Annual Report Workgroup

Transcript
September 04, 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:
Thank you. 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 annual report workgroup of the HITAC. We will get started today with a brief phone call. We have Carolyn Peterson, Christina Caraballo, and Brett Oliver. Aaron Miri will be joining us here a little bit late. With that, I will turn it over to Carolyn to get us started.

Carolyn Peterson - Individual - Co-Chair
Thanks Lauren, and good morning, good afternoon everyone, depending on where you are. We're getting back to our annual report work after a nice six weeks off in the summer. I hope everyone had a good holiday and is rested up and ready to go. Go to the next slide.

This is our agenda for the day. I think it looks pretty similar to what we did in the previous year and months. We will start out with looking at our schedule and then discuss the landscape analysis section for the upcoming annual report. We will talk more about developing the annual report, we'll do a public comment period, and then go through our next steps and adjourn the meeting. Can we have the next slide, please?

Believe it or not, we have actually already accomplished three of our nine meetings, and after today, we will be almost halfway through in terms of the number of meetings we do. That seems pretty amazing to me. We are going to start working on the draft and discussing the landscape section today, and then we will continue to work on that in meetings on October 8, November 26, and December 13. In January and February, we will be presenting this draft to the HITAC for review and comment. Next slide, please.

Here is what it looks like in terms of bringing our work to the full HITAC. We will have a status update during the September 17 meeting in person. We will have an update on the virtual meetings on October 16 and November 13. Hopefully, we will be meeting with the full HITAC in December and then on in January and February we will be reviewing and approving the full draft. Next slide, please.

Let's dig into the landscape analysis. This is in the middle of the report overall. We are going to use pretty much the same structure we had last year, except we will now have a progress area. Next slide, please.

Our instructions, I'm going to go to the draft landscape analysis document and for each of the subsections, consider whether the subsection addresses what it's supposed to and what we think that it should address, consider any additions, anything we want to delete, or any changes to the text or anything else. If there are additional sources or documents, or videos that you think should be referenced, it is a good time to pass that along to Michelle. We also want to think about how the topic placement lines up compared to previous documents in previous subsections. With that, let's head into the next section, please. Next slide.

Looking at the federal activities section, in the draft landscape analysis, we have ONC's regulations for the 21st Century Cures Act. This is info blocking, price information, certification enhancements, application, programming interfaces, and the U.S. core data for interoperability. We have the Trusted Exchange Framework and Common Agreement Version 2. We want to highlight the key changes between those versions. We have CMS' interoperability rule, in particular key provisions that impact priority target areas for us. It could be things like hospital notification requirements, the payer-patient APIs, and other things, and then the soup to nuts federal activities section like the provider burden report, and the OCR federal request for information. Next slide, please.

Let's start with the priority target area of interoperability. We have the background and the current state, information exchange, network exchange, integration of data from multiple external sources, HL-7 FIHR standard, and health IT support for opioid epidemic response. What are we thinking about in this area with regard to the draft landscape analysis?

Aaron Miri - The University of Texas at Austin - Co-Chair
This is Aaron. A question for you; should we talk about anything on here about the RCE or anything around TEFCA, or should we leave it at a higher level of health information exchange, particularly since RCE was selected yesterday with Carequality? Is that worth starting to mention or do we want to leave it more high-level?

Christina Caraballo - Audacious Inquiry - Member
TEFCA comes up in the federal activities.

Aaron Miri - The University of Texas at Austin - Co-Chair
Okay.

Christina Caraballo - Audacious Inquiry - Member
I'm trying to map where we are in the slides with the skeleton we put together. This right here, what section is this in the report?

Carolyn Peterson - Individual - Co-Chair
Oh, goodness, let's see.

Christina Caraballo - Audacious Inquiry - Member
Sorry. Page 7.

Carolyn Peterson - Individual - Co-Chair
I looked at it the other day and I have already forgotten the layout.

Christina Caraballo - Audacious Inquiry - Member
Page 7. To Aaron's point, I think we might have bypassed the federal activities and with **[inaudible] [00:07:06]** announced, it might be something we want to add to this discussion.

Carolyn Peterson - Individual - Co-Chair

Yes, I'm good with that.

Christina Caraballo - Audacious Inquiry - Member
In the report, Carolyn, you said we're good with it **[inaudible] [00:07:32]** perfect?

Carolyn Peterson - Individual - Co-Chair
Yes.

Christina Caraballo - Audacious Inquiry - Member
I have it in front of me if you want me to just say what is in there since it is not in the slides.

Carolyn Peterson - Individual - Co-Chair
Sure.

Christina Caraballo - Audacious Inquiry - Member
It's under the landscape analysis. There's a heading with the federal activities and it has sharers with some items under with cures. I think [inaudible] [00:07:58] information blocking, price information, certification enhancements, APIs, and USCDI, and then there is the trusted framework and common agreement with some of the key changes that have been updated. Then we have another heading was CMS' interoperability rule and some other federal activities, but no mention of the **[inaudible] [00:08:27]** in here.

Aaron Miri - The University of Texas at Austin - Co-Chair
I would just say it's worth noting, especially since that's been decided and publicized. It's something for us to think about. I think as the RCE, as they work along the path they have been drawing out per 21st Century Cures and the proposed rule, there will be things they have to work through, interoperability challenges and whatever else, so it may be worth putting on here as something just to track, and as that goes along, we add to that because it will bring up other discussion points, invariably, that we have to work through.

Christina Caraballo - Audacious Inquiry - Member
Yes, I agree, maybe a heading right now as a placeholder considering it was just announced yesterday.

Aaron Miri - The University of Texas at Austin - Co-Chair
That's right.

Christina Caraballo - Audacious Inquiry - Member
In our draft.

Carolyn Peterson - Individual - Co-Chair
We might want to reference it also in the progress update section, as well. I don't think that would be a place to discuss it, particularly, but it's worth noting that the version was updated this year and the award made, and what has happened to date so far by the end of the year if the contract has been signed, or whatever specifically has happened. It should not be hard to just drop that in.

Aaron Miri - The University of Texas at Austin - Co-Chair
I'm good with that. That's great, thank you.

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
This is Michelle. If we go back a slide, we may want to talk through other items that were in that section around the federal activities while we are in this area if anyone wants to bring anything up.

Christina Caraballo - Audacious Inquiry - Member
It is already in there, sorry. That's the area I was reading. Sorry about that.

Aaron Miri - The University of Texas at Austin - Co-Chair
Is there anything in here? Let's see, interoperability rule and trust exchange, I know that we had talked about this, especially the TEFCA and other discussions we had, around third-party API access and appropriate use. I know that came up particularly in the workgroups for TEFCA and for information blocking. Is there anything worth noting on that, because I know a lot of work has gone into USCDI, as well as, again, appropriate access, or is that for later sections, do you think?

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
Yes, I do think those come up later in the patient section, the policy and trust issues around APIs. Just to remind people, the federal activities section is different this year because there was a lot more activity, so we pulled those out and they are much more cross-cutting, so they did not fit squarely. They would be very piecemeal if we tried to adjust it within each party target area. We grouped those together and it's also just not working because we can definitely switch those around again. It's hard to read sequentially through and think you're tackling all the federal activities in one spot and then all the patient access stuff in another spot. It will be sprinkled throughout because it does overlap, but in general, we were trying to pull together some of the federal activities that were key and top of the mind for the industry and tackle those first, those cross-cutting discussion points, and then dig deeper into each target area. The target areas tend to be beyond government work. It does include a lot of industry activity, as well.

Brett Oliver - Baptist Health - Member
This is Brett. I thought it was a great draft. It was really well-written. I would add one thing to the opioid epidemic response in terms of what health IT has done. It has really allowed for clinical decision support in managing opioid use or abuse in patients that you could not have in a paper world. We talked a little bit about querying PDMPs and things like that, and that's part of it, but it's really more encompassing about more complete clinical decision support at the point of care that you could not do without some of the things that have been regulated.

Aaron Miri - The University of Texas at Austin - Co-Chair
Great point Brett. What do we want to add to the opioid component?

Brett Oliver - Baptist Health - Member
It was well-written. I would just add or modify. I'm sorry that I don't have it in front of me. It talked about specific PDMP querying, which is definitely helpful, but what is even more helpful is when you

take that information that is discreet and you provide it to me in something that is actionable, which we are now able to do. Not everywhere, but it's incredibly helpful that it reminds someone, for instance, that if the patient is on a particular morphine equivalent dosage of narcotics and they don't have naloxone, an antidote for accidental or intentional overdose. If that patient does not have that prescribed, would you like to prescribe it? That kind of decision support at the point of care is transforming for patient interaction.

Aaron Miri - The University of Texas at Austin - Co-Chair
I am good with anything there if you guys want to add to that, but to the degree of it on this page of looking at it, Michelle, I can't think of anything else to add to it right now.

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
Yes, I cannot either. I'm sitting here staring at it, but I am not coming up with any other omission or anything else we should put there.

Aaron Miri - The University of Texas at Austin - Co-Chair
Okay, should we move on?

Carolyn Peterson - Individual - Co-Chair
Let's do it.

Aaron Miri - The University of Texas at Austin - Co-Chair
Do you want me to pick this up from here, Carolyn?

Carolyn Peterson - Individual - Co-Chair
Yes, go for it.

Aaron Miri - The University of Texas at Austin - Co-Chair
Sure, no problem. Interoperability here, the current state, we have patient matching verification, a lot of the initiatives with machine learning and referential matching. I can tell you that, in this space, this is still developing. We have tried a number of solutions here at UT and it has been interesting, but it's still difficult without some sort of unique strategy that everybody agrees to. With SDOH, social determinants, we have been adding things in here around that because we realized it could be used to identify patients with specific needs, continue to enhance patient engagement, and share information across healthcare and social service organizations. We talked about this at the last HITAC in person about SDOH and even things about patient-reported outcomes. There is a whole lot in this space that is growing, so from an interoperability perspective, there will be everything from standards around SDOH to what it actually means, and what the definition is at some point. Any comments around this?

Carolyn Peterson - Individual - Co-Chair
I'm trying to think if there is any cross-pollination here with AI and FDA's paper put out for comment back in June about how to regulate AI that learns itself and changes its own algorithm on-the-fly as opposed to the sort where humans work things out and go in and reprogram.

Aaron Miri - The University of Texas at Austin - Co-Chair
That's a great point.

Carolyn Peterson - Individual - Co-Chair
That may have some effect on the SDOH, but I'm not sure that necessarily fits right here.

Aaron Miri - The University of Texas at Austin - Co-Chair
No, but I think those are elements, right? It's almost like appropriateness for SDOH for further algorithm or machine learning, or whatever else, because we are doing a lot with SDOH here in Texas and not all data is equal when you look at SDOH, so what is clinically relevant versus what is not, I doubt Brett wants every bit of information from SDOH, but it may be important to look at it longitudinally when making clinical diagnosis. Is it the right data you need? I don't know. I think there is some element of appropriateness. Just like we were talking about third-party access, what is SDOH usage? Those rule the road, which I have not seen anything hard and fast about.

Carolyn Peterson - Individual - Co-Chair
Yes. That was just June when the FDA was taking comment, so I have not seen any movement forward on that draft as of yet.

Aaron Miri - The University of Texas at Austin - Co-Chair
Okay, that's a good point, though. We should definitely track it. Any other comments on this page?

Christina Caraballo - Audacious Inquiry - Member
Yes. The other thing I was thinking about of areas we could possibly put in here would be something around consent management. I think that it supports a number of these areas when we start looking at sharing patient data across different organizations, and even patient access to information. If you think about it, it touches everything around sensitive data, social determinants of health, patient-generated health data, and behavior health initiative. I think it's an important piece that we might want to give a quick snapshot of where we are in it.

Aaron Miri - The University of Texas at Austin - Co-Chair
That is a great point and let me ask a clarifying question. With consent management, do you also include that to mean the release of information or just consent of use?

Christina Caraballo - Audacious Inquiry - Member
I think it can be both.

Aaron Miri - The University of Texas at Austin - Co-Chair
Right. I know we've been talking about consent management at the HITAC level for a while, but as I dig into it and I start applying what we do here in the real world, there is a clear difference, particularly when you look at the research. Consent is truly consent, but release of information is another dimension, so it may be worthwhile being specific for the purposes of this report.

Christina Caraballo - Audacious Inquiry - Member

I think that's great and I think putting both of them in and highlighting the differences is important.

Aaron Miri - The University of Texas at Austin - Co-Chair
Exactly.

Carolyn Peterson - Individual - Co-Chair
That would add some clarity, too.

Aaron Miri - The University of Texas at Austin - Co-Chair
Yes. It's becoming very murky. It really is, particularly the blending of research and clinical operations, and it is all patient data, right, but as I tell folks all the time, one consent is not one to rule them all. You have to be explicit and deliberate with the patient, and explain what's going on and get their permission because it's their data. To me, it may be worthwhile, us breaking it down and being very crystal-clear with folks with what we mean.

Carolyn Peterson - Individual - Co-Chair
We might even want to also bring up the discussion of terms of use because for apps and other things, very often, the terms of use is functioning as the de facto consent.

Aaron Miri - The University of Texas at Austin - Co-Chair
Yes, you're exactly right. Agreed. Brett, what were you saying?

Brett Oliver - Baptist Health - Member
Along those lines, I wonder if defining what de-identified data means because I think that gets used quite a bit, and I think as we saw in that case in Chicago where you were able to use social media to take the de-identified data and pretty much tell who it was, some of the terms of use, I'm not sure where that falls. We talked about that a little bit before, but it seems like there is a move in the industry to amalgamate data and the promise is always, don't worry about this, Brett Oliver, it's de-identified. What does that mean? If you give me enough data, you might not give me their name, but I can tell you, it's your address and your birthday.

Aaron Miri - The University of Texas at Austin - Co-Chair
I think that's a great point, Brett. Actually, I ask this rhetorical question that perhaps additional guidance is needed to be given by the OCR on what de-identified really means, and not just for the purposes of where I can identify you from a HIPAA component, but what does it really mean, right? When someone is de-identified, the word is, I can't, no matter what I do, reconstruct that this is supposed to be Aaron, but in reality, it is, let's make sure we don't run a fall of HIPAA in that we are doing our due diligence, but that this can't be constituted as a breach if we have an issue. That's my personal thought. There needs to be some additional guidance at some point. What is the fair use of de-identified data? What kind of consent is needed to be used with it? You can't just do whatever you want to with it.

Brett Oliver - Baptist Health - Member

I agree because, again, there is a huge movement. The power behind AI and machine learning is bigger and bigger data sets, and even somebody like Epic, we're an Epic shop and they're developing their cosmos, and it's all about having this huge mass of 250 million patients that are all supposed to be de-identified so you can gather clinical insights from it, which is great, but what do you mean by de-identified? I think I understand with Epic what we're talking about because they have specifically defined some data points that they are going to collect, but I hear that term passed around a lot and I think getting guidance on what that truly means, at least from the government's perspective, would be helpful.

Aaron Miri - The University of Texas at Austin - Co-Chair
I totally agree. The industry is awash in data, but is it right to use? Is it appropriate to use? We keep coming back to that appropriateness, right? I think it's great to have all these highways and everything that is desperately needed, but we definitely need some rules of the road. Otherwise, everyone is going to be driving whatever they want and whatever speed limit down the road. Any other points on this slide or move on to the next slide? All right let's move on. Next slide, please.

Background area here, again, my favorite, privacy and security. Current state, a lot of protections for data outside of the HIPAA framework and 42 CFR Part 2. I keep mentioning FERPA. We've got a lot of considerations there, and also Title 10, I would add to that, as well. Interstate Data Exchange and privacy considerations, the implications of the California Privacy Act of 2018, and then GDPR and Privacy Shield. Any other current state stuff going on that we should call into account right now? I saw a litany of new laws passed at the state level. Even here in Texas, our recent session that just ended, there is a number of privacy laws, but that's on a state-by-state basis but across the country, I have not seen anything official. I don't know if you guys have.

Brett Oliver - Baptist Health - Member
I have not.

Carolyn Peterson - Individual - Co-Chair
It seems to me I saw something out of Washington State. They were trying to do something earlier, but I think it's a bit challenging.

Aaron Miri - The University of Texas at Austin - Co-Chair
Yes. I bet there will be stuff that comes out in the future Congress or whatever, but to the degree of it, I have not seen anything percolating.

Christina Caraballo - Audacious Inquiry - Member
I don't know how realistic this is, but is it possible to do an overview of the states and some of the differences in privacy and security laws or similarities? I think that is a big list. I don't know if we can do it for this, but it's just something to consider, maybe something we want to add. We could do quick research on it, but then maybe something we want to add to our list of future things to work on.

Aaron Miri - The University of Texas at Austin - Co-Chair

Is the goal there to just highlight the disparity between the states that exist or what are you thinking that would help us put in the limelight?

Christina Caraballo - Audacious Inquiry - Member
When I was working with Get Real and consumer [audio cuts out] [00:26:00] data apps, it was, how do you start parsing sensitive data and how do you know different regulations across the different states? That's where I was starting to think, but a resource guide or something to better understand the differences in privacy and security and how data is shared at a very high level could be helpful for us to better understand the barriers that we are going to have for state-to-state data sharing. It's something I started to dabble into looking at a couple years ago and it is a lot of work. As I said, I'm not sure if it's good here, but if we have some high-level things we can start putting in a little bit of information that we can gather and then start to see if it's something that we really do need to look at more, I'm sure it's something the RC will need to look at, and I just think it's going to become more and more important.

Aaron Miri - The University of Texas at Austin - Co-Chair
Yes, Michelle, surely a document has to be floating around somewhere where people have done that correlation, right?

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
Yes, I think we could do a quick scan and see what's out there. It might not be for this workgroup to dig deep and do the analysis, but we can definitely recommend where that's needed and point people in the right direction.

Aaron Miri - The University of Texas at Austin - Co-Chair
Great thought. Let's go on then. Next slide, please. Patient access to information, current state, patient-controlled data collection, access and sharing, policy and trust issues for APIs. Some of the issues I'm dealing with, companies still don't want to use APIs, which is beyond me. Note this has included in the temporary cross-cutting subsection, federal guidance supporting implementation with OCR. Concerns on modernization and use of data collected via APIs for non-treatment purposes goes back to, again, appropriate and fair use, and use and sharing of patient-generated health data, PGHD, which is very interesting if you read the New York Times article on sharing information with a catch. I don't know if you saw that on Sunday, but there is a lot of question marks around PGHD and what it means to share that data. I think, Carolyn, you had a lot of foresight last year putting this on here as we track it. I think the industry is realizing how deep that rabbit hole goes, per se.

Carolyn Peterson - Individual - Co-Chair
Yes, that was a New York Times article. It has gotten a lot of play this week. It's kind of the same thing coming back around again and again.

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
Are you referring to the one that say, when apps get your medical data, your privacy may go with it?

Aaron Miri - The University of Texas at Austin - Co-Chair

Yes, that one.

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
That is funny.

Aaron Miri - The University of Texas at Austin - Co-Chair
It's interesting, very interesting stuff, but it is something that goes back to consent and informed consent, and fair use, the whole nine yards, that whole thing we just spoke about, so it keeps reiterating itself. Did we leave anything off of this with the APIs?

Carolyn Peterson - Individual - Co-Chair
I'm thinking about how genomic data fits in now that testing is getting so much cheaper and it is becoming so much more mainstream. I don't see a good fit in here for it. Obviously, data collection access and sharing matters, but I don't know if we need to call it out differently from any other kind of data.

Aaron Miri - The University of Texas at Austin - Co-Chair
No. I keep saying this in as many forms as I can. These companies like 23andMe are not a covered entity. They don't follow the auspices of HIPAA and I applaud the FDA. They recently issued guidance to tell folks to stop promising cures to every disease because of genomic profiling because it is not going to happen, but there has to be something done about the gray space of companies like genomic companies that are not covered entities. At some point, we have to come to a decision point on these guys.

Carolyn Peterson - Individual - Co-Chair
I agree.

Aaron Miri - The University of Texas at Austin - Co-Chair
All right, next slide. Emerging issues, some of the fun stuff. Internet of things, we talked about this briefly, but the connectivity of various objects including appliances, devices, wearables, and sensors to the internet or other networks, the potential application in healthcare such as remote monitoring, medical device integration, smart pills, and smart facilities. Security risk increases as IoT object become more integrated with the health IT system. I can tell you I had a meeting this morning with a company that is doing this and actually building an all-in-one sensor to hang in a room to look at things like hand-washing dispensing and identification of patients. It's actually amazing, but I think all of these things become definitely in scope to be considered, and it definitely takes a lot of conversations with legal and compliance, so clarity is going to be needed about IoT in health in the very near future.

Digiceuticals, this is the use of digital apps in a formal role of treating a disease. An example of one large PBM has introduced its own digital health formulary that includes a curated set of digital apps for payers and patients, and I think you're seeing everyday news of new apps that are FDA certified that can help cure insomnia or help with pregnancy tracking, or whatever else. Right after that, you will see an article about another similar app that had a help breach or had a data breach that now impacted X-number of patients, or was sending data without permission to Facebook or other places. There is a lot

of gray around digiceuticals, as well. What is the governance function around this? What is the regulation and responsibility of the patients? Any comments or questions on this slide?

Carolyn Peterson - Individual - Co-Chair
I'm feeling like digiceuticals is maybe a broad term that at some point will bear some breaking into different things. There are some that are more for entertainment and the data doesn't go anywhere, and you just play with it, but eventually, there will also be one with a category of types of apps that send data to providers or PBMs, or the pharmacist or something, but I'm not sure how that really fits into this document. Maybe it is something for next year.

Aaron Miri - The University of Texas at Austin - Co-Chair
A category of digiceuticals, different categories? FDA certified or not certified? I don't know how you do that.

Carolyn Peterson - Individual - Co-Chair
To me, the term digiceuticals say anything different than the term app. We are still at the beginning of this and it's not yet on the market. It seems like, digiceuticals, the functionality will rule some things in and some things out. Some of it will just be cool stuff that you find in the App Store that are not really digiceuticals.

Aaron Miri - The University of Texas at Austin - Co-Chair
I see what you're talking about, or something prescribed by Brett for a patient?

Carolyn Peterson - Individual - Co-Chair
Yes. I'm not expressing this well, but I'm feeling a lack of differentiation between digiceuticals and app.

Aaron Miri - The University of Texas at Austin - Co-Chair
When I think digiceuticals, I think of a certified app that has been FDA blessed to help treat insomnia. That's what I just saw recently. I said that's interesting. That could literally be prescribed by health system for patients that have sleep apnea or whatever if they so choose to, or patient could self-prescribe. I guess you could download it from the App Store and pay them money, but there is some level of, has a provider blessed this and has does the FDA blessed this? Those are the only bumpers I'm aware of for apps. Brett, what do you think as a doctor when you say digiceuticals? Does that mean anything to you?

Brett Oliver - Baptist Health - Member
I just think a subset of apps that I'm actually prescribing our directing [audio cuts out] [00:34:53] from a digital footprint for our organization, the ones that we do want to prescribe that have been vetted, whether it is through the FDA or our own vetting process, a place to put those. When Aaron comes to see me, I want to prescribe this app. You get to a certain place and it's already available for you, it's embedded, but I think of it as a subset of an app.

Aaron Miri - The University of Texas at Austin - Co-Chair

Good point. Maybe pointing out this is an emerging landscape. It's already an emerging issue, but there is potential for further refinement on it, just like IoT.

Carolyn Peterson - Individual - Co-Chair
The market is immature. It's got a way to go. Next year, we will have lots more to say about it.

Aaron Miri - The University of Texas at Austin - Co-Chair
I'm sure we will. It will be the next unicorn market or whatever buzzword we hear next. All right, next slide.

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
Before we move on, just for the IoT in case people were wondering, last year we had it in privacy and security last year, but this year, we saw more use and spread of it, and so now interoperability is more of a concern for that topic. That's why it got pulled out and is in the emerging issue section right now, but we could handle it in a different way. I just wanted to point out that change from last year.

Aaron Miri - The University of Texas at Austin - Co-Chair
It makes sense. It makes a lot of sense. Socio-genomics, it's a scientific discipline that attempts to find a genetic basis of social behavior against evolution. Basically, the datasets can now be combined to create new knowledge, which could both offer benefits like predicting disease risk, and cause harm like discrimination. I think this is definitely an emerging issue and it will be interesting to see how this plays out. Again, a lot of these genomic companies fall out of the realm of a lot of things.

Machine learning, the process by which a computer is able to improve its own performance by continuously incorporated new data into existing fiscal models. This could result in insights from data which could assist with the discovery of new drugs, existing drugs, patient matching, diagnoses, and treatment recommendations. However, again, existing biases of the datasets of the system is trained, which could be perpetuated.

The machine learning component I think is really important to highlight. I'm seeing that specifically when it looks at oncology and detection of various cancers, and having to ask the question, where were these data trained, essentially, that created this algorithm to spot a malignant tumor in a breast or wherever it may be. There a lot of biases because you have to look at the population of datasets to say, okay, who were the patients? Was this the appropriate makeup of the population to create the algorithm? There is so much of this out there that I personally appreciate the machine learning being on here. It's very important. What else are we missing on these two bullets?

Carolyn Peterson - Individual - Co-Chair
The whole issue of how we deal with AI that teaches itself and makes its own changes. How do we regulate that and how do we know what it's doing? What is the standard for being able to reverse engineer that do what we have done? Do we want to reverse engineer it? I would think that's a useful ability, but of course I'm not an engineer, so I could be looking for something that's not there.

Aaron Miri - The University of Texas at Austin - Co-Chair

Some of it may be patent protected. If it's patented and protected, what is that give-and-take between doing no harm and enforcing patent protections so you don't have to lift the curtain? I don't know. This goes back to something that Brett has been talking about this for months. He's a doctor. He is going to trust an algorithm to tell him what to do. It's his license. It is his responsibility to make sure the patient is good.

Brett Oliver - Baptist Health - Member
It's just a big paradigm to trust something that is proprietary, maybe not even copyrighted. Just proprietary. That's part of your agreement with this company. How do you handle that when something bad inevitably goes wrong?

Aaron Miri - The University of Texas at Austin - Co-Chair
How can you tell what the culprit was? When you do your root cause analysis on a near-miss, how do you even begin to interpret that when it's in a black box, per se?

Brett Oliver - Baptist Health - Member
How does it get better? If AI is getting better each time, how is it getting better, because the operational decisions that then come from that to make your operations better?

Aaron Miri - The University of Texas at Austin - Co-Chair
What else on this list, anything else?

Christina Caraballo - Audacious Inquiry - Member
I can't think of anything today.

Aaron Miri - The University of Texas at Austin - Co-Chair
I can't, either. I really appreciate this slide and I wish we could put it in bold and asterisk, or whatever, but we have to somehow in healthcare figure out a way to remove biases out of datasets for everything. Whether it is sociogenomics or machine learning, or whatever, we have to be fair and we have to be as universal as possible. I feel like, healthcare, for whatever reason, a lot of these companies are doing great work, but they are just not considering that. They just gobble up all the data they can without thinking about the universality of it, and healthcare is everybody. It's all of us, so I don't know. At some point, that will come to a threshold.

Brett Oliver - Baptist Health - Member
That's a great point. It really is.

Aaron Miri - The University of Texas at Austin - Co-Chair
Next slide. Sharing of large media files, you brought this up, Carolyn, and I totally agree with you. How do we share things like audio and video recordings, or photographs, and often unstructured data? We do not yet have interoperability standards and large media files cannot be shared electronically among providers or accessed by patients. I should say cannot be shared easily. You can share them, but you will probably break every rule in the book if you have to do it. It's very difficult and again, the standards

really don't exist out there for a lot of this stuff. Is there any more we want to add to this or is it pretty self-explanatory?

Carolyn Peterson - Individual - Co-Chair
I think it's pretty self-explanatory.

Aaron Miri - The University of Texas at Austin - Co-Chair
If I hear though words vendor-neutral archive one more time, I'm just going to pull my hair out. That's not the way to solve this problem. There is so much needed to be done from a standards perspective first. Next slide.

The supply for the development of the HITAC report for 2019. Net slide. This fall, we will edit drafts of the landscape analysis section that we just spoke about. The GAAP analysis and recommendations, we will be presenting the overview in the HITAC progress sections and of course a draft report sometime in the November, December timeframe. As you all recall, last year was our first time getting it together. The ONC team was absolutely heroic and did an amazing job of keeping us on the straight and narrow, made sure we kept it to goal. We got it out in time, but this year, we started earlier thank to, again, great work with the team working on that. We do want to try to wrap this up by right after Christmas or the first part of the New Year and going to the next fiscal year. Next slide.

Before we get to the comments section any comments from the team? Regarding timeline, things we spoke about, is anything on your mind?

Carolyn Peterson - Individual - Co-Chair
I think we have really gotten a pretty comprehensive wrap on these topics.

Aaron Miri - The University of Texas at Austin - Co-Chair
I would agree. I think we will learn some things with the rules being finalized and with the exciting work with TEFCA now that we have an RCE to partner with that is a great RCE. I'm excited. I think we will come up with some really good stuff this year. Brett, Christina, what do you guys think?

Brett Oliver - Baptist Health - Member
I am good. I'm impressed with the document.

Aaron Miri - The University of Texas at Austin - Co-Chair
Christina, does this flow better for you? I know last year you were doing a great job of keeping us in check on the flow. Do the sections make sense? Does it add up? Does it logically speak?

Christina Caraballo - Audacious Inquiry - Member
Yes, I think it looks good. I think we figured that out last year and we can move with it this year.

Aaron Miri - The University of Texas at Austin - Co-Chair
Okay, I just wanted to check. If we are all good with that, do we want to go to comments?

Christina Caraballo - Audacious Inquiry - Member
Sounds good.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, can we open the 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 - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, operator. Are there any comments in the queue?

Operator:
Not at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I'll hand it back to Aaron for closing remarks.

Aaron Miri - The University of Texas at Austin - Co-Chair
I'll say something and then I'll pass it over to you, Carolyn. I did want to comment, also, I think at some point. Maybe not this section, but at some point in the report, and I think, Brett, you were highlighting this around the opioid item. The University of Texas is working with the State of Texas HHS on the opioid epidemic and a number of initiatives that I personally signed on to because I think they are really important.

As I learned about the landscape of what's happening with the opioid crisis, there is a lot there, a lot there that technology can help, and a lot there that all of us as technologists and healthcare providers can help, and I think we would do it right by thinking about how we suss out some of those items, like the case in point that a lot of the EMS folks have electronic medical records that did not fall into standards that the provider organizations had to do, so therefore, they are doing a lot of manual documentation or literally writing on the back of their glove notes about the patient that they then type in later on.

I think there are so many areas that are ripe for opportunity that could help advance things like how we deal with the opioid crisis. If it's in this report, if it is in a subsection, if it is something for a later workgroup, the more I learn about it, the more I think we have to help fix this. There has to be an area here where HITAC can help give recommendations to get in front of some of this stuff. That's my two cents.

Carolyn Peterson - Individual - Co-Chair
I will follow on with that. I am starting to see immediate discussion of other types of prescription drug reviews, and the meth crisis for example, specifically some information about how that has fallen off the radar as people look at prescription opioids, and this diversion around all of that, but there are other substances that are leaving their mark in communities. I'm thinking about the technology, how the adaptations might be made, and starting to look at those things when we resolve some of the issues around the opioid crisis.

Aaron Miri - The University of Texas at Austin - Co-Chair
That's right. I think technology can help alleviate the stigma around some of this and make it an even playing ground to take care of everybody.

Carolyn Peterson - Individual - Co-Chair
I think that is a wrap. It was great to have this conversation today and I'm looking forward to the next parts of the report and our work next month.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay, great. Thanks everyone.

Aaron Miri - The University of Texas at Austin - Co-Chair
Thank you, everybody.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Are there any other comments that came in?

Operator:
No comments at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All right, we will adjourn.

Christina Caraballo - Audacious Inquiry - Member
Can I ask one more question quickly? I completely forgot. On our calendar for after the HITAC meeting to meet, are we still doing that?

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
This is Michelle. We are in progress of correcting the invitation. I think we are getting together over lunch instead.

Christina Caraballo - Audacious Inquiry - Member

That's what I thought. I just wanted to confirm.

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
It's a reasonable question. We are still working on clearing that up, but we are planning a lunch get-together. Rather than a formal meeting, it is a get-together.

Christina Caraballo - Audacious Inquiry - Member
Great, thanks.

Aaron Miri - The University of Texas at Austin - Co-Chair
Thank you, everybody.

Carolyn Peterson - Individual - Co-Chair
Thank you.

Brett Oliver - Baptist Health - Member
Thanks. Bye

Michelle Murray - Office of the National Coordinator for Health Information Technology - Staff Lead
Bye.