Annual Report Workgroup

Transcript
July 19, 2019 Virtual Meeting

SPEAKERS

Name	Organization	
Aaron Miri (Co-chair)	The University of Texas at Austin, Dell Medical School and UT Health Austin	Co-Chair
Carolyn Petersen (Co-chair)	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

Operator
All lines are now bridged.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Good afternoon, everyone. Welcome to the HITAC annual report workgroup meeting. We will get started here. Of the members, we have Carolyn Peterson, Aaron Miri, and Brett Oliver. Hopefully, Christina Caraballo is able to join us later. With that, I will turn it over to Aaron and Carolyn to get us started on our outline for fiscal year '19 report.

Carolyn Petersen - Individual - Co-Chair
Hey, hey, good afternoon, everyone. I hope we are all having a good summer. And it's good to have an opportunity to touch base on where things are at so far and kind of think about how we want to set ourselves up for the fall. I know Aaron has also expressed his excitement, and I will let him share that with us now.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yes, no, absolutely. So, happy Friday everybody. We are trucking along, with lots of stuff going on, so thank you for joining. And then, yeah, I think this is exactly what Carolyn said. This is of the start of a lot of work that is about to occur, and happy to capture it and let's move the ball forward. So, thanks for joining. Carolyn, back to you.

Carolyn Petersen - Individual - Co-Chair
Sure, okay, sounds good. We can start by start by reviewing our meeting schedule. Today is July 19. We are taking August off. I hope that inspires as much excitement in you all as it did in me. We'll start with the meeting early in September right after Labor Day, and then we will have dates to be determined in October, November, December, January, and February. It will be pretty much the same approach we took last year except that we are ahead of schedule. So, hopefully, we will have a little bit less nail-biting toward the end and be able to get an approval of the report by the full HITAC in February so that we have a nice break before we start the 2020 version. A bigger break. Next slide, please.

And then, here is kind of what we are doing in terms of giving the Full Committee the chance to review all of this work. We didn't present in July because we had the last bit of TEFCA to deal with. We are on the calendar to do a presentation in progress at the September in-person meeting on the 17th. But at that point, we would just look at topics and go over the outline. Ideally, we could get some feedback from members about what they would like covered in greater detail. You know, then just sort of the chart of things to keep an eye on. And then, in October and November at the virtual meeting, we will update our status and hopefully, talk more about what we are doing with the landscape in Gap Analysis. We will not be meeting the committee in December. Good news. And then in January and February will be reviewing the draft and getting approval of this report. If we can have the next slide, please.

So, let's go into the outline. This is very similar to what we did for the Fiscal Year 18 report. Executive Summary, the foreword, and the overview. We have a section this time on progress because we've

actually gotten some work under our belt that we can talk about. The landscape analysis and Gap Analysis, some recommendations for addressing infrastructure gaps. And then our suggestions for additional HITAC initiatives, conclusion, and indices of resources and materials that we think are useful to our users to keep in everyone's mind. Next slide.

Now we will get into some of these considerations about the annual report for the coming year. This is kind of a summary of some things that we talked about in June. In terms of the status of the objectives and benchmarks. It looks like we kind of have to keep using that language until ONC makes any changes in it. Where would a review of progress on the 18 recommendations belong? Kind of talked about putting any achievement in the progress section, giving some topics in landscape and gap analysis as appropriate. For me, personally, I think it depends in part on the content of the report. I think this is a good starting point, but if we think that it helps to move something around or mention it in additional places, I think that is fine too, as long as it supports the cohesiveness and the readability.

And then, we had a discussion about the cost-cutting topics like HHS regulations and TEFCA and other things. We were on board with putting them both in the landscape and in the Gap Analysis, separate from the priority target areas. I think that is just kind of a thing that makes sense in terms of showing the HITAC how everything fits together and be sure that everybody is comfortable that we're covering all the things that they care about and the things that they have relayed to us that they feel should be reflected in the annual report. Are there any thoughts or additional questions or considerations about some of these issues or the structure of the report?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
No, I mean the report makes sense to me. I looked it over recently again just for a refresher, because so much has gone on over the past several months. I don't know about the rest of the Committee, I mean, it makes sense to me.

Brett Oliver - Baptist Health - Member
Yeah, I think that was a good summary from June.

Carolyn Petersen - Individual - Co-Chair
Okay. It sounds like we're in agreement with some of that stuff that we worked on in June so, Aaron, why don't you take it over and go to the next section.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yes, no problem. Next slide. All right, so, we're looking at the draft outline. All right, let's see here, so, from a federal activities perspective, again talking about 21st century cares regulation on information blocking, price, certification, all the stuff that we talked about in concept but we didn't go into it because obviously the NPRM's were not released by December 31st, so a lot of it, we kind of just – we knew it was coming, we wanted to note it on the report, but we didn't go into it. But those are obviously key things we want to talk about this time around. TEFCA version two. I've seen some of the articles calling it TEFCA two, which I think is interesting. A lot of the key changes that went from version one to version two, and hopefully a finalized version at some point this year before December 31 would be great so we can talk about it.

CMS Interoperability role, the key provisions that impact priority target area, notification climate, all the APIs, Care Coordination, that whole nine yards, and then of course, other federal activities like the ONC Provider Burden report, GAO patient matching report and I'm certain that this year isn't over with stuff that's going to be launched or done with, so other topics to be announced. Next slide.

Around Interoperability, obviously, we're going to try to use that FY18 description with updates on it, sort of what our currents will be HIEs, you know, cross-network exchanges, a lot of the issues with notes, this is something that have come up from the HITAC multiple times about note bloat, integration reconciliation data from multiple external sources, a lot about FHIR, and what HL-7 can do there, the release of a new version and progress on those issues or any issues there. I will note that even in the, with the CIO hat on, a lot of EMR vendors still do not support FHIR, and it's frustrating as all get out when you ask of them to build something in FHIR and you can't even do it. Health IT Support for opioid epidemic response, PDMP support act, electronic help, you know, the HRA, what they're saying, and the CEC opioid guidelines.

I would also say that there's a lot of push in the industry right now asking about what happens at the actual dispensing locations where there is a CVS, Walgreens, whatever, and if a formulary or a medication has changed, how does the hospital or upstream, how does that information go back upstream to the hospital so that the providers know that, oh, they changed the dosage or went to a generic or whatever else, so that way med rec reconciliation is clean. So, there's a lot of things here, I think, from an opioid epidemic response that we may want to talk about and suggest activities around to continue that progress that's being made. Next slide.

On a privacy security background, again, looking at that FY18 description and updating it with anything relevant, sort of that current state. What about data generated outside of HIPAA? I look at this as things like genetic testing, 23 and Me kind of companies and how there has recently been a lot of press about them selling that data, what is happening to that. 42 CFR part two in FERPA, this one hits near and dear to my heart, particularly being an academic medical center, there's a whole lot of grey space when it comes to FERPA and even Title X. Interstate data exchange and privacy considerations. I think the hodgepodge of laws and whatnot, state Laws versus federal laws, that's something to be taken a look at.

I know I have spent time with Texas state legislators talking about this. I think everybody is aware that there's got to be something that's done to reconcile or crosswalk to something in the future. Implications of the California Privacy Act, again going back to that state-specific kind of thing and how that impacts. And implications of GDPR and privacy shield. In fact, there was a recent article today in major news about a provider that ran afoul of GDPR for folks searching from the Netherlands on records in the States. So, there's a lot of these things that need to be worked through. on records.

All right, patient access information, again using that FY18 description and updating it. So, kind of the current state patient control data collection, access, and sharing. I call that the Apple Health Kit and other accessing data, what they are doing with it, all of that sort of thing. And then, of course, the use and sharing of PGHD, that patient-generated health data. How does that work? What does that look

like? It's becoming more voluminous and in the healthcare arena, we are seeing that every single day where folks show up with something they generated. And how do you reconcile that against a clinically derived dataset and come up to some sort of middle ground? All of that is just a gray area that has to be worked through. Next slide.

And then, some of the crosscutting issues, implications of IOT, policy and trust issues for open APIs. There's been a lot of – there was a political article on this week on this, again, what is the federal guidance supporting implementation, FAQ, that sort of thing. How can or will people try to monetize and use APIs, that data in there that they can collect the screen scape for non-treatment purposes. There are some trains of thought there that the patient's data is patient's and belongs to patients. Some say, hey, if I get access to the patient data with the right permission, I can use it de-identified for whatever I want. There's a whole lot of I think different camps that have to be reconciled. Is that something that, we as a HITAC want to consider. That's something for us to think about.

On patient matching and verification, new reports have come out including a deeper review of the GAO report. There's been a lot of activity on this one recently. Initiative including relevant federal activity, capabilities, machine learning, and referential matching. And then it's become a buzzword but is actually very, very germane with social determinants of health and population health and individual interventions, research efforts, standards development. Near and dear to my heart is patient-reported outcomes. And I know there's some great work that the ONC is doing with some crosscutting teams on setting up initial standards for PRO's. What does that look like? And again, how does that fit into the overall SDOH bucket and how do we track that, right? Are those standards need to be developed, so forth and so not. Next slide.

Another emerging issue here is **[inaudible] [00:12:20]** and this is something that is really the use of digital apps in the role of treating a disease. I think we've seen this with a lot of women's health apps and other apps that are out there, whether it's hypertension and whatnot. So, how do you manage chronic disease and all these different types of comorbidities with digital therapies? So, for one example here a large prescription PBM introduced its own Digital Health formulary that creates a curated set of digital apps for payers and patients. There's a number of things of that are going on in this arena and so how do we as a HITAC consider that, think about that, and as that plays into the larger ecosystem where that fits. And of course, social economics, you know, the scientific discipline that attempts to find the genetic basis of societal behavior, social behavior, excuse me, and its evolution.

Basically, data sets can now be combined with new knowledge. We could offer benefit to patients, predicting disease risk that could cause harm and discrimination, and basically, this is looking at outputs of large data sets and ahead of time prescribing and saying hey, your workforce may be sicker if you do x, y and z, or may be healthier if you do x, y and z. Those are, some of that is obviously regulation and rigor and privacy need to be considered. Some of that is discriminatory and some of that is potential law that needs to be developed around this, you know. How do we get in front of the potential negative effects of now all sorts of types of data and phenotyping of data? Next slide.

And then, sharing of large media files. How do we – besides the structured data and unstructured data that today is exchanged, the Health Information Exchanges and eventually the TEFCA and what not. There's a number of ginormous data files that are transferred and exchanged outside of that whether it's genomics, whether it's PACs, whether it's digital labs and whatnot. All of those go above and beyond are outside the current scope of a lot of the standards that were developed. And so, how do we being to think about making this interoperable? Because let's assume, you know, going back there to Kentucky, as it is in Kentucky and UT want to share information, there's a whole lot of rigor that has to go into place to figure that out. It's not as easy, and so, clinicians on both sides are at a disadvantage. So, how do we work through that and the HITAC and think about all data that are necessary to treat a patient and the total health of a patient? Next slide.

All right, so before we go on to the next section, of all of those things any questions, comments, concerns, head-scratching? Does that make sense? Did I leave something out? What do you all think?

Carolyn Petersen - Individual - Co-Chair
It makes sense to me. As we were going through it, one other thought occurred to me for the list, that would be artificial intelligence.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Good catch.

Carolyn Petersen - Individual - Co-Chair
Certainly, that comes up in regard to socio-genomics and, perhaps, with regard to digiceuticals in the sense of what's training the algorithm, FDA has been looking at that. They had a call for comments recently in terms of software and devices that use a sort of the ongoing AI, as opposed to a device with a static algorithm, and periodically the manufacturer update the algorithm, but they know how they are updating and have a sense of what that would do to the output. Whereas when you have this sort of rolling, learning as it goes along, that is kind of more of a black box.

Brett Oliver - Baptist Health - Member
Well, and I would echo that. Carolyn that's an excellent point, because one of the things I struggle with is I think some of our CDS, our clinical decision-support that's coming in the future, we're not going to be able to create all that internally even if we wanted to, if we want to stay up with state-of-the-art patient care, and so we are going to rely on some of these vendors and outside resources for their AI. Let's say we send it to the cloud, we strap on their particular module that we want, and they send it back to us, that's great; however, whatever their algorithm is more than likely going to be proprietary. That's going to be their whole business model is them figuring that out. So, where is that, who is at fault there? The liability, if something goes wrong because something will go wrong, it does in medicine. And so, is that on the end clinician always?

But if I don't know what is going into that black box, it's tough to make a decision, and so we're going to be presented with, the end-user is going to be presented with this clinical scenario and the computers going to say, hey, based on this algorithm the patient should get this treatment, I were going to say, according to the algorithm, your patient should get this treatment, and we are going to

say what went into that algorithm? We are not going to be able to see that. And so, if there is some kind of vetting process at a federal level, I don't know if that's the answer, that sounds awfully complex, but is somebody looking at that? Or is that going to be left up to the individual institution and clinician? Does that make sense?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yes, it does. It does, and even more so, I agree in clinical operations that are also important, but also in research. You know, recently, I have been facing this personally here to a lot of folks touting some sort of AI. Which is really fancy machine learning. I don't think there's really any true AI yet out there. But it's really, you know, some sort of decision support, whatnot, and from a research perspective even then, deriving how did you actually get to the result, because this equation, you know, in research you kind of have to prove how you got to your expected results of a cohort of patients. It's very difficult to do that when you proprietary algorithm that maybe, you know, sucked in a bunch of data and spit out a result to you, and you are supposed to produce how you get to that result, and they don't want to share what their algorithm was that derived that, right? So, I think on both dimensions, both clinical ops to your point, as well as research, this will need to be addressed. That's a good point.

Carolyn Petersen - Individual - Co-Chair
I will put that URL in the comment box now so that other people can pull down that document that I was talking about. It's the proposed regulatory framework for modification to artificial intelligence/machine learning-based software as a medical device. And FDA presents a lot of good background in that document, and also kind of explore some of these points that we just mentioned. It's good background material, I would say.

Brett Oliver - Baptist Health - Member
Excellent.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yes, okay. Let's go next slide then.

Brett Oliver - Baptist Health - Member
Could I ask one thing, Aaron?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Of course.

Brett Oliver - Baptist Health - Member
On that whole report, do we need, and maybe this – we didn't get into a lot of the detail we were looking at an overview but one thing that I thought about during our last HITAC meeting was maybe in this report we need a reminder of right now, like current state what data we are talking about exchanging. I don't know if you were on the call or not, but if you remember, Cynthia went on this entire nearly 20 minutes almost rant about credit card information being sent, you know, when her information is queried. And unless I don't understand the USCDI as it exists right now, that would not be something that would be exchanged. Number one do I understand that correctly? Number two, is

that something that we need to just kind of reminder of what data is – I mean, I know the intent of the Cures Act is to exchange your entire charter, all your records, but right now we're not talking about that, are we?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
I have not been in my discussions and in my understanding. Maybe I'm missing the boat but to me, that is not part of the scope. Although it is a total amount of information that hasn't been the issue that I've encountered, at least. Carolyn, did you hear differently?

Carolyn Petersen - Individual - Co-Chair
No, no, I mean I feel like I've heard at various points horror stories about download of credit card information, but it seems to me if you are purchasing a service or like you are going to get a test and they have you set up your appointment and put some down payment on it or the cost, if it is a known cost that you know is not covered by insurance, I don't know how you would avoid transmitting credit card data. I guess you could do it in a separate transaction, but you would still be transmitting it even though you're not transmitting it with other information.

Brett Oliver - Baptist Health - Member
Yeah, because we are talking about is U.S. CDI transfer of information and obviously you could have a breach of whatever system you are storing, of the healthcare system you are storing that credit card information, but I was really confused and honestly wasn't confident enough at the time to say why are we talking about credit card information? I did not know that was a focus of the U.S. CDI right now, so anyway, I don't know if that makes sense in the Annual Report, brief paragraph, kind of a reminder of the data exchange as it exists right now and what we're talking about when we're talking about data exchange?

Aaron Miri - The University of Texas at Austin, Dell Medical School, and UT Health Austin - Co-Chair
Yeah, we could do like this, we could say that PCI is out of scope right now, or we're not talking about PCI data. But we're just paying card information. We can definitely footnote that. I think in defending Cynthia's position, I think maybe she was thinking about every bit of data that a patient may have, which would include their financial information, credit card, and whatnot. I bet she was probably referencing the total body of information. But to your point got from U.S. CDI perspective what we are thinking about, what we're really thinking about is the clinical data and more that EMR data, PAC imagery, all that sort of thing. I think PCI is something that is important, but it's not – to me at least, and you guys feel free to disagree. To me, it's not in the scope right now.

Brett Oliver - Baptist Health - Member
Right, I mean if the TEFCA and USCI existed as we know it right now or as it's been proposed, and, Aaron, you query or I query your information because you stopped by Kentucky for a medical reason, I'm not getting your credit card information in the U.S. CDI. Do I understand that correctly? That is what we are really tasked with doing and talking about. Maybe, again, down the line, but I think I did not hear any sort of discussion about that. I don't know, that's what made me think maybe it's part of the report we needed a reminder about what is currently in scope that we are talking about when referencing all of these different things and we're talking about information.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yeah, it's a good point. It's important, but I think right now it's about the clinical information. I think it's a great point. I think it's a good footnote.

Carolyn Petersen - Individual - Co-Chair
Is there a possibility that you would be submitting information, patient-generated information to be put into the record using a consumer app that collected information using, I mean that did the transaction using your credit card?

Brett Oliver - Baptist Health - Member
Yes, but I wouldn't think, we're not talking – like what field would we actually be -- I'm thinking about this practically speaking. If we're going to exchange that data, well, I know what field to map, say, your address to. Or your CBC, your lab values to. I don't know what that looks like. Like I don't know if your Fitbit data comes in and I'm supposed to transmit that, like what that – at least in the U.S. CDI we have not been talking about patient-generated data and where that flows, I mean, we need to eventually, but in the current state. So, your point is well taken that that information can be hidden somewhere, but it's still going to take a discreet, I would think. We're not just taking this in in a non-discreet way or not. I don't know, I don't know. Good point though, Carolyn.

Carolyn Petersen - Individual - Co-Chair
Yes, I think it's in the future at some point, but since we continue to keep a discussion alive about PGHD and PROs, it may be something to keep in the background of our thinking.

Brett Oliver - Baptist Health - Member
For sure, for sure.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yep, yep, totally agree. Okay, we're to the next section now. So, looking at the Gap Analysis areas, from a priority target area of interoperability. One of the gaps that we noted was the limited EHR integration, PDMPs. And sort of the opportunity there, because several states still don't offer EHR integration, so enhance EHR integration with PDMPs and the ability to capture feedback about prescriptions and pharmacies and patients. Incorporating and reconciling data received from outside sources. Again, struggling to – people are – providers and patients are struggling to integrate the data into workflows as I said earlier, and then make the – opportunities to make the integration of data into workflows more seamless. And then, for the unmet needs of additional care setting and stakeholder groups, you know, with the move for the fee to service to Alternative Payment Models, health information must flow to where it is needed across the care continuum.

So, the opportunity is to improve the capability to electronically exchange and use health information for behavioral health, long-term care providers, and I would say really any downstream healthcare delivery entity to make sure that we can exchange information with them. I mean, even social work and whatnot. It's amazing how broken the entire continuum of care is and it's sad how much we rely on paper. I mean, even ambulance transfer forms and intercampus transfers occur still on the pink

forms. And it's just, it's broken right now the way it stands, and it's very ripe for issues. At some point, I feel strongly that HITAC should look at this and say there's a gap here. On that gap, what can we do to help or extend what is currently available? Next slide.

On privacy and security, lack of clear privacy protections for data generated and stored outside of HIPAA framework. Patients don't realize the data is not protected. Again, I go back to the whole 23 and Me and those kinds of things. Then the opportunity there to increase the transparency of business practices, education of patients about privacy protections, I mean, I don't know if folks realize, but those companies that do genetic testing, they could share your data with insurance companies without a problem. There's nothing protecting you. And again, they don't fall under the provisions of HIPAA. So, when they have a breach, and there was one that just occurred last week. They don't have the same reporting requirements. They don't have the same burden where the Office of Civil Rights will investigate them and others.

So, to the degree that how you deal with those types of companies that are falling out from that. Again, we talked about earlier, the variability of information-sharing policies across the states. And the state policies may differ with federal policy, especially with patient consent. And then sort of the opportunity to increase alignment and guidance. And how do we continue to educate the states on how to harmonize the framework across. And one has to think, I think, just philosophically and logically thinking, if we can figure out how to create physician compacts for allowing for physicians to be credentialed across multiple states, surely, we can figure out how to do privacy and security across multiple states. It's just a matter of doing it, of just doing it. Next slide.

Another area in privacy security is the lack of user control to share and disclose information. There's a lot of concern about privacy and security of third-party apps, availability of API capabilities and overall technical capability. Again, sort of the opportunity there is to increase consistency of policies and practices for consent data capture. I would also say that the variability between consent for research and for clinical operations is interesting, and how even your signature, electronic signature captured may work for clinical operations where it may not work for research. So, there's a lot of variabilities there when it comes to consent. For empowering the patients, you know, my institution makes sure the patient has completed and transparency and understands it. But not everybody does that. So, is there a role here for HITAC to get involved and help clean that up? That's something for us to consider.

Variability adoption of cybersecurity frameworks. The challenge is there, liability for healthcare organizations for data breaches of vendors, rising cost to adopt and adapt a cybersecurity framework. Sort of that opportunity guidance about accountability for and then management of the liability risk. This goes back to the discussions we have been having over many months about who's holding the ball at the end of the day, and the issue now with business associates and third parties. And OCR, Office of Civil Rights, has put out there in public that they don't have the same levers over third parties, that they do over current entities. And so, is that the right approach? I don't know. That is a consideration for HITAC to think about, and say is there something more we should do to hold appropriate accountability where it belongs? Next slide.

Regarding patient access to information, accessibility, and usability of patient portals and other patient-facing technology to continue the improvement. The challenges, a large number of disparate patient portals. I mean, I know here in town you go to every single provider except for us and one other that we have partnered with and you have your own patient portal, and that is just terrible. So, how do we get, how do we streamline that? Lack of accessibility of health information in various settings. A need for more user-friendly tools. It goes on and on. Opportunity wise though is an improved design and accessibility as well as patient education. This is about really, and Carolyn, you can speak probably best to this, really empowerment of the patient, and allowing them to get the right information at the right time in the right place in a manner in which they wish to receive it.

For me here in Texas that means the Spanish language. That meets whatever other language as more than half of my patient population doesn't – English is not their first language. Then, of course, the use and sharing of PGHD. The challenges and opportunities understanding the evolving patients' experience of sharing health data with the Care Team, and the providers business reasons and technical ability to use and share PGHD. And I would add, the third domain there is where does that PGHD live? Does it still live with the patient? Or does it now live with the provider once it's exchanged? I don't know. Questions to answer. Next slide.

On the crosscutting issues, the API trust framework, industry compliance with new Regulatory Compliance of providers who use APIs. If you can go back one slide, please. Thank you. To give patients access to their data. The opportunity is to monitor early deployment and identify any concerns for providers and patients as well as policy gaps that arise. And then the need for improved patient matching when sharing data. This I think has been a long-term subject of discussion, and I applaud the Congress, both the House and the Senate, for looking at this, even most recently and making considerations around this. So, I think it's definitely catching traction. So, the challenges were that federate approach to patient matching, and the opportunity to develop a consensus across the industry on how to improve patient matching for the entire exchange ecosystem. And then last but not least, price transparency which we've alluded to earlier related to PCI.

In this case, the limited availability of price data has a negative impact on patient experience. I think you recently saw a Presidential Directive on this as well. And so, the opportunity is to improve the availability and usability of price data. I would also say improved ability to understand and education to patients about what pricing data actually means. It is not an easy subject. I wish it was as easy as making a pizza. It's not and it's one of those things that, I think it will take some patient education to get them to understand that. I think if you can applaud ONC and OCR for the work they've done over the past decade about HIPAA, I think we could do the same traction with the price and eventually get to a point you have the majority of the U.S. public understanding how to decipher and understand how to get the healthcare pricing. Because healthcare isn't a one to one. It's a many to one type transaction which becomes difficult. Any questions? Thoughts? Concerns? Did I leave anything out about gaps? Did we hit on a lot of relevant subjects? Are there other topics that we should consider?

Brett Oliver - Baptist Health - Member

One thing that I thought of, Aaron and Carolyn, if you agree, based on the recent lawsuit against Google, I'm wondering if we don't need to ask ONC to define what is the identified data? In this day

and age with AI and these data sets, you know, the lawsuit I think it's Loyola of Chicago that's being sued, along with Google, they sent what they thought would be identified data and the complaint is, and it's just a complaint, not going to – a conviction, obviously, but the complaint is Google's got so much other data that they could potentially essentially triangulate and identify who these folks are based on the information that they provided. Do we – is that an issue that we think is pertinent enough at this point, but from a privacy and security, what is truly de-identified data moving forward? I feel like we throw that around, but, and maybe those in the industry know that better than what I am aware of.

Carolyn Petersen - Individual - Co-Chair
Yeah, that lawsuit was the University of Chicago and Google.

Brett Oliver - Baptist Health - Member
Chicago.

Carolyn Petersen - Individual - Co-Chair
I guess I've come at this question of what's the identified for some years from the precision med genomic information perspective. And it seems kind of the dirty little secret is more and more people, people who do privacy, security and the technical side of security and privacy are kind of starting to acknowledge that you actually cannot really de-identify data, because although you can implement processes and remove certain fields, when you start to apply what you have from other sources like ZIP Codes, birthdays, et cetera, and if an individual has a particularly uncommon trait-like missing one of your hands, those folks are very hard to de-identified, and it is becoming more of a discussion point that you don't talk about the de-identification you talk about managing risks and give people more choices and help them to understand what is going to happen rather than tell them that something won't happen.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
That's exactly right. I think the other thing here is a move towards a much more comprehensive consent so that patients understand that reasonable and best effort will be made to de-identified but there's no such thing as total de-identification. So, having the patient accept that risk, whether they want to participate in a research study, whether they want to receive care.

And I'm all about as transparent and as forthcoming with the patient as possible, so I'm seeing a huge industry move towards that, where it's about patient education, exactly what you said, and just being honest. I don't think – I think there's a way to de-identified for the purpose of HIPAA, but does that actually de-identify the data? No. You can still take elements, as you just said, Carolyn, and figure out who is what. Just because you check the box that you complied with HIPAA doesn't mean that the patient is safe. You have to put the patient first. HIPAA is just a by-product of keeping them safe. So, being upfront and transparent, there's a lot of patient education component to this, too. That is my two cents.

Brett Oliver - Baptist Health - Member

Yeah, I think if you tell me my data is de-identified, to me, just as a layperson I'm thinking I don't need to worry about that. But if Google gets access to that information or Facebook does and they are like well, we know that he checked into an office three times. And on those dates, he actually then posted on Facebook that he was there for throat cancer. Do you know what I mean? It's just not that hard and who even knows the connections that you can triangulate in the future will be. And so, it's really a tough transparent consent, you know, to be transparent with that consent when as a healthcare provider I don't know all of the different ways that somebody might take your data. That's why I thought if we had that understanding of a national definition of what de-identified means, or we don't use that any longer, it's just, to me that just means, people can't figure out who I am. Sure, I will sign up for that research study. It's not accurate.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Right. No, I think it's a fair question. I think it something we should definitely think about and ask, and this goes back to the other HITAC discussion we have had about having more clarity and transparency around third parties related to API access to data, who holds the ball at that point, that comment earlier about accountability. This all goes back to that which is what is the stance because for whatever healthcare is oriented towards well, let's go smack the hospitals upside the head again for doing a bad job. In this case, it's not necessarily the covered entity. It may be other, and so how is that distinction made clearly and understandably? And more importantly, how is the patient kept informed and as safe as possible?

Brett Oliver - Baptist Health - Member
Exactly.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Any other topics? That's a good one, by the way, Brett. What other ones? I think I have seen some good information coming recently from pew about the UDI, the unique device identifier, and I know we don't talk about here. It's been talked about another context, do we need to think about considering medical devices, implants, and all that sort of thing again? I know it's called for multiple times in 21st-century cures and other places, but it seems to be a slow roll from the industry about this. What do you guys think?

Brett Oliver - Baptist Health - Member
I'm very concerned about it from a privacy and security perspective.

Carolyn Petersen - Individual - Co-Chair
I am concerned about it from that perspective and also from the perspective of, how are we tracking devices and knowing when we need to take another look at something? Given that devices, we often don't know that much about them when they get approved, and they maybe have not been used in the population that they will be used in once they're in the market.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Right.

Carolyn Petersen - Individual - Co-Chair
Given that we know that for 20 years or in the neighborhood of, FDA was taking reports on malfunctions and problems that were not made known to physicians, surgeons, patients, and others. You know the system isn't necessarily going to tell you what you thought it would tell you.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
That is right, exactly right. And the other thing that I have become acutely aware of is the number of implants and materials that come in from overseas. Quality control is an interesting thing, and any disruption or modification to that manufacturing process could impact patient lives very directly. An implant could be faulty. It could have some sort of something in it that is not disclosed, or whatnot, and having to do a fast recall or contact those patients is very difficult without that. So, I think what is that element of privacy and security, which you are exactly right, Brett, with patient safety. How do we reconcile that and leverage UDI in a safe way? It's just going to be, we feel it's a topic to think about, we can marinate on it some more but it's becoming more and more relevant as time goes on, at least in my opinion.

Carolyn Petersen - Individual - Co-Chair
Yes, I think so, too.

Brett Oliver - Baptist Health - Member
Agree.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
All right, so we will add UDI to the list and those types of implantable type discussions. Any others? Any consideration around 5G or futuristic type – I know we talked about AI which has been so overused by marketing teams all over the world kind of like cloud. I'm sick and tired of hearing it, but what about 5G or Quantum computing or any of that sort of thing? Are those things we should consider now or is that just so far off we do not want to worry about that yet?

Brett Oliver - Baptist Health - Member
Certainly, 5G could impact some of those large file image sharing topics. Maybe it joined with that or talked about in that context?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yeah, or rural access. I was thinking about access to rural parts of America with 5G. The promise, again, it's a lot of marketing mumbo jumbo, but the promise of 5G is you should be able to get density into very rural parts. I mean, I can imagine parts of Kentucky are very mountainous or desolate, so could 5G suddenly give them access to now suddenly you can do opioid monitoring or real-time telemetry monitoring on patients that are in the middle of nowhere? Right here in Texas, I know that would be a tremendous benefit, particularly in South Texas where you can go for miles and see nothing but a couple of cattle. To the degree of it, if it holds true and not just marketing mumbo-jumbo could be a lot of value there. So, how do we begin to set the guidelines and parameters around that from a HITAC perspective, just thinking about it? Something to think about.

Brett Oliver - Baptist Health - Member
Certainly, could request some education on it from a non-vendor.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yeah, I'm curious what with the consideration points are. Particularly I know, the President has called for the rollout of 5G as fast as possible and then 6G even. So, with that lens on it that we want to be right in line with where the national direction of thinking is, how do we form a healthcare delivery perspective consider these things? At least consider it. Okay, anything else?

Carolyn Petersen - Individual - Co-Chair
I am sure that more will occur. I feel like there is something that's just out of my – beyond my fingertips, but I feel like this is probably as good a list as I can envision right now.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Yeah, I'm sure HITAC will HITAC will give us a nice, nice laundry list of other items that we hadn't considered yet. Those are some very bright folks that have a lot of great ideas. So, I'm sure there will be more things on the plate very shortly.

Carolyn Petersen - Individual - Co-Chair
Yeah.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Okay, well then, if you guys are good with it then, we can go to, open up the lines. Lauren?

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Sure, can we just get the comments line? Perfect, then Operator, can we open the line?

Operator
If you would like to make a public comment, please press star one on our telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star two 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 star keys.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Do we have any comments?

Operator
There are no comments at the time.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer

Okay. We'll leave the comment line open because I know we are a little bit ahead of schedule, then if we get anything, I'll let you know, Carolyn or Aaron.

Carolyn Petersen - Individual - Co-Chair
Okay.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Anything else?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Sorry, I was talking on mute here. I was talking on mute. That's what I get for it being Friday afternoon. I have nothing else.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Thank you.

Carolyn Petersen - Individual - Co-Chair
Yeah, I really don't either.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Okay, operator, do we have anyone else dialing in?

Operator
There is no other dialing in or comments at this time.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Okay, all right, if there is nothing else, we can adjourn. Michelle, anything else from you?

Michelle Murray- Office of the National Coordinator for Health Information Technology - Staff Lead
No, just that we are looking forward to meeting in September, and hopefully will get a chance to see each other in person.

Carolyn Petersen - Individual - Co-Chair
Yes, that would be great.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Looking forward to it.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer

Okay, have a great weekend, everyone.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
You have a great one.

Lauren Richie- Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Goodbye.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin - Co-Chair
Goodbye.