

Transcript

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

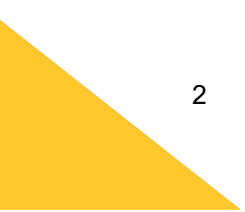
September 7, 2022, 10:00 a.m. – 11:00 a.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Medell Briggs-Malonson	UCLA Health	Co-Chair
Aaron Miri	Baptist Health	Co-Chair
Jim Jirjis	HCA Healthcare	Member
Steven Lane	Sutter Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Brett Oliver	Baptist Health	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 (00:00:04)

Michael Berry

And good morning, everyone. Thank you for joining the HITAC Annual Report Workgroup. I would like to welcome our co-chairs, Medell Briggs-Malonson and Aaron Miri, and with us today is also one of our workgroup members, Eliel Oliveira. Brett Oliver, Steven Lane, and Jim Jirjis may be joining us shortly, but we can get started. I just want to note that public comments are always welcomed, which can be typed in the chat feature of Zoom or can be made verbally during the public comment period later in our meeting. And now, let's turn it over to Medell and Aaron, who will kick us off.

Opening Remarks, Meeting Schedules, and Next Steps (00:00:38)

Medell Briggs-Malonson

Thank you very much.

Aaron Miri

All right. Go for it, Medell. Start off.

Medell Briggs-Malonson

Thank you. Good morning, everyone, and thank you, Mike, for that wonderful introduction. We are just going to go over very briefly the agenda, then I am going to turn it to my cochair to go over our next upcoming meetings, and then we will dive deeply into the continuation of our discussion of the crosswalk. So, today, what we are really going to do is a continuation of our August 30th meeting, in which we are going to continue to discuss the topics that are going in the crosswalk for this year's annual report, and that should take up the majority of the hour, and then, at approximately 10:55 Eastern Time or 7:55 Pacific Time, we will go ahead and start for public comment. So, next slide. I will turn that over to you, Aaron.

Aaron Miri

Absolutely. So, what we are doing right now is obviously, we had our July 28th meeting already done, our August 30th meeting already done. As Medell mentioned today, we will continue to go over the crosswalk all the way through until we officially submit to the HITAC in the December timeframe, and then, obviously, with approval sometime in the January/February timeframe and transmittal to the ONC national coordinator and on to the secretary sometime in the February/March timeframe, so that is how this goes. Next slide.

Obviously, for the full committee to review, we would be reviewing with the full HITAC next week on the 14th, and then sort of updates going forth on the 13th and the 10th of November. Usually, the winter timeframe calls for a lot of email updates. We get some very verbose written comments from our HITAC members and the community, which we definitely take into consideration, look at it, and try to finalize the report during that time, and of course, behind the scenes, you have the ONC team and the Excel team doing a great job, and Audacious Inquiry and others looking at topics and researching for us, so, again, we appreciate Michelle and all the efforts that go on behind the scenes on top of all the meetings that we just walked through. Next slide.

All right, so, next steps. Obviously, we have developed the draft crosswalk of topics. Dr. Jirjis has joined. Hi, Jim. We will present the crosswalk for discussion at the HITAC on the 14th. It should be a good discussion, so we welcome all comments there and hope that this committee will participate actively in that.





And of course, we will develop the crosswalk document during the fall and present brief updates to the HITAC as needed. Next slide.

All right, so, these are the draft crosswalk topics. Again, for the whole crosswalk, we will go through it here in a minute, but we want to consider the gaps, challenges, and opportunities, and activities for some additional target areas to discuss, which is the design and use of technologies with advanced health equity, which we are all very passionate about, and an additional target area, obviously, the use of technology to support public health. As we know, the Public Health Task Force is meeting actively and doing some great work there, and of course, our priority target areas as established in 21st Century CURES are interoperability, privacy and security, and patient access to information. Next slide. All right, I think we are on the crosswalk now.

Discussion of Draft Crosswalk of Topics for the HITAC Annual Report for FY22 (00:03:45)

Medell Briggs-Malonson

We are on the crosswalk, so, yes, if our Excel team can bring that up. Thank you so much. And, we had a very rich conversation during our August 30th meeting to discuss all of these different areas, and so, what we are going to do is move forward to where we actually stopped our previous discussion. So, this here, you see a highlight of our new target area, the design and use of technologies that advance health equity, and if we continue to go on, we were also able to dive very extensively into the additional target area of use of technologies that support public health. Next page.

And we were able to get to a fair number of areas in interoperability, but the last topic that we did discuss was streamlining of health information exchange, which our proposed recommendation for HITAC was to hold a listening session to actually hear what many of the other federal groups are currently doing and really making sure that we can fill in some of those gaps in order to improve the capacity of the public health workforce in particular, and also, we made that connection with the overall health workforce for many different areas to advance not only public health, but also health equity.

And so, our next topic to really discuss is first starting with the interoperability standards, the priority uses, and especially as it pertains to the closed-loop referrals. And, the reason why this was brought up was because there was believed to be a lack of that cross-organizational support for closed-loop referrals, including for social services, and so, there is an opportunity to explore and advance various different standards that make sure that our systems do fully communicate with each other and are able to close any of the various different referrals, whether it is for healthcare services, public health services, or social services. So, we want to open it up to the committee to just receive some additional thoughts about this topic.

Eliel Oliveira

Medell, I wanted to maybe suggest here that we are on the challenge here that is not just a lack of standards, but the fact that we are talking about a variety of organizations now that do not even use electronic health records like we do in clinical practice, so that makes it very challenging to integrate closed-loop referrals with social service organizations that can be of all types, all sizes, and different capacity of resources. I think that might be something to consider adding to the challenges as well.

Medell Briggs-Malonson





Absolutely. Any other thoughts? Aaron or Jim?

Aaron Miri

I like the way it is right now. I agree with Eliel's perspective. I need to see the research literature behind it because there is so much work going on behind the scenes. So, where are we as an industry right now? I know that is what Michelle and team were working on, to get us information on that, but more to come.

Medell Briggs-Malonson

And Jim, I saw you come off of mute as well.

Jim Jirjis

Yeah, are you talking specifically about the closed-loop referrals row?

Medell Briggs-Malonson

Right, we are talking about closed-loop referrals, and then we are going to e-prior authorization.

Jim Jirjis

I find it important of what comments you are looking for, but if we define what the data elements are for equity of quick care, for example, or social determinants of health, one of the tricks has been that capturing that data is one thing, but the more we can also support standards to identify appropriate services through referrals and do that efficiently, the better. As a former primary care doc, it was one thing collecting all this data, but another knowing if there are any resources out there that could actually help you that you could refer that patient to. So, I endorse the way this is worded here, but I do not know how far we are from that reality.

Aaron Miri

Exactly, Jim. You said what I was saying, which I know CMS have been working on this for a while, the payers have been working on this for a while, AHIP had some initiatives around this, so I just do not know where the industry is right now in general with all those efforts. You are exactly right, there has been a lot of work going on for years on this topic.

Jim Jirjis

But Aaron, I think part of these subcommittees and Task Forcess is bringing people in to educate us on where it actually is, so to me, it seems really important, and it might be appropriate to get educated on where the state of the technology or the adoption is and advise ONC.

Aaron Miri

Bingo.

Medell Briggs-Malonson

So, therefore, it sounds like the overall recommendation is to assess where our current state is and where some potential gaps are so that then, we can actually make informed recommendations, but it sounds like just assessing the current state and bringing in, again, all of the various different stakeholders to see where we have been and where our current progress is, right?



**Aaron Miri**

Right.

Medell Briggs-Malonson

Wonderful. And then, of course, Eliel, exactly as you were mentioning, too, that way, we will be able to identify where those additional opportunities are. And so, that goes directly into the next piece, with e-prior authorization, and so, once again, just looking at the lack of common standards and prior authorization across various different payers, and then, really, once again, thinking about what can we do for those opportunities to advance standards that improve our systems for prior auths, which we know is a really significant factor when it comes to access for patients across the country, and so, those prior authorizations and the timeliness of those prior authorizations are critical in order to provide medical services. So, any thoughts about this? I feel like it may be similar to the previous one.

Aaron Miri

I would agree. What was interesting is I just got through reading the book *The Big Fix* by Dr. Vivian Lee, and she actually talks about this at length, ad nauseum, how this became such a challenge and where it came from. And so, I think we have come a long way in all of that, but to the degree of it, you are right, Medell, this is still a big bugaboo. But again, a lot of work has been done. Just like with closed-loop referrals, I just do not know where the state of the industry is.

Jim Jirjis

Hey, Aaron, I would answer that. Isn't there an anticipated CMS rule coming out about e-prior auth and possibly another HITAC Task Force? So, to me, it seemed like we identified the different data classes and data elements necessary for minimum viable product and beyond for e-prior auth, but many of those data elements did not have semantic standards, etc., right?

Aaron Miri

Right.

Jim Jirjis

So, to me, it seems like a very high-priority and important thing, similar to the one above it, to figure out where we are and what next steps are to advise ONC.

Aaron Miri

Right. There was an effort with Dr. Don Rucker, when he was ONC coordinator, with CMS, and this is when we were meeting in person, so, prior to COVID. We actually had a focused discussion on this, and one of our HITAC meetings was turned all about this topic, and there was a lot of interest of collaboration and streamlining, and a lot of the payers presented different ways they were trying to streamline in partnering with Change Healthcare, and Availity, and all these brokerage and clearinghouses to partner. I know people like Epic Systems and others are trying to accelerate this, so there is a lot of work going on. Another summit would be great. I think we all learned the painful lessons of prior auth when we had to go all-virtual for that time during COVID and realized this is a big bugaboo, so it is worth us talking about, in my opinion.

Eliel Oliveira



I was on the Prior Authorization Task Force that we just completed a few months ago. There was a lot of work, and it was very extensive, but it was also in a short timeframe, and we had some great recommendations there. So, it is either that those recommendations, then are integrated into the report or some additional work is done to revise those recommendations to then become part of the report, but again, quite a bit of work was already done just a few months ago.

Medell Briggs-Malonson

Excellent. So, once again, we really need to collate all of that information together so that we can truly see where we currently are, and then can proceed forward with some additional recommendations. This actually brings up the question that we have actually had in some other meetings of some of these different items that we know are currently being focused on in other groups, subgroups, agencies, or whatever that may be. Where is that intersection with HITAC, and is this something that we want to report out on in terms of the annual report, or is this something that we put in the parking lot and we make sure receive information about where a current state is for these types of items, and then, potentially, even next year, make some additional concrete recommendations for it once we have been more informed about where we currently are? So, just bring in a conversation that has been had in other meetings to really make sure that the work that we continue to do is as impactful as possible.

So, last but not least on this page, standards for patient matching. This has always been a hot topic, especially since we have transitioned to electronic health record systems and really trying to focus on interoperability and knowing the various different challenges on matching patients based off their demographic information and their other personal identifiers. So, really, what this is focused on is how do we improve patient matching, especially when it comes to, essentially, our more vulnerable populations, and just really thinking about those opportunities of alignment of incentives and certification programs across domains to encourage that ecosystem approach to improving patient matching, but I would also add thinking about the various different tools that are going to be universally assessable and helpful for not only the various different institutions, but also for patients themselves.

Sometimes, we think of that so much from the tech standpoint, we are not as patient-centered, and we are not as provider-centered as we should be, and so, this is something for us to think about of how can we recommend that those patient-matching standards that is going to be highly inclusive and may even have some additional tiers. So, that is one thing I have always thought about when it comes to patient matching and making sure that we have more avenues, but I would love to hear what the three of you also feel about what we can think about proposed recommendations.

Aaron Miri

I think that there has been a lot of work recently that NIST has done, so, again, this is more research-wise for Michelle's team and others I would like to learn more about. I have been seeing them put out a lot more revisions, the 800-53, and other standards, around identity matching and identity proofing and trying to get us to a very solid level where we can trust this identity with some fidelity that this is really Aaron, with some immutability around it. So, I think there are some updates we can do in terms of where the industry evolves to, where standards evolve to, and then, technology-wise, continues to evolve, although, I will be honest: It is still kind of the way it was always until there is some sort of national direction on this. But in terms of where we are, it is another one of those where we seek first to understand where the industry has evolved





to. I continue to hold my breath and hope, as I have been hoping for over a decade now, that we will get here, maybe even more than that, but we are evolving, so where are we? Biometrics, etc. Jim?

Jim Jirjis

Aaron, I love what you are saying. I get the sense, too, that somebody out there is point on driving to a standard that we can all agree people ought to utilize, but who is the primary owner of that? Is it NIST, is it ONC director, and what is HITAC's role in that?

Aaron Miri

Yeah, great point. I think the way we have approached it in history, because this is a very understandably sensitive subject when it comes to patient privacy and others and we want to be very respectful, is more of the conveyor of people and different authorities. We have had NIST present to us, we have had numerous different agencies come present to us over the years, including, in the old days, Health IT Policy Committee, which has been there. So, to your point, Jim, this is where the ONC's sweet spot of being coordinator, of being air traffic control, for lack of a better term, really comes into play at helping to bring people around this issue together to say, "Where can we go?" Does HITAC have a say? I do not know; we need to ask that question, but I do say that we can definitely point at this as an issue plaguing healthcare and convening the right people together to talk about it.

Jim Jirjis

I completely agree, and I would add to that that given where things are headed with TEFCA, FHIR, and all that stuff coming into play, it is probably one of the most critical things to get right because as different business entities and technologies interact with each other, identity management of patients, to forget providers for a minute, is so critical to avoid overlays or gaps in knowledge. I think it is a priority item, and in addition to ONC's standard coordinating role, it seems like it would be a high priority to keep on the list.

Aaron Miri

Go ahead, Medell.

Medell Briggs-Malonson

I was going to say I completely agree it is an important priority to keep on the list, and I am going to actually provide us some additional perspectives as well. So, a lot of times, we have looked at standards, we have done some of the very basic identifiers, but we have not taken into account some of the nuances of patients themselves, whether it is going directly for providers or if we are talking about FHIR, APIs, and all these other items for other non-provider entities when they are matching, and what has been occurring over time, even if you use various different methods, like probabilistic matching and many other forms, in order to identify patients that may be in different systems, we have failed, and we have consistently failed, especially for patients of various different backgrounds. For instance, they may actually have two last names, but yet, we are only at trying to identify them on one name, and therefore, you miss that.

And so, I believe those are the types of influence that we should be making sure that we are providing to all of these other entities that are trying to develop these standards. In addition to that, we talked about the various conversations above biometrics, but again, biometrics can do wonders, but if we are not careful about even some of these additional ways of identifying patients, and especially because we do serve such a diversity of patients and communities, we can actually lead to, again, less trust for the system because





of the type of biometrics we may be using, such as fingerprints, or even retinal scans. So, this is an area that I think HITAC can have a large amount of influence of not only making sure that we have appropriate interoperability with the right algorithms, but that we are taking into account all of the various different needs of the patients that are currently right now within the nation, whether it is for clinical care or other reasons.

Aaron Miri

You are exactly right, Medell, and here is a real-life story. We employed biometrics here at my organization, palm vein scanning. There are segments of the population who associate that with law enforcement and did not want to use it for registration. Obviously, that is totally fine. We can register them the old-fashioned way. It takes a little bit longer, but that is no problem. So, we were being very respectful. I think all those inputs are very important for our awareness. I emphatically agree with where you are coming from, Medell. Great point.

Eliei Oliveira

I want to add a couple of thoughts. On the first bullet, as far as just the matching itself, it might be interesting to look at other industries where maybe, from there, drive some standards to use in healthcare. I think the example that comes to mind is when you apply for life insurance or some other product, then they have to ask you some specific questions to validate who you are. "Have you ever owned this type of car? Have you ever lived in this address?" They have figured this out to fully get out of the errors that could exist in matching someone, but we do not do that in healthcare, so there might be some exploration to be done in other industries where we can learn from and then drive the standards that we can use.

In the ability to link deidentified data, I think that is where we need some standards as well. Through COVID, as you might be aware, the N3C, the NIH-sponsored large project to aggregate data to study COVID, took place and uses privacy-preserving record linkage solutions, and it works great, and FDA uses it for their Sentinel network, and other national networks use it as well, but there is no defined standard that ONC or other standards bodies are physically saying, "This is what folks need to do when they are trying to link records without identifiers." So, I posted the link here to N3C for you to look. I would say we also need some standards defined.

Aaron Miri

Agreed. I see it this way. I always look at the U.S. military, the DOD and DHS, as entities of expertise, right? DHS can do this with the Fast Pass and Clear Lanes and all these things and figure out a way to keep us secure flying and traveling in this country, surely we can employ some of those things, so maybe hearing from Homeland Security, DOD, or other agencies about how they have tackled this identity management/identity matching in a way that is uniform and works on a national scale would be helpful to inform us on what we are not thinking about. Homeland Security figured it out. They are not perfect, but they figured it out, so how do we do this in a way that works? This is about patient safety, at the end of the day.

Medell Briggs-Malonson

And I love what both of you all are saying, using other industries' best practices to see what we can actually do to inform healthcare, so that is a great idea.

Jim Jirjis





The sense I got was... That is why I asked who is point on driving to a solution in the government, because my understanding is that people were looking at those other industries' cases to see how it could support it or not.

Aaron Miri

Yeah, we have to pull what Congress's charge was. For a while, you have to realize HHS was forbidden from investigating this until recently. Then they were commissioned to do a study, and several continuing resolutions out of Congress alluded to "Let's keep investigating this, let's get reports together." So, ONC has done several studies, the last of which was a year or two ago, if I recall, on where things are. I have not heard if there has been a direction given to ONC that you guys are in charge of this.

I do not know that answer and we have to investigate, but in my personal opinion, it seems to me that the industry has been left to self-regulate this topic and sort of figure out ourselves how we want to do this, but it is just leaving everybody further waiting for someone to just tell us what to do, so I think that is why we need to convene and say, "Where are we?" Let's get this thing to a point where is it really going to be free-form, free-for-all, which, Jim, you articulated would cause issues for TEFCA and others, or are we going to finally rally around some standard, like a biometric plus a password, a biometric plus your Social Security number, or whatever that may be? TBD.

Jim Jirjis

Keeping it on the list, one of the things for us to understand is who are the different government bodies working on it, and what is the path to actually moving the puck on actual use? Is it a CMS rule, where CMS uses its management of its programs to facilitate it? Is there something in certification? How does the government coordinate getting to something that actually accomplishes the goal practically?

Aaron Miri

Yeah. The easy button would just say make it part of USCDI Version 5, right? But that is the easy answer, and nothing is that easy.

Jim Jirjis

I do not know that it is the total answer because it may define the standard, but we are evaluating all the CCDs we are receiving, and the gaps in data fields...

Aaron Miri

Oh, yeah.

Jim Jirjis

So, there is going to have to be some sort of incentive to use it.

Medell Briggs-Malonson

So, we have had a wonderful conversation about this, so I am going to be the timekeeper since we have a few more topics to cover, but thank you for that, and I know our ONC team has captured all of this wonderful conversation and all these ideas. Obviously, this is a hot topic, as we discussed. Great. So, we are going to move on to the next page as well.



**Eliei Oliveira**

Medell, I think we skipped one, if you go back.

Medell Briggs-Malonson

Did we skip one? Okay.

Eliei Oliveira

Yeah, the directory standards and management.

Medell Briggs-Malonson

Thank you for keeping me on track. You are absolutely right. Directory standards and management. See, I was so eager to jump to the patient matching. So, directory standards and management. So, this was actually proposed, and we agreed to keep it on the crosswalk with really considering the struggles that healthcare providers in general have, or anyone in healthcare, actually, with making sure they have a digital contact in order to exchange information with other entities, and so, the opportunity that was proposed here was how do we improve the availability of electronic endpoints for all of our various different healthcare stakeholders? A very interesting topic, and especially as we are talking about making sure that our links are much more solidified between all of us, for instance, whether it is in healthcare, public health, or even in some of our new vendors. So, any additional thoughts about HITAC recommendations for this topic?

Aaron Miri

I could be totally off here, but I could have sworn there was a CMS requirement to provide your information to a national directory by a certain date, like January '23 or '25.

Jim Jirjis

There is, Aaron, but it was just a wall of shame. There is no penalty. It is on some website where it says whether you provided it or not. Shame may not be enough.

Aaron Miri

I do not think that is the right word, but we will go with it. We will go with "shame." So, there have been efforts, it just maybe has not taken adoption, and we wonder why. It would be interesting to hear CMS or whomever tell us, "Boy, we wish we had a carrot and stick," or whatever it takes.

Jim Jirjis

Well, speaking as a provider, three of the goals of 21st Century CURES are to reduce provider burden, increase true interoperability, and increase patient access. The two areas that are huge burdens staffing-wise or whatever are prior auth and referrals, right? So, to me, this seems to be a critical piece. If our future is going to be to use the national infrastructure to manage closed-loop referrals, or even communications of content, then this seems to be a critical piece too.

Medell Briggs-Malonson

So therefore, it seems like it is just more. Our current opportunities are more than just making sure that every single one of the various entities has a digital contact, but it is really how we are going to utilize that in the most efficient manner and how that is truly integrated into some of our other workflows in order to decrease burnout, in order to increase access. So, maybe this is a little bit too narrow. Maybe it is yes, how





do we ensure that we do have that accessibility of the digital content, but how will that information be used appropriately to address some of the other challenges that we are all currently facing?

Jim Jirjis

Agreed. To me, it seems like getting people to use it appropriately has to first get people to actually use it, right? So, what I would say is the focus ought to be is there a service that allows someone to reach out for an NPI, for example, and understand what their HISP addresses are, for example, and I use the plural word. In order to use that, it has to be complete, it has to be accurate, and it has to be standard enough to automate its use. And so, look at an OB/GYN doc. They may have three HISP addresses. They may have their OB clinic and they may have a gynecological clinic, righty? And so, to me, getting into the details of what that should look like and how we move from a wall of shame or compliance to actually having it be hard-wired and reliable for people to actually use it is going to be critically important in the future.

Aaron Miri

All of us are practitioners. When your physician offices move and you cannot even update Google with your new address, imagine trying to keep a directory up to date. If Google cannot do it, then what are we missing here?

Jim Jirjis

Aaron, in a past life, at Vanderbilt, I was charged with developing a communication platform for what turned out to be 35,000 referring providers, and what we learned there, because we tracked over many years what were fax numbers at that point, was that there is a significant number of doctors each year that actually change practices, so that gets to bad data. It has to be kept up, and it has to be complete, and it has to be accurate, and it has to be machine understandable. Then, people will use it as a service. Until then, if the data is really bad, which I know it is, then we cannot even get to appropriate use because no one will use it.

Medell Briggs-Malonson

Great, wonderful discussion, again. And so, it sounds like we have some recommendations for this topic as well moving forward. Now, we have one last topic in interoperability, and then we still have two additional target areas to get to by the end of today. So, use of telehealth, and this was something that we had, a more recent recommendation from our HITAC full committee, and then, making sure to bring it back here, and we actually put it directly underneath our interoperability, but knowing that it spans across just about every single priority area.

And so, the idea behind this was the unique interoperability considerations that exist for the equitable use of telehealth to reduce the digital divide with some of the various different opportunities of improving our bidirectional exchange of information between telehealth providers and the patient care team, and we already do have a few of those recommendations because we did discuss it, but I just wanted to see if there are any other items we want to add. And so, we had discussed last meeting to explore the benefits of encouraging that adoption of a true certified health IT platform by telehealth providers to ensure appropriate interoperability and bidirectional exchange of patient information and care plans. Any other additions we want to add to this topic?

Aaron Miri





Equitability. I think we have talked about it a number of times, but for us, we serve a large, rural portion of Florida and Georgia, and the inability for folks to access telehealth resources, even audio resources, which I thought were available everywhere, and they are not, especially for folks that are hard of hearing and have other ailments, is amazing and sad, the lack of ubiquitous access that people have to care, and it really does break my heart. So, however we can include this, as I think you were talking about, Medell, with health equity components and dimensionality, is becoming more and more important, and leveraging things like social determinants of health, patient-reported outcomes, and other things to pick up on depression and other massive issues that are going on, we have to get away from the episodic nature of telehealth and into more comprehensive telehealth, but what does that look like an dhow do we actually make this work? Because right now, in its current state, it is a lights-on approach versus a tailored approach for respective groups that people feel supported and want to engage.

Medell Briggs-Malonson

[Inaudible – crosstalk] [00:32:58]

Eliel Oliveira

I agree. We have the same experience here, Aaron. We are rolling out mobile applications and doing some work, and what we hear mostly is “Well, I do not have minutes on my phone, so I cannot use this thing, and when I recharge, I only have so many minutes to call my doctor to get ahold of somebody, so I am not going to be able to use it.” That is real, and I am surprised that we still hear it at this stage. The ones that need it most are continually suffering because they do not have access to basic technology.

Medell Briggs-Malonson

And we are talking about the three different domains of, for instance, telehealth and the digital divide. No. 1, the characteristics of our patient population. Aaron, you brought up a perfect example of those that are hard of hearing are those that may be also visually impaired, and then, I would also say all preferred language, and still, our telehealth platforms are still predominantly in English, although we know there are hundreds of languages spoken in our country, especially Spanish being the most common now within our country after English. And then, also, Eliel, I agree with you in terms of our devices and how we are developing these various different apps. We are talking about device accessibility as well as some of the economic aspects of device accessibility and who can actually use what.

And then, of course, the third one is overall accessibility. While we always have mobile, still looking at wifi and broadband, but also looking at the literacy rates of using various different types of technology. So, there is a lot in here that can be brought out, and that is something that we do if we are going to expand telehealth. We have to make sure we are not worsening situations and have it linked to outcomes, so I love what you said, Aaron, about comprehensive care. There have been a lot of studies, even during the pandemic, of how telehealth helped a lot of our aging population with feelings of social isolation in particular, and with depression, how telehealth literally checked on them every single day, and their outcomes, both mental and physical, were significantly better in that aging population versus those that did not have those services. So, there is a lot of area and room for growth and for impact here. Great. Any other items here for use of telehealth? I think we talked about a lot of great areas. All right, let's go onto the next page. Aaron, I am going to turn it on over to you for this next priority area.

Aaron Miri





Absolutely, happy to do it. All right, privacy and security. I love this topic, I always do, and I do not know why. I just always really like this stuff. So, first, alignment of innovation and regulation for consent directives. The gap is we know the pace of industry innovation is faster than our regulatory environment for consent directives. Obviously, this also applies to research consent, which is very different than patient care and treatment consent, and you can sometimes have both, or a variation depending on what your IRB asks you to do. The challenge is the ability to exchange computable consent directives across health IT systems is limited, and I would actually call it abysmal, but it is what it is, and the opportunity is supporting the adoption of common standards and capture and exchange of electronic consent directives.

So, we are talking about patient consent and all the characteristics and permeations of consent. Again, clinical, and then research, and then sometimes just clinical trials and research. How does that work, what are we thinking here, and where do we think the industry is? I will open it up by saying that I have not seen much recent national effort around consent standardization and alignment. I have seen language proposed, like drafts that people could borrow for consent forms and whatnot, but I would also say with consent, if you look at pediatric, there is also assent. We cannot forget that. So, what are we thinking? I will open it up to the floor. Medell, if you want to start, what are some thoughts here?

Medell Briggs-Malonson

Yeah. So, for those of you that do not know me well, my other real area is in innovation and making sure that we are developing various different tools that not only help our patients and our communities, but of course, our providers and overall health. And, it is interesting because I feel like this topic may have changed to really be a little bit more narrowly focused on consent directives versus, I think, some of our previous conversations, which were based off the alignment of innovation and regulation in general, especially with the emergency of more FHIR apps and other types of APIs and really saying as more entrepreneurs and innovators come into the space that are creating all of these various different tools, how do we make sure they are aligned directly with the rest of our regulatory environment and that we are ensuring appropriate privacy/security/interoperability with some of our more healthcare-based systems as well?

So, just now, I did not realize we were narrowing it down to just consent, but I would say that I think there definitely need to be standards. A lot of times, I think a lot of our innovation and our innovators are just thinking about something that is creative that they believe may actually work, but it may not have all of the various different pieces in it that we know are required in order to protect our patients' privacy in general. So, I am just putting that out there, especially for the committee. I think consent directives are great, and that can be included, but I think there is a much larger ecosystem that we can talk about about the alignment of emerging innovation and regulations when it comes to this area.

Aaron Miri

Great points.

Eliei Oliveira

I am thinking here that ONC did fund some pilots to test out some distributed consent systems, right? And I think that there has not been any push of trying to maybe analyze this on a much larger level, something like TEFCA, and how QHINs may be the place where consent is stored and managed in some sessions, and I agree with Aaron. Consent from clinical providers for care is one thing. Consent directives in research





are at a completely different level. I still go back to my days of cancer research, where they are assigned, and the consents are for specimen usage and break down who can use what specimens for, and it is forgotten. It goes into a file cabinet, the patient never sees it again, and it is not the ideal setup. I think maybe looking at what TEFCA or QHINs would give to leverage the network to be able to solve this might be an avenue.

Aaron Miri

Other thoughts? Okay. So, I guess we have to learn some more, is basically what we are assigning it out to. Where are we with things, and where is the industry going? All right, appropriate exchange and use of data. Obviously, the gap is complying with the HIPAA minimum necessary standards, difficult without DS4P, data segmentation for privacy, capabilities. The challenge is there are currently no nationally adopted implementation guides for exchanging data for the purposes of payment in healthcare operations, so the opportunity is to promote the development and adoption of implementation guides to support and improve data segmentation capabilities.

I see it as part and parcel, personally, with all the stuff that has been going on recently with some of these for-profit tech companies that have been having healthcare data sent to them inappropriately or inadvertently, EULAs that are pages and pages long that nobody reads, and then, what is that old saying, that if a product is free, you are the product? Having people be aware of what data they are giving and opting in. Maternal health, I think, has been front and center. A lot of companies have either advertently or inadvertently abused that privileged data. So, there is a lot here around appropriate exchange and use of data. I know that the FTC, OCR, and others are doing a lot of work in this space. It would be interesting to hear their take, but I would love to know what you all think.

Jim Jirjis

I do not know if it is new, but I have kind of a new take on this area, and it goes back to my own organization being in 22 states. And so, when you look at the appropriate exchange of information, some of that has to do with minimally necessary and guidelines for payment and operations, but some of it has to do the phrase that says that information-blocking rules do not supplant HIPAA or local or state law. We have a single patient portal for our inpatient and outpatient areas, and what we have found is even to understand what the laws are in 22 states, they are not in one place. It might be the pharmacy board; it might be here. It is about \$10,000.00 per state every time the attorneys look at it, and you have to keep repeating it. The only reason I bring that up is because to me, it is ridiculous if we land in a place where every provider has to hire attorneys to keep track of what the applicable state and local laws are to adhere to, and I am wondering if there is a role for a private-public partnership or something to help at least track that stuff so that we do not have to have all this additional burden.

And so, when I think of appropriate exchange, I think there is also these state laws. California is very different than other states, and what we have found is that the language in the rule actually says that some who operate in multiple states may pick the state with the most restrictive and apply it to all. Well, it turns out it does not work that way. The things California is doing are restrictive in a completely different way than the things that other states are. So, I guess what I am wondering is if ONC and HHS have a role in figuring out how to support people even knowing what the laws are in each state and how costly that is, sort of a clearinghouse or something. What do you guys think when you hear that?



**Aaron Miri**

Interesting.

Medell Briggs-Malonson

All interesting points. I was just going to mention I interpreted this also from thinking about how we lessen burden and having some additional clear standards on what is not only going to be the minimum that is necessary, back to the points that you two are making, but also what is going to be most practical. Back in the day when we first had our EHRs, we all talked about note bloat, where we had all of this excess information when, as physicians, we are putting those various different notes in, but also, when we are exchanging information between our various different facilities, what is just the minimal amount of information that is needed that can actually be actionable for us to care for our patients? I am not quite sure we have those clear standards that have been defined yet throughout our country, but that may be also something to help decrease burden to help improve healthcare. So, that was just some of my thoughts about this topic as well.

Aaron Miri

Great points. Eliel?

Eliel Oliveira

The thought that I had from Jim's comment was wondering the same. How has the financial services industry handled this across the states without making it so difficult? Is there a federal mandate that actually specifies... And, I know healthcare data is much more complex than just money and transactions, but it is pretty massive. In every state, you have to deal with so much more variation, and you do not even know who to talk to to get the approvals that you need. That is not a bad place to look at.

Aaron Miri

Yeah, if only it was as easy as signing your mortgage with DocuSign, right?

Eliel Oliveira

Exactly.

Jim Jirjis

Aaron and Medell, I think that ONC's role in reducing the burden, in this case, on providers is by understanding how burdensome and costly it is to even track the various state regulations. It fits with the 21st Century CURES theme of reducing provider burden. What could be done to reduce the many-to-many cost problem?

Aaron Miri

Yeah. It would be interesting to hear the work that is going on, and I think there is another listening session for us to learn what is going on. Actually, I do not know what harmonization efforts are going on. Even during Dr. Karen DeSalvo's time, they called a workgroup in '16 of all the governors and the respective attorney generals to figure out how we get HIPAA, privacy, consent, and data exchange all aligned across the states, so there have been efforts for years. I just do not know what the recent efforts are, so we just need to find that out.





Okay, near and dear to all of our hearts, cybersecurity events across the healthcare infrastructure, and again, a time check here. We have to go to public comment in a few minutes, so we are going to try to finish this section up. So, cybersecurity events continue to increase. The challenge is that scales and resources are outpacing the ability of professionals in healthcare to prevent cyberattacks, and the opportunity is operable guidance in the healthcare sector on ways to improve cybersecurity preparedness. There is a ton of work going on here with Section 405D and everything else, but I would love to know your thoughts on this. What can HITAC do?

Medell Briggs-Malonson

Encourage that work to continue.

Aaron Miri

Yeah. FBI and DHS do a really good job. I know locally, here in Jacksonville, we are close partners with the FBI office. In fact, they are helping to run my simulation disaster next month. To be honest with you, who better to run it for me than the FBI, to create a Black Swan event for us and tell us how to resolve it and what we screwed up? So, it would be interesting to hear from the FBI, DHS, and others what they are doing to prepare healthcare organizations. The resources they offer, by the way, that are paid for by our tax dollars are free and amazing. They will do free pen tests for you, free tests of everything, because you paid for it already with your tax dollars. This will all be in DHS. They have programs set up, but does the world know that? Should HITAC help amplify that and partners with the FBI, DHS, and others? Should we talk about what 405D is doing, which is great work there that goes cross-sector? There is a lot of work here that we can do that I think we should 1). Extract what the market is doing, and 2). Publicize, if nothing else. What do you all think?

Medell Briggs-Malonson

Aaron, I think that is a great idea as well, by the way. I think that is perfect to highlight that, so I just wanted to say I agree.

Aaron Miri

Perfect, Medell. Eliel?

Eliel Oliveira

I was going to add, Aaron, that I keep thinking about the fact that a few years back, when I looked at the OCR report of all the breaches, less than seven percent were because of hacking. The great majority was because of social engineering, and that has changed recently, and I am just wondering here if we need to recommend a study of the situations that are causing the most breaches and attacks in healthcare organizations because I do not know, to be honest. There are a lot of data downloads here. I have to look at those, but I do not have the time **[inaudible] [00:48:40]**. But is my organization more prone to be attacked, or are larger ones? What are the different ways to look at that to narrow down and figure out what the key issues are? The example I was giving was that hacking used to not be the major issue, but it seems like that is going, but why? Anyways, maybe learning more of what is taking place might help us address this.

Aaron Miri





Good points. So, more listening, more understanding, then, is what I am hearing from the group. All right, and time check here, we have four minutes until public comments. Let's see if we can get to the last bullet here, privacy of sensitive healthcare data. Obviously, there is a lack of standards supporting segmentation of women's health data, and we talked about this in an earlier section, gender-diverse populations, which I think we expanded upon in our last discussion to make sure we are being very inclusive.

The challenge is the legal landscape, balancing protecting this with needing to make it accessible, making sure everyone is using gender information accurately and appropriately, and offering patient matching and accounting to the patient on how their sensitive health data is being disclosed. The opportunity is obviously improving stakeholders' understanding of existing privacy protections and identifying opportunities to improve technical and operational. We have recommended a couple of activities. Let's see what we want to add to this. So, encouraging the ONC to provide guidance on applicability of information-blocking exceptions to the exchange of sensitive data, which I think is very important, and then, suggesting steps towards a consistent technical and operational approach to protecting sensitive health data while enabling its exchange. Anything else that we should be thinking about? Other gaps? We talked about this last time, but other thoughts? Medell, I will start with you.

Medell Briggs-Malonson

Thanks, Aaron. I think the only thing we may be missing here is, once again, how to use the appropriate information in clinical care. I mentioned previously that especially as we continue to care for more gender-diverse patients, some of our algorithms directly in our electronic records systems are not picking that up appropriately, and they can, at times, provide information or clinical decision rules that may be confusing or not aligned with the providers' and the patients' preferences. So, I think that really, as our world continues to change, we become more inclusive, and people are being their authentic selves, making sure that we are incorporating that information appropriately into our clinical algorithms and clinical decision tools that are built within our health IT systems, so, those types of standards, and I am not quite sure if the Gender Harmony Project is actually working on these entities, but I think that is something that is really important for us to discuss and explore.

Aaron Miri

Great point. I had not thought about that. Great point, Medell. Love it. Jim? Eliel?

Jim Jirjis

I think it is incredibly important too. Medell, is it an appropriate example of what you are talking about that, for example, somebody treating a patient whose birth sex or whatever was male, but are identified and even have had some work done to, even estrogen therapy, etc., and now prefers the she/her, but in the course of care, the doctor needs to make medical decisions based on the fact that there is a prostate, and it could be a prostate cancer screening, how to do that while still respecting the individual's desire to be identified as a woman?

I do not think the informatics is as hard as the actual culture issues there because you get the representation of collecting a birth sex, and then where people are in their journey to their authentic self. I do not think us defining the fields... ONC ought to absolutely facilitate that, but the trick comes with the front desk person, who might have been working at McDonald's yesterday and is now over here, how they actually interact,





and people do not even want to go there and ask the question to complete that bad data, let alone how a skillful doctor or nurse interacts with the patient. Those are the challenges, it seems.

Medell Briggs-Malonson

Yes. So, gender is so technical, and Aaron, I know we are at public comment, but there are some technical aspects that I can give you, real-life examples that my institution had to address, but I know we are at public comment.

Aaron Miri

Yeah, let's go to public comment, and Eliel, I will make sure we get your comments too. Sorry to cut you off here. Mike, can we go to public comment, please?

Public Comment (00:53:34)

Michael Berry

Yup, we sure can. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause for a moment to see if anyone raises their hand. I am not seeing any hands raised, Medell and Aaron, so I will turn it back to you.

Aaron Miri

Perfect. Sorry, Medell, to cut you off, and sorry, Eliel, that you have not made a comment yet, but I will place it back to you.

Medell Briggs-Malonson

Not a problem. I will spend only 30 seconds on my real-life example. My institution is a center for gender health excellence, so we actually do make sure that we are providing comprehensive affirming care as well as everything from hormone treatments to also sex reassignment surgery. So, there are normally three primary areas within an EHR in which you record the sex and gender identity: Your legal sex, of course, your sex assigned at birth, and your gender identity. If any of those areas are not filled out appropriately, there are various different algorithms, especially in our EHRs like Epic and Cerner, that can actually lead to erroneous lab values, for instance, if your sex assigned at birth is not there, and maybe you do not have a legal sex, but you only have gender identity, or you have one or the other.

So, depending on the completeness of those fields, what may occur is that you may be given more of a narrow lab value for different forms of screening tests, which may seem that you have an abnormal result, which will then lead to potential overuse or overtreatment, but then, also, in addition, what can occur is what you are saying, Jim, in terms of preventative screening. So, for instance, let's say you are assigned female at birth, but now, you actually identify yourself as nonbinary or even as a trans man. You still may have your biologic organs, which still means that you do need to be screened appropriately for cervical screenings and many other types, so that is just something for us to think about as we are hearing from more gender-diverse populations.

Aaron Miri

Great point, Medell. Eliel, your turn.



**Eliei Oliveira**

Yeah, I have two quick ones. First, is there a consideration that this becomes part of the elements protected under HIPAA? Because it is not even part of the 18 elements that are considered PHI. The second one is in some of our projects data, when we are collecting data using the new standards, using FHIR and USCDI, they are very different than what is captured by EHRs and by health information exchange, meaning we are not able to match anybody, so I agree with Jim that there may be a collection or storage of specific information on gender for two different purposes, and at this point, I do not even know how I would even fix the EHRs and exchanges to be able to link data if standards like FHIR or USCDI do not match them. It is a part of the algorithms of matching to use gender.

Aaron Miri

Yeah. Linking us back to the past, we have proposed, as suggested items for further investigation, some sort of application clearinghouse. I am loosely going to call it a Better Business Bureau for health apps. Is it the FTC? Is it the ONC? Is there some sort of CHPL that is set up, like the ONC has for certified health products, that show bad actors and good actors? Because even at that, if you were to download a consumer app, it could be written in some country with loose data law jurisdiction that falls out of HIPAA, like genomic data, like 23 and Me falls out of HIPAA. HIPAA does not protect you when you give your genomic data to 23 and Me and similar companies. So, how do we warn people, like a Better Business Bureau, for lack of a better term, that the privacy of your data is at risk so that if you do want to be respected, as we all should, and receive care and information appropriately, that your data is not going to be misused or used against you for that point? I do not know of a clearinghouse like that. It is sort of left to the wild, wild west.

But, FTC and others are trying to tackle this. FDA is trying to tackle this. So maybe we listen also to what the other agencies are doing, similar to what we did before, and say how are you all contemplating this? Because right now, it is on the providers and the physicians to have to explain to the poor patients, "Hey, that app you downloaded that tells you this thing was really written in a country that you really do not want to be sharing your data with." I do not expect physicians to know that. That is not fair. So how do we do this to make it a very democratized, open way and transparent way? Those are conversations we should have and consider having with other agencies to say, "What are you guys doing?" so we can bring attention to this. All right, that was enough of me on a soapbox. We are at time. Medell, anything you want to say in closing? We have to close this out.

Next Steps and Adjourn (00:58:21)**Medell Briggs-Malonson**

No, this has been a wonderful, great discussion, like always, and I really appreciate all the various different feedback, and also all of the ideas, so we appreciate all of you all.

Aaron Miri

Great conversation. Thank you all. ONC, thank you, as every time. We appreciate you. Mike, Michelle, thanks.

Medell Briggs-Malonson

Thank you.

Michael Berry



You are welcome. Glad to help.

Eliei Oliveira

Thanks, everybody.

Aaron Miri

All right. Bye, all. Talk soon.

Medell Briggs-Malonson

Bye.

