# Health Information Technology Advisory Committee Annual Report Workgroup Meeting

Transcript
November 13, 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 |

## Call to Order/Roll Call (0:00:14)

**Operator**
All lines are now bridged.

**Lauren Richie**
Good morning, everyone. Thank you for joining us here a little bit on the early side, but this is the HITAC Annual Report Workgroup agenda meeting. We have the full group today, Carolyn Peterson, Aaron Miri, Christina Caraballo, and Brett Oliver. With that, I will turn it over to Carolyn and Aaron to get us started.

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

**Carolyn Petersen**
Thanks, Lauren. Good morning, everyone. I echo Lauren's appreciation for your showing up early this morning so we can take a very brief and broad look at some things, and see how things are going as we continue working on the draft. Aaron?

**Aaron Miri**
Yep. I agree. I appreciate everybody being here this morning. It is a timely workgroup. I appreciated a lot of events going on in the Health I.T. space, particularly around privacy and security, which I been following very closely and third-party access of data which is definitely something for us on our list. I think this is a very talented workgroup and I appreciate everybody joining. With that, do we want to go into it, Carolyn?

**Carolyn Petersen**
Sure. Our agenda this morning is pretty brief. We'll have some discussion of proposed topics for the gap analysis in the recommendations section. We'll have public comments, and then we'll briefly confirm our next steps and adjourn.

## Discussion of Proposed Gap Analysis and Recommendations Sections for HITAC Annual Report for FY19 (0:01:40)

**Carolyn Petersen**
If I could have the next slide, please? Again, here is our grid of meetings. We are in number six of our ten meetings leading up to the finalization of the annual report. Yay for us! We're halfway through. We will have another meeting on November 26th, and then one on December 13th where we will continue finalizing. We will present the draft to the HITAC and have some discussion in January of 2020, and then look to wrapping that up at the February HITAC meeting.

The next slide, please? For the full committee, we will meet again in January and February to wrap that up with HITAC. Next slide? In our own work, we're reviewing outlines and drafts. We've taken care of the landscape analysis. We've done the HITAC progress section, and now, we're working on the gap

analysis and recommendations section. That's kind of the meat of what we do. We'll look at the draft report later on.

Next slide, please? Getting into our discussion, the outline. As you know, we have the nine sections from the executive summary through the forward overview, the HITAC progress in 2019, the landscape analysis, gap analysis, recommendations for addressing the gap, suggestions for additional HITAC activities, and the conclusion and appendices. Today, we're going to be focusing on that gap analysis and also the recommendations for addressing the gap.

The next slide, please? Coming to the proposed topics for the gap analysis and the recommendations, there were some recent events. We reviewed the draft outline of the gap analysis in July. We presented that draft landscape analysis in September at the HITAC, and the draft outline of the gap analysis has been updated to reflect some HITAC member suggestions for the landscape analysis.

Next slide, please? We had sent out to you that list of proposed topics for the gap analysis and recommendations section. Our next steps are to review and discuss the list of proposed topics at the workgroup meeting today, and also, to review the proposed topics before our next meeting at the end of the month so we can discuss those things more fully and make some decisions. Today, we're looking at thoughts around newer topics like the unique device identifier and privacy and security concerns for social determinants of health data. Also, we're considering if we have interest in more ordering or grouping of topics within those priority target area sections. For example, we could show them by tiers like high importance, medium importance, lesser concerning. Or if we wanted to number them in order, I think we already kind of thought that is a challenge and would be something that might be difficult to get an agreement with at the HITAC level. So, perhaps tiers are the best or we can go without that if we think that might be difficult to use as a mechanism for coming to some agreement about what to do next year.

Do we have any thoughts around those considerations?

**Christina Caraballo**
Yeah. This is Christina. Going through the grid with the privacy and security around the determinants of health, there were no recommended action items on that. I think we should remove that one. I think that social determinants of health, in general, are covered in other areas and was highlighted in two different places within the grid. I think that just doesn't make sense.

**Carolyn Petersen**
Okay.

**Christina Caraballo**
Another thing, I think privacy and security are addressed within other areas that are broader. This just seemed like an outlier of a topic to me after reviewing the full chart.

**Carolyn Petersen**
Okay.

**Aaron Miri**
Carolyn, do you remember why we specifically called that out? I want to say there was a committee member that actually brought that up. I don't recall the exact conversation, but there was some logic behind why we split that out. Do you recall?

**Carolyn Petersen**
I know that recently there was more legislation presented in Congress in relation to device identifiers that has to do with some of the proposed action and discussion that the FDA has been bringing forward. They've released a series of guidance in September at the end of the month. I want to say six or eight in almost a day or two. Some of that was brought up in some of those proposals. It's kind of been coming to the forefront as a discussion topic.

**Aaron Miri**
That's true.

**Carolyn Petersen**
That is not to say that it is necessarily going to go anywhere in a way that would result in actions that HITAC could undertake to forward health IT, but it's a topic that's in the news and in the air more quite recently.

**Aaron Miri**
Got it. Christina, go ahead.

**Christina Caraballo**
My name was under this one and I gave it a little extra thought because it caught me off guard of bringing it up. It's not that I don't think that privacy and security around social determinants of health are important. I just think it's not the right place for it. I think that we bring up social determinants of health in other areas in the grid and we're looking at things like HIPAA, and consumer rights, and consumer education. I just think that this just seemed a little off to me. I wasn't sure what we were going to do with it. I feel like privacy and security around all data, not just social determinants of health are more what we should be looking at. It seemed like an unnecessary call-out on a very narrow topic when it should be broader.

Does that make sense?

**Aaron Miri**
Yeah. It makes sense to me. I hear you.

**Carolyn Petersen**
Yeah. I agree. I think we can stick it in with the other privacy and security topics unless anyone has any concerns.

If we agree that we want to do that, then we have the other question about ordering or grouping topics within priority areas. Do we want to tier things? It seems to me –

**Brett Oliver**

I think it might be worth tiering them. I understand that it's a little bit more work but it allows the committee to try to help prioritize efforts rather than just a huge drop of problems that we see out there.

**Carolyn Petersen**

For grouping the unique device identifiers in the privacy and security concerns and not calling it out separately? Is that what you –

**Brett Oliver**

I'm sorry. I was going back to your original question before we got down this rabbit hole of did we want to group them by tiers. We said we didn't want to put specific numbers on, and I agree that would be a never-ending process. But to put green, yellow, red, I don't know whatever, some kind of tiering to the overall topics.

**Carolyn Petersen**

Yeah.

**Brett Oliver**

Sorry. I anticipated the question. Sorry about that.

**Carolyn Petersen**

No. That's okay. I put two questions on the table at once and I think that's making it a little bit confusing for us.

**Christina Caraballo**

Yeah. I like the idea of a tiered green, yellow, red type of concept.

**Aaron Miri**

This is Aaron. What criteria would we use to rank priority? I'm in my head thinking can we say patient affecting? Every health IT issue could be spun to be patient affecting. Do we say it's directly twenty-first-century care related? Well, I could basically stretch any topic to that. What're the criteria to rank?

**Carolyn Petersen**

Yeah. I suspect you could wind up with a lot of back and forth about trying to switch things back and forth between categories. I wonder if we want to group them in terms of things that seem more timely right now. Perhaps they're either related to legislation that's being considered in Congress or new policies or procedures that have been announced by different agencies. Things where there might be some activity that we should be undertaking sooner rather than later.

**Aaron Miri**

That's fair. That's a fair way to do it.

**Brett Oliver**

Yeah. I hadn't thought through it in detail here, but I was thinking more along those lines. More of the immediacy of needs rather than a necessarily overall importance because you're right. Getting in front of that whole thought with everybody's different backgrounds and priorities, that could be never-ending as well. Maybe more immediacy of needs.

**Aaron Miri**

Okay. I'm good with that. I'm definitely good with that. I try to keep up with the health landscape as does everybody. Maybe ONC could also help us and kind of tell us what's percolating on the horizon. They have insight just as guidance.

**Brett Oliver**

Yeah. That's a great idea.

**Carolyn Petersen**

Is there some kind of master list of ONC projects or work that's underway right now? Lauren, do you know?

**Lauren Richie**

Not off the top of my head. I can't say there's a master list, but we have just our major program priorities. There are obviously the big things like the certification program, everything that we're working on under 21st Century Cures would be the big bucket items like the HR reporting program and so forth and our proposed legislation. But if there's something that we need relative for the report, we can maybe try to just come up with a brief list for this group for the report purposes.

Michelle, unless you can think of anything that I'm missing.

**Michelle Murray**

The thing that came to mind and we've already started thinking about this was the planning for the HITAC itself which is a joint process with ONC right now. We presented in October and that's underway to be reviewed again in January. The timing is not perfect for this report, but we at least have a sense of where that's going. I think that's another factor to consider.

**Lauren Richie**

Yeah. That's just relative to the HITAC. It's not encompassing across all of ONC.

**Michelle Murray**

Right. So, it is just part of the picture but it's another element to look at.

**Lauren Richie**

Yeah.

**Aaron Miri**

Okay.

**Carolyn Petersen**
Okay. Is that something that you could send out to us before the next meeting so we could look at that offline and be ready to prepare some thoughts about how we might order things? We can have our own kind of personal preliminary grouping.

**Lauren Richie**
Yeah. We can try to get you something in terms of priorities across ONC as a whole. In terms of specific topics, I think, Carolyn, as you know we're still working to refine the specific list of topics for the committee next year. We'll definitely put something together.

**Carolyn Petersen**
Okay. That sounds good.

**Aaron Miri**
Yeah. That's super helpful. Carolyn might have – And this is just me solutioning out loud, but it's almost like if you have a topic and one column said HITAC priorities and then match it up with an ONC project on their list. Then we could also say maybe a topic that's mandated by 21st Century Cures. Let's just pick on something. Third-party access for privacy, right? We think that's important. That lines up with maybe what ONC is looking at some legislation or ruling or whatever. And then it's, oh yeah! There's 21st Century Cures. Now that rubric makes sense and we push it to the top of the list.

**Carolyn Petersen**
Yeah.

**Lauren Richie**
That's fair.

**Carolyn Petersen**
That makes sense to me. Do you have any thoughts, Christina, or Brett?

**Brett Oliver**
No. I like that idea.

**Christina Caraballo**
I think that sounds great.

**Lauren Richie**
Okay. Let's plan to go that way with it.

**Aaron Miri**
All right. Are there any topics that we're thinking about that are not on the list that was sent out which has bubbled to the top or we want to add to because of recent events, or executive orders, or

legislation, or whatever? Is there anything that you all have heard of that we've just not thought of yet?

I think the only one that I'm thinking about in my mind as I talk through this, and I think we covered it in our listing and in other topics but we may want to add some more meat to it, is what is permissible under HIPAA and really talking through that. Because I think there are potential implications to TEFCA and to information blocking the NPRMs due to what I look at as how third parties access data, even what is permissible under HIPAA. Specifically, I'm referencing all the recent activity with Google and Ascension and Google and the University of Chicago and Google and Mayo Clinic and all the fever fury that's going on right now in the industry around us. One is an educational aspect to it. Two is what is actually permissible and what does it mean when you have a provider like Brett who has full rights and privileges to be able to ask for data for patient treatment purposes? But it doesn't mean that people can also then shoe in research and QR requests underneath that same umbrella.

So, I don't know if there's any more need for us to expand on any of the privacy and security topics, but that one is getting a lot of press right now and a lot of attention from everybody.

**Carolyn Petersen**
Yeah. I –

**Christina Caraballo**
So, looking at –

**Carolyn Petersen**
Go ahead.

**Christina Caraballo**
I was just looking at the grid and I think they're captured. Aaron, where do you see that we haven't adequately gone through –

**Aaron Miri**
No. I was saying I think we did capture it. I just wanted to make sure that if anybody had any different perspectives that needed to be added to what we captured already, let's add it given how much focus is on it. I was saying I do think that maybe we already captured it, but I just wanted to make sure that we didn't miss some specific dimension somebody wants to speak towards third party access. That's all.

**Christina Caraballo**
In reviewing this, one thing that I wanted to point out, and I know this is really little but, in the section where it says the draft plan for the HITAC there's a part that says, "Intersection of Medical Devices and Health IT in Potential". I'm doing a lot of work right now within the standards development organizations and HL7. One of the things that have come up as kind of something to be aware of is when you think of medical devices, we also need to include consumer apps. They're different and they have different rules and regulations. You've got the one side of the spectrum which is the medical

devices that are FDA approved and have their own set of guidelines. And then we've got the other side that's consumer apps that don't have the same guidelines. I think there is a growing disconnect on how they kind of cohabitate. I just want to point that out.

Instead of just putting medical devices, I would say medical devices and consumer-facing applications, consumer apps. Just expand upon it.

**Carolyn Petersen**
I think that would be very helpful, not just for the public but for folks in Congress who get calls from concerned constituents and need some kind of brief, sharp document that helps them understand the issues so they can respond appropriately. We step back to that in a second. We're right at 8:55 so we need to go to public comment. We'll likely have another minute or two to chat.

## Public Comment (0:21:05)

**Lauren Richie**
Operator, can we open a public line?

**Operator**
If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the * keys.

**Lauren Richie**
Do we have anyone in the queue at this time?

**Operator**
There are no comments in the queue.

**Lauren Richie**
Okay. Carolyn, I'll hand it back to you for a few more minutes.

**Carolyn Petersen**
Okay. Yes, this whole question of what's allowed under HIPAA and what are the differences between health IT like electronic health records versus health IT like consumer apps and differentiating and understanding that's certainly a hot button topic right now and very relevant. I think it's valuable to all if we include something about that in the annual report.

**Aaron Miri**
Yeah. I agree. And the enforcement crossover, right? There's an FTC perspective, obviously, when it comes to third party consumer apps. There's an FDA component if it's an app that is medical device in nature. And then there's, of course, OCR if it's a provider. Of course, a provider could also be all three

of those and have to deal with all three agencies. There's even a jurisdiction question on the back end. Who do people go to if they have questions?

**Christina Caraballo**
That crosses over to the interoperability section of our report, too. You can think about it just like data standards and approaches and ways to implement applications so that consumers can have this plug and play concept that doesn't currently exist. CMS points to the concept of bring your own device, but you can't do that right now. So, what data standards or approaches are enabling this expanding ecosystem with more and more cool consumer-facing applications to be able to actually be a part of the ecosystem?

**Aaron Miri**
Yeah. What's interesting is that there was actually an interesting article from Health Affairs that came out yesterday articulating the need for another agency that actually does that full time. They're almost like a national transportation safety board type of thing that looks at all this stuff and makes recommendations and helps guide the public. I'm not advocating for another agency. I'm just saying there's a lot of interesting trains of thought out there dealing with this very complicated issue. There are things to think about that there may be, I'm not saying an agency, but I'm saying there may be other legislative vehicles or levers to pull that could help clear the air or at least set some direction. I think we're all **[inaudible] [00:23:58]** that this is really murky.

**Carolyn Petersen**
Yep. I'm pulling that up right now so I can post the URL in the public chat space before we close our call so that gets captured. I did see that too. I thought that was interesting. I haven't thought about the full implications of that down the road and the challenges that would result from that agency trying to work with ONC and others that would be involved. But it's certainly something to think about.

**Aaron Miri**
Yep!

**Carolyn Petersen**
Okay. I got that in the public chat so that it'll get captured. Yeah. That's a very interesting concept and it might be worth considering how else information could be managed or what the implications are for trying to look at that in a different way than the system works now. Maybe that's a discussion topic for HITAC for next year too.

**Aaron Miri**
Yeah. That will be interesting. I foresee third party access rising to the top of our list quickly. This all plays into that.

**Carolyn Petersen**
Yep. I see we are now at the top of the hour. I'm wondering if anyone has any closing comments before we end our meeting?

**Christina Caraballo**

I know we're out of time, but why did you call out the unique device identifier? Did we want to discuss that or are we out of time?

**Carolyn Petersen**

We're out of time. I think we're going to put that in the section with the privacy and security concerns.

**Aaron Miri**

Yep.

**Carolyn Petersen**

We're not going to call it out separately.

**Christina Caraballo**

Okay. That sounds good.

**Brett Oliver**

Thanks, everyone. I think I'm going to have to drop.

**Aaron Miri**

Yeah. I appreciate everybody.

**Christina Caraballo**

Me too.

**Carolyn Petersen**

Thanks, everyone.

**Lauren Richie**

Ok, guys.

**Aaron Miri**

Thank you all. Have a great day.

**Adjourn (0:26:18)**