Transcript

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

August 30, 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 one of our cochairs, Aaron Miri. Medell Briggs-Malonson, the other cochair, will be joining us a little bit later, and we have a few workgroup members with us today, Hannah Galvin, Jim Jirjis, and Eliel Oliveira, and hopefully, Anna McCollister will be able to join us shortly. Hans Buitendijk is not able to join us today. I will just remind everyone that 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. And so, now I would like to turn it over to Aaron to get us started.

Opening Remarks, Meeting Schedules, and Next Steps (00:00:43)

Aaron Miri
All right, hello, everybody. We have a pretty big agenda today. We will go through and really get to the meat of some questions and issues to work through here. We are definitely going to wrap up and start going through some more meat of the crosswalk and really start walking through some of the issues and questions that are still outstanding as we get closer and closer on the report. So, in our agenda today, obviously, we are going to talk about the scope and membership of this workgroup as well. I know there are some questions, especially for the new members, as to what all the Annual Report Workgroup is charged to do, so we will talk through that. Of course, we will talk about our meeting schedules, the draft crosswalk, as I talked about, and then, of course, go to comment and adjourn. So, the agenda today is pretty busy, but we should be able to get to the goal and wrap this thing up. Next slide.

So, again, this is sort of an orientation. I know there were a lot of questions last time on exactly what the whole point of the Annual Report Workgroup is, what we are supposed to be doing, and what we are doing, and it is always good to refresh, ask ourselves the question, and make sure we stay grounded in our founding charter here. So, our overall charge is to inform, contribute to, and review the draft of the final version of the HITAC annual report to be submitted to the Secretary of Health and Human Services and Congress each fiscal year. As part of the report, that workgroup helps track ongoing HITAC progress. Think of it as a way to report back what HITAC has done, what we are working on, what we are contemplating, and anything that is outside the normal charge of what the HITAC was established for that we want to ask for consideration on and ask if we should go down this road or not, and it is a sort of “seek first to understand” kind of approach, and it has been very helpful and grounding in all the great work done and work to come.

So, the specific charge here, as some of the specific feedback of the content, as required by the 21st Century CURES Act is to look at and give an analysis of our progress as HITAC, assessment of the health IT infrastructure and advancements in target areas, like public health, cybersecurity, and others, analysis of existing gaps in policies and procedures for those targeted areas, and ideas for potential HITAC activities to address and identify gaps. Again, just like we have been, we are going down the route of here is what we think the issue is, here is what we think the problems are, and here are some proposed solutions, or these are things that we need to figure out as we have listened more and gotten informed so we could come up with situations, and, of course, what do we want to work on? What should we go tackle? There are a lot of thorny issues, and there are some issues that obviously are out of our jurisdiction, but it is not like we cannot highlight those, and we can always recommend to our colleagues that since HITAC cannot look at this, maybe they do. Next slide.

All right, this is the makeup of our committee. We refreshed this year with some great additions to what we had last year and the year before. We keep growing and modifying, and we have some great, great partnership with the ONC, as always, to give it up to Michelle and everybody on the team who make it happen for us behind the scenes. Next slide.

All right, our schedules. Obviously, we are working on August 30th, today. We just did the 16th a couple of weeks ago, we presented to HITAC in between that, and of course, we have the 25th coming up and so on and so forth, so we are right in the middle of the frenetic sprint, as I call it, to get to goal and present a final draft on the HITAC for approval late next winter or early spring. Next slide. Of course, the full committee of HITAC will discuss this meeting, updates on the 14th of September, and really, in the past, I have always seen some great feedback coming from the HITAC members about this point, when the new members really start getting engaged and are understanding, saying, “Hey, have we thought about this topic?” or whatever it may be, so we can expect some great dialogue with our HITAC colleagues in September, October, and November. That is really where the fun happens. Next slide.

Of course, today, the workgroup will develop and craft a crosswalk of topics on gaps, opportunities, and recommended activities. We will present this to the HITAC on the 14th of September, and then, we will continue to develop that crosswalk. That is the best way to do the document over the fall, and then we will present brief updates to the HITAC as needed. I have noticed that as things unfold, as health IT events unfold in the community, ChatGPT is announced, or something interesting hits healthcare, those topics tend to flare up midyear, so, whatever the fall du jour is, expect there to be new health IT happenings coming up as topic from our HITAC colleagues. Next slide.

Let’s go right into the crosswalk, please. Next slide. So, we are going to look at the crosswalk here, and we want to consider all the gaps, challenges, and opportunities. Again, we are going to focus on some of the priority areas we have not gotten to yet and then go from there. Next slide. I think we are at the crosswalk stage, yes. So, go to the crosswalk, please. All right, so, the first priority target area is interoperability. We need to fill this thing out, so I want to solicit some feedback from the group here and see what you all think are some of the areas here that we need to identify. Obviously, supporting interoperability standards and priority use cases… In prior slides, I think we have spoken about the gaps, but I want to hear from you all what you think some of the gaps are, again, synthesized at a high level so we can begin to put this on paper. Eliel, you have your hand raised.

Discussion of Draft Crosswalk of Topics for the HITAC Annual Report for FY23 (00:06:44)

Eliel Oliveira
Hi, Aaron. Thanks. Last time we were meeting, I think we stopped right at this point, and I think we ran out of time, but I wanted to provide some suggestions, so that gave me time to actually put that down.

Aaron Miri
Good!

Eliel Oliveira
I am putting it here in the chat, and I can explain these five areas that I feel are important for us to address so I can go over each one of them, and then, everybody can comment on what we do or do not do. As you

can see here, I feel like a key priority to put on the top there is what our strategy is on data linkage specifically. As you know, we do not have a national patient ID. I think we lifted the prohibition, but we never made advancement on actually coming up with one. It affects all kinds of things, such as research and surveillance. You see the CDC working quite a bit with BPRL, and we had a great discussion with Adi and the groups there on how they are advancing that. We see TEFCA coming up and the possibility of API access, but if we do not have a patient ID that is universal across providers, how do we really get a full medical view of someone's data?

Anyways, there are tremendous use cases out there that could benefit from this at the same time that others have achieved that. The NHS in the UK is an example, and other countries have solutions. It seems to me that this will be an important topic now that we have done the US@ project, and TEFCA is coming together to look back and bring some expert opinions on how we can at least take some steps toward maybe not a patient ID, but at least some standards on how we deduplicate or allow for linkage because if you look at the example of the N3C, the COVID research network, that has done something that can link data, but then you look at another project, like the ones at CDC and FDA, everybody is doing their own thing. If there was a standard on how that tokenization of IDs and linkage could happen, maybe we would all benefit from something like that. So, that is Topic No. 1. I do not know if you guys want to comment on that or hear other comments on these other four areas that I have listed there. Anna wants to comment.

Anna McCollister
To me, that is an interesting question, and it is one that has been present in my mind as I think through this stuff. I understand tokenization, I know how it works, broadly speaking, and I am certainly not a technical expert on it, but given the weird cultural constraints that we have around national patient ID, is using tokenization or other kinds of linking technology a reasonable approach to doing any kind of real-time interoperability and data exchange? That is just a question that I have. I do not know. If so, maybe we should suggest ONC move forward in that direction, and maybe we should also recommend we do a cost-benefit analysis of however much time, resources, etc. are required of us to have that approach versus just coming up with a national single patient identifier. Maybe you guys are sufficiently expert on that issue to answer that question, but it is a question I have.

Aaron Miri
I think it is a good point, Anna. Like I was saying before, there is no expectation that we are all experts on tokenization. We understand to some level or degree what the reality is, and maybe Eliel happens to be a deep expert in that knowledge, though maybe I am not. So, it is always something we can recommend investigating in exploratory ways to bring in experts as a panel to talk to us about different methods, including tokenization, that they have done to achieve this in the private sector and work from that. So, I think it is a good point that in the report, we need to raise awareness in the whole HITAC of these possible investigatory solutions. That way, you feel comfortable, others feel comfortable, and I feel comfortable with the dimensions and nuances. For every positive story, there is always the other side, so we have to understand the full spectrum of what that means. That is a great suggestion by Eliel. Does that help, Anna?

Anna McCollister
Yes. I think we just have to accept the fact that we have weird cultural issues around the universal patient ID, and if that is the case, rather than just saying we need that, let's come up with other ways if we do not do that one.

Aaron Miri
Agreed. So, let me just take one step back to make sure we are filling in these two blanks. I think we answered the gap, which was that there is a disparity in systems being interoperable because of things like a lack of a UPI, noncongruent standards, or all these other pieces, so we have established that as a gap. Just like you are talking about right now, Anna, we have these unique perspectives or policy approaches, for lack of a better word, on different avenues of success being tempered by legislation, policy direction, or whatever it may be in this country, so we have to work through those, as well as the technical issues, such as noncongruent standards, systems that do not talk, etc. I am trying to repeat to you guys what you have said. I will have to make sure I am saying it right for Michelle. She is writing all this down. The opportunities there are things we have like tokens and what Eliel just put in chat, requirements for reference labs, RxNorm codes, and all these pieces as potential opportunities. Again, just to put them in buckets for us, is that what we are saying here? I just want to make sure I say it out loud to you so we are getting the right pieces.

Eliel Oliveira
Aaron, I think you described the gap and challenge perfectly. To me, the opportunity is that we all maybe agree on a standard way to do that linkage, and Anna is correct. Hoping for a patient ID might be too much, but at least a way that everyone agrees on how we allow that linkage to happen in some capacity would be an opportunity here. The other four things I have listed there, Aaron, are probably additional lines here on the topics to also pursue, so it is different than the whole ID and linkage point.

Aaron Miri
Sure, that makes perfect sense. Let me ask Hannah or Jim to comment here. Any thoughts from you guys?

Jim Jirjis
Jim here, thank you, Aaron. I love Eliel's ideas there. I am just curious. So much of certification is around the EHRs, and I know we have recommended that they pursue certification for public health agencies, for example, the example there being you cannot have all the requirements be on one player when interoperability actually includes more than EHR, so I am just curious about things like pharmacy. I know during the pandemic, there were other information systems beyond the EHR that created burden for providers because the providers had to normalize data. And so, I just threw pharmacy in the chat as one of them, and I see Eliel has put labs in there, too. A). Does ONC have the authority or can it work with CMS, and B). Are there other partners that need some benefit of certification as well?

Aaron Miri
That is a great point, Jim. I like that. I honestly do not know, unless there is a certified health IT system, what pharmacy systems or others go under that auspice. I am sure there are numerous other situations we can think about, but it would be another opportunity to learn what the panacea of intersection points is. In my mind, I think of a Venn diagram with overlapping systems and how they all touch. That is what I am seeing in my head, but it is a good point.

Jim Jirjis
Even if you do not have incentives like CMS just yet, there are many that would benefit from a defined standard and might actually manage that. The authority to actually compel people to use the certification is another issue, but I wonder if we ought to recommend ONC look into that. It would decrease burden and

increase timeliness of care. Just for those who have not heard me on the call, working for HCA, we were in 22 states, and so, when the pandemic came, we had to normalize 225 different labs' terms for COVID, so that is why I love Eliel's comment about requirements for reference labs. But I wonder about pharmacy supplies, hospital bed management systems… All these systems are proprietary, but particularly in the day-to-day course of activity, some of these would benefit, but especially when there is a crisis.

Aaron Miri
Jim, that is a very good point. Hannah, any thoughts from you?

Hannah Galvin
Who, me?

Aaron Miri
You are there.

Hannah Galvin
Can you hear me all right?

Aaron Miri
Be a little bit louder, if you can.

Hannah Galvin
All right, let's see. How about now? Is that better?

Aaron Miri
Yes, two thumbs up.

Hannah Galvin
Two thumbs up. So, back to the discussion on data linkage, I think it is fine for the HITAC to say, but to explore other algorithms for data linkage, I do think it is also okay for us to make a recommendation and cite, as we talked about last time, Aaron, how many times in the past we have made the recommendation for a national patient identifier. That is a continued recommendation from the HITAC. I also think that if we want to think about tasking the ONC to look at a standardized algorithm for data linkage or an NPI kind of algorithm, we should do that with an equity-by-design kind of lens or mentality because those demographic elements that would be used in such an algorithm are not equal across the nation.

In the algorithms that have been used, for instance, by Sequoia, and that have been tested, that is presuming somebody has a home address to go to, that somebody has a mobile phone number that does not switch every two months when their data plan runs out or is limited, and so, it presumes some sense of stability in order to be able to do those linkages. And so, I think that it is a fine recommendation for us to make, understanding that those types of linkage algorithms have some presumption of stable populations and some access to technology, and so, they may be underrepresenting rural populations, homeless populations, other more transient populations, and those who may have digital barriers. So, I think that should be reflected in any type of recommendation.

Aaron Miri
Good points, Hannah. Jim, you have your hand up.

Jim Jirjis
As one other area of focus, it seems like a lot of our focus has been on the pipes, if you use the water-through-the-pipes model of interoperability. FHIR, data standards, etc. are all in the standards for data once you decide what you are going to transmit, but one of the things that we found that is hard to make use of as a provider is what is actually being said. There is no consensus around it, right? For example, I had my team do a survey of a hundred different CCDs that we got and evaluate what was in them. Though everyone was using the standards and terminologies, many places were just sending information from the last encounter. The VA sends three years of info.

And so, I think I mentioned if you are somebody who is a cardiac transplant surgeon receiving a patient and you only get information from the last appointment, which happened to be a dermatology appointment, then you will not get any of the cardiac stuff that you need to see the patient. So, I know that might improve when brokered FHIR comes because the recipient has more control over what they want, but I wonder if it is worth having HITAC work on what minimum standards are. Should it be a year's worth of data? Should it be just the last encounter? Because the recipients do not know, and therefore, it is not that useful because very little information is actually being exchanged. Most people are only sending the last encounter for their organization. What are the group's thoughts as they hear about that?

Aaron Miri
That is interesting. Eliel, your comment?

Eliel Oliveira
I could not agree more, Jim. We have been dealing with C-CDAs here in Texas, and we have a group that has actually worked on trying to use the CDAs for their decision support and standardize some ways of using that across hospitals. It has been an extensive amount of work, and exactly what you are saying. Everybody does it a different way and to a different depth, and there is nobody necessarily saying what the minimum there should be, so it becomes really hard to get anything useful out of C-CDA.

Jim Jirjis
At HCA, there is a big focus on data, like in many places, and I was selling the idea that we would be getting all this data, so as we started receiving it, we were connected to CommonWell and getting enormous amounts of data. We lost a lot of credibility because when we looked at what we were getting, it was so anemic.

Aaron Miri
Yeah, bare minimum stuff only.

Jim Jirjis
Absolutely. We can build all these highways, and then only have tricycles on them.

Aaron Miri
That is a great analogy.

Jim Jirjis
So, when I started selling this idea… You cannot see things like when the last colonoscopy was. I do not know how we would approach it because HIPAA says "minimum necessary." The problem is that with the push model, there are so many different potential recipients that you do not know what the minimum necessary is, so maybe we ought to define the minimum data so at least people can understand what the minimum amount they are getting is, whether a year or a day.

Aaron Miri
That is a very good point. Hannah, your thoughts?

Hannah Galvin
It reminds me that these were some of the conversations that happened early in the days of CommonWell, when we had vendors coming together and saying, "Hey, how should we do this?" It was not just the technical specs, but it was this kind of implementation guidance around what data should be shared and how it should be serviced. I wonder if that is in ONC's purview. Should that end up being policy, or should there be workgroups? Should we ask ONC to sponsor some learning sessions and bring stakeholders together to have those discussions and publish whitepapers around this with best practices and approach it that way?

Aaron Miri
Good points. Eliel?

Eliel Oliveira
I will add here that C-CDA is a nightmare. Many of the health information exchanges do not even handle it anymore because it is so hard, like Jim was saying, but even though ADTs are better, it is still not perfect. Every time you are going to go talk to a vendor, even though you are trying to get the same stuff, you are looking for the USCDI. It is a lot of back and forth of technical negotiations to get the interface done when it should be like "You are certified EHI, we need an ADT from you, and this is what we in the community are asking for," and they could flip the switch and have it on, but instead, it takes six months, it takes a lot of money, and it takes a lot of back and forth. It is frustrating, to be honest, because we do not have that specific mandate or determination about what the minimum necessary is that needs to happen.

Aaron Miri
I think what you all are raising is a very good point. It is not just interoperability standards, but the amount of data and data-transmissible standards behind that. What is the expected data set behind it so that we are not, to use Jim's analogy, riding tricycles down the interstate? What I am thinking in my head is if there is a subgroup of USCDI, which ties back to the USCDI process, so it is not only interoperability, but a potential here for us to define what the minimum necessary data set is for that. It is a great point, and it is something that is starting to jam us up. Jim?

Jim Jirjis
Switching topics, I am just thinking out loud here, but every third one might be a good idea. One of the things we were promised with TEFCA, and maybe it is too early to realize it, is that the expectation is we will one day all be a member of one QHIN because the QHINs will all talk to each other. If you join more

than one QHIN, then you have all the duplicate data, chattiness, and burden on the system, right? Where I am headed is that when we last left our hero with CommonWell, they were connecting to eHealth Exchange through Carequality, but it was very incomplete because they had to figure out what data was there, and it was only 70 or 80%. I wonder if there is any work that ONC should be doing to address the actual interoperability of content between QHINs because right now, we are connected to CommonWell, but we only get CommonWell members' data. Well, now we get some data from eHealth Exchange, but…

Aaron Miri
You do get Carequality data. It is not complete, and vice versa. We recently switched EHRs from a CommonWell-specific member to a Carequality-specific member, so we see across the divide, but I can tell you that what comes in as standard versus what you have to add for fields and hope both sides are sharing takes a lot of arm wrestling, a lot of discussion, and a lot of not seeing your standard labs, notes, or HEDs unless you enable all that. So, out of the box, what can be there? I think it is a good question to ask, Jim. It almost appears that if the data elements do exist, what is standard, out-of-the-box, QHIN-to-QHIN communication so that we do not have to go through the arm wrestling, the discussions, OCA agreements, and all of the other things that our friends in legal departments feel are necessary. So, there are a lot of question marks there. I think it is a good question to ask.

Jim Jirjis
I am even talking about how CommonWell has a record locator, which is part of the issue. It is one thing we like, and there are so many marks that we cannot whitelist, like the Epic model, when you had to whitelist which in your region you want. Even fencing does not work, as people are snowbirds, and it is hard. So, the challenge we had was even identifying all the patients because the models were so different between eHealth Exchange and Carequality. Anyway, that is just a suggestion. Maybe we should even just give an update to HITAC on how complete that is, recommending an analysis of how complete the QHIN-to-QHIN exchange is.

Aaron Miri
I think that is a fair question, and we should put it out there and research. Again, I do not know the answer to that. There may be an awareness on some technical standards. I know we have had Mariann Yeager and team come to update us a couple times on what the QHIN-to-QHIN process is, but it may be worth a question mark.

Jim Jirjis
There are use cases. For example, one use case is what happened at the last encounter. Here is another use case to test the model. "When was your last colonoscopy?" Well, first of all, that could have been nine years ago and in a completely different QHIN. So, I think we at HITAC could construct different use cases that would pressure-test the success of QHIN-to-QHIN transfer, let alone the topic we mentioned a minute ago about the tricycles, right? The only reason I say that is we are doing this to save money and make it more efficient, with better care, so that is why, now that the pipes are connected, we are focusing on the completeness of the data and how many of these use cases are not helped.

Aaron Miri
Right, okay. I think we have gotten some good meat on this one. Michelle, hopefully I gave you some good notes to start writing down. I am sure we will come back to this and keep filling in the blanks with further

and further refinement. Let's go to the next portion here, which is these topics below. So, in the HTI-1 Taskforce, there were some questions brought up. I recall this was a conversation we were talking through with Dr. Steven Lane and several others, and there was a question of whether these suggestions were in scope of the HITAC annual report and if there was an underlying health IT policy theme that should be looked at. Again, this is all in that debate and discussion around HTI-1 rules. If you recall, we voted in June to certify the recommendations, so the goal here is to ask if we should.

So, let's look at the first one here, infeasibility. So, "Consider recommending that ONC consider and address concerns raised in the 10-day response timeline for determination of infeasibility under the information-blocking rule exceptions as far more complex issues. This time window may be too short. So, while there must be clarity in reasonable and certain response, ONC should explore extending this to 14 days across the board with the possibility of requiring a single additional extension of 7 to 14 days in extenuating circumstances." Okay, to bring you back to the topic, this is all about infeasibility, meaning that I cannot meet the regulation for some specific reason, whether technical, outage, or something else going on. How do we determine that specificity around it? Is this a topic that the HITAC Annual Report Workgroup needs to double click and look into? Thoughts from the group? Eliel, you had your hand raised. I do not know if that was on accident or planned.

Eliel Oliveira
No, it always goes back to the things we were discussing, so we can address this point and then go back, no problem.

Aaron Miri
Okay. Jim Jirjis?

Jim Jirjis
Sorry, I was on mute. Thank you. I just have a question about this. I am viewing it from a provider standpoint. HCA plans to use the infeasibility exception quite a bit for certain pieces that just are not feasible yet. Are we saying that when somebody alleges information blocking and then the organization that has been accused of it has used the infeasibility exception…? I do not quite understand what the 10-day is. Can you help me?

Aaron Miri
This is coming from **[inaudible] [00:32:10]** that she wanted to ask. The conversation was on whether there was a time limit. So, let's back up a second here. Is the topic of infeasibility for information blocking a topic for this workgroup? Before we get into the meat of it, let's answer that question. Do we feel information blocking infeasibility merits a topic in this case? The next one is registries. Is this a valid topic?

Jim Jirjis
I think so.

Aaron Miri
It is? Does everybody feel that way? Hannah, Anna, others?

Eliel Oliveira

Aaron, I am just thinking here that it seems like we ask you for 10 to 14 days, so I do not know if that really helps a lot, but I guess the last piece, which is adding a possibility on the addition or extension of seven or 14, which is fine, but what triggers allow that extra seven or 14? Maybe people are always going to go for the 24 days anyway. I do not know if this is complicating too much. Ten to 14 may not be enough. Are we saying they should do 20 or 30 days?

Jim Jirjis
Eliel, sorry to interrupt. I think they are saying 10 to 14 days, and also the possibility of requiring a single additional extension in cases with extenuating circumstances. Your question, Aaron, was does this belong in this taskforce?

Aaron Miri
Right. I am not saying this is not a meritorious topic. That is the question I am asking. Go ahead.

Hannah Galvin
This is Hannah. One of my questions is when does this even occur? Does this occur at the time of auditing, and is that then OCR and not ONC? Does this occur at the time that there are penalties and somebody is accusing someone of infeasibility? Because then, I am not sure that it belongs in discussion here.

Aaron Miri
Good questions. Anna, thoughts?

Anna McCollister
Sorry, I was eating lunch, so I went off camera. I agree with Hannah's question. I am having a hard time understanding. Let me take this from the perspective of a nerdy consumer who lives with various forms of information dysfunction. What is the 10-day response responding to? Is that for information related to an individual's actual health, or is this…? Perhaps I just do not understand enough about what this barrier is.

Jim Jirjis
You are right that there are not enough nouns or objects in here. In other words, when someone is accused, like if an HCA was accused of information blocking, they have 10 days to respond that they met the infeasibility exception. I think that is what it means. Alternatively, it could mean that OCR has 10 days to pursue it. I think it is the former. Aaron, is that correct?

Aaron Miri
That is what my recollection is. I would say to even take a step up from this, before we even get to solving infeasibility. Let's assume that information blocking as a topic is important for this workgroup. A subtopic underneath that is infeasibility in registries. I would say it may be worthwhile for us to listen to folks from the OCR, OIG, or the investigatory bodies and say, "What is your approach to this?" What we may be seeing here is a need for harmonization about the definition of infeasibility and/or what the recourse is, and thus, time to remedy or remediate the issue. Again, I am just trying to boil this up into higher-level thoughts.

Jim Jirjis
I think you are right, Aaron, because by listening, we will find out… If someone is accused of information blocking, it may be that a third-party vendor they are working with has not built the capability yet.

Aaron Miri
Right, that is oftentimes the case.

Jim Jirjis
It may take a week to even get them to answer the phone.

Aaron Miri
Well, the other issue I give pause to and wonder if it is the right time to tackle is that we still do not have the penalties for provider-on-provider information blocking. Without that guardrail, it is very hard to understand what the right answer is here because it does take the panacea of that, in my humble opinion.

Jim Jirjis
Aaron, you are correct, but I do think we have the rule now for tech developers and HIEs.

Aaron Miri
We do, **[inaudible] [00:36:58]**, that is correct.

Jim Jirjis
Some providers are HIEs, right?

Aaron Miri
Yes.

Jim Jirjis
Even though some providers actually do software development, like us, who built our own portal. So, I understand where you are headed. I do think it is probably okay to do it at this time.

Aaron Miri
Okay, good points. Eliel, and then, Hannah, I think you had a comment. Eliel, you had your hand raised.

Eliel Oliveira
Yes. I was going to say, Aaron, that on the question of if this is a topic for us or not, I am going with not, because this is regulation that went out, there was a comment period, and folks were able to send that through that pipeline. I would think that the ONC legal and policy teams that worked on this for a while had so many considerations about something like this to come up with the conclusion and these definitions, so I am not sure what our role would be, if it is just to pass the message on because it got lost in the comment period or whatnot.

Aaron Miri
If I recall, I think the question was should this go in our report that we, as a HITAC, have noted discrepancies that need to be resolved and potentially legislated? There is a policy angle to it if there is, and it could be clarified in public statute, or maybe even law if necessary. So, it is a question mark. Hannah?

Hannah Galvin

I was on mute. I think I was just nodding in agreement that 1). There is more information around the provider penalties that we are awaiting, and 2). There is a still a question to me as to where in the workflow, so to speak, this lies. At what point is somebody, vendor or provider, going to be requesting an extension or needing a 10-day or 14-day timeline to determine whether infeasibility is accurate or not? My thought, as I said, is that they would be having that discussion or responding to OCR, so ONC may be clarifying that in the statute, but do we have enough information about what that looks like yet in the real world to be able to further clarify that?

Aaron Miri
Interestingly, there is a taskforce coming together soon, I believe, to look at infeasibility and other items around information blocking as charged by the ONC, so it may be also timing, not that this is a bad idea to look at, but it may be worth keeping in the parking lot as a consideration point to say we should get it further down the road, finalize the provider-to-provider information-blocking proposed penalties, and then, that taskforce will kick off and we can look at it and see if there is anything on the back side of it we need to address, just as an option, because it is an important question. Jim, I think you bring up some great points. We really should begin to double click and understand the details of it, but again, that is summing what we have just talked about here. So, am I hearing collectively that this is important, we definitely want to keep it on the radar, but it may be just too early in the game yet to make a call, and maybe we should revisit it in a couple of months? Am I hearing that across the group? Medell, you joined, and I know you are catching up here, so if you have comments, I welcome them, too.

Medell Briggs-Malonson
Thanks, Aaron. I am just catching up, so I will defer to the workgroup right now.

Aaron Miri
Okay, no problem. If anybody is opposed to what I just said, speak up, please, Eliel, Jim, Hannah, or Anna.

Eliel Oliveira
I agree. Put it in the parking lot.

Hannah Galvin
I agree.

Anna McCollister
It makes sense to me.

Aaron Miri
Okay, I think that is everybody. All right, so then, we are going to registries next. I do have to hop off early, so, Medell, if you do not mind picking it up from here, I will see you guys soon.

Medell Briggs-Malonson
Thanks, Aaron. I am more than happy to tag you out now.

Aaron Miri
Yes, ma'am.

Medell Briggs-Malonson
Well, hello, everyone, and thank you for your patience as I was a little bit late coming in. Both Aaron and I had a conflict, so I had conflicts at the very top of the meeting, and as you can see, he has a conflict at the very bottom of the meeting. So, why don't we continue to move on through our various different areas? We were just finishing discussing the supporting interoperability standards priority use cases, and we have two additional topics that are here. They are not fully within the table yet, but we wanted to bring them up to the workgroup because there were some comments from HITAC. So, the first topic is information blocking and infeasibility.

Jim Jirjis
We just covered that, Medell.

Medell Briggs-Malonson
So, you did cover all of that? Okay, great.

Jim Jirjis
We did not cover registries. We did not cover the second bullet.

Medell Briggs-Malonson
Excellent. Thank you, Jim, for that. So, let's move on to the registries. In terms of information blocking, "Consider recommending that ONC clarify whether nonprofit and other private organizations that operate disease or patient registries are considered actions with respect to providing health IT and treated the same as public health with respect to providing access to registry data." So, I just want to hear everyone's thoughts on that in terms of even where the gap may be more the challenge and the opportunity. Hannah, I see that your hand went up first, followed by Jim.

Hannah Galvin
Thanks, Medell. I do think this is scope for us. It pertains to the HTI-1 proposed rule. I cannot remember whether or not we actually commented on this and requested more information in our comments, but I think that also would have been fair for us to submit in our comments. There are commercial registries and also nonprofit registries now, and I think determining whether or not they are considered actors within the context of the 21st Century CURES rules is a reasonable request.

Medell Briggs-Malonson
Great, thank you for that, Hannah. Jim?

Jim Jirjis
I just had a couple questions about what it means. So, there is a promoting interoperability requirement, for example, that you have to connect to registries, etc. Are we saying that they should define whether not-for-profit and private organizations outside of government qualify for providers to connect with to satisfy the requirement, or are we saying the opposite, that these private registries are required to meet some sort of IT standard? Because public health is not yet required, though I think there is talk of certification. So, I am trying to figure out if we are talking about for providers to meet the requirement, they are considered like public health, or are we saying that these private entities would need to meet a certain technical spec?

Medell Briggs-Malonson
Just to comment on that, I was reading and trying to figure out something very similar. We think about all of our disease registries in particular and, say, our quality registries. Immediately, I was thinking about our surgical quality registry, in which so many of the various different provider organizations do push information to that and pull information back. We also know that we have numerous others nationally that we have, and that brings up a really good question about what we are asking in terms of if this is a requirement or we are saying that they should at least be designed and developed in a way that does allow for appropriate interoperability because right now, there are significant burdens of actually reporting out to some of these registries, and so, maybe that is where the question is of clarifying what is meant, but you are right, we need to figure out where **[inaudible – crosstalk] [00:45:31]**.

Jim Jirjis
What is the authority?

Medell Briggs-Malonson
Right, exactly.

Jim Jirjis
And what is the authority? If there is the American Thoracic Society, for example, what is the authority to require them to meet a certain technical standard?

Medell Briggs-Malonson
Right, or is it just simply that we are saying interoperability would be very helpful, so consider developing and designing all of these registries that would comply directly with, for instance, certified health IT for that interoperability? I agree. There are lots of hands. Everybody has a thought. I saw Hannah, Anna, and then Eliel.

Hannah Galvin
I have a couple of things. First of all, I think that our wording in this section needs clarification. I think that it is our wording, the HITAC's wording, that says "with respect to providing health IT and treated the same as public health with respect to providing access to registry data." I probably would remove "treated the same as public health." I think you bring up a good point, Jim. What do we mean by "treated the same as public health"? Under the CURES Act? The CURES Act does not necessarily regulate public health, so we may want to consider removing that.

But, there are certain registries that are certified registries, and so, maybe we would think about understanding which registries could fall under this, the ones that have received whatever certification that makes them registries that qualify for MIPS data exchange, those types of registries. There are a ton of registries out there that are not certified registries, and so, what specifically are we asking, that they have to provide information directly to patients under the information-blocking rules, that they have to be exchange in a certain manner with other certified health technology? I think that would require clarification.

Medell Briggs-Malonson

Hannah, to your and Jim's point, I almost feel like we need to blow this up and say how we, the Annual Report Workgroup, want to define this because there is a lack of clarity in what this statement is even saying. So, let's see what Anna and Eliel have to say, and then, let's see if there are some additional revisions we want to make through this statement. Anna?

Anna McCollister
I have a lot of thoughts and questions on this. "Registry" is a really broad term that refers to a whole bunch of different things. There are registries that are required by FDA around specific drug or device approvals, there are registries that are set up by different professional groups, and then, there are registries that are set up by small patient organizations for rare diseases who are trying to figure out how they can start collecting data and patient-reported outcomes to create a natural history study. When I first read this, I was thinking about it from the context of a lot of these smaller patient groups, any patient group, are trying to get access to data and be able to get access to data that they can include in their registries so that they can create natural history studies of the disease based off of clinical data or other types of device data or patient-reported outcomes.

The easier it is for that information to flow into their registry, the better off they are going to be. I was not thinking about it from the context of placing some sort of requirement on these groups to then be able to share the information. It is an interesting thought that any data that is collected about an individual should be accessible to the individual. I think that may be worth consideration, but from my perspective, I see this as an opportunity to say if this data exists, then it needs to be accessible in a structured, machine-readable, downloadable, transportable way to these individual disease registries. Does that make sense? Did I render you all speechless?

Medell Briggs-Malonson
No, I was trying to come off of mute, Anna. That is incredibly insightful and more for us to think about, and I think it goes back to amplifying how we want to phrase this and what we think is going to be the most important when we are thinking about information blocking with the diverse array of registries that does exist. So, please, let's hold onto those thoughts that she mentioned. Eliel, then Jim, and then let's see what we can do for this topic.

Eliel Oliveira
Aaron was asking earlier if this is something we should consider. In my opinion here, as some have alluded to already, this is a very complex ecosystem of registries that we probably cannot even get a handle of how many there are and who regulates them. I know some examples, like in Louisiana, a cancer registry created by the state. I can tell you because we tried for years as a public health institute to get access that it is not likely something we are ever going to get. The fights over that access get very political. Beyond that, a key point is the fact that there are so many for different purposes that it is going to be really hard to figure out, and they do not necessarily have an electronic system. These are databases. It is not like there is going to be an API-standardized way to access this data because everybody can be using a different type of database, but it is just data.

But my point on top of all that is that in-the-hand registries, to me, are not creators of data. The data is still being created by EHRs, providers, and some of those are that are listed earlier here, Medell, that I would love to go back to in a second because you are probably not seeing the whole text from the beginning of

the call, but there are other, if you will, actors that are creating data, and that data can go into a registry, but it can be used for other things. I am just not getting the point that we need to ask the registries to share this for some purpose when the data is really coming from elsewhere, such as providers and EHRs, so it seems to me to be a box that, if we open it, in my opinion, it is going to take the attention from other specific topics here that help us with interoperability, and those are some of the things that I had earlier.

I will put them in the chat again, Medell, to maybe talk a little bit about that, but there are things that I know we did not have access to during the pandemic. We talked about data leakage before you joined, but I mentioned here how we need to explore labs, pharmacies, data, and to follow a standard, because right now, it is still not the case, and there are things like long-term post-acute care that are not even using certified systems that we can actually talk to. To me, in terms of the things that we are addressing, like emergency, data access, and interoperability, that would be make a big impact.

The final thing there in 42 CFR Part 2… We have an HIE level at the same time we are dealing with academics. We have a hard time delineating what is 42 CFR and what is not, so, usually, what we say is let's not exchange at all because we do not want to get in trouble. There has to be some way that we can create enough metadata that allows an electronics patient to say that this provider that is providing this type of service cannot see this data because it is 42 CFR Part 2, but this other person can, and in these conditions. We do not have a way to parse that right now. So, in summary, what I am trying to say is that I think this registry discussion here is not even related to systems. It is going to be very difficult to implement and maybe take some attention from other things, like these ones that could really enhance interoperability as reduced to data and maybe prevent some of the emergency situations that we have had with COVID, hurricanes, and so on and so forth.

Medell Briggs-Malonson
Thank you, Eliel. So, what I am seeing, very simply and in a summary, is that you are saying this may need to be deprioritized, and there are many other aspects of interoperability that may be more impactful than this one itself. So, thank you for those thoughts and comments, and then, Jim and Anna, and then we will have a conversation about what we want to do with this subtopic of interoperability.

Jim Jirjis
I appreciate Eliel's comments. I have a little bit of a different take on it. Being a healthcare provider organization, we have teams of people that only exist so that we can actually report to all these different registries that are out there. And so, yes, I think you are right, it is not as life-and-death as in the middle of a pandemic, so I would not suggest we bump any of those things, but I think it is worth keeping in. I think the thing we can do about it ought to be to define the question a little bit. For example, even though we may not have authority to tell all these different registries how to conduct their business technologically, there could be a problem that actually points to what the standards should be because many of them may actually adopt it. So, I would not deprioritize it, I would not remove it, I would have it stay on the table because it will reduce provider burden, and it is a requirement that providers actually interact with all these registries. I think the job of HITAC is to recommend that ONC evaluate, right? So, we do not have to solve it, but, in my opinion, it is a significant burden to providers that is caused by lack of interoperability standards.

Medell Briggs-Malonson
Thank you, Jim. Eliel, did you want to respond to Jim, or was it something different?

Eliel Oliveira
Yes, if I can, quickly. Jim, I like the way you put that. The way that I am reading this is how do we make that an actor so we can get data out of registries? What you are saying is how do we send data to them in some supervised way? I think that getting out is going to be a tough…

Jim Jirjis
I do not think they are talking about getting it out. Who wants to get it out?

Anna McCollister
There are some people, like researchers and equity practitioners. There are a few people.

Jim Jirjis
My only other comment before moving to the next person is with each of these two bullets, infeasibility and registries, we are trying to read the minds of what the HTI-1 Taskforce meant, and so, it may be worth checking in with them again to get more precision on the questions because we may be concluding and answering things that were not actually their point. These are just poorly worded fragments, right?

Eliel Oliveira
That is what I am reading here, that patient registries are considered actors with respect to providing health IT and treated as public health with respect to providing access to registry data. To me, that is a tough ask, providing access to registry data, but I agree with Jim. Having standards to send data to these registries, definitely… We have the Public Health Taskforce working on that, and I think we have made great advancement, so there is still a lot of work to be done left for other types of registries beyond ELR and other forms that we can send to CDC. Anyways, to me, getting it out is a tough one. Putting it in in the right standard format makes a ton of sense.

Medell Briggs-Malonson
Thank you, Eliel. Anna, thank you so much for your patience.

Anna McCollister
No worries at all. It is fascinating. Again, I am coming at this as a patient data nerd/advocate, but the issue that I have seen and witnessed via my friends who are trying to construct registries for patient groups is that it is really difficult to get access to the structure of machine-readable data that they need, and the patients have to get involved in mediating that process, and some patients are better able to do that than others. I cannot possibly imagine what the statutory authority would be or why we would think that ONC would have domain over registries created by somebody else for a different reason for a different budget that did not receive money from the federal government. How could we or ONC require anything? But, if we could require that the clinical data owners, so to speak, or device manufacturers make data available and not block it from being incorporated into registries, that would make it a lot easier for patient groups or other groups to establish registries that could then be used to further disease understanding, trials, etc.

Medell Briggs-Malonson
Yes, you are right, Anna, in every single way. So, really, all of you all had some great insights and points to this topic, and we do have many other topics to get to today. I am going to try and summarize this. No.

1, let's go back to our HTI-1 Workgroup cochairs and see if they can further define what was intended for Topic 1 in terms of infeasibility as well as the topic for registries. However, it also does seem that if we are going to go this way, we do need to refine this, and I just want to make sure we are all clear. It sounds like we are discussing at least setting up some recommended standards. We do not really necessarily say if there is going to be certification, which is another item on the table, but just some recommended standards of how these registries would actually be designed and implemented to allow for more efficient interoperability of data coming in.

But, I would also we should even think about some pieces of data going out in order to ensure that that flow of data is as effortless and comprehensive as possible. Also, that allows that flexibility for some of these other new data sets or registries as well that Anna was mentioning. Normally, people try to set up a lot of other different registries also. We should have some of that structure and those standard recommendations.

Jim Jirjis
Medell, a quick comment here. I think we are seeing a theme now. Now that FHIR is coming, there are FHIR implementation guides and profiles. We are getting granular now with what the building blocks of healthcare interoperability are, both in content as well as transport and structure. The next question, then, is between the government, QHINs, and provider-to-provider, people will start using them, but whether it is public health agencies, registries, or others that consume information, they need to be aligned with that. Otherwise, people are going to be doing redundant work with proprietary interfaces. I think that is what this is addressing. And so, that is where I think it is in scope, because now that we have built to this current level of granularity, we want others to use it, and that includes people who might be private registries. We want them to move so that providers across the country do not have to come up with a different data model for every registry.

Medell Briggs-Malonson
Right, 100%. So, it is setting up that standard framework so that everyone can actually adopt those frameworks to enhance interoperability throughout all of the various different contributors and stakeholders there. So, this was a great discussion. I think we are going to move on, and we will ask Michelle and the rest of our ONC colleagues to try to help us a little bit with some of that background work of seeing from HTI as well as some of the ideas that were captured here about pushing forward some of those standards for registries or any other type of data systems. Let's go to the next slide.

Now, we are in the priority area of privacy and security. After this, we have even more topics that I know will probably start a fair amount of discussion. First, we are starting with the privacy of sensitive health data and reproductive health. The gap that has been identified is that the inconsistent legal landscape governing reproductive health data, combined with the difficulty in segmenting this data regularly, creates barriers to its exchange. The challenge is that current health data privacy laws do not sufficiently protect sensitive health data, particularly reproductive health data, putting it at risk of being compromised. So, this is very much a hot topic that we even discussed last year on HITAC, especially when all of the various different rulings came down throughout the country. How do we protect this very important reproductive data? Hannah, what are some of your thoughts on this?

Hannah Galvin

Thanks, Medell. I agree it is a very hot topic around reproductive health data specifically. I would not limit this to reproductive health data. There is lack of harmonization among state laws around numerous types of sensitive data. Some years ago, I believe under Karen DeSalvo, there was some talk, at least at that time, of an attempt at harmonization or to at least approach the states around harmonization of state laws when it came to different types of sensitive data, particularly related to adolescents at that time. I think that an approach like that would certainly be welcome. Now, it is much more politically charged, specifically related to reproductive health data, and I do not know that that is something that ONC would be able to or want to take on.

One of the things that occurred in light of the *Dobbs* ruling is that states do have their own laws, and they are very different regarding how they are handling their reproductive health laws. I think in light of that, what we are seeing is that different states are enacting laws around how data should be exchanged, not exchanged, or protected. For instance, Maryland has enacted a law around not sharing any reproductive health data outside of the state, but that is very problematic from an informatics standpoint. How are you defining reproductive health data? How are you not sharing that outside of the state? What if you have a health system that incorporates multiple sites, including Maryland, Virginia, and Washington, DC, and how are you not sharing that across your health system laws?

So, I think that having some guidance from ONC, at least around the sharing or protection of data, if not around the harmonization of state laws, would be helpful. Also, one of the things we really need is a standardized terminology value set to define this data better. There is not a current steward for SAMHSA's previous sensitive data VSAC value set, and I think that would be very helpful in supporting some of these laws that are arising and helping to understand how to execute on those laws.

Medell Briggs-Malonson
Great, thank you, Hannah. There were a lot of great recommendations and thoughts about how we can move this forward from you. Eliel?

Eliel Oliveira
Thanks, Medell. Hannah, I want to connect the dots between this specific line and the last bullet point on my list of things which, to me, is similar. It is a sensitive type of data. I was talking about 42 CFR Part 2 and the fact that we usually do not exchange because we do not know what to do with it, and it is better to just stay out of trouble and just put up a wall. As an example here, a behavioral health provider for the region sends data to the health information exchange, we link everything that is there, and provide them access to other pieces of data from those patients across the community, but our FQHCs or hospitals cannot access the data from the behavioral health side. The reason for that is that we cannot segment who can see what from the other side. There might be a psychiatrist in a hospital or another healthcare provider that actually has the right because it is their patient, but because we do not have a way to say if it is this provider, block it, but if it is this one, it is good, it becomes tricky.

So, I would think the same about reproductive health, where it is about the metadata. I think the standards are there, but how do we define in the metadata that this specific piece of information can or cannot be used for a specific situation, in this case for reproductive health, that then, depending on the legislation of a state, a technical implementation can take place? Basically, by a state saying it does not allow this at all, a developer of an electronic system can basically say, "In this state here, it is not okay, so we basically

have a firewall here because the metadata says that that data is the type of data that we are talking about," while in another state, the regulations might be different.

I would even use another example here around pediatric patient consent and assent. Every state has a different age, and when the parents are supposed to… If we had some metadata around age that different electronic systems could utilize so that we could automate those decisions of assent and consent, that would help quite a bit. I know that is a very small example, but between mental health and reproductive health, I think there is probably value here in working on some standards for metadata that allow for electronic parsing of these pieces of information.

Medell Briggs-Malonson
Thank you, Eliel, especially for bringing in that metadata aspect. I would likely even add in that although we tend to see mental health as larger umbrella, I would separate it into mental health and behavioral health, with some of the behaviors that various different patients may have. Hannah, I am going to jump in very quickly, and then I will get to your hand as well. I am going to put on my physician hat when I speak right now, and also my administrator hat. This is also a very challenging area here, given some of the various different laws, as you all have mentioned, that we are having, and it does directly impact care. I would actually recommend that we go beyond reproductive health and actually call it gender health. The reason why is that right now, we are not just dealing with gender health in terms of various different laws, for instance, an individual's right to make various decisions about their reproductive rights, but also, we are also talking about gender in general.

And so, I would actually expand this to include some of the other privacy aspects of individuals throughout their entire continuum of life and some of the various different things they may face when it comes to their own different gender identities as well as the medical care that we seek. As we know, there are various different privacy limitations in terms of transporting data across lines and whatever that may be, very similar to what the two of you mentioned, and I think that part of this is also still hearing even more of a listening session for what OCR is doing. We did have a small presentation about what they are doing in response to the *Dobbs* decision and some of the other statewide decisions, but I might also recommend an additional listening session so that we are aligning with OCR, but then, as you all are saying, just thinking about what some of those standards are going to be to allow for safe and effective exchange of some of this data, which is critical, oftentimes, to overall healthcare. So, those are just some of my various different thoughts that I wanted to add in. And then, I see that your hands are up, Hannah and Jim. Hannah?

Hannah Galvin
Thanks, Medell. I will try and be brief on this. I could talk about this all day. Just to respond quickly to Eliel's point, as you know, there are standards that have been ANSI certified and are HL7 standards around 42 CFR Part 2. Specifically, DS4P is a standard, and there is now a DS4P FHIR standard with an IG as well that has been piloted in a number of places. Part of the issue is not having some of this implementation guidance sorted out, and that is what we are trying to do with Shift. We are starting a Delphi process next month to sort through some of these things. If individual patients say, "I do not want to share my data about my substance use disorder, but let me share everything else" or "I do not want to share my history of my abortion," and then they just go straight into an emergency room where they are having some post-procedural complications, there are concerns about that causing a patient safety issue. Should decision

support interventions pull in that data to those algorithms? How does that work, and how do we discuss those things? That has held up a lot of this from moving forward.

But while we are doing that and holding that up, we really only have blunt functionality or blunt algorithms, and people who have sensitive data, no matter how I define sensitive data, which could be this more traditional reproductive health data, gender data, or behavioral health data, or it could be that I have a knee injury, and I am Tom Brady, and that is sensitive to me. As Medell mentioned, gender could be something **[inaudible] [01:14:50]**, or that could be a core part of my identity, and I could say, "That is not sensitive data, that is something I do want shared and I do want people to know about me." But, if I do not have sensitive data, I get all the benefits of this interoperable ecosystem that we have been working to develop over the past 15 years.

Medell Briggs-Malonson
Hannah, I am sorry to interrupt, but go ahead and wrap it up because I want to get to Jim and Anna.

Hannah Galvin
All right. But if I do then have that sensitive data, then I do not get those benefits. I have to decide if I share all of my data or none of it. And so, it really ends up becoming an equity issue, and as we think about equity by design, this ends up really being a core equity issue, so I would like to think about that in that framing. So, I will wrap it up there so that Anna and Jim can make their comments as well.

Medell Briggs-Malonson
Thank you, Hannah. I appreciate that. Jim, you were next.

Jim Jirjis
I was just going to comment on this one. I agree that "reproductive health" may be narrow and I understand what you are saying, but we should not make it so broad that we lose focus on the current and present real risk of litigation and adverse consequences to both patients and healthcare providers, given the recent state laws that can be very harmful. That was my only comment. I get the gap. The gap says the inconsistent legal landscape makes it difficult because we cannot segment, so it sounds like what this is about, then, is that because we cannot yet segment well, we ought to develop federal privacy laws to address that this information cannot be used to prosecute people. Is that what they are asking?

Medell Briggs-Malonson
I think that is exactly right, Jim, and that is one of the different reasons why I mentioned gender instead of just reproductive health, because we do have some laws, of course, coming out of states, especially when it comes to children or, unfortunately, even soon to be adults that are requesting affirming medical care, and so, that is why I did say a broadening. That is the reason why, because that is a current hot topic right now, one that is both legal and political. That is one of the reasons why OCR is trying to figure out themselves the best way, to your point, of preventing forms of litigation for providers that may be even outside of those states of still ensuring and supporting the appropriate exchange of medical information that is absolutely needed to provide appropriate healthcare.

Jim Jirjis
Maybe, then, it is as simple as saying "gender and reproductive health."

Medell Briggs-Malonson
Yes, we could definitely do that. I like that.

Jim Jirjis
I guess it is within the purview of HITAC to recommend that ONC develop privacy laws. Is that right?

Medell Briggs-Malonson
I think that would be a question for ONC. This is one of the reasons why I mention that maybe one of our HITAC recommended activities would be to have a listening session with OCR, since this is definitely within the OCR domain, and they are working on it, but maybe having that listening session so we can understand a bit more of where the gaps are, and then, hopefully, we can help to recommend some additional action based off of where those gaps may be with the privacy laws or the privacy approaches that they are taking, but those are all great questions. I think that is a question for ONC. Anna?

Anna McCollister
When I think about this issue, it is so remarkably frustrating on many different levels, and I have no idea if this is in ONC's purview, but there needs to be a focus on privacy and making sure that state officials do not have access to sensitive health information. I would think that would be clear based off of HIPAA, but I am not a HIPAA expert. I have concerns that we are creating these great pipes for a lot of tricycles, which is such a great metaphor, Jim, and thank you for that. The whole point is to make this data interoperable and sharable so that if you end up in the emergency room or wherever, they will have access to your information, including if you are unconscious or whatever. So, that is the point. If we are restricting information about things, whether it is reproductive health, HIV, a genetic predisposition toward ALS, mental health issues, or whatever it is, then that is going to significantly impact whether or not all of this is a credible or usable system.

One of the key things we could do to make people more comfortable with allowing their data to be shared rather than just focusing on the ability to restrict it, and we need to restrict it, is disclosures about who is accessing it, for what, when, and how it is being used, and I think that is very much in the purview of ONC. Now, it may have been difficult to do from an electronic perspective 10 years ago, but it is increasingly feasible, and I feel as though just giving individuals the ability to see who has access to their data, what they are using it for, and when it was done is really important information because if I have a sense of who is using it, then I will be more comfortable allowing the data to be shared because the vast majority of uses will be informing that plan of care.

Medell Briggs-Malonson
Right. So, Anna, what you are saying is let's inform our patients and put the decisions into their hands in terms of their sensitive data.

Anna McCollister
If we are going to give people the ability to choose, and I think we certainly should, we need to give them the information that they need to be able to make that choice in an informed way so that they will benefit from the health benefits of having information be shared, but they do not have to live in fear that it is going to be shared for the wrong reason with the wrong person. There certainly needs to be some legal stuff and

privacy issues dealt with to make sure of that to strengthen HIPAA or whatever new law may need to be developed, but in the meantime, since 99.9% of all of the data access presumably is for the benefit of the patient or potentially to inform research into a disease or whatever, me being able to see who has accessed my data and for what will help give me peace that it is not being used against my own interests.

Medell Briggs-Malonson
Yes, absolutely, and I think that is very important from a patient perspective, and also considering what we may need to do from that provider and physician perspective as well, especially in those states in which we now have various different legislation in which you truly can face some type of disciplinary action or worse for performing certain procedures or sharing different data. So, all of these are very important pieces. So, team, we are at our public comment time period, so I am going to turn it on over to Mike to lead us through the public comment.

Public Comment (01:23:06)

Michael Berry
All right, thank you, Medell. We are going to open up our meeting for verbal public comments. 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 press *6 to mute and unmute your line. So, let's pause for one moment to see if any members of the public raise their hand. I am not seeing any hands raised, Medell, so I will turn it back to you to close us out.

Next Steps and Adjourn (01:23:36)

Medell Briggs-Malonson
Excellent. Thank you so much, Mike. So, looking right now, we have about five minutes, and I do not know if we can actually get to some of the other topics, but Excel team, if we can just go one slide back, let's just wrap up the privacy discussion. If it is too hard to start it, that is okay. That is okay, Excel team. We were just going to wrap up that last discussion in terms of privacy for gender and reproductive health. So, I think there were a lot of great ideas that came into play from all of us on the workgroup, so what we will do is try to put all of those different ideas together and try to distill them a little bit more to make it more focused because we do have various different vantage points for that, but also, seeing what is in scope for ONC and exploring what OCR is doing in this space so that we can make sure that we have the best and most informed recommendation possible for that section.

So, thank you, everyone, for a wonderful discussion. Our next workgroup is on the calendar, as was demonstrated earlier this morning. I think we can give a little extra time back into your day. If there are any other thoughts or comments about any of these topics, please just send them to me and Aaron, and we can send them on over to our ONC colleagues, and also, moving forward with some of the other topics we did not get through, we do have a fair amount to get through next time during our workgroup meeting, so if you are able to take a look at some of those topics in advance, think about some of your recommendations because we absolutely want to wrap up the crosswalk by our next meeting. It was wonderful seeing everyone, and we will see all of you all at our general HITAC meeting. Have a great day, everyone.

Eliel Oliveira
Thanks, everybody.