

Transcript

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

September 16, 2020, 3:00 p.m. – 4:30 p.m. ET

VIRTUAL





Speakers

Name	Organization	Role
Aaron Miri	The University of Texas at	Co-Chair
	Austin, Dell Medical School and	
	UT Health Austin	
Carolyn Petersen	Individual	Co-Chair
Christina Caraballo	Audacious Inquiry	Member
Brett Oliver	Baptist Health	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Michelle Murray	Office of the National Coordinator	Staff Lead



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

Operator

All lines are now bridged.

Lauren Richie

Hello, everyone, and welcome to the HITAC Annual Report workgroup virtual meeting. We have our small but mighty team, our two co-chairs – Carolyn Petersen and Aaron Miri – also joined by Christina Caraballo and Brett Oliver. With that, I want to thank you for your time, and we'll turn it over to our co-chairs to get us started on next steps for the report.

Opening Remarks and Meeting Schedules (00:00:28)

Carolyn Petersen

All right. It is great to see everyone this afternoon. It feels like we are making a lot of progress really fast, and I am excited that we are able to get in another meeting this month and really keep things moving. Welcome.

Aaron Miri

Yeah. Welcome, everybody. Glad to see everybody on – and some new folks, too, I see, that have joined us and are part of the participants today. So, thank you for joining us. For those of the public listening, we have been making some great progress.

I think the last HITAC meeting was very illuminating. We got some great feedback, which we can talk about today as we go through the various topics. And I think our discussion, also, on electronic case reporting is the way it started on public health domain, but then it expanded to a number of public health components, specifically, around COVID, but also, in general, were very, very illuminating. You will also see it reflected in this report. I think after what Carolyn said, I feel very confident we are on the right track with topics. I think we are also on the right track in terms of things we should be considering or ask for consideration to think about next year. I also think that this group has done a great job of pulling out of the industry-relevant, salient topics that we should be thinking about, whether it's artificial intelligence, whether it is things like that. That will be on the near-term horizon in no time at all. With that, I think we should get into it. Carolyn, if you want to kick us off and I'll pick it up at the crosswalk.

Carolyn Petersen

Sure. Okay. So, here is our usual approach. Today we are looking at a crosswalk of topics, and we will see how far through this we get. We might finish early or we might not, depending on where we are at. We will have our public comment period and then adjourn until our next meeting, being pretty soon. Okay. So, here we are. We are working on the crosswalk of topics today and, potentially, that will continue at the next meeting at the end of September. If not, we will just keep pushing. We have got a meeting in October and November and December, and then after that we are looking to bring the draft to the full HITAC for review and approval. And here we are on our schedule. This is the HITAC schedule. The big meeting on the 21st, the 10th, and then next year.

So, today we are looking at the draft crosswalk of topics, and then we will be presenting an update on that crosswalk in October at the full HITAC meeting. The October meeting is a week later than usual, so that



should give us plenty of runway to get this in good shape and feel like we have a good solid base for discussion. Slide, please. Okay. And I think Aaron was going to grab it from here.

Discussion of Draft Crosswalk of Topics for HITAC Annual Report for FY20 (00:03:30)

Aaron Miri

Yeah, let us do it. Let us go into it. All right. So, next slide. All right. We are going to go into the crosswalk now and talk about these four priority target areas. For those of you who listened to the big HITAC call the other week – we also spoke a bit about this – but we are going to go into details now. So again, the first targeted area are technologies that support health – like I mentioned earlier – second target area is interoperability, third is privacy and security, and fourth is patient access information. You will recognize these topics, also, for those that are new to joining us and listening in, that a lot of these were directly from 21st Century Cures and what we were charged with looking at as terms of the HITAC. We want to make sure we stay as close to charter as possible on these kind of things.

Next slide. All right. Oh, that is the public – let us go into the actual crosswalk now. Can you pull it up, please, for me? All right. Perfect. Let me blow that up. All right. Okey doke. So, Michelle Murray, can you keep me honest? Which one did we leave off of last time? Because I do not want to rehash the past, unless there is a topic – Which one did we leave off of? We start here at the top?

Michelle Murray

You ended in interoperability with the new topic idea about health equity. So, the next one would be sharing data with the research community.

Aaron Miri

Perfect. That is where we were. Okay. All right. For those who are new listening in – or anybody listening – the way we do this is, again, we went by each of the category areas and then each of the items within. And so, we are going to pick up where we left off last time, because you can imagine the topics on this. So, we are starting again here with the sharing data with the research community. The gap that this group identified was a challenge by data quality and consistency concerns, limited governed instructions and policies allowing access to data, inconsistent limitations across technical architecture and varying needs of individuals and organizations that create and use data. And some of the challenge here are human subjects in the common rule, consent, and privacy. I think there are consent items here.

We have found a number of issues with sharing data, particularly with other restrictions that are in place in academic healthcare systems. We have been warned by federal agencies of foreign actors attempting to get data, particularly recently it has been the COVID-19 data. So, there has been a lot of how we share data appropriately in addition to data quality, data provenance, consistency, all these other items. And so, what we want to talk about as a group with us is, what do we think we should present back to the HITAC as what we need to do around this?

I will give you a real-world example. I think you all know me by now, and I like to talk about stories. Here at UT, we have a number of initiatives and research that we are partaking in. One of those is trying to get in front of dementia and delirium. And getting in front of patients that are delirious, or potentially have the onset of delirium – which is one of the most cognitive destructive states out there –to get that data requires... This is a research project – a giant funded research project. It takes data from EMS, takes data from us,

4

takes data from other hospital systems in the region as well as long-term rehab, nursing homes, all sorts of things. It has been very difficult, and the data that we do get imported into us – even with the right data agreements and whatnot – has data variability in it. We have to really massage it to get it to know what we are looking at. As they always say, data is not insight.

But the problem is that there is no true standard of how to share data on a research level. Maybe that is something that TEFCA could help out with one day. But even then it becomes difficult – becomes murky – and you have got to make sure you have consent, or an IRB waiver, or something to that effect. I say that with – this is a very broad topic when it comes to research, but it is very salient, particularly, with COVID-19 and other issues going on. There may be a way – whether it is leveraging USCDI standards, whether it is proposing standards, whether it is proposing more in-depth research taskforces – that we could tear this item apart and really solve it thoroughly. What do you all think? Maybe, Brett, we will start with since you are the physician. Go ahead, sir.

Brett Oliver

Is the gap data beyond USCDI? Or is it more the quality...?

Aaron Miri

It tends to be both, actually. From my perspective, it is both. So, you have got data. Obviously, some of it is structured, especially from the notes or from the medical records. Some of it is unstructured because you have got ambulance transfer forms, the pink slips. Those are literally pieces of paper that are scanned in to some PDF. You have got other – and I am using my delirium example here – and then you have got all these other data sources that are from EMRs that were not, unfortunately, given investment dollars into it about a decade ago for the ARRA. So, you have got systems that do not fall under the auspice of having respective standards they have got to follow. It is a little bit of everything which is impacting that, at the end of the day, the result. And then it is, say, Brett, you are doing a QI project, or even an IRB approved research project. You are frustrated, because you are like, "What am I looking at?" Right?

Brett Oliver

Right, right. I almost feel like it ought to be on the timeline but later, in the sense that we do not know what opportunities are going to open up with just simply the information blocking rule and USCDI going into tech in November. There are several things, just from my perspective, that we are holding off on. For instance, we have... our EHR has a community connect piece and we get a lot of interest from other practices saying, "Hey, we want to connect to your instance." I am encouraging them in our organization just to hold off a second. Because all these EMRs that are going to be forced to exchange this data, maybe that is going to be enough for CINs and ACAs and things. At least, wait and see. I do not know. I do not live in the research community to be able to say something has to happen now. I am just wondering if the USCDI and information blocking is placed – is made live. Everybody has to comply. What parts of this challenge – this gap – are covered and which ones still are not?

<u>Aaron Miri</u>

That is a great point. Carolyn? Christina?

Christina Caraballo



Yeah. One thing to think about. I think there are groups that are not going to wait. So, when we think about things like initiatives, social determinants of health, we have got great work happening as we have talked about extensively in the gravity project. And they recognize that they need to expand the domain more quickly and get an implementation guide out, because industry is asking for it more and more. I am currently working in the D.C. market on a project with social determinants of health, and they are trying to align with national standards, but the standards are not moving quickly enough. But these projects are moving. They need to happen.

More and more community-based organizations are really interested in getting clinical data and information, and then making informed decisions to help patients. I think this is becoming an increasingly important and hot topic. And when we think of health equity, I think it is really, really important to start thinking about how we are enabling data and ecosystems to reach populations that are more vulnerable and are suffering because of lack of interoperability.

Aaron Miri

Good points. Carolyn?

Carolyn Petersen

Yeah. I agree about groups of people moving on things they think are important, particularly the SDOH disparities. I think that could be happening with health equity, also. I mean, it is certainly something that is trending all across society right now, not just health and health IT. I do not know how this exactly fits in, but I am anticipating that there will be greater pressure on patients. Because people are in more extreme financial situations right now with challenges, in terms of paying for care because of reduced employment and all the COVID stuff that makes life more challenging and forces us to do things that add costs. So, it is important, but it is also complex – this area.

Aaron Miri

Yeah. That is a really good point. Let me just try to tease out a couple of bullets that I just heard from you all as I was taking notes here. One is, obviously, this is a major stumbling block that has multiple arms. I think of it like an octopus. So, there are numerous arms – numerous tentacles we have to go after here and go deal with. So, is it worthwhile? Because I know that HITAC has talked about this a lot. And particularly, you have folks like Les and others that have brought this up numerous times, that we need to deal with research. And I agree with that. Is this something we should call and ask for experts to come testify in front of the HITAC and illuminate some of these items, knowing that work is ongoing with information blocking and TEFCA? But at least we tease out all of the different dimensions that are true bug-a-boos today, like I just spoke about in my one example. I am posing it as a question. What do you all think?

Brett Oliver

Yeah. I am fine with that approach, Aaron. I do not know how it is going to be fruitful for people to move ahead. We have a USCDI process in place. So, is that not what we should be funneling these lack of consistency in data quality concerns through? Maybe I am just missing the point of that. If groups are moving on, that is their prerogative, but that doesn't mean that we change our priorities that have already been outlined by ONC. I am just confused with what you were saying, Christina.

Christina Caraballo



Yeah, Brett. And I hear you with the telling your community data connect group to hold for a second. I think what we should potentially do is take a step back and listen to both sides, the provider organizations that might be saying, "Okay, we have got a lot going on right now. This is what we are doing, and this is what we can support," and those that are trying to push forward and build scalable solutions around things such as social determinants of health, that are trying to use standards so that they are able to scale. And I think what we might find is that we have... Let me think through this a little bit.

I think an evaluation of where we find a happy medium, and advise on how to implement with standards and understand where the big gaps in standards exist, would be helpful. I also think when we are talking about more advanced standards that the hospitals might have, some of these smaller community-based groups may not be able to support them. So, there is also a growing... Another reason that we should look at is the haves and have-nots of technology capabilities that are still trying to implement solutions that can interoperate amongst themselves.

Aaron Miri

Okay. I think what I am hearing is that we are recommending as a group for this item – so we can move on to the next item – is that we want to know some more specificity about the different dimensions of impact. Whether it is data quality and provenance. Whether it is process issues with how to advance a new class. Whether it is, "Does USCDI match and align to what the research community needs?" Et cetera, et cetera. And I do know that a lot of work has been done in this dimension as well. So, we should not try to recreate the wheel. And if I recall – top of memory only – that the ONC five-year plan also referenced research in there. So, we should probably align to some of that work that has already been done, too, of what is already ongoing in the community. Does that sound like a plan?

Christina Caraballo

Yes. And I do agree with Brett that going through the USCDI process is the right approach.

Aaron Miri

Okay.

<u>Brett Oliver</u> Christina, were you saying – Were you –

Christina Caraballo

It is just identifying what other areas have.

Brett Oliver

Maybe I can understand a little bit better. So, are you saying, maybe, okay, there is the USCDI process and then... but perhaps ONC could come up with the data standards, even if it is not required. But here are the standards to use for this dataset so that there is some consistency there without it being part of the USCDI at that point?

Aaron Miri

You may be on mute.

ONC Annual Report Workgroup Meeting Transcript September 16, 2020

Brett Oliver

Christina?

<u> Aaron Miri</u>

Christina, are you on mute?

Christina Caraballo

No, I am thinking.

Aaron Miri

Oh.

Christina Caraballo

I actually just... You guys might have moved on to the research community, too, and I was also incorporating the health equity, which we might have moved past. So, I might have been a little off-topic in calling myself out on that.

Aaron Miri

Okay.

<u>Christina Caraballo</u> [Inaudible – crosstalk] [00:17:22]

Brett Oliver

I just want to lay on thick, I get what you are saying is, before we make it a requirement, could we throw out standards. That makes a lot of sense.

Aaron Miri

Like voluntary? Like a voluntary framework?

Brett Oliver

Yeah. Here is the framework we would recommend. It may become part of the USCDI in the future, but to expedite some of these...

Aaron Miri

Yeah. That is a fair idea. And I think – I don't know, Carolyn. Is that something we would propose as an idea to the HITAC? Because we did it with the pediatric standards.

Carolyn Petersen

What... gosh. Lauren may not even know. It is only September. Do we have anything coming up, Lauren, in terms of work for the HITAC next year that we already know about where this would fit in? I mean, I am thinking the pediatric stuff. Would it not fit with the work that we were doing in that point in time? So, it was not that we specifically wanted to go after the pediatric, it was that it was part of the NPRM.

Lauren Richie

8

ONC Annual Report Workgroup Meeting Transcript September 16, 2020

Yeah. Yeah, no. So, we are currently working on the work plan for the committee next year, so we do not have anything to share at this time. But we will have an opportunity for the members to weigh in on the broader plan for the committee next year coming up soon.

Aaron Miri

Okay.

Carolyn Petersen

Let us put this on the list, then, as something that emerged from this working group and submit it as an idea on behalf of this group. Because I do think it is relevant, and I think it will probably be of significant interest to at least some of the people on the full HITAC.

Aaron Miri

Oh, yeah. Absolutely. Okay. Keeping with time, then, I am going to move us on if everybody is okay with that to the next one here, which is the establishment of common metadata and nomenclature and use. This is determining the types of metadata and related standards necessary to facilitate machine-based clinical data management, including management of exchange data, to reconsolidate it for multiple sources. I am going to go on a ledge. I am not the one who came up with this one, but I am pretty sure this ties right into the research community discussion. Does my memory serve me correct? Carolyn, do you remember this?

Christina Caraballo

I think that's relevant.

<u>Aaron Miri</u>

I thought this – yeah. This is part of it. I think this is part of that discussion.

Brett Oliver

I think you are right, Aaron.

Carolyn Petersen

Yes. It was a broad and all-encompassing discussion, as this topic usually is.

Aaron Miri

Yeah. Okay. So, for Michelle and for everybody, I think we will combine these two together in terms of data with the research community, because I think this was a subtopic of that one. And we will use the same promotion of, hey, let us find out some more about this from the full HITAC where we can go into more details about it. All right. Next item here. Correction of incorrect data and ramifications of exchange of incorrect data. So, there is a limited ability to correct data that has already been exchanged. As a result of incorrect **[inaudible] [00:20:17]** persists to be further disseminated. Transparency of that accuracy shared lacking from patients with it affects patient safety. This was Clem that said this, right? I think I remember this comment. I agree with him.

So, the problem is without the standards in place that have been adopted, without those kinds of things, both in research and clinical operations – and as USCDI is not in effect and being followed – this is an issue. But I think, again, this goes back up with the research item. A lot of this, we have to fix it upstream





for the downstream effect to look right. Call me crazy here, but that is how I see it. Carolyn? Brett? Christina? What do you guys think?

Carolyn Petersen

Makes sense to me.

Brett Oliver

I think that is where you have to start, Aaron. Somebody is going to have to define what my responsibility is as a provider and as a system. And I guess anybody that is producing the data... What is my responsibility if I find out...? What I got from you, Aaron, somebody moves up from Austin, and you tell me, "Hey, that CBC machine was off. We have corrected the values." Oh, well, they have already moved onto somebody – that piece is... the liability piece is pretty nebulous. We just got done working with EPIC on a data accuracy in the interoperable world workflow for other EPIC customers. So, it is out there. It is a topic that I do not think anybody has got all the answers for.

Aaron Miri

Yeah. Okay. Christina?

Christina Caraballo

Yeah. I am in alignment with everyone else on this one.

Aaron Miri

Okay. So, then, what I am hearing then, Michelle, for this one is that we will bundle this also with the research one, but make it a little bit more broad in terms of... If we fix the upstream stuff, this should get better. So, I do not want to ever take any HITAC comments and put them aside, but this one could be mitigated with upstream work that we are also talking about. So, it fits in line with that. Okay.

Michelle Murray

Could I ask one question?

Aaron Miri

Yes, ma'am.

Michelle Murray

This source was a patient advocate on the HITAC. So, I think they are trying to get at a patient access concern. So, I just want to make sure we are still keeping that in the discussion as well.

Aaron Miri

Thank you. Thank you for that. That is what I was try – okay. So, this is patient access related, which... I still stand by it, though, that the upstream work and the stuff we talked about last time – and for folks that were not on the call, it was around health equity. And when I say health equity, I mean by an even playing field for all patients of all demographics – of all types, sizes, colors, whatever – where they have equal access to their data, and thus healthcare, and the abilities to be delivered care to them. And that is health equity. And so, there is a strong push – and I agree with it – that it should be a level playing field and even for everybody. And so, access to the right data, the right place, the right time, is absolutely part of that



ONC Annual Report Workgroup Meeting Transcript September 16, 2020



equation. So, if that is the case, then I still stand behind that this should be bundled in and will be addressed upstream. What do the rest of you think?

Brett Oliver

Michelle, that was helpful. Because I remember that conversation now. It was more around – if I remember correctly – that if the patient thought something was wrong – not that it was objectively wrong – and wrong lab, it was the wrong patient. Patient says, "No, I do not have this problem." And that is an obviously a very sticky and legal liability question, but that is where I think that came from. So, transparency in terms of what is available to review is one thing, but whoever creates the data should be the one that has the ability to correct it. That make sense?

Aaron Miri

Mm-hmm.

Brett Oliver

It is a pretty slippery slope, but patients do not agree. "I do not have diabetes. I do not, so you better take that off of there." Really? Who makes that call? Do you remember that, Michelle?

Michelle Murray

I remember the conversation. I do not remember the nuance that you are talking about, but that does not mean it did not happen.

Brett Oliver

Okay. No, I did not mean necessarily the diabetic one, but it was the patient could not change what was in there. And I am not sure that is what you want to do.

Michelle Murray

Yeah. I think that is what they were getting at. You are right. They wanted to have more of a voice in what is in their record and be able to fix it. And it was also an exchange issue. They were worried about the data being wrong and being forwarded to other groups and not able to correct it there either.

Aaron Miri

Oh, I remember this conversation. Yes. That is right. That is right. That just jogged my memory. Okay. So, are we still standing by our recommendation then, team? That this is an upstream, and this will be fixed downstream? Or is this something specific we want to talk about?

Carolyn Petersen

Or do we want to move this to the other topic area?

Brett Oliver Where would you move it, Carolyn?

Carolyn Petersen

Patient access.



Aaron Miri

To patient access?

Carolyn Petersen

[inaudible - crosstalk] [00:25:09] topic area. As I recall, there was not a whole lot there.

Aaron Miri

That is fair.

Christina Caraballo

Yeah. I think that makes sense to move it to patient access.

Carolyn Petersen

I am just thinking, since that was the context in which it came to us.

Aaron Miri

Yep. Okay. So we are going to move that to the other area. Okay. I am good with that, then. Do we want to move on, then, to the next target area? Or do we want to stay on that topic?

Carolyn Petersen

Is there more to say about it?

Aaron Miri

I do not think there is, but I just want to make sure that we did not miss any of the dimensions. Michelle is doing a good job of keeping us honest.

Michelle Murray

My question to you is, do you see specific challenges, opportunities, or recommendations you want to help fill in on the chart at this point? Or do you want to come back to it and talk about it more later on?

Aaron Miri

I think we come back to it.

Brett Oliver

I think I would like – I would just say, in the future, I would like to have a better understanding of what are the legal statutes that already surround this.

<u> Aaron Miri</u>

Mm-hmm.

Brett Oliver

Because we are about information exchange, and nobody on this call or on the HITAC really has a problem with that. We are talking about correcting the data. And maybe that is not even the right phrase, but having data that is in dispute... What happens there?



Aaron Miri

Mm-hmm.

Brett Oliver

And I do not know what the law says currently.

Aaron Miri

Yeah. I do not know enough. That is right. I do not know. Okay. So, we are going to come back to this, if everybody is okay with that. We are going to go find out more. All right. Let us move on.

Privacy and security, my favorite topics here. All right. Topic is protections for data generated outside of HIPAA framework, federal privacy laws, and regulations beyond HIPAA. So, the gap is lack of clear rules for data not subject to HIPAA protections. And the challenge, of course, is third-party access to health data. There are implications of private protective partnerships between absent payers, e.g. what we saw play out in the news between Google and the Ascension healthcare system. And as we have seen publicized – although probably buried with all the other news going on with COVID – folks like 23 and Me selling the data – your genomics data. Other companies that fall out of HIPAA jurisdiction, but that do not really fall into FTC jurisdiction, and it is this gray area. I feel like there has been a lot of discussion about this in the past couple of months, again, interspersed with COVID. What do you all think? Because I think this is a huge gap, but there is a lot of work going on here. Carolyn, what do you think?

Carolyn Petersen

Yeah. I certainly agree it is important and I think we all know about the gap. And there is no shortage of perspective pieces in high-visibility journals addressing the fact that we need to do something about data that is not covered under HIPAA. If HITAC could have a joint meeting with representatives from other organizations that get at some of these issues – like FTC, for example, or OCR – I would support a meeting similar to some of the hearing that we have had in the past on other topics. I would support launching some kind of shared interagency activities to try to do something about this. And I am totally behind it all the way. It seems that, so far, it has been a really intractable thing, because we just do not have power to make things happen as a HITAC.

Aaron Miri

Right. Brett? Christina? Your thoughts?

Brett Oliver I like the way Carolyn has outlined it.

<u>Christina Caraballo</u> Hey guys, can you hear me?

<u>Aaron Miri</u> Yes, ma'am.

Christina Caraballo

Okay. Sorry. I got kicked off the call at the bottom of the last one. I just got back in. Where are we?





Aaron Miri

We are talking about HIPAA and data generated outside of HIPAA that does not qualify – like genomics data, partnerships with third parties, like Ascension and Google, that sort of thing. So, the idea was – and Carolyn brought up a good point – which is we can call a hearing and have folks from the OCR or other agencies come talk to us, and then tell us what they are working on. I know there is work going on in Capitol Hill – or there was – related to this issue, again, before COVID. So, this is not something that is lost upon folks. People know there are issues here. What do you think?

Christina Caraballo

Yeah, that sounds great. I think I came in when I heard Carolyn say "OCR" and summed up. And I think that – what you just said – a hearing around this sounds like a really great idea.

Aaron Miri

Brett?

Brett Oliver

Agree. Thanks.

Aaron Miri

Okay. All right. And then, I think the next item here is the same as this first one here, which is protections for data generated outside of HIPAA framework, the lack of clarity about parameters of data sharing and disclosure and implications. We need to learn more. There is so much going on here, that I would hate for us to go recreate the wheel, or go against what is already being worked on. And the committee could probably all learn about what is going on between the agencies, I would think. So, I am in favor of bundling these two items together.

Carolyn Petersen

Did we unbundle them previously, because the actors who would work on them – or could work on them – were different? And you might be looking at a separate set of activities, even though they would hopefully keep each other in the loop. Or am I misthinking?

Aaron Miri

I do not recall, but that may not have been part of that conversation, Carolyn. I do not recall that, but that is logical.

Michelle Murray

This is Michelle. On this list, I think they were unbundled principally because the gaps are different. But I think they are different probably because of what Carolyn is saying, that they are different actors, and therefore maybe different approaches. So, if you do not want to keep them separate, we do not have to, but they were because they might be slightly different discussions.

Aaron Miri

But it would be the same agencies, right? Carolyn and team? It would be the same folks, right? You have OCR, FTC, potentially FDA. These are the same people. It is just different activities.





Carolyn Petersen

I am not sure.

Aaron Miri

Okay.

Carolyn Petersen

I think that there has certainly been more activity around – more interest behind – some privacy legislation that might not come at it from the "We are here to deal with the non-HIPAA stuff." It might just be a general privacy thing intended to cover social media at large, consumer over-the-counter genetics kits, over-the-counter – god forbid – COVID tests, and so forth. We think about it in terms of something that FTC manages. Privacy as something that FTC manages because it has a security role, and it can use that to leverage what people do that affect privacy. And we think about OCR because there are discrimination aspects, but that is just a pre-existing framework based upon historical situations. And we could really be looking at something completely different in the future. Especially if there is a decision to go down the road with, say, COVID test ports, or some kind of scheme for reporting and verifying test results so that people can travel, or when you go to the hospital you can have visitors with you, or you have to go alone because your visitors do not have the kind of proof that they should be not transmitting right now, or other stuff.

Aaron Miri

Okay. No, I agree with you. So, do we want to, then, recommend the same thing? Or do we really need to know more? Or maybe we can ask for more research on this? I do not know, Michelle, if there is time, because as we said the AI gives us a landscape update on what is going on.

Michelle Murray

Yeah. I can look into that for you.

<u>Aaron Miri</u>

Because I just feel like I do not have enough eyeballs on all the different pieces moving on this, regardless of who the actors are.

Michelle Murray

That is cool.

Aaron Miri

Okay. So, we are going to come back to this one then, unless – Brett or Christina – unless you guys feel differently? Let us get some more data in front of us and then figure out we are going to recommend it to the HITAC, because I think this is an important topic. But I do not want to go there without up-to-date knowledge. Right?

Christina Caraballo

Mm-hmm.

Aaron Miri



Okay. All right. Internet of things. There is limited interoperability between IoT vendors. As IoT objects become more integrated into health IT systems, security risks increase. Additional concerns have been raised regarding the challenges of informed consent – yes, that is for sure – for use of IoT technologies. Michell, is there anything else on the next page on this one?

Michelle Murray

Not on that one. I want to make sure we do come to one before it, because I think we skipped that one.

<u>Aaron Miri</u>

No, no, no. That is fine. That is fine.

Michelle Murray

Okay. I threw it away.

Aaron Miri

Nope. That is fine. Yep. All right.

Michelle Murray

Keep it.

Aaron Miri

So. All right. So for internet of things, is this something that is relevant to today or not? I will give you a specific example. Again, more stories for you. So, one of the programs we put in place to manage our COVID-19 population was home monitoring. This is temperature home monitoring. So, we prescriped Bluetooth thermometers that patients could take with them if they were suspected COVID, or COVID positive tests came back. That way they could check in via a remote app – Android, iOS, or web-based – on a periodic basis and then we could intervene if their temperature was going and passed certain thresholds. And we built in some clinical decision support rules to automatically alert. Like if your temperature shoots up to a 103 or something within a short range, so we could immediately intervene and get to you before you have a major event occur to you.

Obviously, it took a lot of consent. It took a lot of consenting for people to do that. It took a lot for us to work with the actual manufacturers of these technology stacks. We had a really good third party we were partnering with that helped us navigate that, but it was not clear. And it really was not clear to make sure that that data was only ours and that once the patient consented in, that it was being used for – in this case – COVID-19 treatment purposes and that it wouldn't be used for other reasons. There are a lot of items here around consent and IoT that just were murky. And we may err oon the side of caution and ask too many times for consent. But you know what? I would rather ask 10 times than not. So, we tried to cover all of our bases, but it is not clear.

So, if you look at these things... And then getting that data back. How is the data structured? How would it be imported into the chart eventually? That sort of thing. It was a lot to work through. So, a lot of that mapping had to be done, a lot of manual work. So, that is just a real-world example of how IoT devices play in your ecosystem, and some of the behind the scenes challenges to integrate them. Not that that is a bad thing. It is the right thing to do, but each manufacturer tends to have their own playbook. And it comes back





down to standards, and it comes back down to other concerns – security concerns – what data is stored on the devices.

In my case, thermometers do not store really anything locally. It just transmits. Or it is stored in random access memory, nothing long term, so it is really short-term memory. So, to the degree of if we were able to overcome any compliance concerns or security concerns, but still, it is a risk. Knowing that this is the problem with IoT devices, but yet they are absolutely presenting themselves – and even with the new Apple watch yesterday – now announced that can do O2 monitoring. How do we feel we should tackle this? Because this is another big, deep, and wide topic. What do you all think?

Christina Caraballo

Aaron, as you were talking through example, it seems to tie into the topic above with the HIPAA framework. I am specifically thinking of third-party apps and getting patient-generated health data, both getting it to the app and the app sending it back.

Aaron Miri

Mm-hmm.

Christina Caraballo

I see where they could be separate. But if this was emerging – But that identified hot topic within this, we could potentially put it up in a bundle with the others, with the HIPAA framework ones.

Aaron Miri

That is a great though. What do you all think? What does everybody else think?

Michelle Murray

Yeah. I could do that.

Aaron Miri

Okay. Brett, what do you think, sir?

Brett Oliver

Yeah. I think that makes sense.

Aaron Miri

I am curious, Brett. From a practitioner's perspective, as a provider seeing patients every day, when it comes to IoT devices, you have said to HITAC numerous times that some of that data is worthwhile to you as a physician. Some of it just is great background reference material. When we say IoT devices, is there any qualification in your mind, as a physician, that certain types of devices – I am going to give an example, a Pulse Ox device, or something that does true EKG and has been validated. This has more – I am going to use the word – weight or merit in your mind from a clinical sense than, say, a thermometer. So, are there classes of IoT devices, is what I am getting at, that we should be paying attention to if we do elevate this is part of a HIPAA, or whatever else, so that we are not trying to boil the ocean?

Brett Oliver

ONC Annual Report Workgroup Meeting Transcript September 16, 2020

Oh, boy. And that is a great question. There is certainly that data that we request – and maybe it is an IoT device or it is something that we have already integrated. So, there is that piece versus someone's heart rate from their Fitbit, or something that clinically we did not ask for but a patient wants to share with us. I would have to think about that a little bit more. I do not know.

Aaron Miri

I totally appreciate that, because this is a big topic. And my only worry is if we elevate the totality of internet things into the HIPAA discussion, we will get lost in the weeds because it is just so wide. But if we focus it on classes of devices – maybe it is FDA approved IoT devices, which I am seeing them approve new devices every single day. I see the announcements. I am thinking of a watermark, so that we can still get to the root of the issues, but we focus it on what we will maximize traction at first, and then we can boil the ocean back. That at least is how I am seeing it in my head.

Brett Oliver

Yeah. That is a pretty good approach if you go into FDA devices. Because there is going to be a framework that comes from that that would potentially be applicable to non-FDA approved devices. But to your point, it would at least allow some level of filtering to have the discussion.

Aaron Miri

Okay. Carolyn, Christina, is that an okay watermark? So, I think we would bring this up. We elevate it and bundle it with the other items. But we try to focus on our own FDA-approved IoT devices.

Carolyn Petersen

Yeah.

Christina Caraballo

I think there is still a gray area on that. I know back in my days of working for Get Real. So, we were an app that got data and information from devices such as a Pulse Ox or a suite of devices. And some of those devices may have been FDA-approved, and some may not be because that is a big gray area right now. Some of that data is still very valuable. But a lot of these groups within the consumer app world have done a lot of work to vet which are more reliable and which aren't. And many of them are sourcing where the data is coming from, like specifically saying this is from a Fitbit, for a provider to know, for example. So, limiting it to FDA-approved, I think, narrows the scope too much.

Aaron Miri

Okay. Is there a category – I think you can see the logic of what we are trying to think about here. If we do not say FDA-approved only, is there another way for us to slice this pie so that it is digestible in your mind?

Christina Caraballo

Hmm.

<u>Aaron Miri</u> Do you need to think about it a little bit?

Christina Caraballo



Yeah. Let me think about it. [Inaudible - crosstalk] [00:42:52]

Aaron Miri

Yeah. Marinate on it.

Christina Caraballo

I think there is a class right under, and I cannot remember what it is.

Aaron Miri

Okay. All right. So, then, Michelle, we will get back to you on that slice of it. But bundling it and then looking at IoT devices with some lens on it is what we are recommending. Does that make sense to you?

Michelle Murray

Yes.

<u>Aaron Miri</u> Perfect. Okay. All right. Next item here, please. Scroll down.

Brett Oliver

I think we missed the synthetic data one.

<u>Aaron Miri</u>

Oh, did we? Did I skip over one? Sorry about that. Where? Oh, yeah, I did. I just totally... Boy, I -

Brett Oliver

It was yours, too, Aaron.

Aaron Miri

I know. My goodness. Come on, man. All right. All right. Privacy and security and synthetic data. Determining unique privacy and security considerations driven by the emergence of synthetic data. Imagine being able to conduct research, train machine learning model, et cetera, without the constraints of HIPAA. All right.

So, let us, again, talk about examples here. One of the issues that we have encountered and run into is modeling. And so, it is the next level of data analysis there – data aggregation. Typically, when you look at real-world data sets, you are either going to get an informed consent from the patient saying you can use this data for research purposes, or – if it is for a true research project that is IRB approved – you get a HIPAA waiver which allows you to use data appropriately, to use like a COVID-19 data result, whatever else. But that takes time, and that draws a lot of resources and a lot of time and draws things out. And if you are looking at some things like – I do not know – creating a vaccine for COVID-19, every day counts.

Synthetic data allows you to mimic – or perhaps take a real data set, completely jumble it up to fake names, so that Aaron becomes "A. Aron" or something. I do not know. It is some fake information, but the information in there is relevant enough that you can model and begin to start generating what could work, what could not, and then tease out those other issues. That is synthetic data, for lack of a better term. It is





data that you are able then to really create those learning models that are self learning. And then once you have actual data to plug in, you are able then to really extrapolate and hit the ground running. It just shortens your runway to goal.

So, the question, then, is with synthetic data and even deidentified data that is sometimes considered synthetic – and even though we all know there is no such things as true deidentified data anymore – What are those items that we should think about? Because all data should be treated respectfully and appropriately, and all data should be treated with careful gloves on. But there is not really a rules of the road when it comes to that. In my mind, though, I see this as something that ties also into the research domain, and also with the earlier frameworks – for earlier topics – around research that we need to – how to exchange data with the research easier. So, to me, my suggestion up front would be to bundle this as one of the subtopics under the research item, but I will leave it to you all to come up with your questions. What do you all think?

Brett Oliver

Aaron, help me understand a little bit further. So, how does that differ from just, say, machine learning?

Aaron Miri

No, Machine learning is done on synthetic data, or on actual data. The more data you feed a model, an algorithm, the better that model becomes. And so, what we have turned to are these giant data sets of, again, mirrored data, mimicked data, whatever – but they are not actual patients – to try to create those models. But then what do you do with this? Is it the wild, wild west? Is it not? We treat it like HIPAA data here, because we are just overly cautious about everything, but I am not certain everybody does that. And there is a lot of big market now for synthetic data, and getting bigger.

Brett Oliver

So, you take a data set that is identifiable, and you create, essentially, fake patients from that data, like randomize it.

Aaron Miri

Yep.

Brett Oliver

What are you protecting HIPAA from? Because it is based on some actual data that may be able to extrapolate back?

Aaron Miri

Yes, that is exactly what we talked about in HITAC, is that at some point, if you had enough specificity in the data set, you could pick out the unique patient or two, especially if something was very, very unique. You could still try to get back at that with reconstructive learning. And that is the whole problem with the deidentified data, is that there is no such thing – as research has shown – as truly deidentified. And so, the same logic applies for synthetic data. There is really no such thing as true synthetic data.

Brett Oliver

Yeah. Thank you for your patience. That makes a lot of sense. It seems to me like it fits nicely with the previous HIPAA discussion. But what do you all think? Carolyn? Christina?

Carolyn Petersen

I am trying to think if there are devices that we do not typically think of as health devices where you would want data or connection, and that might bring additional issues or needs or baggage that would essentially implicate different agencies in terms of regulation or oversight.

Like, you do not think about a thermostat being a healthcare device, but if you could monitor how the thermostat was set and you saw that it did not change one morning when it was cold outside, that could be a signal that an elderly person had fallen and was not able to get up in the morning and turn up the thermostat. And that might be a signal – a trip – that someone should call the house and do a well check, for example, if they did not want motion detectors in the house. Some people are not comfortable with that, and I do not know that I would be myself. But the thermostat, that is something where your kid could be monitoring it on the premise of it is part of the deal with paying the electric bill, or helping you manage the house and used that way. You do not think about a thermostat – the thermostat is not like the wearable, or the tracker, or something. It is not designed for healthcare, but you can... By looking at what it does, you can extrapolate healthcare uses for it.

Aaron Miri

Yeah, that is true. That is true. Okay. And that can feed into a synthetic data set. That is true. Okay. What else? Christina, what do you think?

Christina Caraballo

I am thinking. I probably am less versed in this topic. I like that what you laid out, Aaron, putting it in potentially with the research. I am not sure.

Aaron Miri

Okay.

Christina Caraballo

The picture you painted sounds pretty. I think it is really important.

<u> Aaron Miri</u>

Yeah. It is very important, and it is getting even more important. So, I think that it was another one of those... It is like the IoT item. It was more emerging and now it has become pretty standard, particularly in the research community, academia... I would use the term "data hungry" but I think that is not doing it service. It is like a voracious appetite for data in the research community. I see this every day. Maybe not everybody does, but I do. And so, it is becoming more mainstream, because, obviously, that is what is feeding all the machine learning and augmented intelligence algorithms that are out there is data, data, data, data. Right? So, what are the protections of that? How do we insure that there are rules of the road that are commonly understood? That is what this nets down to. I am hearing from this group, then, to promote this item into the other buckets. We are talking about the research bucket. Correct? And then this is a subtopic of that. Did I hear that right?





Christina Caraballo

Yeah, I think so. I think it is an important subtopic, too.

Aaron Miri

It is important. Yeah, it is very important. Oh, okay. All right. Michelle, is that clear for you?

Michelle Murray

Yes, but the comment also talked about – like you already mentioned – training machine learning. And I think it would apply to when people are developing software and needing to test software. So, do you think it goes beyond research-based on what the original comment was? You can scope it however you want. I just do not want to lose that by accident.

Aaron Miri

That is a fair point. That is a fair point. It is beyond research. Although, I would consider R&D, even developing product, as research. But that is just my personal lens on it.

Christina Caraballo

But you can make data. You can just create fake data for R&D purposes. Right? Like you actually need real data **[inaudible – crosstalk] [00:52:18]** that.

Aaron Miri

Right. Right.

Christina Caraballo

And I think that [inaudible - crosstalk] [00:52:21]

Aaron Miri

Yeah. Right. If you are creating an algorithm on OB patients between the ages of 20 and 30 that have Type 1 diabetes that live within a certain – AKA one of my exact data requests that are sitting right in front of me right now, that I am reading here for one of my researchers. I need actual data on patients, and that is going to result to tens of thousands of patients, whatever, for the past decade or so. And then, if I need more to finish this model, I create synthetic data, or I find a synthetic data model, of these similar types of patients. But you are going to need women who are pregnant in those age groups that have comorbidities, like Type 1 diabetes. You are going to have to have that. So, that is the worry, is could you – from that bolus of patients – find that one or two unique patients – say, in this case, Travis County here in Austin – that have some other condition? And it is like, oh, man, now what? I am going to stand by – this is my personal opinion. I want the group's opinion on this. That this still could be promoted within the research domain knowing – and we asterisk it – that it applies for more than that. But it starts with research and R&D. At least that is how I see it. Any objections with that?

Carolyn Petersen

I guess I am not sure that it starts with...

Brett Oliver

Not for me.



Christina Caraballo

[Inaudible - crosstalk] [00:53:37] what you said. Go ahead, Carolyn.

Carolyn Petersen

I am not sure that it starts with R&D. I think there is any number of people who would be more than happy to dive in if it helped them down the road with a commercial purpose.

Aaron Miri

Okay. So, how do we want to present this one then? What do we suggest?

Michelle Murray

Aaron, you could leave it as a standalone item for now and see what evolves, as you think about more gaps and opportunities and see if it starts to sit somewhere else.

Aaron Miri

Okay. That is a great suggestion, too. But I think we all agree it is an important topic. We just do not know where it belongs. Is that what I am hearing?

Carolyn Petersen

I think so.

<u>Aaron Miri</u>

Okay. And again, this was emerging for some time, right? It does not surprise me that we are all trying to scratch our heads. I think the market is doing the same thing. All right. Then are we going to take Michelle's suggestion into consideration, then? Let us hang on to this one and come back? I am going to hear it as a yes. Okay. Let us keep going. Let us keep going here. All right.

Next one is patient access information. All right. The topic is patient-controlled data collection access and sharing. The gap is a safety of mobile health applications. And then the challenge is of course the safety and effectiveness concerns with consumer-facing mobile health applications. Boy, I could go on and on about this one. All right. I, personally – this is my, again, my take is that this feeds back to oversight and enforcement activities for mobile health applications. That app that you downloaded off the Android store that is spoofed and actually built in some foreign country that is taking your data and selling it, or TikTok, or whatever. How do you make sure that there is granular consent and control for your data? What has happened with it? Who is accessing it? Et cetera, et cetera. I see this in line with the other components that we are trying to research around HIPAA and FTC jurisdiction. But I am curious of you all's thoughts.

Brett Oliver

Aaron, I guess I read it a little differently. It sounds like you are taking more of a security focus. I saw it as a safety... from how do patients know? Is there a process? I know if something has FDA approval in one regard – or my organization has vetted it – I can give that to a patient with some confidence. Michelle, is that where this one is coming from? Or is it more of a security piece?

Michelle Murray



Yeah, I think, Brett, it is what you were saying.

Aaron Miri

Good. Okay. Good. So, then it is all about making sure that people opt in, essentially?

Brett Oliver

Or they understand that if there is not going to be a government insight or approval process for health applications that you can pick up on – to your point – the Android store, app store for an iPhone, or something. That there is some kind of language that patients can understand that this has not been vetted by anyone outside of the company. So, they know what they are getting. Does that make sense?

Aaron Miri

It does. Correct me if I am wrong. I thought a tremendous amount had been done on patient education – and continues to be done on patient education – around that awareness to their own consumer health. There was that website that ONC put together a few years ago. There has been a lot of literature put out there. I am not saying that this is not important, but I know there is a lot of work underway on this stuff. Right?

Brett Oliver

Yeah, you may be right, specifically with mobile app., I do not think there is anything that I am aware of that they are doing right now. But if there is, then somebody teach me, and we can move on.

Aaron Miri

Yeah. I will give a real-world example. So, we ruled out Apple HealthKit here two years ago now. And it was a big consumer education push – patient push. Said, "Hey, you know, you are empowered. You have your own access to your own data, and it is actually pretty easy to just download right into your Apple HealthKit." It ended up turning my doctors into a bunch of techs, because people do not know how to work their iPhones. And it did not go over too well because of it. And so, we had to do a lot of reeducation, and eventually helping our call center on how to do Tier 1 support for folks. And if they do not know, refer them back to the Apple for support. So, there really was not a way to level set. But this does tie back into health equity, and ties back to a lot of other topics we have already been talking about. Right? How do you empower patients and consumers to use these tools? But I know this –

Brett Oliver

Well, and to understand what they are using. To your example, the Apple HealthKit. There is nothing that – they can encourage you to exercise. I am thinking more of along – download a diabetic app that starts telling me how to adjust my insulin with no data to support it. And that is dangerous. I cannot think of anything with my Apple HealthKit. Because we did the same thing a couple years ago. I do not think there is anything with that that could be dangerous. It is more of the information exchange. Whereas we are entering an era of actual digital therapeutics. For me, that is where they will claim "blank" and what kind of... Maybe it is a patient education piece. I am not arguing that at all. But what kind of ssafety measures do we have in place so that patients understand, just because it is on the Apple store, that does not mean it is legit. They do not do that kind of vetting.

Carolyn Petersen

ONC Annual Report Workgroup Meeting Transcript September 16, 2020

And by extension, how are we helping patients to understand the safety options available for the things that they are doing and make some of those decisions themselves. Not just us guarding data, but them becoming proactive in managing. I think that that is –

Brett Oliver

You are exactly right, Carolyn, because that is the gap here. We are giving patients a bunch of information, and we are expecting them to be their own provider. And that is what we were trying to do for years and years. And so, they can come to us and we can do that, but that is not going to always happen. So, even thought they cannot all have an individual physician every time they download an app comment on that. That is what we are asking to do. And so, to me, that is the gap in safety. Where if there is not going to be government oversight on what is approved, or there is not an approval process, letting folks understand what they... Again, just because it is published – or it is available, excuse me – that it is accurate or that it can improve your health. It could be dangerous. So, again, Aaron, maybe it does go back to patient education is what I am saying.

Carolyn Petersen

Well, I think that it is also about understanding what you are trying to do for yourself. Because the diabetes management work is what has gotten a lot of the press. But there is another community that – I think it is on hiatus right now – that is looking at CPAP data and trying to do similar kinds of self-management things and self understanding. And when you think about it, almost any kind of device that involves some data iterated in some way is something where someone could want to access that and potentially use that in their own healthcare decision-making, or for self-observation or other things.

Aaron Miri

Okay. Christina, what do you think?

Christina Caraballo

Yeah. When I was thinking through this, there are two buckets I see. When I was at Get Real, we did the certification and we had a privacy notice for patients. I forget what it was called. It was for HealthIT.gov, but it told patients what they could expect from the app, what the... The vendor would have to fill it out. You had to say how the data was being used. But that was required for certification or highly recommended. But there is another group of mobile applications that are not aligned with what HealthIT is doing, but patients are using them. It is almost like another gap. It is not just... It is the safety, but also the vetting of certain applications and even more education – echoing what others have said – about how patients can find out better going to actually work and have more of a gold star of approval.

Aaron Miri

So, like a – I am going to use this very loosely – Almost like a Better Business Bureau seal of approval on an app for certain criteria?

Christina Caraballo

Yeah. It is –

<u>Aaron Miri</u> Is that what you are saying?



Christina Caraballo

You have got the challenges of safety and effectiveness concerns. To me, that is being able to guide patients into using things that are safe and effective. And there are some apps that are educating patients as part of the process, and then there are some that are not. As Brett said, how do you control what someone just downloads from their apps on their phone?

Aaron Miri

Okay. So, what are we recommending then in terms of next steps then on this one? I think we all agree this is important. We all want to make sure that there is informed consumer awareness – patient awareness, whatever. Do we want to do some more research on this and come back? Do we want to...? What are we thinking?

Christina Caraballo

In previous conversations, had we not had it as a proposed recommendation to look at ONC's patient engagement playbook and just do a reevaluation on it? This one seems like that could be bundled into that work.

Aaron Miri

Okay. That is a recommendation I recall us saying. Do we feel that is comprehensive enough, though, to meet the concerns you guys just brought up? I am not saying it is not. The ONC has done a phenomenal job. I have said that a thousand times. I am just asking the question generally. Are there any other activities HITAC wants to bring up? Or do we want to just refer to that?

Carolyn Petersen

Would this be part of a broader patient safety initiative effort by HITAC?

Aaron Miri

It could be. It could very well be, Carolyn. I like that idea, actually.

Carolyn Petersen

It is sort of like an emerging area of patient safety, because so much of the work that is done in that area relates to technology that patients do not have any access to and cannot be engaged in. But this is one where the implications and the opportunities might be broader.

Aaron Miri

Mm-hmm. Mm-hmm.

Carolyn Petersen

I am sitting here and thinking what Raj's team might be perhaps doing along these lines? Or what might be the kind of thing that they would be interested in? Even if they are not doing it.

Aaron Miri

I do like that dimension of patient safety. I have always said this. At some point, I want folks to stop talking about cyber security as some abstract thing. That it is actually about patient safety. At the end of the day,





this is about "Do no harm." And so, I love that idea, Carolyn, that we could recommend to the HITAC that we need a patient safety workgroup that talks about this and other things.

Carolyn Petersen

Yeah. Patients taking control of patient safety, perhaps, or patients taking a more active role in patient safety.

Aaron Miri

Right. Right. Because it puts providers like Dr. Oliver in the firing line. Right? They are going to be asking him, "Hey, man. Should I download this thing or not?" And he is like, "You know..." We are not arming our clinicians with the guidelines here.

Carolyn Petersen

Shared work. Shared work.

Aaron Miri

All right. So, are we all in recommendation then to bring this as a potential recommendation back to the HITAC of a more broad...? This could fit into a more patient safety workgroup where this is talked about in others, and going into some specificity which could include using the ONC playbook on patient education. Again, it has been great work, but it could also include other activities. Is everybody in agreement with that?

Brett Oliver

Yes, sir.

Carolyn Petersen

Yep.

Aaron Miri

All right. Okey dokey. I think, Michelle, if I am not wrong, that is it, right? That was the whole list between this meeting and last meeting and the meeting before that.

Michelle Murray

That is correct. And the only question I had for you – if you want to do this – is Brett was not able to attend last month, so I am wondering if there is anything... We might want to bring up some things we discussed before they are marked in blue.

Aaron Miri

Let us see.

Brett Oliver

I am sure you all had it more than adequately mapped out.

Aaron Miri

Yeah. I mean we talked about this. We even talked about it at the HI – I would say, I think before the last big HITAC meeting, that some of these I would definitely... I would say, Brett, you would want to weigh in,





but you did weigh in on them during the HITAC. We talked about public health and vaccine tracking, clinical data exchange. We talked about those things. Unless there are items here that you want to go into. Please do.

Brett Oliver

I will tell you what, I am not seeing it from this last time. So, how about this? I will take a look and then just share any comments to you guys by email. Is that okay?

Aaron Miri

Yeah.

Carolyn Petersen

Yeah.

<u>Aaron Miri</u>

That is perfect. Perfect. Okay, Michelle, what else do we have? Those are the two items, right?

Michelle Murray

Yep. That is everything.

Aaron Miri

Carolyn, do you feel good that we can go to public comment now? Or are there other items, other business, we should be talking about?

Carolyn Petersen

I am good with that.

<u>Aaron Miri</u> Okay. Lauren, if you are comfortable with that, too?

Public Comment (01:09:20)

Lauren Richie

That works for me. We are just pulling over the public comment slide and then we will ask the operator to please open the public line.

Operator

Thank you. If you would like to make a comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star 2 to remove your comment from the queue. And for participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment while we pull for comments. There are no comments at this time.

Lauren Richie

Thank you. Carolyn and Aaron, anything else before we close out?



Next Steps and Adjourn (01:10:10)

Carolyn Petersen

What should we be thinking about in our heads as we go about our daily life? I think the plan for the next meeting on the 30th was to work on the crosswalk some more. I am wondering if that will be the full meeting, or if there are things we should be thinking about before then.

Lauren Richie

I am actually going to defer to Michelle on this. She can probably better speak to the over – unless we want to go look at the timeline slide again.

Carolyn Petersen

No, I think this is fine. There is a comment I could make that if – just like Brett offered, too – if any of the rest of you have written comments you want to make – because I know you are kind of on the spot in the meeting sometimes and things occur to you later. This is a perfect time to do that. I will be working with our audacious inquiry team to make the updates you have made and use the research. They have already filled in the blanks. And then we will get at the next meeting more reactions, a more complete document. And we can show you a redline version at that time, so you can see where updates were made based on the original version. So, if you have any more, email – all of you have any more email comments, we are accepting those before the next meeting. Preferably within the next week or so, so that we can integrate them. Because the next meeting is only two weeks away.

Aaron Miri

Okay. We can do that. All right. So, everybody needs to be studious on email and just thinking and marinating. That is it. That is a good suggestion. And I would also say, listen, I think right now it is time to listen to the community some more, especially as there are reports of a second wave of COVID that is starting to spin up in the northeast corridor again. I know here in Austin, we just got through our first wave – I think I can say that – where things are calming down, but it is inevitable. So, we will hear of many other barriers and challenges to all these dimensions very soon. And so, just keep your ears open. And if there is a topic that comes up that we have not talked about, please, let us bring it here. As I like, real-world stories always tell the tale. So, bring those stories.

Carolyn Petersen

And if we are going to tell stories, maybe we should start thinking about how we integrate stories into the annual report. If we do.

Aaron Miri

I like that. Actually, I like that idea a lot.

Carolyn Petersen

Then, yes, I think we need to think about ways to incorporate those so that they are not super long - 150word pieces, maybe, that get sprinkled through in relevant places, or something else. Michelle is probably groaning inside right now as I say that. So, we should get your feedback as well.

Michelle Murray

I really like it. I think it would humanize the report because it is very academic at the moment, so I love it. And we can visually make that work pretty easily as well. Just one thing we might want to do is find a way to source them somehow, either by person or a written source, just so they are clear who is saying them.

Carolyn Petersen

Yeah, we can look for stories in the popular media, and then referring to a CNN story or something where it is pointing to – it is not establishing as God-proven fact.

Aaron Miri

Right. And what I like is... At least I know from the academic healthcare side, there is some great storytelling, even recently, in the New England Journal of Medicine and some of these other more journal type things, that just tell the tale of what is happening – specifically COVID. Other conditions... So, there may be some relevant scientific articles that we can point towards to tell the story as well. There is no cause of concern of any bias depending on what data source we point to. Right? That is the only other thing that we have to worry about, the lens the story is told through. Because we want to keep this as fact-based as possible.

Carolyn Petersen

Yeah.

Aaron Miri

All right. Well, if that is all. Then, Carolyn, unless you object, I say we can give 10 minutes of time back to folks.

Carolyn Petersen

Let us do it.

<u>Aaron Miri</u> All right. Everyone has a great one. Be safe, please

Carolyn Petersen Thank you all.

Brett Oliver Thanks, everybody

<u>Michelle Murray</u> Thanks everyone. Take care. Bye-bye

<u>Christina Caraballo</u> [Inaudible – crosstalk] [01:14:28] Thank you

Carolyn Petersen

Bye-bye

ONC Annual Report Workgroup Meeting Transcript September 16, 2020

Brett Oliver

Bye.