Transcript

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

August 16, 2023, 2 – 3:30 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)

Mike Berry
Hello everyone and thank you for joining the HITAC Annual Report Workgroup. I am pleased to welcome our co-chairs, Medell Briggs-Malonson and Aaron Miri, along with workgroup members Hans Buitendijk, Jim Jirjis, Anna McCollister, and Eliel Oliveira. We are hoping Hannah Galvin will be also joining us soon. Public comments are welcome, which could be typed into Zoom chat or could be made verbally during the public comment period later in our meeting. And I would like to turn it 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 and it is such a pleasure to be in our second annual report group meeting for this year. And so we have a lot of great items that we are going to go over today and especially the discussion of our draft cross-work of topics. And so we look forward to a really engaging session as we continue to walk through those items. Aaron?

Aaron Miri
Welcome. Medell, what you said. Let us jump into it. We have got an agenda going today and want to give all the time in the world for us to talk through things. Let us start.

Okay, so I will start off. I guess I will go through the first few slides here. So, obviously, here is our workgroup. Here is all the membership of everybody. We are trucking along this year. I cannot believe we are halfway through August, but here are the members, next slide. All right, and here is where we are with our scheduling perspective. Right now, we are, obviously, the 16th meeting. We have another one on the 30th. And then the 25th, this is the fast-and-furious time where we are starting to get things done and bring it back to the HITAC, for consideration, next slide.

This is dates we will be going to the HITAC, so obviously we will be updating them, Medell and I, on the 17th. And then so forth and so on throughout the fall as we get to next springtime for transmittal, next slide. All right, so next steps here. Obviously, we are going to go through the crosswalk and talk more about some gaps and opportunities, along with recommended activities. We have gotten some feedback recently, from various HITAC members, great feedback, actually, around items we should consider. I know Michelle has been incorporating that, so we will be walking through the draft crosswalk and presenting on the 14th of September, and then, of course, over the fall, next slide. Okay, Medell do you want to take it from here?

Medell Briggs-Malonson
Sure, I will take it from here. And you know, Aaron, there are so many items. How about we split this up as well, and we will do a couple of sections each?

Aaron Miri
Done.

Discussion of Draft Crosswalk of Topics for the HITAC Annual Report for FY23 (00:02:31)

Medell Briggs-Malonson
Wonderful. Let us ahead and dive right on into the draft crosswalk of topics, for this year's annual report, next slide. So, as we did very similarly to last year but also the years prior to, we have the crosswalk divided by specific target areas. And so just to orient everyone to this again, and especially because we have new members of our annual report group, if we go across in the columns we have our landscape analysis topic, which will actually deliver each one of the topics that we are going to discuss, followed by the gap column. So why are we even thinking about this topic, to begin with? Looking at the challenges and meaning the true implications of this topic and these gaps on how we deliver care, and how our systems work. And then, that is where all of us come in, in terms of the various different opportunities that we have in order to address those gaps and challenges, as well as propose recommended HITAC activities in order to support ONC as well as other entities.

Starting up with the very first target area, this is the design and use of technologies that advance health equity. The very first topic is artificial intelligence. The gap that has already been identified by several members of HITAC is that AI holds significant promise in solving healthcare problems, yet research and regulation are necessary to ensure that bias and harm are not implemented in the design and use of the new technologies. The challenge that has been identified is that AI that furthers inequities and biases is a significant concern that must be balanced with the potential benefits, as policymakers develop efforts to regulate AI. Now, we are going to open it up to all of the various different annual report group members, so really talk about where are some of our opportunities. And this is also in relationship to even the proposed rule for HTI-1 and some of our HITAC recommendations there. So, we will open it up to the group for this very first topic, and say what are some of your thoughts? And what are some of the proposed HITAC activities that we can provide?

Jim Jirjis
Medell, it is Jim Jirjis. Just so I understand, in the annual report there are things that we did, that we recommended for HITAC, or responded around demonstrating in the EMR, for example, limitations to any particular algorithm. Are we describing here what we have done, or are we also talking about what we should do next year, or both?

Medell Briggs-Malonson,
It is a little bit of both. I think that there are some opportunities to 1.) We will absolutely highlight some of the other workgroups that have been working in various different areas. So for instance, the HTI one group was a very large workgroup from this past year and so we will highlight some of those, that work and recommendations. But also from the annual report group, we want to see if there are any additional recommendations, that may not have been developed directly by the previous workgroups that we want to propose to ONC as well.

Aaron Miri
I will give you an example, Jim. Aaron Neinstein had a great point around patient-generated health data interoperability, so platforms not expressly covered as certified health IT systems. But tangentially get into the health IT ecosphere, that maybe do not have the same rigor and requirements as others. But we, obviously, on the provider side leverage those in some cases. So, how do we deal with that? That is a net-

new per se topic that does touch upon previous topics of prior years. But now it is a good time to talk through that, right? So, that is a consideration point. Just as an example, Jim, that kind of where Medell is going towards.

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Jim Jirjis

Well, in this one, I was going to say the FDA has been doing a lot of work, at least with publishing their guidelines or whatever their approach to this. And it sounded like HTI-1, we were actually embracing that by operationalizing what the FDA was suggesting. So, that is something that we did. One thing that we might think about is, okay, let us say that all happens. Is there an opportunity? I mean, what happens if someone suspects an algorithm is not performing, or is being used in a way that is that is biased or creates harm? Is there an opportunity for us to recommend any kind of reporting? Or is that the FDA's responsibility?

Aaron Miri

This is where we get into lines of demarcation. What does ONC have jurisdiction over or not? And where we usually as a group defaulted historically was, if it did not cross into our swim lane, we invite that agency from the swim lane to come talk to us and brief us on what they were doing. And we try to incorporate that as a process. Or if there are things on the ONC side that we can assist them with and recommend to the ONC to do, better communication, better documentation, better standards development, co-standards development, those kind of things, then we can help them.

Jim Jirjis

Well, then one suggestion would be if there are third parties that do not fall under the umbrella that are providing algorithms as a service, if they do not provide that baseball card that gives the different attributes that we are talking about, how are we going to track whether people are actually providing it or not? That might be a recommendation.

Aaron Miri

Yeah.

Medell Briggs-Malonson

I agree with that, Jim, as well because even with of our prior conversations, we had clearly discussed it is really more focused on the interface between some of these other FDA-approved technologies and the interfacing with certified health technology, which is maybe more in the ONC side. So, exactly as you are mentioning, making sure that we amplify what we had mentioned before about appropriately monitoring and documenting when certain standards or requirements that are defined by FDA and others. So that we can actually propose to ONC, of saying if this does not happen then maybe there is some additional lack of certification for those various different technologies.

Jim Jirjis

You are right. Like with FHIR, I know that Ken Mandl and I, and a couple of others worked on EMR reporting requirements for FHIR, just for the EMRs to report to ONC what people were exchanging, etc., through FHIR. Without any consequences, step one might be simply us recommending that ONC develop a reporting program so they understand who is and is not adhering to, particularly, these third-party vendors, so at least they get information because if they find that all of the third-party vendors are adhering, that is a

very different problem than if they find that only 5% are doing it. So maybe we start with just a reporting so they can get data to determine what next steps may or may not need to happen.
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Aaron Miri
Good suggestion.

Medell Briggs-Malonson,
Absolutely, so we have a lot of hands up as well, that I know **[inaudible – crosstalk] [00:09:44]**.

Aaron Miri
Oh, sorry, I raised **[inaudible – crosstalk] [00:09:44]**.

Medell Briggs-Malonson
That is okay. That is all right, great conversation, Hannah, I think your hand is up next.

Hannah Galvin
Thank you. As we have mentioned, there was a lot about AI and bias, as well as, being transparent about the AI technologies in HTI-1. I know that ONC staff cannot comment on rulemaking in process, but I wonder if we have a sense of when that final rule is going to be coming out because we have made a lot of comments around the NPRM, and that a lot of what may shape the Annual Report, may be based on what actually ends up in the final rule. Do we have a sense of whether that is going to happen in the next few months or after the first of the year? I think that may shape a lot of this category, and if it is going to happen sometime soon, we may want to come back to this category after the final rule is dropped.

Medell Briggs-Malonson
Really important piece. Michelle or Mike, of course, cannot comment on that now. But is there a way that we can get a ballpark from ONC regarding when that may finalize?

Michael Berry
Yes, we are working hard to finalize HTI-1 by the end of this year. Assuming it makes it through all the clearance processes involved, that is the goal.

Medell Briggs-Malonson
Thank you so much, Mike.

Aaron Miri
Which is a really good point. In prior years, for new members as a committee, when there was a rule going through rulemaking we did try to table things and put it into a parking lot, so that we allow the final rule to come out, allowing for any adjustments or incorporation of feedback, or whatever else. Obviously, suggestions matter. If there was something very timely, we always encouraged the individual to write in those comments and comment in officially. But to the degree that it is a great point, that during our rulemaking we probably will parking lot an item just to see where things land. Example being what we did with TEFCA many years ago related to the final rule. We just want to wait until that was out.

Anna McCollister

Does that risk it not being considered when it should be considered if there are elements that we recommended as part of HTI-1?

Aaron Miri
No, that is what we were saying. If there are urgent items identified, we would try to then say, why do you not write in officially, and comment directly to the ONC. And say this thing is reading wrong, or I just have a suggestion, or whatever it may be, because the ONC is accepting every bit of feedback. And they incorporate, they read, everything.

Medell Briggs-Malonson
All right, Hans, so really great points, though. Hannah, thank you for bringing that up. Mike, thank you for the clarification, and Aaron, also some of the context of how we can continue to proceed that way. Hans, your hand is up.

Hans Buitendijk
I was wondering if there will be something between what was proposed and not likely nothing in the rule. Something will likely be there. And then looking at the timelines that will be proposed, if adopted as proposed and discussed, two or three years out is before we are starting to see that roll into where it applies to certified HIT. And I think as part of the conversations, and why I emphasize HIT, I think we want to be very crisp in this conversation around, are we talking EMRs and EHRs, or are we talking HIT? And is part of the scope for ONC those systems that actually provide and create the AI, and where that learning occurs the algorithms are defined, and the outcome of that is being used by EHRs and provide focused systems to then apply that in their workflows? Or that it is not directly in patient-specific workflow. That it is part of their decision-making on protocols, processes, and enhancements, changes in practice, whatever it might be, because it is population-based knowledge that is being garnered from that.

So I think that we want to, in whatever we talk about, recognize that are different points. EHR may have AI capabilities directly in it, but also it might not and it comes from somewhere else. We need to distinguish that, and not put everything in the EMR and EHR bucket. But looking at that and not knowing what is going to come out, the extent of what could come out is transparency in what the capabilities do, and from that, we can provide that information. But a big dependency where the comment has to come from that scorecard report card, layover, whatever we want to call it, on the actual developer and the actual performer of the AI.

I am wondering whether that means in that period of time of two or three years when things are starting to ramp up, is the recommendation, besides what Jim is making off maybe report card or otherwise, is it proper to suggest that there is a task force, a workgroup opportunity to, now, based on what is in the rule, identify opportunities what kind of guidance, education. awareness, otherwise, needs to be built. Where do people need to look might already be out there. Maybe not that ONC has available, but FDA or otherwise, but that we look at the space. What can we do as recommendations to prepare for, and already inform whoever is going to develop such AI and otherwise to be used, and again not just focused on the EHRs? Yes, that is where ONC mostly focuses with its certification, but other HIT that can be certified, or HIT or IT that contributes to it that may not be certified ever.

Medell Briggs-Malonson
Awesome point there, Hans, and so what I am really hearing you say is what can we do in the gap?

Hans Buitendijk
Right.

Medell Briggs-Malonson
And what can we do to actually be proactive, very similar to what Jim was mentioning? I think that is a really great idea. Aaron, I do not know if we have done this before in the past, and Mike and Michelle might also have some insight. But when we are in the process of an interim rule in which it has not finalized, have we as HITAC ever taken what we proposed for that proposed final rule. and just almost done a gap assessment of saying, like, we do not know where it is going to hand, but A). Are there any other areas for opportunity that we can recommend, so similar to Jim as well as Hans's comments? And B). If some of these items do not go through, what are some additional recommendations so that we are not just waiting, for instance, for a long period of time for some of these different rules to go into play? Have we ever done that as an approach?

Aaron Miri
I am racking my brain, Medell. In my recollection, no. We have always done the HITAC recommendations to go into the interim ruling, but never that post interim, prefinal reassessment, that I am aware of. Michelle and team, keep me honest here.

Hans Buitendijk
Maybe as a follow-on there, is that by the time, a task force, would be pulled together, or group of sorts pulled together, the final should be out because we are talking next year. So, I am not sure whether it would be focused on what would be due until the final rule comes out. But a reasonable assumption, the final rule will come out. We just do not know what is in it. There will be areas of work to be done. If everything is filled in or if something is filled in, there will be work to be done to get ready for it as part of the next two years to ramp up. Is there something we can do in recommendations to ease that path?

Aaron Miri
Right.

Hans Buitendijk
And ensure the path lands where we want it to be.

Aaron Miri
Mike, Michelle, do you guys know for certain? I cannot recall any time we have done that.

Michael Berry
Michelle, did you have a comment first, and then I will make mine?

Michelle Murray
Sure. Yes, I was around then, although I did not work directly on that stream of work. But what I observed was that there was a formal, written effort to create a plan to capture everything that did not make it into the comments or through into the rule, but that as ad hoc concerns came up we addressed them through task forces and hearings. So, it was more of an ad hoc approach. But what you are suggesting is maybe be a

little more strategic. If we have a good list of things, I think somebody else just mentioned, that we might not know what is the rule yet. I do not even know, so timing is a bit of an issue for this cycle. But it could be next year's report that needs to take up some of these more explicitly. There could be more of a general topic or action for this group to recommend, that when that is clearer we tackle that. I do not know if that clarifies or not.

Medell Briggs-Malonson
It does, thank you. Mike?

Michael Berry
Of course, the comment period for the proposed rule is closed, so everybody at ONC is working on adjudicating those comments, currently, and so the final rule is the final rule. The focus could be on items that you did not already recommend because, of course, the HITAC was a big contributor to that public comment period. So, if you have items that were not discussed in the task force that the HITAC did not already recommend, then those are fair game to list in your report and be helpful for the future.

Medell Briggs-Malonson
As well as the proactive approaches, correct?

Michael Berry
Correct.

Medell Briggs-Malonson
Okay, great, thank you for that clarification. Eliel, we see your hand, but Anna you had your hand up, I think, before Eliel, but then your hand went down. Did you have any additional comments?

Anna McCollister
I feel like that was four thoughts ago, so I am not sure what it was. It is fine.

Medell Briggs-Malonson
Okay.

Anna McCollister
Maybe I need to take better notes on my thoughts.

Aaron Miri
It will come back to you.

Anna McCollister
Part of my struggle, as I am trying to figure out, exactly, A). What the role of this group is, and how it works, and B). In light of that, how I can be most constructive in terms of my input and what I suggest? Part of what I struggle with, HI1, as well as some of the comments that were made earlier with this group, is what is the difference between the jurisdiction of FDA over AI, AI uses versus ONC, and is it duplicative. Do we need to suggest that there is more of a line demarcation? Or would that be a lost opportunity to have some type of regulatory fair play if they are missing pieces in FDA policy that ONC could then write?

Jim Jiris
Can I make a quick comment on that?

Anna McCollister
Sure.

Jim Jirjis
My understanding is that the Office of the National Coordinator, that there are a couple of functions. One is there is direct responsibility to draft regulation through its regulation process, the HTI-1, etc. But the other responsibility is to coordinate across organizations. And we have seen Mickey do a great job with coordinating asking with CMS. Sometimes rules come out at the same time that complement each other, right, the FDA, the CDC? HITAC advises the ONC. There is a role, to make comments about if the FDA is up to something, what can the ONC do to complement that? And I think we saw that in HTI-1, around Public Health reporting. In my opinion, and I would love others' thoughts on this. But Aaron and Medell, it seems to me that it is fair game to actually recommend collaboration. That is because that is part of their responsibility. Is that accurate?

Aaron Miri
I look at ONC, and I have voiced this directly multiple times, as a very sophisticated air traffic control. They help coordinate the agencies and work efforts. I think, to the point of it, if we take an analogy, Anna, to your point, let us assume there is something squirrelly in the FDA's ballpark. It is one of their innovation items or AI items, something specifically they are doing. But it does have an intersection point with something around certificate health IT that we are working on. Clearly, most things they do, do. Then we could recommend we do need to work collaborate and collaborate on X, outside hold a joint hearing on XYZ, or whatever that topic as is, as air traffic control would do when dealing with airplanes. I think it is a great point. It is fair game to recommend that. We just cannot mandate, right? ONC has no way to tell the FDA thou shall do this. That is not how that works. They really help with the coordinating entity and do a great job of it. Hopefully, that is a little bit clear situation for you.

Anna McCollister
It is. It is very helpful, so thank you to everybody. For instance, with the algorithmic bias, one of the recommendations that I and others wanted to put into what we ultimately recommended to ONC, was transparency about inputs and aims as well as outputs. I think that is going to be absolutely essential, both when you are looking at racial and ethnic equity or other types of health equity issues, as well as differences in different populations. I use a continuous glucose monitor. That calculation is driven by AI.

Because I was on an advisory committee overseeing one of the label changes for that I have an idea of what the data is. I do not think it is particularly reflective of data that CMS would need, etc.
If they could be more transparent and open about what exactly are the inputs to specific algorithms for various things, which should be doable, then that would be beneficial across all the HPCs and for individuals. Is that the kind of thing that you are interested in?

Medell Briggs-Malonson

Yes, and Anna, to directly address what you mentioned, and then also to add onto what Aaron said. And I love his analogy of air traffic controllers. The other piece is really making sure that those recommendations that we provide are within the authority and jurisdiction of HITAC as well. Technically, we cannot say that these other agencies should do, A, B, or C. We are here as an advisory committee to ONC, in particular. So, we just want to stay within our scope.

But yet, of course, you know ONC has done a fantastic job as everyone has said, in terms of coordination. So, we do want to look. We are set here to really focus on how we can be very forward-thinking and make sure to bring our areas of expertise to the table, to help support ONC and everything that is within ONC's scope and jurisdiction. While that can also, of course, mean we love the collaboration. That collaboration is very important because then there is that bidirectional partnership, and we can ensure that all of the various different areas are cared for in order to provide the best services to our patient populations, as well as to have structures that are based on integrity and justice. So all of those different pieces that you mentioned, but just kind of within our own playing field as well.

All right, Eliel hopefully you did not forget. It has been a little while.

Eliel Oliveira
Thanks, Medell. I do not know how many of you are familiar with this. I will put the link on the chat about the trusted AI playbook that HHS put together. But I got familiar with it because I was asked by the Office of the Assistant Secretary for Planning and Evaluation to take a look at it and provide some suggestions and met with folks about that. So, I had to actually understand it really well, and there is so much content here related to our algorithmic bias that we are talking about, that I think we can really benefit. What Steve **[00:27:12]** and others are doing at ONC, who were a part of putting together the playbook, so I think it is a resource for us, maybe as a proposed or recommended activity here, a listening session of deep-dive on that playbook that could influence what we talk about here.

But as I was participating in that session with them, with us, and others, one thing that became apparent reading all that is that we do not have an identified agency that actually regulates anything on AIs, as you all know. And, of course, we at times talked that the FDA could end up being on that. But I think that maybe the opportunity here is to advance a little bit because I think the federal government is trying to figure out exactly what to do on that front. And in our charge is how do we then define what are the standards for any AI to interact with EHRs and other electronic systems? What are the certification criteria and other things that we need to have in place? Anyways, I hope that is helping. It seems like that could be an activity for us to learn more about the playbook, and then see how that intersects with what we do in terms of the standards. But also keeping an eye on the fact that maybe that is where ONC can also provide guidance and that we need a definition of who validates these methods and algorithms and approve them, And how we then allow those to interact with the electronic systems.

Aaron Miri
It is a good point. Historically, when we have new technology emerging on the market we always held listening sessions to seek first to understand what is happening across the agencies. And then to your point, to be able to responsibly have oversight for patient safety purposes or whatever may be the point, Eliel. I think it is a great point. I honestly, do not know if there is an AI, this is Aaron's words here, a tzar of some sort to oversee all those efforts. I do not know that. I know there is a lot of work going on. But it would

not hurt for us to learn more, as this Workgroup or as HITAC, what is going on with AI policy regulation and development, and how do we best help coordinate that with our response, if that is what you are going after it is a great point.

Medell Briggs-Malonson
Yes, I agree. In fact, I was actually in a discussion, literally yesterday, about that exact piece of what you said, Aaron, And also what you are mentioning, Eliel, is that there are so many different agencies, so many different other entities that are working on this; but who is actually coordinating it, and what are the true policies and standards that are rising to the top? Just to summarize what everyone is saying because this is a wonderful conversation and discussion but we are only on the first topic, so from what it sounds like, and we can come back to this, it sounds as if we, as the annual report workgroup, are recommending two items for this landscape topic.

Please let me know if I have this correct or not. 1.) To do a listening session to understand more about the AI policies and work that is being developed by the various different federal agencies, but also all of the other entities that are out there. 2.) To develop a task force that will look into appropriate support and implementation of the final rule for HTI-1. Therefore, that task force can go a little bit deeper into exploring the various different opportunities that we as HITAC can recommend in order to ensure that the rollout of the rule in two or three years will be as successful as possible.

Did I sort of capture that, or any other modifications?

Hans Buitendijk
No. That sounded great.

Eliel Oliveira
Sounds great.

Medell Briggs-Malonson
Okay, wonderful.

Anna McCollister
Thank you, Eliel, for sharing that report. I had not seen that, nor did I know we had a Chief AI Officer in HHS, so that is helpful to know. I love the idea of getting some sort of a note.

Medell Briggs-Malonson,
Absolutely. Okay, great, everyone. Thank you for that. Now onto Topic No. 2, missing health IT infrastructure for health equity and social drivers of health data. And one thing for the annual report group to notice is that we have now officially adopted the term “drivers” versus determinants of health, in order to really incorporate how dynamic these drivers are versus determinants being very static, and almost seem deterministic. But really that we can impact people’s health by addressing these drivers because of their ability to either improve or worsen one’s health and overall healthcare outcomes.

The gap that we actually have and noted, is the collection of health equity and SDOH data remains inconsistent due to a lack of standardization and frequency of the recording of this data, and the lack of

adoption of IT tools by community-based organizations. The challenges that we know exist are that additional standards are needed to support the collection and electronic exchange of health equity and SDOH data. And many CBOs lack the IT infrastructure to support collecting, sending, and receiving SDOH data. So, I want to definitely open it on up to the group and get some of your thoughts and feedback on this very important topic that we have discussed as well. Hans?

Hans Buitendijk
Yes. A question that I have around the first bullet, that perhaps we need to be more specific in our recommendations, or is there an opportunity for otherwise identifying what they are? And part of it is just that there are a number of standards that are currently being updated to enable exchange of such data. Some of that is starting to be published. Some of it will not happen based on where they are, over the next six to eight months, etc. So, there is work in progress that will address a body of work there. But is there something missing there? And how can we identify what that might be? Or is the work in progress covering it, and once it is published then we have the standards? It is now a matter of implementing it. I am not sure where we are on that space, and whether we have a clear understanding of what is the full data set. The core, I think, is understood. But is that, indeed, the complete set that is relevant, of interest?

And second, is then what kind of work is actually needed to add that to the standards? But mostly, probably, how do we go about implementing, adoption, utilization, etc., of the standards that have been published?

Medell Briggs-Malonson
All of the above, Hans, I would say. **[Inaudible – crosstalk] [00:34:33]**.

Aaron Miri
Sorry, Medell, I apologize.

Medell Briggs-Malonson
Yes, really quickly because we know there is a large amount of work that is being done in order to try to define them. This is very similar, I feel, to AI. There is a lot of work being done on SDOH and health equity data, but is there a primary core in which we know that it is fully comprehensive?

Hans Buitendijk
Right.

Medell Briggs-Malonson
And that is even one of the areas that I have struggled with. That is something that we **[inaudible] [00:34:59]** that can be part of our recommendations and making sure there is full clarity in terms of what is being worked on, and even we as HITAC, do we feel that is very comprehensive? But then also what you mentioned, Hans, about the true integration of that within all of our health IT systems, as well as the adoptions and the appropriate use of that data is also very key.

Aaron Miri
You are exactly right, Medell, I apologize for stepping on you a second ago. I thought you finished your thought. What I was curious, Hans, just double-clicking on what you said, do you mean data elements outside of the USTDI process? We started to touch on SDOH elements, as you know, with a certification

process. So, I am taking it you are looking at all other dimensions, all other aspects of those determinants that are already on the USCDI list. Is that what you are asking?

Hans Buitendijk
Yes, because effectively I do not think it is just about **[inaudible] [00:36:01]** additional standards, but if we talk about this topic, it is what is there when it is coming out, we have them. But now it is also the promotion and inclusion of those appropriate.

Aaron Miri
Got it.

Hans Buitendijk
There are aspects that are not to standards or technology. Data is hard to collect. What is the right place to collect it? What is the best source that people feel comfortable to share the data, where they might or might not? And how is then the privacy and security, privacy particularly, how is that managed to make sure that it is used correctly, appropriately, etc.? We have to be careful that, in order for it to work, ONC clearly focuses on the technology and standards aspects for that. But we need to recognize that those other elements are in play as well, to actually make it useful and indicative of what we are looking for.

Aaron Miri
Thank you for clarifying.

Hans Buitendijk
And unfortunately, I need to jump.

Aaron Miri
No problem, Hans. Thank you for your comments.

Medell Briggs-Malonson
Thanks, Hans. Have a great presentation.

Hans Buitendijk

Thank you.

Medell Briggs-Malonson
Eliel?

Eliel Oliveira
This is a good discussion, and from my perspective, given the **[inaudible] [00:37:10]** that you guys saw and I presented a little bit, you may recall how I was talking about, even within one provider, their needs assessment was 53% of the data elements they were capturing did not have a standard on gravity. So, there is a need here to probably continue that gravity of work, to expand the definition of standards because there is still a lot of empty spaces if you will. I think that is one of the discussions we had on our side at the face-to-face HITAC meeting. But then the other piece that becomes quite important, which, I think, is related

to the CBOs like IT infrastructure and all that, is some work around pilots, beyond the one that we just demonstrated a bit. And how a landscape analysis of the systems that CBO uses or not, that can allow us to maybe advance on how the CBO's integration would be advanced.

There are so many types of CBOs out there. What electronic systems do they use? Do they even have computers? A landscape analysis would help us quite a bit in terms of defining a pathway to developing a way to integrate these organizations in an electronic system. I hope that makes sense of the two things that come to mind when I read this.

Medell Briggs-Malonson
It definitely does. Extending the work that the Gravity Project has done in order to ensure that we do have that full comprehensiveness of some of the various different elements, but then also how do we support the CBOs. If I can add one thing, that infrastructure, and especially for those of us that work with the CBOs and really trying to address social drivers of health, the infrastructure is not there because the money is not there. Hannah, I see your hand.

And so, that is something that we also really need to consider, the financial aspects of actually, helping to support the IT infrastructure, as well as the training of the staff in order for them to fully understand the full interoperability capabilities, as well as how to use the data appropriately. That is all part of this, the funding for both the creation of the structures as well as for personnel support, as well as sometimes even for patient support. That really has to be considered. Hannah, we see your hand.

Hannah Galvin
Thanks, Medell, I want to echo that. ONC has developed programs in the past where there has been a need. We are a public health IT workforce program where there was a need and highlighting the need for IT infrastructure for community-based organizations in this case, specifically, around social drivers of health. Not just around social drivers of health, but the ability to share PAMI data, problems, allergies, meds, with -based organizations, with schools and school nurses, that type of information in a structured way. I wonder if that might be one ask, is a program that would develop the framework up to fund CBO in some type of **[inaudible] [00:40:57]** based way, doing house grants for CBOs to have that infrastructure.

The second thing I was going to say was working with HHS and other executive branch partners around how social drivers data will be used in creating policy and legislation around that. People are going to disclose social drivers, and they are incorporated then, not just into the health record, but we have more and more payers that are asking for this data, purportedly for the benefit of patients, to be able to get them transportation services, and other sort of services that they need, food services, if they need them. But this data is out there then, and can be used, ostensibly, in algorithms. We already know that patients who have social drivers of health have more healthcare needs. And it is not launched. It is not happening already that payers or others who create actuarial algorithms are going to start using this data in those algorithms. Working with legislative partners to understand how this data would be protected and not used in a way that might be compromising to the individuals who disclose it, will be important the more it is shared across the agencies.

Aaron Miri
Good points, Anna, great points.

Medell Briggs-Malonson
Absolutely, definitely that area of privacy as well for our patients, absolutely. All right, so, any other thoughts or comments about our missing health IT infrastructure?

Aaron Miri
I like the comment, Medell, that Hans made, and tying in what Eliel and others have been saying around determinants, those data elements. If I take patient-reported outcomes, PROs, as an example. They have been around for a hot minute, but we are still struggling to incorporate PROs as standard nomenclature into our data sets. And how do you distribute that and share it and is it a part of a data set you share with others, all of these things as just one element of social determinants. How do we double-click that and expand upon that because there are so many different types of PROs beyond a PHQ2 or PHQ9, beyond a GAD, or beyond a **[inaudible] [00:43:39]**, beyond all the things, how do we begin to get those data elements that go into those, just as one example? And how do we begin to distribute that so that it is interoperable? It is a great question mark, and I do think as we get further into USTDI rulemaking, we are seeing the gaps more and more apparent. So, it is a great conversation.

Medell Briggs-Malonson
Absolutely. Anna, you just gave a great comment in our chat. Thank you for raising your hand as well.

Anna McCollister
Sure. Building on my comment and my understanding of social determinants of health is the data that would be relevant, maybe some of it is capturable and structured, but it would not be traditional health data. So, like, the number of grocery stores within a particular neighborhood, the number of physicians or specialists within a particular neighborhood or driving distance. Some of that kind of thing is accessible via an API in a structured format, but it is what I would traditionally think of as being within the domain of health data. And I am just wondering if ONC has jurisdiction over requiring and creating standards for whatever word we want to use, that sort of data input. If you tell somebody they need to eat more vegetables and there is no grocery store, then their ability to get it, then it is pointless.

Medell Briggs-Malonson
Agreed, and that is what we know we have been missing so often in healthcare for so long, of truly putting the experience of all of our patients right at the very middle, instead of just assuming that people and their families, it is all equal, they have access to equal opportunities when we know that does not exist, and this data is really key.

Summarizing what everyone has been mentioning, we have gone all the way from thinking about the technical aspects of social driver data, and we know that it continues to evolve. And so, what can we do to continue to support that evolution, as well as to ensure that there is full adoption, appropriate implementation, and use of that data? Whether that is through USCDO, whether that is through, again, charging the Gravity Project to continue all of their amazing work to expand that. But then also, how do we support our CBOs because we know this cannot work without our CBOs at all? We know that the CBOs historically have lacked a lot of the various different resources that they need, both physical resources, financial resources, and personnel resources, in order to help us to close this loop because, this has to be done in a partnership. So, what does that look like?

Even going, Hannah, what you were mentioning as well, some of those pieces are really important, and it kind of goes back to Eliel, about maybe additional pilots in order to continue to support and identify some of those best practices. But then also thinking about the use of that patient data, and the privacy of that data. And then Anna, we have to think about even the data that is going to be most relevant.
So, a lot of important concepts here, Hopefully, with this discussion, our ONC team will be able to help us sort of bring out more themes, for us, to really kind of drill down on it even more, so we can have some very clear proposed recommendations in this space because there are a lot of areas within this space, in order to really support this infrastructure.

Hannah, I see your hand too.

Hannah Galvin
Thanks, Medell. I just wanted to follow up briefly when we have the benefit of having Sarah DeSilvey from the Gravity Project on the HITAC, and we may want to just ask her her thoughts here. But I know the Gravity Project has done an incredible amount of work. I also know that they continue to struggle for funding. One recommendation may be, and we would want to, I think, consult her specifically, or the rest of the others in the Gravity Project about this, is an opportunity for a LEAP Grant or something like that to help fund this work going forward?

Aaron Miri
Same.

Medell Briggs-Malonson
Wonderful. That is a great recommendation.

Aaron Miri
Yes, great suggestion, Hannah.

Medell Briggs-Malonson
Any other thoughts or comments on this topic? Okay, not seeing any. Let us go on to the next one, increasing access to and accessibility of telehealth services. Telehealth has been a hot topic for many years, but this is also within the target area of designing the use of technologies that advance health equity, so the gap that was identified. Telehealth continues to bring access gaps but still poses a risk of exacerbating disparities, and so the challenge is patients. including those with limited English proficiency, visually-impaired, as well as space accessibility challenges in using telehealth. This is an area for us to also speak a little bit more of in terms of, how to do we really address this need to be inclusive as much as possible, in terms of not only our designs, as well as the accessibility of telehealth services.

Any thoughts? And I am just going to point to Eliel, because Eliel, I think this was one of the primary topics you brought up too in the past.

Eliel Oliveira
Yes, thanks Medell. I think that aligns well with the point that I put on the chat, about access to connectivity is a big challenge still for many individuals that are trying to get telehealth. I know that is not a standard, but

I think as part of our discussion here, is you have seen how much funding has become available federally for broadband. We talk about that here in Texas quite a bit. But then that is going to organizations in rural areas, not to individuals. And the underserved individuals continue not to have access. So, it is not necessarily a problem for HITAC, but, I think, important to highlight, that that is a big gap, still, to allow telehealth to exist.

And then when it comes to standards, I do not know of any well-established ways that telehealth tools; we all jumped on the bandwagon through COVID because we had to. But now that the dust has settled I do not know of any specific requirements that we have put in place yet to say that there is an integration pathway here for patient portals, and EHRs, so that these calls guarantee that I am having the discussions with the right individuals. I think that is one key concern I have always had. If you are on a phone-based call, especially now with AI voice, how do you know who you are really talking to? I have all kinds of concerns there, in terms of making sure that it is a secure channel that is initiated by the right individuals and organizations, and that we are not opening a door for social engineering, which you know, when is the biggest issue I have seen in terms of data breaches.

There are no standards that I know of on how these technologies are integrated to the systems today, so I think there is an opening door here for us to make some great advancements and start defining what that should look like.

Aaron Miri
Good point, Eliel. The standards I know of are really related around HIPAA or what the OCR has put up there, and pro tip, the 90-day grace period is expired. So, we go back to what is a HIPAA-compliant telehealth modality and what is not. So, I think to your point, Eliel, there is also some sorting through, post-COVID, what telehealth looks like now that the waivers that were relaxed are reinstituted, and those sorts of things. So, it is a great point on standards development now, interoperability, and what should it look like based on what we learned, during COVID. It is a great point, in my opinion.

Medell Briggs-Malonson
I agree. Not seeing any hands up on this topic I will jump in too. My observation was also about standards. In a lot of our other technology, and this is technology most of the time even outside of healthcare, there are certain standards that that technology has to be built with. I am not aware. Maybe it does exist. But I do feel like we are missing standards in terms of the overall accessibility and inclusivity of our telehealth platforms, especially those that deal with more video telehealth. We have some listed here in terms of limited English proficiency. But what I was thinking of as well is what standards do we have in terms of ensuring that all of our various different technologies truly are linguistically diverse in order to help to support our patients that speak other languages at home that are not English.

But in addition to that, we also know that we have so many diverse abilities of our patient population but are there standards to ensure that all of our telehealth platforms do support those who are visually impaired, and do support those who are hard of hearing as well? It seems like we need to have some baseline requirements. And maybe we have some **[inaudible] [00:53:49]** but I have been looking for some baseline requirements to ensure that there is full inclusivity of people and their various different identities, and their experiences, so that everyone is receiving equitable care. And it seems like that would fall directly within ONC's jurisdiction primarily due to the fact it is part of certifying health information technologies.

So, Hannah, I am sorry, Anna, I see your hand first, and then Hannah.

Anna McCollister
I guess I am a little confused about certain aspects of this one because, from my perspective, I feel like telehealth has helped get over some of the barriers to access, particularly for people who live in geographic regions or areas or have difficulty with mobility and getting access to care. So, I feel like it has actually gotten rid of some of the barriers to health equity as opposed to, increasing them. I say that knowing that it does require bandwidth and all of that kind of thing. And there is technology there, but smartphones are relatively ubiquitous at this point. Even people who do not have cable or a laptop have access to smartphones. Just thinking about my family and my relatives who live in different places that are not necessarily in big cities, it has actually made it easier for them to get care.

I am a remarkably white person from Ohio who speaks English, so I admit from the get-go that maybe I am missing something. But I feel like we do not want to restrict the emergence of new telehealth by putting a lot of burdens on **[inaudible] [00:55:58]** these start-up telehealth companies that might make it so cumbersome it might be a barrier to entry.

Medell Briggs-Malonson
Anna, thank you so much for those comments. I think that we can all agree that telehealth has actually increased access, as well as streamlined the ability to receive high-quality care through telehealth services. But one of the things that we have clearly noticed with the expansion of telehealth, is that those that are marginalized have become even more marginalized from those services. Eliel had previously mentioned in his chat, how, while we know that the vast majority of people have mobile phones, what happens is that in order to really get on a lot of our telehealth platforms you do have to have data plans.
And those data plans, at times, are not inexpensive. So, because of that, that does add some additional barriers.

In addition to that, what some of the different factors that I was referring to, about the inclusivity based off of one's ability as well as one's language; we have noticed significant differences in the ability to take care, to take part in telehealth services because of that, because our technologies are not really focused on that. So what we are really trying to get to is not really cause more hoops for our health IT innovators to jump through, but we are trying to make sure no one is left out, no one is left behind, and especially those that are most marginalized, that they absolutely can benefit from some of these new technologies. I always look at this as we have Phase I, great. A lot of people were helped. But how do we help those that have traditionally been pushed out to the margins really more of this access to this incredibly incredible technology to help their overall health and outcomes? So, that is what we are really referring to.

And a lot of these different pieces, again, a lot of these standards exist in other domains. But it would be wonderful to also incorporate them into our health IT domains as well. But thank you for that comment for sure.

Hannah?

Hannah Galvin

Thanks, Medell. So, I was going to comment on some **[inaudible] [00:58:28]** what you said, and a few comments. The first is absolutely we need additional infrastructure around broadband access and funding for this. Here in Massachusetts, there is an organization called the Mass Broadband Institute, that has a lot of funding from the state and is disseminating that funding to invest in infrastructure, and I think that is a good model. I think there are some other models in other states that have been doing this for those areas that really have not caught up, technologically, especially in public housing, and other areas where some of the most marginalized populations do not have access to broadband. Also investing in community-based organizations, and public infrastructure, libraries, schools, where people can go to get private telehealth services, and looking at sort of creative solutions there. I think that is one, investing in those types of programs.

Two would be thinking with, again, other agencies and partners, with the WIC program, and the food stamps program, that do currently provide smartphones. But how those could beef up data plans, specifically for telehealth? And I think the third is around parity between audio telehealth and video telehealth. Right now with the end of the PHE, we are seeing that a lot of the commercial payers, and even, Medicare and Medicaid, are really restricting the use of audio telehealth. Even when they say they are not if you actually really dig deep into the facility charges and how to bill for the facility charges, it is making it untenable to continue to allow for audio visits for patients who really do not have the bandwidth to do video visits. And so, really working with our partners at CMS to really understand those disparities, who is able to access the video televisit and who is not? And having a payment structure that will support those who may not have access to high broadband Internet.

Medell Briggs-Malonson
Hannah, those were all amazing points, and especially as it integrates with some of the various different policies that we are seeing coming down from some of the other agencies. I think those are all really, really key. Thank you for those. Okay, so time check, we are going to start going through a little faster because Aaron and I are kind of getting the nudge to get through a few more topics, so one more is reducing the digital divide. This one is the last one, I believe, for the Health Equity Target area, so reducing the digital divide, further requirements and initiatives are needed to reduce the digital divide, including encouraging health equity to be a core design feature and component in healthcare. Lack of or limited access to broadband and mobile Internet is correlated with worse patient health and Public Health outcomes.

So we were kind of already discussing this in the prior topic. Although they are still separate there is some overlap of them, but any additional thoughts outside of what has already been mentioned?

Aaron Miri
Almost one and the same, right, the topic we were just having, to your point, Medell, in my opinion.

Medell Briggs-Malonson
Agreed.

Anna McCollister
I think there is a substantial overlap. My question I just put in the chat is how much is within our domain to recommend? Do we recommend things like providing broadband more ubiquitously throughout the country

or incentives for the creation of services for specific languages? Is that within our domain, or do we need to think about stuff in the context of data standards?

Aaron Miri
I think we can recommend. I do not know what authority ONC would have to do it, but they could coordinate with the various agencies that provide funding back to causes in health. I think there is an opportunity to link that together. It is a great point. There is a lot of money out there for different folks, all about broadband. So, I do not know what the linking play is. Even the White House, right, did not the president recently make an announcement that broadband should be as ubiquitous as electricity and water or something to that effect? So, there is even interest in the White House. I do not know. It is a great point.

Eliel Oliveira
My recommendation here is we probably could advance this, and it has a little bit to do with standards, is the fact that individuals that are underserved who do not have access to anything, do not have the resources to, they usually have to apply to some service and their eligibility has to be validated. And sometimes they do not even know how to get that paperwork together. What happens is they end up not getting the services. So, is there a way to develop the necessary standards here in data access, necessary to preemptively kind of, define who needs to have that service and be provided to them, as opposed to making this complex process where folks just do not get to it? Everything else gets impacted by the fact that someone does not have digital access. That might be where ONC can play a role here. I have seen solutions like that out there, where you tap into different data sets in a de-identified way but are we able to determine that someone does not own a car, does not own a house, they do not have an employment in place?

And automatically we could know this person should be having a device so that we can actually communicate with them and help with other things. I think the opportunity here might be that, is how do we accelerate the process of getting folks access to technology to the Internet, as opposed to having this cumbersome process, where someone is already struggling to just survive. They do not have transportation, cannot even get the food that they need. And now they are going to have to go through an application process to get a phone line? I think we can probably do better than that. Those are my thoughts of the opportunity I see ahead of us. And maybe the recommendation here is to learn where all this comes together, and if there is an opportunity for ONC to set up standards for data exchange that allows this to be predetermined, and the services be provided kind of automatically.

Medell Briggs-Malonson
All great comments, and it almost looks like a combination of, Eliel, what you and Anna were saying. Is there a way that we can help to influence this and back into it, saying here is a standard? Let us streamline this. But then, Anna, what you are referring to is even for the innovators, is if we have various different standards, how can we also ensure that the innovators have some type of push, whether it is an incentive, or something else? In order to comply and jump on board to enhance these technologies? All are really, really important.

Hannah, your hand is up, and then we will wrap up and go to the next topic.

Hannah Galvin

Thanks. I have two comments about this, No. 1, Eliel, I love that idea, back in 2017, AMIA, the American Medical Informatics Association, recommended that broadband access be included as a social driver of health. I think that maybe ONC, or at least this group, could echo or socialize that recommendation. I think that that is a really good way to have it included as a standard, and proactively ask that question. I think it needs to be defined a little bit better in terms of what does that mean when asking patients do you have access to broadband? People do not necessarily know what that means across, just on asking. The second thing is that I might recommend working with the FTC. The FTC does have the ACP outside Affordable Connectivity Program, where we can refer individuals who need affordable broadband. They get a discount for their households depending on their needs.

But the application for that program is really difficult, and often people need to sit with a digital health navigator or someone else to help figure out the application for the program. And so, I think that one of the things we may think about recommending is that the FTC simplify their application. I do not know if we can make that recommendation to them and have it in multiple languages. They do have it in a few different languages on their Web site, but I am not sure the application itself. Just filling out that application itself. I have seen has been a barrier to people getting those services. And so, I think in ONC's role as coordinator perhaps that is something that we could do.

Medell Briggs-Malonson
Wonderful, and, Hannah, those two points, technology, health technology, both access as well as digital literacy, are absolutely social drivers of health. For instance, I can tell you within my work I have always included it as a seventh domain of social drivers. And it would be fantastic, I agree with your recommendation, if ONC, as we are now embracing SDOH even more, that is part of what we set up as a standard because it is a very impactful social driver.

And thanks, again, for this, and Aaron, also, thanks for sending out the link. And in terms of what we can do to really help those that need these services most, and it is unfortunate we sometimes put those that need the most help through the most barriers. And so, making recommendations to say let us think about who we are serving and what we can do to assist, I think that would be a really great piece there.

All right, everyone, so we have a lot of different recommendations for this area that do overlap with the previous subtopic, so we are going to move on to the next piece. Aaron, I am going to turn it on over to you.

Aaron Miri
Sounds good to me. All right, so the use of technology to support public health, gaps in infrastructure, and standards. The gap there is a need for infrastructure support and data sharing, as well as standardization, and standardization coordination across different systems and data sources. The challenge, obviously, with the infrastructure gaps in public health reporting capabilities, so surveillance issues preventing public authorities in healthcare from receiving timely information. We saw this with COVID. We have talked about this in a lot of the prior reports. So, I think the question we should be asking ourselves, as a report workgroup, is are there other pieces like we have spoken about today earlier with SDOH Interoperability? Are there other pieces and gaps that are inhibiting data-sharing in general?

I will be honest, and also open it up here, and it is a true statement that we are not seeing an understanding with the health IT vendor community on what data can be promulgated and shared, especially with some

of the main electronic health records vendors, and I would have said this with Hans in the room. It is nothing to do with any of these vendors. But it is the understanding of what is information blocking what is not, which leads to interoperability questions and abilities there. A lot of health IT vendors are still reluctant to share data, for whatever reason, standards or not.

So as we talk about gaps to mean infrastructure, the infrastructure also is policy adherence now. We used to be in policy creation. Now it is policy adherence to sharing data. So, to me, it is both. But that is my take. So, what are some opportunities and recommended activities from the HITAC, or from the group? What do we think?

Medell Briggs-Malonson
So, Aaron, as everyone is thinking about this more, we had this as a subtopic or as a topic last year as well. And we specifically worked on a lot of our various different exchanges of all of, for instance, our ECRs, and other items too. It just makes me think, do we need to have a quick review of what we recommended last year in this area? And then that will help us to build upon still the existing gaps, as well as some of the new gaps that we have experienced even after COVID. I feel like we have taken one step forward, but we still have a long way to go, as you mentioned.

Aaron Miri
Yes, I think that is a great idea. I do not think we have time this afternoon to do that, but I think we can definitely review that offline and come to the next report workgroup with some clear thoughts in mind to double-click on this, to your point. It is just not going fast enough. And as we have all articulated many times over, it is not a technology challenge. The tech exists to make this happen. It is another challenge, which we have got to nip in the bud. Enough is enough.

Eliel, you are next. Go ahead.

Eliel Oliveira
What is coming to mind here is related to an opportunity in this area, is that I was in the public health reporting group last year. A lot of the discussion there about the submission of the forms and all that, and how EHRs are going to standardize on that, and there was still a lot of discussion about the type of format, and if you are using FHIR or not, and I think that is all great. I think it is a process by which there is a push of information taking place from EHRs, from an organization to the CDC, or whoever needs to receive that information. I think we have done tremendous advancement there since COVID, so great work there.

I think that is great because the level of precision of the data that is needed in those reports is necessary, and it had to be captured the right way. But I feel like there is an opportunity to maybe develop sensing technologies that can look at the data at that national level in a deidentified way, but it is capturing how specific things are taking place so that we can have an early warning of some public health event before we are capturing and analyzing these forms and data that will be submitted. The analogy I think when I think about this, is what we had related to, I think we called sewage epidemiology. Where instead of trying to get lab results from anywhere, you are basically looking at sewage, and measuring levels of elements that basically can determine that there is something going on within a city or a region.

And I think that it may be a bit different than what we do currently in terms of data. But I believe it to be an opportunity to innovate, to define these standards by which EHRs maybe have to expose the levels of data elements that are being captured. And by easily doing so you can see the metrics of where a specific lab result, for instance, is measuring across the country at any second in time, and how it is changing. And by that, then you can have a warning system, that can say we are catching more flu incidences here in this specific region. What is going on there, and so on and so forth? To me, that is an opportunity because, yes, we have a great process still in place that leads to high-quality data but requires a lot of analysis, time, and processing. And there may be an opportunity to be an early-warning system on this front.

Medell Briggs-Malonson
That is really insightful, Eliel, just to make sure that I am understanding this, are you referring to that one of the recommendations is to set up an infrastructure for, as you mentioned, early warning systems, where we are literally hot-spotting where new incidence of, whether it is an infectious disease or some other public health incident that is going on. And so that is a centralized system of some sort in order to alert others throughout the country what may be going on in a certain area based off of various lab tests, based off of various different analyses. Is that what I am hearing?

Eliel Oliveira
Yes, and, again, it needs to start somewhere with standards. It could be a specific use case. Let us say we are just going to monitor influenza, and that everybody is exposing that **[inaudible] [01:17:04]** API, influenza. and the CDC is basically pinging that every second of the day. They are able to capture by region what is going on, and then they create a baseline. But then when you start seeing spikes someone is being alerted that there is something taking place here that we can react quickly, and that is one example. Influenza is one thing, but there could be hundreds of monitoring like that taking place. And I am dying to hear what Hannah says as a physician as well, but I think that is the idea. There is probably a definition of standards. How something like that can happen, and now that we have FHIR it is feasible.

Medell Briggs-Malonson
Right, absolutely, with truly real-time data for us all to act upon in the clinical and the public health settings. Hannah?

Hannah Galvin
Yes, thanks Eliel. I had a couple of thoughts and questions. One is getting public health sharing of data **[inaudible] [01:18:03]** on the TEFCA roadmap. So, I want to sort of better understand where this lies with TEFCA. I think it is not a use case they have, one of the first use cases. I think they are not trained **[01:18:16]** on individual access and where they are in getting to this. As we make recommendations, do we recommend that this gets moved up as TEFCA builds out these frameworks? To Eliel's point as well, I think one of the big barriers that I have seen here is around patient matching as well. So, do we make some recommendations here back to Congress around a national patient health identifier? This is one of the big holdups. Is this the place to do it? So, those would be my two comments here.

Aaron Miri
I am giving you a virtual high five, Hannah, because worldwide we have the national unique patient identifier in the past four annual reports, probably longer than that because we talked about it even in the policy committee and standards committee days. And as you know, all the rigor and other items holding that back,

so I think that is a great point. The other thing we could do, I think, related to your TEFCA comment and I am opening it up to the group for comment, it is my feedback, though, I think it is a great point. We also talked about that in the past couple of reports, related especially around Public Health surveillance and how TEFCA would play into that, so bringing that back up as now TEFCA is getting off the ground, the QHINs have been awarded. What does that look like, so dusting that off?

It is a good point you brought up, and I had not thought about this, so I am asking this out loud for the group, could we reference prior reports, in my mind, it is like since we brought this up now, multiple years in a row, as an issue, using unique patient identifier as an issue, is there sort of big gold star to put beside it to catch people's attention, like, guys, this is holding us back? What else do we have to do, like shake the earth kind of thing so people can see that this is a major, major issue if HITAC feels that way? It would be interesting. Now that we have a history with the reports to say we have brought this up numerous times, and nothing is getting done. So, what have we have to do to move the ball on this? **[Inaudible – crosstalk] [01:20:31].**

Hannah Galvin
I do not know about the history and pre-pandemic annual reports, but I think we said something like we brought this up even before the pandemic.

Aaron Miri
Yes, we did.

Hannah Galvin
Now, after the pandemic, and throughout the pandemic we have brought it up. But even more so, going through this experience we see even more the value of this, and being able to do real-time public health reporting.

Aaron Miri
Yes.

Hannah Galvin
But obviously, we defer to what ONC staff think in terms of the sort of structure of the report and how those are usually done.

Anna McCollister
Yes, should we recommend that ONC or somebody do some sort of a cost analysis of not having patient identifiers?

Aaron Miri
I could have sworn, and this is a recollection, that there was a CBO assessment that was done not too long ago on this exact same topic or something to that effect, and it was asked for HHS to provide that, and I believe they worked with an agency to make that happen. It is a great question, Anna. We need a research that, of what analysis has been done, and do we need to dust it off and redo it given how things are going down. I do think it is a question we can go research and come up with, but not just the cost financially but patient lives. We know that there are sentinel events or near misses that occur because of a lack of a unique

identifier. We know that. It has been codified. It has been reported on widely in the industry. So, how do we quantify and qualify that, good questions? That is a good question.

I am going to do a quick time check here, we have got to go to public comment. If there is time, we can come back to talk about the last area here. Medell, if you are in agreement, do you think we can go? All right, so, Mike.

Public Comment (01:22:28)

Mike Berry
All right, thank you. 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 raise-hand function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press star 9 to raise your hand, and when called upon, press star 6 to mute and unmute your line. Let us pause this for one moment to see if any members of the public raised their hand.

In the meantime, I want to remind everybody our next annual report workgroup meeting is August 30th, I believe. We hope to see you then. Not seeing any hands raised, so I will turn it back to our co-chairs. Thank you.

Aaron Miri
Wonderful. Let us take the last five minutes here and see if we can knock out this last item unless there is further comment on the prior topic.

Anna McCollister
Are we going to get to other items in the meeting in a couple of weeks?

Aaron Miri
That is exactly. That is why there are several of these meetings stacked up to get through all this because it takes some time to have these conversations in depth. Accel team, do you mind? There we go, perfect. Put it on the previous. All right. last area here, really quick, let us see if we can target through this thing, interoperability, supporting interoperability standards for priority use cases. This is similar to what we have been talking about with gaps, but what are the missing links? Again, I use the comment or question, and suggestion we got from Dr. Aaron Neinstein regarding PGHD, patient-generated health data, and lack of interoperability standards around those health systems that are not patient touching. Are there other gaps, we will start here, that we are starting to see in the industry becoming a major issue and impediment to care? That would be the question we start with here, open it up to the floor.

Give an example.

Anna McCollister:
I would say there are absolutely gaps.

Aaron Miri
Go ahead.

Anna McCollister
Sorry, I should have raised my hand, but this is a big area of concern and frustration for me, as somebody who uses a lot of data-generating devices that are far more relevant than some of the stuff that is collected within standardized EHRs. Physicians have to go to an external portal to be able to view the data. If they can view it, it is non-standardized, from blood glucose meters to CGMs to the blood pressure cuffs. And now all of it is digital. None of it is incorporated into any of it. And it is therefore of only limited utility in terms of meeting with my physicians on the side, take the time to structure it, download it.

So, yes, I should not be the one developing the standards, but I do think we need standards for how this can be incorporated. I wanted to include it in USCDI 4, but it did not make any sense because I knew those standards really were not there.

Aaron Miri
Right, not yet at least, point, good points. Eliel, I know you talked a lot about HIE dependencies and lack thereof, of various systems or systems to talking to HIE, and you use the awesome HIE as an example at the last HITAC meeting I believe, or maybe before that, so maybe there is something there you want to articulate with respect to specific gaps you have seen around leveraging those.

Eliel Oliveira
Go ahead, Medell, while I am thinking.

Aaron Miri
Medell, then you are next.

Medell Briggs-Malonson
Okay, well you passed the baton to me, sounds fantastic. One of the things that I have noticed even in my own clinical practice, and also supporting providers and clinicians, along the lines of PGHD, Aaron, you mentioned it when we were talking about public health, but I think it comes into this area as well.
There is a pretty significant resistance to interfacing with all of these other products and services out there that are collecting the data. And there is a large amount of physician burden right now that is existing because, of this lack of, I would justice say urgency, as well as really, feeling like, especially our EHRs, should bring these other data sets in. The question is, in addition to, yes, the interoperability and making sure that some of these systems are certified, what are we going to do with some of our EHR vendors in order to make sure that they understand that we have to bring this data in at some point?

And yes, there may be a safeguard on how we bring this data in, and how we validate that data. But by having all the data in disparate locations it is causing, No. 1, significant physician burden. But then, No. 2, what it is causing is that it is not a streamline in terms of the care that we are providing to patients as well because oftentimes a physician is like, "You know what? I just do not have time to look at that data and go through that data, and that does also not interface with some of the other hospital or clinic-generated data." And therefore, while this is very important data, if it is collected in an inappropriate way it is essentially not going into the plan of care.

I think that there are just two pieces and two gaps and changes here. Not only thinking about all the data that is being collected in these various vendor platforms, and making sure it is appropriate and validated

data, and that hopefully we can have some type of interface with our certified health IT systems. But then also, directly when it comes to our EHRs, how do we decrease that resistance for allowing this data to flow in?

Aaron Miri
That is a great point, Medell. That is a great point. And it does tie together with what I said earlier, but at the same token, there is a lot more around that. To your point, it is a very complex issue.

Anna McCollister
One of the things about this.

Aaron Miri
Oh, shoot a monkey, we are past time. We started getting into it. I just realized it is time. We have got to go. Sorry Anna, I apologize. Jim, I saw your hand held. If you guys will e-mail in your comments, we were so deep in conversation I lost track of time. Have a great afternoon, everybody. Thank you very much. Next time we will pick it back up. Appreciate you all.

Medell Briggs-Malonson
Thanks, everyone. Have a good day.

Aaron Miri
All right, bye.

Next Steps and Adjourn (01:29:22)