ONC | HealthIT ADVISORY COMMITTEE

Transcript

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

January 30, 2023, 1 – 2:30 PM ET

VIRTUAL

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Speakers

Name	Organization	Role
Medell Briggs-Malonson	**UCLA Health**	**Co-Chair**
Aaron Miri	**Baptist Health**	**Co-Chair**
Jim Jirjis	HCA Healthcare	Member
Steven Lane	Health Gorilla	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, thank you for joining the HITAC Annual Report Workgroup. I am pleased to welcome one of our co-chairs, Medell Briggs-Malonson along with workgroup members Steven Lane and Eliel Oliveira. We are expecting Aaron Miri and Jim Jirjis to join us shortly.

Aaron Miri
I am here.

Michael Berry
Great! Public comments are welcome, which could be typed in the Zoom chat, or could be made verbally during the public comment period later in our meeting. I would like to turn it over to Medell and Aaron for their opening remarks.

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

Medell Briggs-Malonson
Thank you so much, Mike. It is a pleasure to be here again for our Annual Report Workgroup Meeting. This may be one of our last ones as we wrap up some of the amazing work that we have been doing over the past year to streamline and bring together all of the important priorities in order to go into this report. I will also turn it on over to my colleague Aaron to see if he has any additional remarks and then we will go directly on through the agenda.

Aaron Miri
Thank you, Medell. Just to echo what you said, I look forward to today's discussion. Let us put our caps on this year and get this thing ready to go.

Medell Briggs-Malonson
Absolutely. What we will do is, in terms of some of our various next steps, we are going to go forward and really focus on looking at some of the additional revisions that have come from our HITAC members. For we as a workgroup, just really ensuring that we consider those different revisions and see if there are any modifications we need to make to the report. In addition, we will also go over some of the supplemental background research document revisions. Of course, before we end today's meeting, we will also open it up for public comment.

Next slide. Very briefly, we will go over the meeting schedule and the next steps. Next slide. This, once again, just shows the entire meeting schedule for the annual report group and all of the great items from all of our prior meetings as the annual report workgroup. Today, we are going to update the fiscal year 2022 annual report in order for it to be submitted to the full committee next week for comments as well as approval. Then for the full committee, that will take place on February 8th, which is actually next week. We hope that there is going to be a full approval of the report so that we can go ahead and submit it to ONC, as well as to the national coordinator. Next slide. Great.

Aaron, do you want to take us through the next steps for the development of the annual report?

Aaron Miri
Sure. Let me just pull over to the side here. Sorry, I am driving.

Medell Briggs-Malonson
Never mind. Aaron, no worries, I am more than happy to take it.

Aaron Miri
Thank you, I appreciate you.

Discussion of Draft HITAC Annual Report for FY22 (00:02:56)

Medell Briggs-Malonson
Absolutely. Anytime. In terms of the next steps for the development of the annual report for the fiscal year 2022, today, as mentioned, the workgroup will discuss the list of members' comments and any revisions to that draft report. In addition, what we will do is that we will then present the revised report for approval at the HITAC meeting on February 8th. Then we will transmit it to the National Coordinator for Health IT as mentioned in February.

Next slide. All right. Now we actually get to start some of the discussion of the various different comments that we received on the report from our HITAC members. If we can actually bring up some of those different comments on that next document, that would be great. So far to date, we have only received revisions from one of our HITAC members, which is Deven McGraw. One of the primary areas that she focused on was, you will see further on down, in terms of privacy as well as more interoperability.

I am sorry, Accel team. If we can go right back just to actually mention her overall comment. Overall, what Deven did mention is that the recommendations address important issues, and are all worthy pursuits for the HITAC to take on. Setting priorities is definitely challenging as we have all experienced, even during this annual report process. We can scroll on down. This is where some of the various comments came into play. When really focusing on target area privacy and security, the original language that we had underneath the recommended HITAC activity was to track the work underway in TEFCA, to adopt use cases that support the exchange of data for payment and healthcare operations.

However, Deven wanted to make sure that we took into account a few additional considerations, especially when it came to our language. One of the things Deven recommended through her written comments was the issue of data segmentation is not just a matter of assuring that minimum necessary can be met for the sharing use cases for which the minimum necessary standard applies. It is also critical to ensuring that data can be shared in accordance with the wishes of the patient. This is relevant even for sharing of data for treatment purposes due to the application of sensitive data protections, for example, Part Two, and state-sensitive data loss, as well as hiding concerns regarding the cross-border sharing of pregnancy-related data in the wake of the Supreme Court's opinion in Dobbs.

Given the heightened concerns regarding the sharing of sensitive data in ways that could potentially harm patients and providers, the evolving legal landscapes regarding the sharing of substance abuse treatment data, and the slow uptake of existing technologies for data segmentation, this issue should be elevated in priority for HITAC to address. While exchange of PHI for payment and operations use is important, both of

these use cases have been deprioritized for TEFCA, which suggests a great importance to dedicating resources now to resolving for treatment use cases involving sensitive health data.

Revision proposed by ONC to the recommended HITAC activity is that it would then be track work underway in TEFCA to adopt use cases that support the exchange of data for treatment, payment, and healthcare operations.

We just want to pause here and open it up to the workgroup to opine on this recommendation that definitely our colleague brought up. Also some of the proposed language that at least ONC is giving us to make sure we center treatment in addition to payment and healthcare operations. I believe that is one of the things that we were discussing during many of our work groups. I would love to open it up to the workgroup to see any thoughts or comments.

Steven Lane
Yes. I am happy to chime in here. First, let me just say that Deven has become a very good friend. She and I do a lot of work together. I just have a world of respect for her. I am so happy that she has joined us on the HITAC. Her insight and knowledge in these areas is really unsurpassed, I think, in our community. I take everything that she says to heart, and I agree with her entirely.

One point of disagreement is the notion of deprioritization of healthcare operations and payment under TEFCA. Just to be clear, those use cases are moving forward. They are moving forward deliberately. They were not included in the very first use cases to be supported under TEFCA, which of course are treatment and individual access services. There is a proposal for payment of healthcare operations exchange, but it is specifically being focused on basically risk identification and management. It is a more limited use case, I think, in that sense. Perhaps deprioritization is an appropriate term here.

I think that these issues about the privacy of particularly sensitive data are critical. I completely agree that we should be highlighting this in our report. She mentions the fact that there has been slow uptake of the technology to support the specific protection of flag data. Deven and I have both been serving on a number of workgroups that have been looking into this. We had a CIVITAS conference a week or so ago that we participated in. There is the DS4P standard which has been included in the requirements for Certified HealthIT, but it is optional in its use. It has been used in a very limited manner. It is a technical standard that is well established in the CDA world and is now nearing the end of the balloting process, I understand, in the fire world.

It is very powerful, quite flexible, and provides a remarkable toolset that we can use, whether we are talking about Part Two Data, Adolescent Confidential Data, data related to sexual or gender care, reproductive care, etcetera. It also provides the ability for individuals or providers to specify that certain aspects of data are highly sensitive, and then engage the patient in having some control over how that data can be shared. I think, again, everything Deven points out here is great. The one small edit that she suggested, adding the word treatment, I absolutely agree with that. I think there may well be an opportunity for us to slip in a paragraph that captures the substance of what she has identified here.

Medell Briggs-Malonson

Great. Thank you so much, Steven, for all of those thoughts and comments. Any other thoughts or comments about the proposed revision?

Eliel Oliveira
Yes. I completely agree with Steven and Deven. I agree as well that just bringing back treatment here probably may not do good enough for this important point that she brought up. We constantly see the need of being able to allow individuals to control who, in a specific way, accesses a piece of data here at the medical school, as we engage in different projects.

Among the several examples, one that comes to mind that also leads to learning across the nation, different policies of different states, relates to the consent of young adults or children that varies from state to state depending on the age. That makes this even a bit more complicated of what a young adult is sharing with their psychiatry doctor as related to substance use, and what their parents should see or not see, as an example. If we do not have a good sense of where things stand in every state, it becomes really hard for electronic systems to also comply with those. I wanted to highlight that more because it is the one that we grapple with quite a bit day today here. Great comments.

Medell Briggs-Malonson
Absolutely.

Steven Lane
Yes. I will pile on there. The challenges of variable state privacy laws is certainly something that we have dealt with for ages back in the paper world. Now in the digital world, it only becomes more than an acute problem. I do not think ONC would necessarily see that as within their wheelhouse, but they certainly would have the opportunity to collaborate with OCR or others within HHS, to see what if anything could be done to at least understand the diversity of privacy laws, to document and maintain that.

I know in our company, we are looking at contracting with a law firm that charges tens of thousands of dollars a year to help you keep track of the privacy laws of every state. If there were a federal resource, at least, that allowed us to be aware of this and keep up with that, that would be a great thing. It would save everyone a lot of timeand heartache and potentially, at least, get us on the same page while we are simultaneously looking for opportunities to standardize and raise the floor of privacy at the federal level so that there is not so much of a perceived need to raise the ceiling at the state level.

Medell Briggs-Malonson
Great suggestions. Aaron, I know you that may not be able to unmute, but I want to make sure you had a chance as well.

Aaron Miri
I totally agree with what everyone is saying. I do think more needs to be done around privacy security in general. We have talked about it over the years. A lot to develop, and a lot to learn is all I would say. I agree with everything that has been said.

Medell Briggs-Malonson
Okay. Thank you.

I also agree. I think Deven brought up some really important considerations that not only should go into the report, but also, of course, in terms of the recommendation for additional HITAC activity. At the very bottom, especially listening to all that has been said, we have a revision proposed by ONC to the recommended HITAC activity. That proposaling, which was trackwork underway in TEFCA to adopt use cases that support the exchange of data for treatment. That was the addition. Payment in healthcare operations.

What I am at least hearing from everyone here on the workgroup is that we need to probably expand that a bit more and make sure it is illustrating, really, what our thoughts are. Most importantly, some of these different thoughts that Deven brought up. One proposed revision may be trackwork underway in TEFCA to adopt use cases that support the exchange of data for treatment, payment, and healthcare operations, especially in the application of sensitive data protection. We add to that so it is very clear what we are referring to, instead of very general.

Also, we discuss all of the various different variations and state laws. The question is if we want to add that into the recommended activity here in the report, oractually add more language in especially the supplemental data document in order to, again, provide more context. I just want to bring that up to the workgroup. A). Do we want to add that additional specification as it pertains to sensitive data protection so that it is very clear what we are talking about? Really highlighting that as well. Then also, taking a lot more of this language that Deven mentioned and adding it to the supplemental document so there is more robust context when looking in this area.

Steven Lane
I guess, Medell, I do not think I would tag these sensitive data protections onto the sentence about tracking work underway in TEFCA. As far as I know, there is not a lot of work going on in TEFCA about sensitive data protections. I think the idea of tracking the work in TEFCA as it relates to treatment as well as payment and healthcare operations, I think the sensitive data protections probably warrants a different sentence or paragraph. Yes, I believe that it should not only specify our interest in sensitive data protections but add some of the richness that Deven identifies here as to why that is important.

Medell Briggs-Malonson
Got it.

Steven Lane
Perhaps, our own editorial team has time to capture some of that and make a proposal back to us. That would be nice. Deven, obviously, would probably be happy to propose a paragraph.

Medell Briggs-Malonson
Sure. Thank you, Steven. Any other thoughts?

Eliel Oliveira
Yes. Medell, I would like to suggest that the ONC team can probably draft some content. I would imagine that the general report probably can have some mention but not too much detail. It is already a long report. The intent is not to focus on one specific problem so deeply. The other one would be a better fit.

Medell Briggs-Malonson
Great. Wonderful.

Once again, we are hearing, we are going to keep the sentence unless our ONC team can buff it up a little bit. My main concern is that although TEFCA is very general, there are some key things that were brought out. Sometimes even making that example, for instance, may actually help. If we want to keep the sentence, perfect. Then just making sure we are adding more of the context to our supplemental document, not necessarily the report, but the supplemental document. In order to make sure that we have all of the context for this specific target area and for this recommendation.

Aaron Miri
That works for me.

Steven Lane
I also really love the fact that Deven captured this notion that the inappropriate sharing of sensitive data can potentially harm both patients and providers. I think that is a key point that we need to keep in the focus point.

Medell Briggs-Malonson
Absolutely.

Michelle Murray
Medell, I have a question for you. It is Michelle.

Medell Briggs-Malonson
Yes. Hi, Michelle.

Michelle Murray
In the report right below this topic area, there is the topic area of privacy and sensitive health data. I am wondering if this overlaps with what we have already done, or is it a new or different perspective on it? We can bring up thereport if you would like to show you that line item.

Medell Briggs-Malonson
Great point, Michelle. That is also a nice segue. If we scroll up, the Accel team, to the next one, I believe Deven has more comments. No? Okay.

We went directly into more of our innovation and regulation. What I would propose right now because we do have some additional comments. Michelle, if you and the rest of the team can kind of take a look at what we already have for that section of protected sensitive data, and let us just make sure that at least the report has all of the comments we just mentioned, regardless of which area it is in. Most importantly, it just needs to be in the report and in the supplemental documents. If that can be proposed back to us, then we can make sure that we are capturing all the information we want to capture.

Does that work, Michelle? Great. I will take that as a yes. Yes, Michelle?

Michelle Murray
Can you hear me?

Medell Briggs-Malonson
Now, we can hear you.

Michelle Murray
Okay. I said that sounds fine.

Medell Briggs-Malonson
Great. Thank you so much for that.

Steven Lane
Thanks for the reminder that we already had a section dealing with this. I am sure there is some subtlety from Deven's comments that we can add there.

Medell Briggs-Malonson
Exactly. All right. Great. Let us go on to the next section. The next section, again, target area, patient access to information. This subsection was in alignment with innovation and regulation. We had some of our original language here which focused on clinicians and hospital systems adopting APIs but are concerned about unauthorized data exposure and added liability. We had a list of three recommended HITAC activities. I am going to read them, especially because Aaron may not be able to look at the screen. Number one, learn about federal regulatory activities affecting privacy and security for areas of HealthIT innovation, especially APIs. Number two, support awareness and education for providers, patients, and other interested parties about relevant federal regulatory activities. Number three, support the development of guidelines that assist provider organizations, and more efficiently resolve the concerns around data access.

This also came from Deven. The written comment itself was, clarification of liability for exchange of data is a genuine issue. Frankly, one that is areal current obstacle to more widespread adoption and scaling of interoperability. Given that it is a current obstacle and with TEFCA only a voluntary network, I recommend moving it up as an immediate need versus a long-term initiative. Right now, where we have this, and Michelle please definitely correct me if there needs to be additional clarification, this currently is within our long-term initiatives. What Deven is recommending, is that given that this is a pretty significant topic at this time, to just move it up as an immediate need for us to address. Especially when it comes to our HITAC proposed activities, versus a long-term initiative.

I will open it up to the workgroup again to consider this recommendation and add any additional comments about it.

Steven Lane
I will just say what I said before, which is, Deven is brilliant and insightful. I think she is right. This needs to be kept on the front burner. This is a critical challenge in provider adoption of APIs and provider support of an openness to the use of apps and partnership with app developers who fall outside of the protections of HIPAA. I do think it makes sense for us to keep this as a current focus. I think there are real opportunities

for ONC, once again, to partner with other federal agencies including the FTC, to raise the bar here, and to advance improvements in HIPAA or other privacy regulations to help close this perceived gap.

Of course, there is a lot of work going on in the industry under the CARIN Alliance among others that, actually, Deven and I are both involved in. ONC does have an opportunity to really support advancements. Good call.

Medell Briggs-Malonson
Thank you, Steven. Any other comments?

Aaron Miri
Go ahead, Eliel. Go ahead.

Eliel Oliveira
Not much to say here. I have been wondering all along that TEFCA is now a reality. We are going to get the QHINs up and running. We have HRS within the endpoints. There are going to be quite a bit of challenges here on how the taxes and security of those endpoints are going to be managed. I still do not know. Even if **[inaudible] [00:24:59]** can clarify within ONC and HITAC, I think that is a great place to start. Others out there are probably wondering the same thing. How do I do this?

Sorry, Aaron. Go ahead.

Aaron Miri
I was going to say very similarly to what you are saying. I agree with what Steven and others have said. I think it is important and we should consider it. Is it more important than everybody and everything else? I do not know. We do not know who we do not know. I do wonder if after the announcement on the 13th for the first QHINs that are picked, will more federal agencies be talking about TEFCA. I hope so. I really hope to hear the FTC talk about TEFCA or others. TBD.

Medell Briggs-Malonson
I want to echo what Eliel and Aaron both said. I remember when we had this conversation. We had that exact conversation. What does the landscape look like? Yes, it is incredibly important. We also were looking at things from a prioritization at that point in time. It is just so challenging with so many different pieces. Especially after all of the various different announcements, are things going to move much faster? We already know this is critical. I am going to take it even from the direct patient care lens and outside some of these other aspects. Really making sure that we do have that full alignment when all of these new pieces and all these new APIs are coming out. That they are meeting some type of standard in order to protect patient care and to have the appropriate exchange of the various forms of data.

Yes, it is important. It is probably now going to move even faster. I know that we did have the same conversation about where it should actually fall in relationship to all of the other priorities that we are looking at. We are in a new landscape and new time. The question for the workgroup. Do we want to move this up as an immediate opportunity, or leave it right now for long-term opportunity?

Steven Lane

I guess, given our perception that this is a zero-sum game and we can only have so many immediate opportunities, it may make sense to keep this more long-term. I mean, it is something that is not going to go away. It is not going to change quickly. I do not think there are quite the same immediate opportunities as there may be in the privacy space. I would add any detail here that is missing from our current report. The other thing, just as an aside, which strikes me, and I do not know if we have this in the report already, but the role of HITAC vis-à-vis TEFCA and its evolution. We do not have a TEFCA workgroup or task force per se.

We are left up to you all as HITAC co-chairs to say, "When do we get updates? Is it just in making theseremarks, or is there going to be something more formal?" As TEFCA continues to advance, I think it is important for us to think about what role HITAC can or should play. There are obviously lots of rooms in which TEFCA is being discussed. The Sequoia Project. RCE does a great job with public engagement. I just wonder. I am truly wondering whether there is more of a role that HITAC should be playing in helping support ONC specifically, and the RCE team within ONC, as this moves forward over the coming years.

Medell Briggs-Malonson
Yes. Thank you.

Aaron Miri
There was a workgroup. There was one. Remember that, Steven? Back in the day. It was a long time ago.

Steven Lane
Yes, when the first draft came out we did one.

Aaron Miri
Yes. Yes. That Genevieve was leading and everything. Yes. It was a big meeting.

Medell Briggs-Malonson
I was going to say the same thing, Steven. I think that is a really great idea and insight. Especially as things are really kind of picking up even more. Not only for that awareness but foreseeing how we can lend a hand and lead some additional insight. I know that we do have Mike. We can really see what some of the potential next steps can be for something like that. Thank you for that.

Steven Lane
One additional thought, Medell. As you guys work with ONC to plan our longer, in-person meetings in the spring and fall, whether it might be appropriate to calendar or put in agenda items for a deeper dive into the TEFCA space there.

Medell Briggs-Malonson
Thank you for that. Great idea. Great. Do we have any objections to just leaving this item where it is? Remember, long-term does not mean that it is long-term. Long-term just means not within the next 12 months per se, but definitely within longer than 12 months. It is still on the radar. Any objections to leaving it where it is right now?

Okay. I see lots of head nods.No. Okay. Great. We will leave this one for where it is right now, and then we will go on to the next piece of the next revision or recommendation. This is also from Deven, for patient access to information.

This was patient consolidation of health information from multiple sources. Our current language is that we should propose a plan to monitor and assess the successes and challenges with the implementation of the 2015 addition Cures update API criteria. Underneath that HITAC member suggestion, Deven mentioned that, and I can also see below for the same topic, so also in the supplemental research document. There are a number of obstacles to the ability of patients to access data from multiple sites of care. Yet the draft report and recommendations focus on actions to improve access through fire APIs. Exploration of this challenge should also include exploration of the barriers that patients face in obtaining their complete health information by establishing and maintaining connections to multiple fire endpoints and how TEFCA can be leveraged to allow individuals through a single on-ramp to acquire all of their health information. At least for institutions, practices, and networks participating in TEFCA, without having to connect and maintain connections to multiple endpoints.

The single on-ramp is the ultimate promise of TEFCA. Individual access is one of the first to priority use cases for TEFCA. Consequently, this should be a short-term versus a long-term priority. I think these comments by Deven are really incredibly insightful. I am just going to jump in there. I am actually wondering if our original language even kind of captures what she mentioned. Meaning, she brings up many important points that I think we have been talking about, but I am not quite sure that it even was conveyed in that original language per se, as much as what it could have been.

The question is, number one, do we want to move this recommended activity up to a media priority versus the longer term? I would put another question out to the workgroup. Is this current original language the language that we really even intended when we were discussing the importance of our patients having direct access to multiple sources of their own protected health information?

I said a lot there, so I am curious to see what the group thinks.

Steven Lane
I think, again, Deven is pointing out an opportunity for us to be more specific.

Medell Briggs-Malonson
Agreed.

Steven Lane
Deven currently works for a company that does just this. It supports individuals, mostly with cancer, but potentially other complex illnesses, incollecting all of their data to support all of their care, research, needs, et cetera. She is acutely aware of this challenge. I think we are all aware of the challenge of the requirement today in the industry for OAuth Two identity verification as opposed to leveraging the IA Two standards which are also out there, which would allow us to accomplish what Deven is describing here. That single on-ramp of doing identity verification once and then really requiring data holders to respect and accept that.

I think, again, this is kind of like the other thing she pointed out. This is an acute challenge. There is an available technical solution. Policy changes could be implemented by ONC or others. That would be a forcing function to move this forward. I mean, like we were talking about before, if you require the use of DS4P, if you require the use of IAL Two, we would break log jams. I think these are the kinds of things that should be labeled as high-priority because there is a shovel-ready solution and it is really just the will of the policymakers to allow us to move forward.

Eliel Oliveira

I have quite a bit of thoughts about this subject because I did quite a bit on this front. I will post some links there in the chat of the results of the work that we did from one of the LEAP Awards that we received from ONC in 2019. Piloting exactlythis type of scenario where individuals, basically, sign-up once with some basic information and we link them to their data from a health information exchange. That was the resource we had back then.

It might be still today, but I think with the creation of TEFCA and QHINs coming about, the lessons learned that inform exactly how patients could do that very simple sign-up without much effort and get to their data. We provided a summary report to ONC of our findings which does not get published publicly, I guess. Things that you are going to find there, and that we continue to learn as we use real settings here in Austin are things like, “Okay, the patients basically get access to everything. Should they?” Lots of clinicians are questioning that. Right? We often make a delivery of lab results to patients. They get it in realtime. Clinicians have asked, “Should we allow that specifically?” Does their law define? From what we understand from the Cures Act, you should have access to all of it. There are many situations there where I can see how questions could arise about the timing of that access.

This is just an example of some of the challenges around this. There is definitely a lot that could be done here to advance these aspects. I do not think of it as a technical problem as much. I do not know how I feel about prioritizing this. In one sense, I think the priority is more on these types of questions that are not technical, of data access. To me, maybe the patient access section of our report, along with health equity, might be able to tap into some of those points. I am challenged to think about how to prioritize this. I think it is very important. We started working on this a while back. There are still opportunities to improve, and great value to deliver to individuals.

Medell Briggs-Malonson

Thank you, both of you, for those comments. Aaron, any thoughts? There is definitely some really deep insight in thinking about, again, the reports and how critical each one of these various different items are as well.

Aaron Miri

I appreciate, Medell, the topic. I do want to make sure we balance order of operations. Right? I do not think we are saying in any which way that privacy and security or cyber security is not important. We are simply saying that in some cases, the market has still got to develop a little bit. Like TEFCA, as an example. We have got to see what happens with it. There is a whole lot of speculation right now until that thing is live. It is not even mandatory, as Deven was saying. She is right. It is voluntary for right now.

I think there is a lot that we want to do. We need to see what happens. I just want to caution this group that we are not in any which way saying none of this stuff is important. We are just simply saying, "When does it happen, so that it makes sense?"

Eliel Oliveira
I agree. I tend to agree. I think I am challenged because I love the subject and the fact that I believe that that is the right way to go. At the same time, when I look at our list about Health Equity, public health, TEFCA rollout, it is hard to not think that those are more immediate aspects to focus on. These are very important, but maybe not as immediate.

Medell Briggs-Malonson
Yes. That is one of the reasons why I mentioned the activity itself is proposing a plan to monitor and assess the successes and challenges. Does this activity even capture what we do think is the appropriate next step in order to address the patient consolidation of health information from various different sources? I feel like we are at just multiple crossroads of so many various important things that we know are critical to not only supporting our patient and community care but then also operations and interoperability in more ways than one. When we are looking at how we are proceeding, what is the next step for HITAC to get to the ultimate goal that we all want to get to? In terms of, for instance, even that single on-ramp which we know is critical for so many different reasons.

That is why I also propose to you all, is this language even right here enough for us, or do we need to be more specific in what we are referring to when we are talking about proposing a plan?

Aaron Miri
Personally, I think specificity matters. Even if it is a listening session to understand the landscape of all the things going on and go in stepwise, I am all about specificity.

Medell Briggs-Malonson
Good. Yes. Steven and Eliel? We are very broad with our recommended HITAC activity.

Eliel Oliveira
Yes, I agree with Aaron. I guess we are agreeing that we need to mention additional details maybe on the supplemental report. To be specific about this, but not necessarily raise this to immediate priority given that there is so much more for a place like TEFCA. We just need to see what is going to happen. I think I agree on that specificity. Again, this is so important. Next year when we look back and try to have the same discussions of what the key priorities are to focus for the following year, it might be that after TEFCA and other things are coming into play, that we look at this and we already have some solid definition of what this is about, to pick up from.

Medell Briggs-Malonson
All right. Thank you. Steven, any thoughts about that?

Steven Lane
I agree with everything that has been said.

Medell Briggs-Malonson
Okay, All right. Just to summarize, this is very important. We know that this is where we need to be in more ways than one. However, given where TEFCA is right now and given even all of our various different items when it comes to the various different sources of health information as they are quickly evolving, at least right now, our goal is to still propose a plan to monitor successes and challenges. For our ONC support team, if we can just be a bit more specific into that of saying how we want to monitor and assess. What are some of those different ideas? We will leave it right now underneath a longer-term priority, but only because we are waiting for the rest of the landscape to evolve so we can be even more specific for our next immediate steps.

Did I summarize that okay?

Michelle Murray
Medell?

Medell Briggs-Malonson
Yes, Michelle.

Michelle Murray
In actuality, I think it is currently in immediate level, rather than in long-term. That would be a change if we push it to long-term.

Medell Briggs-Malonson
Okay. Is it already in immediate level?

Michelle Murray
Right. Yes. I have that loud and clear.

Medell Briggs-Malonson
Okay. Okay, yes. I think right here, Deven's comment was just saying that it should be a short-term versus a long-term priority. Okay. All right. That changes it. Right now, we are still in immediate. Maybe still adding some of that additional specificity is going to be key, especially as we are watching the rest of the TEFCA landscape evolve.

All right. Any other thoughts or comments about this?

Steven Lane
No.

Discussion of Draft Supplemental Background Research Document (00:44:09)

Medell Briggs-Malonson
Okay. All right. It sounds like this was already in the immediate opportunity priority level. We are all set there. All right. Let us keep on moving to the next area. I think that was it. One more. One more. All right. The very last area. This is in the supplemental background research document. This is still in the target area of patient access to information. Once again, we were just talking about patient consolidation of health

information from multiple sources. We have some of our original language here that is going deeply into the ONC Cures Act final rule that requires standard space APIs to be used to provide data to apps that help patients access and consolidate their health information from across different portals. We have some additional explanatory language that is after that as well.

Coming from Deven, this was, I believe, one of the last comments directly on the research document. It was mentioned here that there are a number of obstacles to the ability of patients to access data from multiple sites of care. Yet the draft report and recommendations focused on actions to prove access through fire APIs. Exploration of this challenge should include exploration of the barriers that patients face, and obtaining their complete health information by establishing and maintaining connections to multiple fire endpoints and help TEFCA can be leveraged to allow individuals through a single on-ramp to acquire all of their health information. At least from all the various different institutions, practices, and networks participating in TEFCA, without having to connect and maintain connections to multiple endpoints.

Again, thinking about that single on-ramp is the ultimate promise of TEFCA. Some of the proposed text by ONC is to add into the research document. This may help with some of the conversations we were just having. In addition, patients face burden due to the difficulty in accessing multiple API endpoints to aggregate their health information. The TEFCA proposes to reduce the burden of access on patients by providing them with one access point to request data from all organizations participating in TEFCA. Our main proposed solution for us to discuss should be whether to add the proposed text directly to the supplemental document, or not. Right now ONC is recommending that we accept this change.

Any thoughts about whether we should add this text or any other revisions you think are needed?

Aaron Miri
I support the revision.

Steven Lane
I do too.

Eliel Oliveira
I do too, Medell. This looks great. I think I will go back to my point as well for us to keep in mind. The balance between allowing patients access to all of their data in real-time through a network like we are putting together. If that could cause harm. I heard from several clinicians basically saying, “Are you really going to be providing patients with the delivery of all their lab results and scan results in real-time?” What issues could be there? Who can determine what should be done or not done based on the Cures Act? I think that is an important point for us to address at some point.

Steven Lane
Yes. I think I agree with you, Eliel. You have a couple of clinicians on the line here.

I am always concerned. The vocal clinician pushback against information sharing as it has been promulgated by the Cures Act final rule. The sky is falling mentality. The desire to preserve paternalistic data silos and disengage or maintain the disengagement of patients from their own data. I take care of patients. I totally understand this. We have the technology, workflow, and human communication tools to

do this absolutely great. I think that those who are trying to fight this evolution in health data access are largely distracting us from our goals. We can have that conversation elsewhere.

Anyway, that was just to your point. To the recommended text, I think it is great to wrap this into TEFCA and our approach to TEFCA, but again TEFCA today is purely voluntary. Saying that individuals will have the right to access all of their data that happens to be available through TEFCA exchange is a very hollow promise. Today, there is no data available through TEFCA exchange. I have no idea whether this calendar year, there will be any data available through TEFCA exchange. Until we have more substantial care acts and it eventually sticks, there will not be a significant amount of data available through TEFCA exchange.

Hitching this wagon to the TEFCA horse is to me a way of kicking the can down the road, as opposed to looking for levers that we can implement today through ONC, CMS, CDC et cetera. To either incentivize this behavior or incentivize TEFCA exchange. We have to do one or the other, or I could be retired and dead before we see any progress.

Medell Briggs-Malonson
Two different thoughts about what you each said.

Eliel, going back to your comment. Access, especially allowing our patients to have access to data, is, 1.) Very important, but it definitely does bring significant concerns from physicians. Not just because of, “Gosh, we have got to block them,” from a paternalistic standpoint, but also, oftentimes, I think, from a compassion, empathy, and care standpoint. For instance, if I am taking care of my patient and I do a CT scan and it is very clear that they now have a primary malignancy that potentially is spreading through their abdomen and chest, I want to be the physician that actually goes and speaks to them about those results before they are actually hit with that radiology or pathology report that is telling them that they have cancer. They have not had a chance to: A). Hear it from a provider, but most importantly, talk about what the next steps are.

There is that compassion, empathy and high-quality equitable care aspect of it. As Steven said, I think there are different technical levers that we can deploy in various different types of scenarios. I do feel it needs to be very thoughtful, or else we will cause more harm than what we have all intended in these particular cases which I know that so many people around the country have thought very deeply about. It will be really important to move forward, but we have to reassure, I think, our physicians in particular, that those safeguards will be in place so that it does not take away from that beautiful and important patient-provider interaction. Especially in these times of greatest levels of patient vulnerability.

Yes, Steven, I agree with you as well that we have to push forward with having that access to information. TEFCA may be one vehicle, but are there other vehicles? Maybe that proposed text that ONC is providing is actually using TEFCA as an example instead of **[inaudible] [00:52:37]** centering it as the be-all-end-all as we are continuing to see what continues to evolve with TEFCA.

All right. Wonderful. Go ahead, Eliel.

Eliel Oliveira
Thank you both. I just want to say I completely agree with Steve there on TEFCA. The fact that, yes, it is voluntary, so we may not get to that on-ramp in everything. That is a great comment. On the earlier

comments about the paternalistic controlling of data, I am completely there with you as well that we have got to pass beyond that. Right? We need to let individuals get access to their data. To me, that is the most important thing.

I raised that point as well because that is one that I keep hearing a lot out there when we are talking about these possibilities. What do we say? What is our answer? Are we really saying that in the Cures Act, basically, you have to accept the exceptions that we have on information blocking, or not? How do we define that?

On your same point, Medell, I have had that situation in my family where someone had that diagnosis, cancer, for the third time. We did not hear of the results until we called back two to three weeks after. It was necessary for that to have been an immediate response. Right? That someone had reached out. Now we have a family member, two weeks further into cancer treatment that was going to be very difficult when we needed that immediate response. It is very hard to define where we draw the line. Anyway.

Medell Briggs-Malonson
The technical workflows have to be directly coupled with clinical workflows and accountability as well.

Steven Lane
And with the training of clinicians.

You and I both know this Medell. This can be done through strong communication skills and compassion. These are human skills. This is not a technology problem. We should not use technology as the scapegoat for failing to empower patients with access to their data.

Medell Briggs-Malonson
Absolutely. Great conversation everyone.

It looks like we are going to approve this language, but maybe with some small revisions as well. Especially because right now it looks to me that it is centering on TEFCA. Maybe modifying thatlanguage a bit based on the discussion we just had so that it is very clear we have to move forward, definitely with TEFCA. Also, just in general, we have to move forward with increasing patient access to information.

All right. We can proceed on, Accel. We can keep scrolling down. I think this is the last one, yes because we are now as to the references. Once again, I am looking at patient access to information. This is another revision coming from Deven. I am looking at the safety and impact of mobile health apps. This is always an area I love diving into as well. Our language was that there are a few private-sector efforts underway to vet out. For instance, there is the collaboration between the American College of Physicians, the American Telemedicine Association, and the organization for the review of care and health applications called the Digital Health Assessment Framework. This framework assesses apps based on data and privacy, clinical assurance and safety, usability and accessibility, and technical security and stability.

What Deven is actually recommending based on what our original language is, is that the issue of lack of assurances for privacy and security and reliability and validity of patient-facing apps is a real issue. Yet the draft mentions only private-sector effort aimed ataddressing these gaps, which suggests HITAC has already

made a decision to recommend a single existing resource initiative.While I agree it is valuable to look at existing private-sector efforts, the record seems a bit thin to suggest landing on or even mentioning one particular effort.

The proposed language by ONC is that the CARIN Alliance offers a code of conduct with best practices that encourage better and safer apps to which app developers can attest. The organization for which the review of care and health applications offers Health IT developers assessment and accreditation for their technologies.

I just wanted to see what everyone feels about this. In terms of not only Devin's comment which is definitely spot on. I do not think that we were recommending one single additional resource. I think that was put in there as an example. That actually shows we may have needed to highlight that that was an example. We did put, “For instance.” I wanted to see if there are any other thoughts or comments about this piece as well as the proposed new text by ONC.

Steven Lane
Well, Medell, I agree that this is spot-on and appropriate. I like expanding it. One thing I will add, and I am not sure if it needs to be in this text because it is a work in progress, is that Deven and I and Genevieve and a couple of other people are actually on a task force presently with CARIN. We are developing an iteration of the CARIN code of conduct that would apply to intermediaries such as Genevieve’s company, Deven’s company, and my company, that want to be able to participate in and support the CARIN code of conduct. That original document was really designed for the B to C app developers, as opposed to the other links in the chain that support this data exchange with the apps.

There is more work being done on this, but I do think this particular proposed text does make sense and captures the key point.

Medell Briggs-Malonson
Thanks, Steven.

Eliel Oliveira
Thank you Medell and Steve. I think, given all the work that we did on this front, I know how important this is because apps are coming out from everywhere. I do believe, though, that just like EHR certifications through ONC, there has got to be something beyond just a code of conduct. Someone that actually authorizes, or not,certain apps that access healthcare data, should they not be available to the individuals.It is something that does not exist today. Right? We have FTC regulating access to information online. We have HIPAA and some other regulations. I do not think we have anything for this. I think there is a lot of open space here for harm, in my opinion, and some oversight is necessary.

The example that I am going to draw here might not be a perfect one, but it is one that, I think, creates a motive for this. We see the ecosystem of apps for the Apple App Store, and we have an ecosystem of apps for the Android App Store. Right? In the Apple App Store, Apple basically says, “We vet every app. Nothing we do not like is going to go.” We have an environment that, honestly, I trust. That somebody is watching for me and making sure I do not have anything that is going to create a challenge. On the Android, I think,

maybe things have evolved, but he last time I checked it was open market. There are benefits to that as well. There is more innovation and other things, but I do not trust my Android devices as much.

What I am trying to say is that there has got to be in healthcare, in terms of this app, maybe, both ecosystems. At some point, some federal agency needs to have that control, just like Apple in a safe environment that patients can trust. That this app here has been vetted by someone. I do not believe the code of conduct is necessarily going to take care of that fully.

Steven Lane
I agree, Eliel. It is interesting to note in that context that Epic's app store was renamed. Now it is being decommissioned, essentially. They have just decided that they are going to get out of the business of vetting apps. Even to the point of doing development review, which is what they had been doing for some time. I think it highlights the point that we cannot necessarily rely on private industry to self-police and self-regulate. I think the code of conduct and all the work that Ryan Howell and his group have done is wonderful and critical. It has really helped to raise the importance of this, but this is one of the roles of government. Right? ONC, I believe, should be working with other branches to help move this forward.

Medell Briggs-Malonson
Especially because of these types of applications. How often do we have patients come to their clinics or hospitals or emergency departments and say,"Hey, this app told me this," or,"This is what my calculation on my heart rate or blood pressure was"? In all actuality, if we do not have closer monitoring of the clinical validity of these mobile applications, without a doubt, it causes more harm. I agree with every single thing you are all saying. I think it is beautiful to have frameworks, but I think there needs to be some form of true review as well as certification of these apps. Especially because we are dealing with people's overall clinical outcomes and well-being.

This was something that we discussed when we added this in, which is one of the reasons why we wanted to include this. Now looking at that proposed text, does it capture all that we would want, or are there any additional items that we would want to include as well? It seems like we are all saying we do need to figure out some type of governance or accreditation, a true source, that may likely live more within a governmental agency versus, for instance, in the private sector.

Steven Lane
I think including a specific recommendation to ONC to engage with other applicable federal agencies to review kind of like they did with TEFCA. Right? Either identify or develop a federal framework to solve this problem. In the TEFCA space, they decided to kind of start from scratch and created the RCE, etcetera. Maybe the right thing would be to deepen the commitment to CARIN and the work that they are doing, and push that forward, or this other group. I think a specific recommendation to ONC to really take hold of this and move it to the next level. Not just identifying that there are these efforts going on out in the ecosystem.

Medell Briggs-Malonson
Correct, but actually really, truly, developing some type of structure review and certification process.

Steven Lane
Federally supported.

Medell Briggs-Malonson
That is federally supported. Agreed. All right. Any other thoughts or comments about this last piece?

Michelle Murray
I need clarification. Sorry. It sounds like we are accepting this change to the supplemental document. Are we now proposing another change to the report to add the recommendation, or is that in the parking lot for the future?

Medell Briggs-Malonson
One of the things, Michelle, we likely, now that we have had this conversation, need to look back at the report to see if there is any language that needs to be strengthened there. We have a little bit of time. Even if we can pull up the report to that particular area. I think this actually revealed that we are all in agreement that there needs to be some type of formalized structure for review, as well as certification of these mobile health applications. Making sure that it is rooted within one or more governmental agencies, versus just kind of exploring what is out there. We know so many of the different implications of these mobile apps when it comes to individuals' health. Is it possible then that we can bring up that section of the annual report in order to see if there is any additional language that we need to strengthen there?

Eliel Oliveira
Michelle, I want to bring up one thing. I will put the link here in the chat. You may be familiar with this IFI that the science and technology policy office issued. We responded to it and sent some suggestions to the White House related to this. They also issued a report that had some language related to what we are talking about that we can maybe use. I am happy to send you our response to them. I think there is nothing wrong with the language suggested. I think what we are saying here is there is a little bit more than needs to be done in terms of certification of these apps. They cannot just be open for anyone to do whatever they wish without oversight.

Steven Lane
Well, official government certification, not **[inaudible] [01:07:17]** various enslavers of private industry certification.

Medell Briggs-Malonson
One addition may be, there is a lack of meaningful governmental analysis and certification of mobile health app efficacy, as well as guidance on data security. Potentially just adding in that governmental oversight of not only the analyses but also the certification. We can kind of take that thread and go directly through our recommendations as well.

Michelle, what are your thoughts on that?

Michelle Murray
A lot of thoughts, some personal and some in my role as supporting this workgroup and also past work in patient access area. I know in the history of ONC, there is a lot of debate, whether it is in script or not for ONC. I think I would have to get some input from our leadership if they are comfortable with going this far right now. Especially in this late stage of the report. I tend to think this is more of a parking lot issue to pick

up in May when we regroup and go deeper then. I think there is interest in ONC, just looking at it. They are probably not willing to say we should be the group certifying now or in the future. It does not mean we will not get there, it just means right now, I know it is an issue. I guess I would recommend being a little cautious here at this late stage in the report, but it is of interest to us.

I do not know if that answers your question or not, but it is kind of my perspective.

Medell Briggs-Malonson
Thank you, Michelle. Yes, if you are able to receive any feedback from leadership about that. At least one of the things, and if we do need to table until May, in which we can then go deeper into it as far as we are kicking off our upcoming priorities, maybe at least making sure we are adding in the importance regarding the clinical validity and safety of mobile health applications. Really highlighting that piece is going to be important. What we are saying is that we want these apps to be rooted in clinical evidence that we knowwill not cause harm. Eventually, there will be some type of oversight of these applications and their development in order to be certified so that patients, as well as other providers, know that these applications are safe. That they were not just kind of developed in, excuse my language, the wild wild west, without any true input or clinical thought behind how they were developed.

Wonderful. Anything else for us to add on this piece? Okay, great. Robust conversation. Thank you, Accel team, for bringing up the report for us to take a look at what we had so far. We will be able to just work a little bit offline, Michelle, based on what you are able to receive from leadership. If anything, just refine the language a bit more so it is very clear that we are leading up to what we believe will be necessary. Whether it is something that is truly within ONC's scope, or if it is something that we would recommend for ONC to potentially explore with some of the other governmental agencies. This is a really important and emerging area of technology that we know directly impacts health.

Okay. Great. Yes. Let us pull up the next slides then now that we have seen the report. Are we able to go back to our original slides, Accel team? Thank you. No problem.

Well, we definitely thank Deven McGraw for all of her amazing comments. This has been very great. It has led to some wonderful discussions. We already went through the outline of the draft supplemental background. All of the revisions. We already touched base on that one. I do not believe there are any additional HITAC committee member revisions or comments on this document. We can go to the next slide.

Steven Lane
Medell, I will just point out that Deven had actually sent me some of her feedback before she submitted it to the ONC team. I am suggesting to her that she consider joining this workgroup when we reconvene later in the year. I think it would be great for us to have her fine mind and legal insight as we are doing this work next time around.

Medell Briggs-Malonson
Absolutely. Thank you for that,Steven. All right. Well, I will turn it over to Mike at this time for public comment.

Public Comment (01:12:38)

Michael Berry

Great. Thank you, Medell. All right, everyone, we are going to open up our call for any public comments. If you are on Zoom and would like to make a comment, please use the hand raise hand function which is located at the Zoom toolbar at the bottom of your screen. If you are on the phone only, press star nine to raise your hand, and when called upon press star six to mute and unmute your line. Let us pause just for a 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 and Aaron.

Medell Briggs-Malonson
Thank you so much, Mike. Let us move on to the next slide.

I think that may conclude today's workgroup meeting. I want to specifically thank all of my amazing esteemed colleagues that are on this workgroup. To truly just say thank you for all of your efforts, engagement, perspectives, and expertise that you have contributed throughout the past several months. We really do appreciate it. This report would not be where it is without each and every single one of you. We really do appreciate and are very grateful for you. I wanted to just say as well, thank you so much to our ONC team that has continued to support this annual workgroup over the past several months in order to get us to where we are today. There has been a large amount of work that you all have done. We really do appreciate you. Michelle, we thank you for your leadership. We again thank everyone else for all of their contributions as well.

Aaron, I know that you may or may not be available. I just want to make sure to give you the floor in case you have some additional closing remarks as well.

Aaron Miri
No. I appreciate it. **[Inaudible] [01:14:25]** good discussion. I am glad we are at a finishing edge here. It was good.

Medell Briggs-Malonson
Yes, it is. Thank you everyone for coming today.

Steven Lane
Medell, can I just pile on?

Medell Briggs-Malonson
Yes, Steven.

Steven Lane
A little more gratitude first to Aaron for helping co-lead this workgroup for a number of years now, and really setting the tone and rhythm that has kept this moving along. Medell, especially to you for you stepping up this past year as a brand-new HITAC member. Taking on the co-chairmanship of this with aplomb, elegance, and insight. I cannot thank you enough for the great job you have done in helping getus to this point.

Next Steps and Adjourn (01:15:08)

Medell Briggs-Malonson
Thank you, Steven, for the kind words. We appreciate you.

Great. Wonderful. Everyone have a wonderful day. We will look forward to seeing everyone at the full committee HITAC meeting on February 8th.

Aaron Miri
Thank you all.

Medell Briggs-Malonson
Thank you all.

Michael Berry
Thank you, everybody.

Medell Briggs-Malonson
Bye-bye.