Health Information Technology Advisory Committee Annual Report Workgroup Meeting

Transcript
November 26, 2019
Virtual Meeting

SPEAKERS

Name	Organization	
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Co-Chair
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
Seth Pazinski	Office of the National Coordinator	ONC

Call to Order/Roll Call (0:00:08)

Operator
All lines are now bridged.

Lauren Richie
Good morning, everyone. Welcome to the HITAC's Annual Report Workgroup. Thank you for joining us. Happy early Thanksgiving to our members and our public members as well. With us today, we have the full team: Carolyn Petersen, Aaron Miri, Christina Caraballo, and Brett Oliver. With that, I will turn it over to our co-chairs for a continued discussion in the Gap Analysis and Recommendation sections of the report.

Opening Remarks and Meeting Schedules (0:00:37)

Carolyn Petersen
Good morning, everyone. Welcome to the meeting, and thank you for making time as you get ready for your Thanksgiving holidays. We have some good discussion to have today as we further our progress with the annual report.

Aaron Miri
Yeah, and good morning to everybody here, and happy holiday week. If you are listening in, thank you for that because I know everybody is busy gearing up for the holidays. This should be a fun conversation. There has been a lot of great work by the ONC team to synthesize our thoughts and recent discussions into some manageable and easily discernable charts, so think today will be a good conversation for us to walk through and start firming up what our recommendations are going to be to go back to the full HITAC. Carolyn?

Carolyn Petersen
Hey, hey. So, what we have today is meeting schedules – of course, we always go over that so we can keep in our heads where we're at – a discussion of proposed topics for the Gap Analysis and Recommendation sections, we have our public comments, and the next step is an adjournment for turkey. With that, we can go to the next slide. So, this is our schedule for our own workgroup. Today is the 26th, and we have a meeting next month – mid-month – and then look to be presenting the draft of the annual report to the fall HITAC in January with the goal of finalizing that and moving on in February. And then, in terms of the full committee, we aren't going to be doing anything with them in December, and again, we'll have our meetings with HITAC in January and February. Next slide, please.

Discussion of Proposed Gap Analysis and Recommendations Sections for HITAC Annual Report for FY19 (0:02:28)

Carolyn Petersen
Here is our updated plan. We had taken care of the Landscape Analysis section and the HITAC Progress section, and now we're looking at the Gap Analysis and Recommendation sections today, with the goal

of looking at the fuller draft fully next month, although there will still be some loose ends because we won't quite know what may be happening with the rule and other things. Next slide, please. So, moving into the discussion of proposed topics, again, looking at our draft outline, we've done the first four items and had a little bit of discussion about No. 7, but we're not going to focus on that today. Today, we're on the Gap Analysis and Recommendation sections. Next slide.

So, this is slide No. 8. Our next steps are we're going to continue the discussion we had a couple weeks ago, and then we'll look particularly at a few questions for the discussion. I think we're going to start here because we know Brett will need to take off early today. We're looking for some thoughts about particular gap areas, like the unique device identifier, data integration, application of international regulations to data exchange in the U.S., and third-party access to health data. There are a couple of notes there – the relevant topics in the draft HITAC plan for 2020 and the related ONC benchmarks for 2019-2020 – and we should also be thinking about the proposed tiers. Are we thinking about what is or could be immediately done by HITAC or topics within a priority target area section? We also might want to think about how many tiers we use to break things up – what breakout makes sense – and if we want to recategorize anything. With that, I will let Brett start the discussion of some of these items. I'm sorry – Aaron. Good morning! Like I said, it's early.

Aaron Miri
Brett, you can have at it. Would it make sense for us to go to the chart, Carolyn, talk through it there, and answer these questions from that?

Carolyn Petersen
We could do that. Let's go to the next slide and find that.

Aaron Miri
All right. Could you guys blow this up?

Carolyn Petersen
Thank you.

Aaron Miri
All right. So, Brett and Christina, do you see the chart?

Christina Caraballo
Yes.

Aaron Miri
Okay, perfect. To answer a couple of questions in here in specificity, as the slide deck was saying, when we're looking at this, it's a little busy, but it's a good synthesis of all the topics and everything that we've been talking about. Two questions came to mind as we were talking through this openly. First, some of these topics are very deep and may warrant breaking them up into two parts. When I looked at these things, I was saying, "Okay, what does it take for" – I'm going to make this up – "the association between EHRs and patient safety?

Well, to be able to do that, we have to be able to answer unique device identifier integration because it's the only way you can figure out how an EHR is used for a patient when a med device is put on a patient and what happens to that patient subsequently. So, there are some things here that go in sequence, as well as some things that truly have multiple phases to them. So, first, generally thinking, is that something we want to do – break up some of these topics into parts 1 and 2 – or should we keep them as one domain that we research? What do you all think? Was my question confusing?

Brett Oliver
No, your question made a lot of sense, but for one particular topic, it seems like it would make sense to break it down, whereas for others, it might be better to do the research and take it on broadly.

Aaron Miri
Got it, okay. What else?

Carolyn Petersen
Some of these topics could be very deep, even just to lay out all the issues. We could get into a lot of text.

Aaron Miri
So, are we then more in favor of keeping it as one topic area versus breaking it up, just in general? I think we should keep it an even format for this whole thing. Otherwise, it may get confusing for people.

Christina Caraballo
What about a hybrid, where you keep them in the topic area, but in some, you might have – I don't know, but as we start formulating the report, we might find that in some of the more complex areas that can be broken up, we might prioritize first, second, and third steps for priorities within the topic.

Aaron Miri
I see what you're saying. So, within the actual topic itself, we break it up into the different opportunity sections or what the recommendation of opportunities is. I see what you're saying. Yeah, that's a way to do it.

Carolyn Petersen
That would encourage the detail, too.

Aaron Miri
As always, Christina's thinking outside the box. Thank you for that. That's a good one.

Carolyn Petersen
Christina needs more coffee.

Aaron Miri

All right. So, that's a good proposal. I'm sorry, was someone saying something? All right. So, the next question on there was about the proposed tiers. This is about the final column that's there. It says "immediate," "medium-term," or whatnot. Generally speaking, do you all agree with these types of classifications for this chart? The majority of these are immediate, and that means that it's something HITAC should go after and address. We're not really proposing the activity, but we're saying it's a gap right now that's urgent. And then, the medium-term is something that's important, but really does need some of those immediate topics addressed first before we can tackle the next set of issues. Does that make sense to you all? Is there a different way we should categorize these? I don't want anybody misunderstanding that we're saying something's unimportant, we just have to say there's some sort of logical sequence, and we can't bite off more than we can chew.

Christina Caraballo
Yeah, that's a good point. When I first looked at this, I did read it as priority, where it's more what we can manage, so it's almost like readiness and long-term, something we can start tackling now that can make an impact versus stuff we need to start thinking about that may be more long-term where we might not see results right away. To take one example, we look at the opioid epidemic, and it's medium. Well, that's obviously a really important topic right now that we're trying to tackle, and it's larger than just our health IT world, but how ready are we to support what we know would make the largest impact?

Brett Oliver
Is the impact on the opioid piece?

Christina Caraballo
Yeah.

Brett Oliver
I could make an argument for that over price transparency in terms of being technically ready. There are some political opponents to getting these PDMPs integrated. The government could make it happen pretty quickly. So, I want to be careful how we phrase the proposed tiers to the group in January. If we're saying we are prioritizing and there's only so much we can do, that's one thing, but if we're saying the way we came up with these proposed tiers is, for instance, this opioid one, it's not quite ready, so we're going to put it in "medium-term" even though it's important. I want to be sure we have the expertise to say that. Does that make sense? I would argue that by that definition, that particular one would not fall into the medium term.

Aaron Miri
That's a good point. The goal of this was not to try to send a signal that we think something is less important to the other. That is for darn sure. All these are important topics, and they're all relevant topics, but to your point, we're trying to sequence it at least.

Brett Oliver
But, we can at least tell people – no one's on the long-term track. I don't know if I missed that or not, but I didn't see anything like that.

Aaron Miri

No, nothing is long-term. We could turn them all to medium, but the problem is there's no way we could get that done. That's not going to be fruitful, and we won't get the quality work that we've been producing for the past 12-18 months or so.

Christina Caraballo

I think we just need to define how we got to the criteria. I'm sure the team working on this grid had some criteria when we put in the medium, intermediate, or immediate. I think we just need a written definition for when we present it to the HITAC so that they know how we came up with the buckets, or else it's just going to be around a conversation that is never-ending.

Aaron Miri

That's fair. Okay.

Michelle Murray

Aaron, this is Michelle. Do you want me to speak to that a tiny bit?

Aaron Miri

Yes, ma'am.

Carolyn Petersen

Yes, please. I didn't want to put you on the spot, but yes.

Michelle Murray

I was thinking whether I should speak up or just send a note. At the moment, they're very closely related to the draft HITAC plan for calendar year 2020, which was presented publicly in October, and then will be updated in January. So, the timing's not perfect for this work. We're having to accept the public draft that's still being iterated upon, so those could change. They're not pinned down. I did put in the footnote that there is a link there. That's one criterion for choosing – whether it was immediate or medium-term.

Another thing we realized as we worked on this is that they probably need to be tied to the opportunities rather than to other specific HITAC opportunities, partly for how it would work inside the paper once you start writing these up. It's easier to group them and keep them at a more general level that way so they're tied to the opportunities. Those are the two factors that were used in determining whether it was immediate or medium-term. As you noticed, we didn't find anything that looked long-term under the current timeframes we were given to work with by the workgroup, and then we realized that there may only be two tiers – immediate and long-term. You're already getting to this thought process that happened at ONC.

Christina Caraballo

That makes a lot of sense.

Aaron Miri

Part of it is that that final plan is still coming together, so I think that plus, like I was saying, even yesterday on our working call, we tried to prioritize and categorize these things based on some logic. It is difficult because Brett, you make a good point. We know the opioid crisis is a major thing, and all of us, especially on the provider side, are experiencing it firsthand. We don't want to send the wrong optics and the wrong signals. That's for sure. Okay. So, in looking at this – go ahead.

Christina Caraballo

Really quickly, I think presenting it and thinking through it in this way – Michelle, thank you for that overview, that was really helpful – we are actually mapping back to the priority areas that have been identified, and then coming up with tasks and our recommendations to address those areas. I think that's a really impactful way to present this, and a good approach in general.

Michelle Murray

This is Michelle again. I'll actually make a point here that I wrote up and passed on to our leadership a lot of ideas you had at the last meeting as a workgroup that may be input to the HITAC planning process, so this is also a way to give some feedback on that planning process.

Seth Pazinski

This is Seth Pazinski. I'll just add a point to Michelle's. One of the things that's really helpful is clarity on what exactly the HITAC would take on. A lot of times, when looking at the potential topics, we try to understand if it's a clear charge that we're ready to have the HITAC look at specific issues and make recommendations, or is it more that we need to have further discussion as a HITAC and have some understanding of where it fits in that scope? That can help determine if we're ready to take a first step to have a conversation around it and help shape what the specific charge would ultimately be versus something that's ripe for a clear issue, charge definition, and description.

Aaron Miri

That's super helpful, Seth. Thank you. Are there other thoughts or ideas about this chart or groupings? Is there anything here that doesn't make sense? More importantly, is there anything we feel is missing?

Carolyn Petersen

If it seems that the term "medium-term" is confusing, maybe that can be changed to something like "later," "post-2Q 2019," or something like that if you want to frame "immediate" as something we look at in in the first part of the year and the other things as stuff we might consider later on.

Christina Caraballo

I'm less concerned with the term and more concerned with defining it. Once Michelle gave an overview of the thought process behind it, I think it was fine. I could go either way, but I think we really need to explain to people the criteria that was used to classify.

Aaron Miri

Brett, I was going to ask you – when you're looking at this as a provider, for the providers who are watching what the HITAC is talking about and working through, especially as the various things go into final ruling, does this chart make sense if you're just a practicing physician looking at this in terms of what we're doing, why, and what we're focusing on, or is there a different way you would want to see it, just putting your provider hat on?

Brett Oliver
No, I think it makes sense, Aaron. With this chart, even though these are obviously big areas to have the challenge and the gap listed, I think that brings it out in terms of what we're talking about – for instance, with the opioid one and its specific gap. Obviously, you can go a million different ways in terms of attacking that, but from our perspective, having limited integration with the PDMPs – that's what we're talking about. From a scientist's perspective, which most of us have, it's laid out nicely.

One question I had – and, I certainly don't want to revisit things – I see a potential gap that I'm not sure where it fits. It might fit multiple places, and I'd like to get your feedback on it in terms of the data accuracy and exchange and what you do with incorrect data that you identify. For instance, let's say someone comes to the ER, they're seen, their name is John Smith, of course, and we thought we had the right John Smith, but we find out later it was on Jane Smith, his twin sister. Then, we're in HIE or exchanging data with other organizations, but we determine that's inaccurate.

What does that correction process look like? Where are we required to notify? Maybe there are laws I'm unfamiliar with, but this is one of those things where I'm looking at this chart, and then doing something with Epic on a data accuracy steering committee, and then I realize we're not talking about that – or, at least I haven't heard us talk about what we do with inaccurate data. There's going to be inaccurate data out there – we know that – but, it's data we identify as inaccurate because the further it goes downstream, the further its effects multiply, whether it's with research or what have you. Is there a place we could look to add that? Do you all agree?

Aaron Miri
Well, we have that one in interoperability under "health information exchange." That is clearly one of the challenges with reconciliation of data – incorrect or inaccurate data – and that could be a multitude of reasons. Obviously, a lot of it is where you misidentified the patient, you put the wrong armband that was scanned, people did a hack and just put an armband on a cow and scanned that versus scanning a patient – all the things that happen to us in the course of care. So, for me, you could put it in one of these topics without a problem. I think you're spot-on, Brett. I agree with you.

Brett Oliver
Patient identification is one thing that I know is obvious, and we've talked a lot about that, both in our workgroup as well as with the full HITAC. I wasn't even thinking about – what if we have an algorithm within our lab that goes off, so for a month, we have hemoglobins and blood counts that are off? So, we figure that out, but in the interim, through Care Everywhere or other information exchanges, other organizations and providers have gotten that inaccurate hemoglobin. To reconcile it with the chart, I'm not going to know – I get it if a medication comes up and it's like, "What? A male with birth control pills? That doesn't make any sense." I can clinically reconcile that.

What I struggle with are the things I would think would be accurate coming in – a chest x-ray report with the patient's name on it, or a lab value. Again, maybe it fits perfectly under that, and I don't want to belabor the point in terms of discussing the topic, but I just wanted to see if you guys felt like that already fit, maybe under the HIE section, and whether that's something we need to elaborate on or we can just move forward and it's something I'll have to deal with.

Aaron Miri
No, it's important. That's my personal sense. It's very important. Maybe we should specifically call it out under one of these sections, and maybe that goes back to what Christina had suggested, which is within the actual topic itself, breaking it into pieces like No. 1, No. 2, No. 3, but I think that's something important we should call out as to data inaccuracy in general and what that reconciliation of data inaccuracy is. What does everybody else think?

Brett Oliver
You could extend that further into the internet of things, patient-generated data, and all of that.

Aaron Miri
Yup, you're exactly right. Carolyn? Christina?

Carolyn Petersen
I think that makes sense. I like that.

Aaron Miri
All right. So, we'll look to add that under the HIE piece for right now, but we'll call it out specifically, Brett. I think it's a good point. I think it varies from organization to organization. I know some organizations that don't do any notification or proactive notification, 1). Because they often don't realize they're wrong, or 2). They realize it after the fact when they have to do corrections of the chart, and that will create an overlay, a merge, or something to that effect, and it becomes an even bigger mess. But, you're right. There should be some – to me, it's a quality and standard-of-care thing, but it's something we can talk about as a larger group. Carolyn, what other questions did we have on this chart? Do you recall?

Carolyn Petersen
I think there were a few specific topics that we mentioned on the previous slide that we wanted to go into in depth. Other than that, it's just a very packed document in terms of information density. I don't know if it's worth going through topic by topic and asking whether we have anything to be concerned about on this or if it would be easier to tackle it by priority target area. We could certainly talk for quite a long time, but I don't know if that's necessarily helpful because we've looked at the topics individually in the past.

Aaron Miri
That's a good point. How about this? Let's look at those three questions. I just pulled up the slide so I could see it. The first question that we had was the unique device identifier data integration. This

would be – if you scroll down… I'm overlooking it right now. Let's see. Here we are – page 2, close to the bottom there. Basically, it's limited unique device identifier integration, lack of tracking UDIs makes it difficult to track medical device usage, and then, challenges of adoption of UDI data integration into existing workflows and claims data. And then, what we're proposing is to convene a hearing – we talked about it, but this proposal idea right here is to convene a hearing to understand trends related to UDI data integration and what has affected clinical workflows. To me, this is something that keeps coming up, and I keep hearing more about it in conversation and whatnot. What do you all think? Are there other aspects of this? Does the timing make sense if we're thinking it's immediate? Is this important? Brett, do you care as a provider? I'm curious about your thoughts on UDI.

Brett Oliver
I'm concerned about it from a security perspective more than anything, just keeping track of them and knowing where – if I can't determine where the remote patient monitoring data is coming from or it's confusing, then obviously, it has a clinical impact.

Carolyn Petersen
What about the cybersecurity aspect of things in terms of devices being hacked?

Brett Oliver
Yeah, or just shut down. It's not been an area where we have seen a ton of activity, but Aaron, you can speak to it better than I can. It's an area of great concern.

Aaron Miri
There's tremendous concern. It's just keeping up with – I give a lot of credit to the major medical device manufacturers. They're trying, and I'm getting more and more bulletins about "Hey, we have this patch we have to apply," but it's a bit of a hassle because there's no way for me to then go back and reconcile who all has used this device or who's on it right now. Can I update it right now or not? Is it in circulation? There are a zillion things that I have to do using the device as a MAC address right now versus as a UDI. A UDI would help me tremendously, particularly as I go all the way through and do all my quality reporting and whatnot.

So, for me, maybe it's critical from a cybersecurity perspective, but from a quality and efficacy perspective, it's important. I've seen situations – not in recent times, but in relatively recent times – where we've had malfunctioning devices, and the clinician caught it when they saw the blood pressure readings didn't make any sense, but the blood pressure cuff was broken and they had to resort to the manual squeeze blood pressure cuff. It would be great to have UDI to be able to track those things and make sure it gets out of circulation, is sent for repairs, and things like that.

Brett Oliver
I think you're exactly right. The practical part of that is that broken blood pressure cuff would get thrown back into circulation until someone else tried to use it again, and it would be involved in the quality controls.

Aaron Miri

That's right. If you go to any hospital or healthcare facility, you'll see devices with a little sticker on them saying "Sent to IT for repair" or "Sent to biomed for repair," but they're pushed in a corner because physicians don't want to give up their assets because there are so few of them. So, if you have UDIs, you help increase the efficacy of these devices and the accuracy. To the point of cyber and everything else, it's a quality issue at the end of the day. It really is – at least, that's the way I see it.

Carolyn Petersen
Well, quality, but also the bigger-picture issue of device tracking for adverse event reporting and trend understanding. The FDA hasn't done a great deal in terms of the unique identifiers and a registry of medical devices, but that certainly may come back to a discussion point as we go forward, get a better handle on cybersecurity problems, and think about tracking people who are doing things remotely. They need to get into the clinic every three months so the provider can see and notice any issues the user might not be aware of.

Aaron Miri
Right, and the other thing is now, you're able to prescribe a ton of devices to go home with the patient if they wish, whether it's a Proteus, a Holter device from back in the day, or whatever. Some of these devices are leaving my four walls, so it's not like I can track it on my wi-fi forever, so I have to have something for it to be trackable when it goes home with the patient.

Carolyn Petersen
And, of course, as we do more with telemedicine, there will be more devices that don't come back at all.

Aaron Miri
Right. So, I'm hearing that we're all in agreement with this topic and this urgency. Is that right?

Christina Caraballo
Yes, I think so.

Carolyn Petersen
Yes.

Aaron Miri
All right. The next question on here was the application of international regulations to data exchange in the United States. This one is…

Lauren Richie
Page 5.

Aaron Miri
Thank you, perfect. Third from the bottom there. The specific issue is uncertainty about GDPR applies to data exchange from the U.S. to countries covered under GDPR for services sought in the U.S. Say I'm a European citizen from Germany, I come to the United States to the University of Texas for care from

a specialist, I'm seen, and I go back to my home country. I have a right to be forgotten and I want to be deleted by Texas and all the other things that go under GDPR. How does that work? The question there is "International regulations such as GDPR may require U.S. healthcare organizations to comply with additional privacy laws outside of U.S. legislation."

What we're looking to do here is increase knowledge of the impact of international regulations. We're thinking to identify educational approaches that offer increased transparency for international regulations such as GDPR. Does this also go into the data privacy and secondary uses of data, including GDPR? But, given the complexity and relevancy of these laws becoming finalized and even more strict, especially if you look at countries like Germany and France, we're looking at this as more of an immediate item. What do you all think? Is this something we should care about right now? Is this something we should focus on? Is this something we should put under "immediate" rather than "mid-term"? What do you all think?

Christina Caraballo
I think we're seeing an increase in dialogue around this topic, and it's something that is going to become more and more important. It might be somewhat narrowly focused; I'm not sure. I think the broader topic of interoperability across different countries globally is important. There's a new council that was formed, the Joint Initiative Council, and I'm not exactly sure when it formed, but it looks at global health informatic standards, and it is an international initiative, and some of the big players on it include CEN, the Personal Connected Health Alliance, IHE, HL7, ISO, SNOMED, DICOM, and some others, so I do think this is a good topic to include.

Aaron Miri
Good point.

Brett Oliver
I think it's a good topic, and I also think that the answers are out there, we just need someone to help define them. It's not like we're going to go create a new technology. We just need legal minds and compliance folks to help outline these educational pieces. Maybe that's naïve, maybe they don't exist, but it just seems like we need the right people to answer these questions, and to Christina's point, it seems like a month doesn't go by that I don't see an announcement that a U.S.-based hospital organization or healthcare organization has bought a hospital or other organization in Europe or other places. We need to understand that a little bit better.

Carolyn Petersen
I absolutely agree with that. Even the term "GDPR" seems to be coming up more in discussions about what's happening in the U.S. as people realize that it really is still out there, even if it's not our law.

Aaron Miri
Christina, were you saying something?

Christina Caraballo

I just have a question. When we're coming up with these priority areas, we asked what the HITAC was going to do. I'm just trying to formulate what I'm going to say… For this, is this something that the HITAC should look at? I don't know the answer, but I guess my question is are there certain things on this list generally that we are identifying that we recommend the HITAC look at, and then, are there certain things on the list that we've identified, but may not be a priority for the HITAC, and we want to label it as a recommendation for ONC, the industry, or whomever to take on?

Aaron Miri
That's interesting. We didn't actually discuss that component, which is recommending the industry or others. We were really looking at what HITAC should look at, but that's an interesting thought process there. Carolyn, what do you think?

Carolyn Petersen
I agree totally. There's no reason we should be any later in looking at this.

Aaron Miri
That is interesting, Christina. Who all would you see – would you say this is something we should recommend HITAC plus HHS or whoever else look at as well?

Christina Caraballo
Yeah. If we've got some things that we might not have the expertise to take on or that might be outside the scope of what we can do, we can recommend certain things that the HITAC could do in this space, but then identify where additional work needs to be supported, and we may or may not define who needs to support that, but at least it gives a more robust overview of what we think needs to be done and where the gaps are and a narrow focus on what the HITAC is going to do to support the larger work that needs to be done to get us where we need to go.

Aaron Miri
That's fair. Basically, you're saying we should stage this in a way that there are pieces of it that we would do, there are pieces of it that somebody else would do, and the combined effort is the resulting net of what we come up with as a solution. Is that right?

Christina Caraballo
Yeah. It's how HITAC is supporting the larger industry work. I don't want to overcomplicate it.

Aaron Miri
I think you have a good point. This is multifaceted, but I… I don't know. I'm looking at the coinage that it's an immediate issue, and I'm beginning to feel it is because of how much data exchange occurs with other healthcare institutions, with other countries, for research, and for clinical operations. Does everybody agree that this is immediate, or is this a medium-term issue?

Brett Oliver
I think it's immediate.

Aaron Miri

Okay. Carolyn?

Carolyn Petersen

I was thinking if we see continued pressure to change HIPAA, or to expand it or try to make it applicable to things that have not traditionally been healthcare data, like data from trackers, social media, and other stuff that's health-related, but haven't been typically housed in the record, it could be both a medium-term and an immediate thing. Of course, once you get the changes, then that will change the relationships and the procedures. It's not like a problem that you solve, it's like an ongoing situation you deal with.

Aaron Miri

Right. Good point. So then, we will keep the topic, keep the urgency, break the recommendation into a couple of pieces, which is the HITAC piece which we do, and then what we recommend the industry go do, or partnerships with HIMSS, CHIME, HEMA, AHA, or whatever, and try to get the word out about this. What's interesting is all these regulations that are coming down that step from 21st Century CURES and before – when I look at the industry and talk to my peers in the industry, it's amazing how unaware people are, and I think this is one of those topics that is really going to catch people flat-footed if we just don't make people more aware and attuned to the fact that they have to be mindful of this. They can't just pretend it doesn't exist. For me, I'm seeing this every day as a critical item.

Christina Caraballo

I agree.

Aaron Miri

On the third question here – third-party access to data – we talked about this a little bit last time, and this is – what is this one? I'm trying to find it.

Carolyn Petersen

Pages 4 and 5.

Aaron Miri

There we go. Okay, perfect. Thank you. It's part of what we've been talking about with privacy considerations, but it's also part of the protections for data outside the HIPAA framework and federal policy. So, basically, if we're looking at this – I'll read this one – "The protections for data generated outside of HIPAA and federal privacy laws" – so, lack of clear privacy protection for data not subject to HIPAA protections, patients don't realize the data is not protected, so we're thinking about the opportunity to increase transparency and patient education for businesses not covered under HIPAA. So, there are a bunch of proposed recommendation activities – identify educational approaches, technology mitigators, and potential regulatory solutions, develop recommendations for additions to HHS, review consent policies for early adopters for SDOH, and those sorts of things.

And so, there's kind of that intersection – in the draft plan, it says, "Intersection of medical devices and health IT for data privacy and secondary uses of data." What this comes down to is there has been a lot

of recent news about third-party access to data and what kind of notification is necessary to patients or not. Just because you follow HIPAA, does that relieve you of any ethical or other obligations you should be doing around patient consent or notification? It's this murky area that really needs to be cleaned up. Brett, I'm sure that every day in your life, you're seeing how many vendors are trying to vacuum up data. That's their entire existence right now – "Give me all your data." It's like, "No…" So, to the degree of it, this and then some is not just immediate, but super immediate. What do you all think?

Brett Oliver
I agree with you 100%, Aaron, and I think with ONC's push to put the chart on your smartphone and boil it down into the sentence, there has to be a robust understanding of your privacy – what you're giving up with that and what you still have.

Aaron Miri
Right. I'll give you a real-world example. The other day, I literally had a patient ask one of my clinicians if they could put their information into this smartphone app that no one had ever heard of before. There wasn't an API required or whatever, but he was literally just going to shoulder-surf the physician and just type his vitals into this app, and the doctor was like, "Sure, it's your information, but what are you putting it into? What is that app?" He said some name, and it was this really kooky – "Okay, it's your data. You do what you wish with it, but be aware of the risks." At some point, there has to be some awareness of the reconciliation. If that app on that patient's phone decides to sell the data or weaponize it in some way, what's the recourse for the patient and what's the liability of the health system? There's a lot of that stuff going on that is really unknown.

Carolyn Petersen
Some of that stuff just goes way beyond what the health system can take responsibility for. People are going to come up with bizarre apps that haven't been heard of or are unfamiliar regionally or locally, and I think we as HITAC can continue to promote the resources that are available to help people understand the things that ONC has developed in the past and continue to look at activities that raise awareness, but there's a point where you can't take responsibility for someone else's decisions.

Aaron Miri
Right, and what's the recourse of the patient? Do they contact the FTC? The OCR? The FDA? What's the roadmap for that? There's no Better Business Bureau for health apps that I'm aware of, so it's just interesting. You're in this really murky space.

Carolyn Petersen
No, you're absolutely right.

Christina Caraballo
I was going to save this for what's missing on the chart, but I think it ties into this conversation. I think we have another bigger area that we need to put some more attention on. I'm going to go off-topic and then come back, but when I was reviewing this grid of what's missing and not missing, I noticed that there is not an area on here that really looks at the patient access, choice, and needs of the patient. I know that in the past, I've mentioned the need for a concept of a consumer hype hub where

a patient can come in and access all of their information, and in their comments for TEFCA, HIMSS pointed to the need for a patient-facing QHIN. From some of the conversations I've had, I don't think the industry is quite ready for that, but I think people are more and more interested in it conceptually.

So, in thinking through this on a lot of the topics that we have on here with privacy, security, and HIPAA – and, Aaron, you just mentioned the roadmap for this – I think one area we look at expanding is looking at the work that was done previously by ONC and the previous committee – I think it was the policy committee, and Carolyn, I think you actually helped with this – they've got the patient engagement framework. I think one thing we could do is recommend a revamp of that with these growing needs, especially with the app ecosystem, patient access, and patients being able to "bring their own devices." How is this really working in the industry?

Every time we discuss these topics, it's kind of like the Wild West, and I think we really do need to tighten it up and come up with a roadmap and a vision of where we are now, the gaps we see, and where we want to go to actually get to the point where patients can access their information when, where, and how they want it and aren't tied to a specific EHR or provider, and we're not there yet, but it would be nice to start looking at a strategy and the steps we need to take so that we can get there.

Carolyn Petersen
The first thought that comes into my head around that is maybe a workgroup that looks at how FDA, FTC, potentially FCC, and DOJ approach these issues and what the limits of their authority are to enforce and make regulations and look for gaps, and then see about HITAC helping or encouraging ONC to start doing some of that work with the other agencies. I think one thing that we keep running up against whenever there's a major breach or a big something is that it's not an area that's really owned by one agency, and so, you look at it and say, "Whose job is it?" It's really nobody's job, and everybody's affected. Maybe HITAC can be a leader in helping to clarify what the specific gaps are, not just the sense of futility that things aren't working right, and be the go-between that brings some of those players to the table and starts getting some really constructive ideas about how to go forward.

Aaron Miri
So, almost using HITAC as a broker of conversation, basically?

Carolyn Petersen
A trusted broker, a shuttle diplomat – whatever we need to be. I don't mean that in a negative connotation. I think that from agency perspectives, they have specific tasks that, by law, they have to do, they have certain limits in terms of their power, and in many instances, there's an under-resourcing situation, so people are reluctant to try to step out of their bounds and do things that could be useful since they really have no authority. But, if there was another group that was charged with taking issues on and looking at general improvements in the health IT environment, which is what I see ONC and HITAC being, that might be a way to start getting things going, where agencies aren't in that uncomfortable position of trying to be the one that gets the ball rolling.

Aaron Miri

That makes sense. So, am I hearing correctly that we should include Christina's comments, we should leave this as a topic area, probably expand it even more so, and that we should also call out pieces that might require industry or partnership, like Carolyn was saying? Am I synthesizing that correctly?

Carolyn Petersen
It works for me.

Christina Caraballo
It works for me.

Brett Oliver
I like it.

Aaron Miri
Okay. Brett, is there anything here that we're missing? I know that if you think about the course of care – and, we had talked about AI and stuff like that, but if we're just talking about data, is there anything else here, privacy and other, that you think should be honed in on from a patient care perspective?

Brett Oliver
I don't think so. I think we've covered it pretty well. I spoke earlier to the data correction piece, but I can't think of anything else.

Aaron Miri
Okay. So, then we have that question. Carolyn, am I missing any pieces of this third-party access to health data? I think that was it. I want to make sure I asked the question in totality.

Carolyn Petersen
Yeah, I think so. We will probably continue to see new permutations or wrinkles to old problems going forward, but I think we've got a good, solid wraparound to start, and certainly, our own visions will change as we get into the work.

Aaron Miri
Right. Are there any other topics this group wants to talk about or any other specific things we should be thinking about? I think we've all talked about what was in the back of our heads. I just want to be sure we've grabbed all the thoughts.

Carolyn Petersen
Or, anything else in the chart that we need to go through more or that we want to revisit.

Aaron Miri
Right. Well, this was a good discussion. I really appreciate the thoughts. There's a lot that we have to do as an industry. It's going to be interesting. I think at the next HITAC in general, I'm going to bring up the point that the more we can do to make the various industry trade associations aware, to get the word out to people about what's coming down the pipeline, the more helpful we can be because I truly

think people are asleep at the wheel right now in general and are not aware of all the regs that are coming out, from information-blocking to others, including these topics as they are discussed and worked through, and whatever comes of them. So, education to the industry really is key. Carolyn, I'm turning it back to you. If you want to take us to the next slide, I think we're going to finish up here soon.

Carolyn Petersen

We're at public comments, unless there are any last thoughts that anyone has about discussion points or any other stuff we want to go through. Are we too far ahead of schedule, Lauren, or are we able to do a public comment now?

Public Comment (0:54:00)

Lauren Richie

We're a little bit ahead, but we can do public comment and give folks a minute to dial in, and then we can wrap up. Operator, at this time, can we open the public lines?

Operator

Yes, thank you. To ask a public comment today, please press *1 from your telephone keypad. To remove your public comment, you may press *2.

Lauren Richie

And, do we have anyone in the queue at this time?

Operator

There is no one in queue at this time.

Lauren Richie

We'll leave the number up for a minute or two. I'll turn it back to you, Carolyn and Aaron, or to Michelle if she has anything else before we adjourn.

Aaron Miri

Actually, that's a good point. Michelle, are there any other questions here that we talked about yesterday that my mind may be blanking on, or did we get everything we need to continue working? I know that time is getting shorter, and we want to be as concise as possible and respectful of folks' time. Are there any other outstanding questions that you had in your notes?

Michelle Murray

I think you guys did a great job of covering everything that's key at the moment in the crosswalk chart, and next, we'll be turning to an actual draft, so that's where we'll continue to work out any concerns and details, so I think we're on track.

Aaron Miri

Groovy. Thank you very much. Carolyn, anything from you, ma'am?

Next Steps and Adjourn (0:55:30)

Carolyn Petersen
I'm just wondering if Michelle has anything she would like the workgroup members to be thinking about or working on before the next meeting.

Michelle Murray
Good point. During this meeting, I was thinking we could iterate one more time on this crosswalk through email, and then, we'll be getting the draft report to all of you before the next meeting. Those are the two things – you'll want to review the crosswalk changes again and look at the draft report when it arrives.

Carolyn Petersen
That sounds good.

Aaron Miri
Michelle, are we still trying to circle up and see if there might be a time during the next in-person HITAC that this group meets, or are we still working through that?

Michelle Murray
We'll need to come to you all and start planning meetings for the new year, and maybe try to get together during the next HITAC in-person meeting if possible.

Aaron Miri
Groovy. Any other final thoughts from the group, or anything anybody wants to say?

Lauren Richie
I'll just check again. Operator, are there any public comments?

Operator
There are no public comments at this time.

Lauren Richie
With that, we will adjourn, and I believe the next workgroup meeting will be December 13th.

Aaron Miri
Fantastic.

Christina Caraballo
Bye, everyone.

Brett Oliver
Thanks.

Aaron Miri
Bye, everyone. Happy holidays.

Carolyn Petersen
Happy Thanksgiving.

Seth Pazinski
Ciao.