaboration between CMS, CDC, and Micky on this topic.

Aaron Miri
Absolutely.

Jim Jirjis
I love the idea of the listening sessions and advising ONC to develop a consensus standard around it. I would be really surprised if this was not in their crosshairs as the QHINs start to communicate with each other.

Anna McCollister
Didn't we also talk about doing an economic analysis of the cost of not having a unique patient identifier?

Aaron Miri
I think we did. I believe that is right.

Anna McCollister
That is what Congress…

Aaron Miri
Well, it is also hard to quantify when we actually have not had QHIN-to-QHIN transactions, so it would be interesting to marry that data up with what we learn later this year and say every transaction costs you X amount of overhead or you are losing X, so that is a good thought. I think we have this one tagged up. Is there another section of this? We are getting close to public comment. Next slide. Is there anything else? Perfect. All right, cybersecurity events across the healthcare infrastructure. We do not need to worry about this, do we? Of course we do. All right, the gap is that cybersecurity events continue to block access, cyberattackers' skills and resources are outpacing the ability of cybersecurity professionals in healthcare to prevent cyberattacks, including, apparently, the casino and gaming industry as well. What do we think the opportunity is here? This has been a topic since the beginning of time. Are there new things here we can begin to suss out in terms of what we want to do to be able to mitigate cyber events? And, of course, we need to propose action.

So, I would say an opportunity for us here is to be able to better understand some of the sophistications and methods of attack. Some of those indicators are compromised. Some of the partnerships now with H-ISAC have really taken off. Some of the Section 405(d) work has been going on across the federal sectors. There is some great work that has happened over the past few years that we could leverage. I am getting into recommended activities, but I do think the opportunity is here to be able to mitigate the risk and the financial impact, as well as clinical quality impact, and in my personal opinion, it is patient safety, so I just opined my thoughts. Any others from the committee? Come on, Eliel, I know you are a cybersecurity fan too. You have some comments.

Anna McCollister
I know ISAC has done some important work too.

Aaron Miri
That is true. Other thoughts?

Eliel Oliveira
Aaron, when I think about OCR and HIPAA specifically in terms of enforcing data security, data breaches, and all that, it focuses a lot on the rules and policies you need to have in place and how to implement this. It is a very mechanical process and does not necessarily equate to outcomes or improvements on getting organizations that secure. The penalties are there, so you have to follow those steps, as opposed to a model that has incentives for best practices. It feels like a system that is punitive and somebody is eventually going to fail.

We have seen that some organizations actually do better in terms of information security and how they organize things, and others not so much, maybe because they are able to attract the best individuals and have the best structure in place, but I feel like it is always a burden for organizations that have to carve some amount of budget out to make sure they do not fail there. I know they are going to hedge with some cyber insurance so that if they do fail, they can pay OCR a few million dollars for it, but there are no federal

incentives to allow organizations to actually do this, and in the end, I feel like that should be something to be considered. The losers in the end are the population.

When there is a cyberattack and a health system or payer is down, like some situations we have had where the payer is basically saying, "Now we are going authorize everything except for cancer treatment. You need to call in for everything else because we have been hacked." It is a punitive system, and I feel like there may be an opportunity for more incentivizing best practice with financial resources and requiring specific things to be in place. Maybe an opportunity here, Aaron, would be to look at the organizations that do this really well, that have not failed and have a coordinated center that knows what the best practices are, has learned it, and incentivizes others to adopt specific pathways, but they are required to basically do certain things.

I am saying this because I look at different organizations that have a different level of cybersecurity, and I have seen the ones that function so well and the processes that they have in place, and I have seen the ones that are still working with 1990s security parameters of resetting the password every 90 days. It makes their lives so hard, but it does not necessarily reflect a better security practice and outcome. Anyway, I think the opportunity to incentivize as opposed to punish might be a way to prevent the patients from suffering, as they are the ones who do so in the end, and the population as well.

Aaron Miri
That makes sense. Anna?

Anna McCollister
I agree with Eliel around incentives, but rather than thinking about it in terms of the way we have structured incentives in the past, maybe we should just do something simple like require bug bounties for companies who have certified health IT, or maybe ONC sponsors bug bounties for any certified health IT vendor, product, institution, etc. That would be a simple way of doing it, and of incentivizing good hackers to identify an issue. A lot of private-sector companies do that, and it works well. Secondly, a good friend of mine used to do cybersecurity stuff, had a cybersecurity lab, did DARPA work, and he is actually now in healthcare and might be a good consultant for this. They used to run these teams.

I have a limited memory of what exactly they did, but they would have these different hacker competitions amongst different PhD students or whatever, where they would try to hack into the White House system or the DOD system, etc., so maybe that could be a fun annual ONC event where these graduate-level cyber experts and coders, maybe even at DEFCON, try to hack into different types of health IT structures to see what they can get, and you could have prize money.

Aaron Miri
A hackathon, I like that. That is a really cool idea. That would also be interesting because at one point, ONC actually had innovators in residence, and those innovators in residence usually tackled some of those issues as well, so maybe there is some work we could do to uncover what they did back in the past around this topic, around cyber. Any other comments or thoughts? I do think coordination across other industries is important. I think listening to what other people are doing is going to be interesting. I do think it would be interesting to talk to Section 405(d), which is a federal coordinating entity, and hear what they have going on. They pull together a pretty good cross-consortium of medical device vendors, providers, vendors, etc.,

and we could talk through what they have uncovered. That is all relatively in the past couple of years, so maybe there are some advances we are not thinking about. A listening session with them may be fruitful.

Anna McCollister
[Inaudible] [01:18:48] a lot on this, so there are probably some things we could learn from their approaches in terms of identifying vulnerabilities and incentivizing good hackers to identify them as well.

Aaron Miri
That is right, and there is an international component as well. There are some phenomenal nations, like Israel and others, who do a great job in this domain at being proactive and preventative in cyber defense. Maybe we can learn and adopt things we have not thought about from them. In the vendor community, there are a lot of AI applications nowadays as technology as advanced where AI is fighting the bad guys using AI, so maybe there is something there we could adopt and identify. There are some companies focusing on ePHI now using 100% AI algorithms to help protect the crown jewels, per se, so there are some great approaches that are just novel to healthcare these days because technology has advanced. All right, we are approaching the time for public comment. We have about three minutes left. What do you think, Medell? Should we go to public comment and come back to finish up the time now, or should we try to tackle one of these and break?

Medell Briggs-Malonson
This is a nice time to go to public comment before we start jumping into one.

Aaron Miri
That is what I thought. Mike, can we go to public comment and then use the remaining time to start this section?

Public Comment (01:20:10)

Michael Berry
Yes, absolutely. We are going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. I do see one hand raised so far, Susan Baer. You have three minutes. Go ahead.

Susan Baer
Hi, thank you. I guess you cannot see me. Am I able to share my visual, or not?

Michael Berry
No.

Susan Baer
Okay. Hello, my name is Susan Baer, the founder of Baer Technology. We have been providing IT security and consulting for the past 29 years, we are SBA certified as women in small business, and over the years, we have been working on a system for safely gathering and transmitting complete and accurate patient data on one platform. We facilitate patient-to-doctor, doctor-to-doctor, and medical-institution-to-patient

communication. I am here to ask if there is a particular person or organization that I could meet with so that we can work together on getting this amazing product to everybody who needs it, which is everybody in the country and beyond.

Michael Berry
Okay, thank you, Susan. I am not seeing any more public comment, so I will turn it back to our cochairs.

Aaron Miri
Fabulous. Let's see if we can sprint through one of these other items here on the crosswalk. All right, patient access to information. The gap is lack of a uniform public-private approach overseeing mobile health app development, and results are inconsistent. The challenge is that these apps are built without an authoritative source, and without using sound clinical knowledge, they can produce incorrect conclusions or readings that can impact patient safety. I think we have seen that play out in the industry, unfortunately. The opportunity here is to get standardization and harmonization. I would also say that the opportunity here is to provide appropriate oversight and guidance. I know that FDA, FTC, and others are all trying to intersect at different points here and start to develop guidelines, and they have put out some decent progress notes on what is going on there. There is opportunity here. Hannah, you are up first.

Hannah Galvin
I also think the AMA has put out some guidance around privacy recommendations, so I think trying to align some of the guidance that is out there may be a role for ONC in its coordination. There are many organizations and bodies that are putting out this guidance, so perhaps aligning some of this guidance or even pointing to the guidance for the public may be a role that we want to recommend.

Aaron Miri
Great points, Hannah. Medell?

Medell Briggs-Malonson
Thank you, Aaron. This is also an area very near and dear to my heart as well, and as you mentioned, FDA, FTC, and AMA, though I have not seen theirs yet, are really trying to put some guardrails around the integrity of mobile health applications. We talked a lot about this with HTI-1 and all of these external sources: What does it even mean to be aligned or even possibly aligned with certified health IT? But, I think there is another piece of this that we have to start looking at, and it kind of goes into the patient-generated health data aspect of this as well, as they are all connected, of making sure that once we do know that they are rooted in integrity and clinical evidence and not causing harm to patients, which is the oversight and monitoring of even the development of this, and making sure they are highly inclusive in design in terms of people with diverse abilities or language.

But then, I think this other piece is the interoperability into some of our certified health IT, and especially our EHRs, so that we do not have those barriers that we sometimes have seen where a patient says, "Hey, this is what my mobile app says," and we as the providers say, "Oh, no, that is not the correct information" or "Yes, we want that information, but we want to be able to use it as we are developing your plan of care." Those are just some of my thoughts. So, I agree with what Hannah said about continuing to coordinate and with what you said, Aaron, about coordinating with all these additional parties that are already looking at it, but I think one area for ONC is us still looking into the interoperability. Whether it is a certification level or

not or a standard or not, what can we do to ensure that information flows to all the different places that it should be going to once it is deemed to be rooted in integrity?

Aaron Miri
Good points. Jim?

Jim Jirjis
This is the topic we were discussing when I was at HCA recently. Trying to imagine something that actually looked at the safety and clinical veracity of apps seems like a daunting task for the ONC. It seems like each of the specialty guilds would have to do that because just the sheer knowledge needed for a nephrology app versus a diabetes app… I am not quite sure what ONC can do, except encourage the Good Housekeeping Seal of Approval from each of the specialties. Am I missing something?

Aaron Miri
No. In the past, Jim, we actually thought about leveraging the ONC CHPL as a way to track apps that have the Better Business Bureau Seal of Approval, to your point. That has been tossed around a lot, but as you can imagine, the CHPL is pretty sacred ground, no pun intended, so it is going to be interesting to see if we can do that, but it is an option.

Jim Jirjis
The resources needed to validate each app for clinical veracity seem enormous and highly specialized, but maybe I am too pessimistic.

Medell Briggs-Malonson
No, Jim, I agree with you 100%, which is why I was saying we have to ensure these apps are rooted in integrity and clinically based evidence, but it is kind of out of ONC's scope, so the least that ONC can do is say once they are rooted in veracity and integrity, then how do we ensure that there is that level of interoperability for any data? But no, I agree with you fully.

Aaron Miri
We have one minute, guys. Eliel and Anna, can you go really quick?

Eliel Oliveira
I agree with Jim, and I was going to make exactly that point. One thing that is needed to solve this is a business model that allows for a coordinating center of some sort to generate revenue that then allows you to get the specialists to be able to validate those things and then allow them to go to market, so that is the mindset I have had on this.

Aaron Miri
Good deal. Anna, close it out for us.

Anna McCollister
I have done a lot of advocacy on this in the early days, but especially the DAJA report, and my bias as a patient who relies on mobile health apps that connect with medical devices is that ONC needs a very light touch on any assessment of the validity of it. The original impulse was to shut that stuff down until we had

all this stuff figured out, and that would have been a really bad move for patients. I have a lot of thoughts on how to do this that I am happy to get into, but clearly, we do not have time.

Aaron Miri
No, but please send them in, Anna, because we want to fill this out with all those thoughts. That is a great opportunity, so if you have those, collect them and send them to us. All right, all. We are at time. Medell, any last words?

Next Steps and Adjourn (01:28:27)

Medell Briggs-Malonson
No. Thank you, everyone, for such an amazing meeting today, and we will have another meeting in about another two weeks. It was great seeing everyone, thank you.

Aaron Miri
Bye, everyone. See you.

Medell Briggs-Malonson
Thanks, everybody. Bye.

Eliel Oliveira
Bye, take care.