

# Transcript

# HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE MEETING

March 25, 2021, 2:00 p.m. - 3:30 p.m. ET

VIRTUAL

# Speakers

Name	Organization	Role
Arien Malec	Change Healthcare	Co-Chair
David McCallie	Individual	Co-Chair
Ricky Bloomfield	Apple	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Jim Jirjis	HCA Healthcare	Member
Edward Juhn	Blue Shield of California	Member
Ken Kawamoto	University of Utah Health	Member
Victor Lee	Clinical Architecture	Member
Leslie Lenert	Medical University of South Carolina	Member
Clement McDonald	National Library of Medicine	Member
Ming Jack Po	Ansible Health	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Scott Weingarten	Cedars-Sinai Health System	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Wanda Govan-Jenkins	Office of the National Coordinator for Health Information Technology	Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	Staff Lead





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

# **Operator**

All lines are now bridged.

# Michael Berry

Great, thank you. Hello, everyone. Welcome, and thank you for joining the Interoperability Standards Priorities task force. My name is Mike Berry, I am with ONC, and we really appreciate your time, participation, and input today. Let's get started with our meeting. I am going to start with roll call, so when I call your name, please indicate your presence. I will start with our co-chairs. Arien Malec?

# Arien Malec

Howdy.

Michael Berry David McCallie?

David McCallie Present.

Michael Berry Ricky Bloomfield?

# **Ricky Bloomfield**

I am here.

# Michael Berry

Cynthia Fisher? Valerie Grey?

# Valerie Grey

Present.

#### Michael Berry Jim Jirjis? Edward Juhn?

# Edward Juhn

I am here.

# <u>Michael Berry</u> Ken Kawamoto? Victor Lee?

Victor Lee Present.

# <u>Michael Berry</u> Great. Les Lenert? Clem McDonald? Jack Po? Raj Ratwani? Ram Sriram?





# Ram Sriram

Present.

# Michael Berry

Great. Sasha TerMaat? Andy Truscott?

#### Andrew Truscott

Present.

#### Michael Berry

And, Scott Weingarten? Okay. Thank you, everybody. If I missed your name, I will keep watch of the incoming sign-ins and I will take note for our roster. I would like to thank all of you, and I will turn it over to Arien and David.

# Introductions (00:01:28)

#### Arien Malec

Good morning and/or afternoon, depending on the time zone that you are occupying at this moment. First of all, I just want to thank David. I have had a week where I have not been feeling especially well, and David took the heavy lifting for this week, so if we show off as ill-prepared, it is on me, and if we show off as wellprepared, it is on David. But, I think we are going to walk through, again, a re-review of the concepts we have been talking about. We have put together a lightweight prioritization framework, we will have a discussion on some of the attributes of that prioritization, and then that should lead into viewing the projects in something approximating priority.

As anybody who has been through prioritization through purely objective metrics such as Delphi-submitted metrics knows, the real art is how you weight the outputs to get the outcome that you are looking for, but we will mostly look at the sorting to see whether there is a violent disagreement about the sorting or whether there are some things that are surprisingly low-rated or surprisingly high-rated to see whether our prioritization tuning is appropriate. And then, we are going to assign some homework at the end as soon as we figure out what that homework actually is, and I think that will provide a pretty good agenda for the meeting. David, is there anything you want to tack on?

#### **David McCallie**

No, I think that covers it. I hope the process of capturing the workgroup members' notions about what is a priority for them will help us come to some consensus as a group on how we should prioritize our time and expert testimony that we will solicit to help us go deeper in some of those priority items, but I think it should be seen as fluid, as Arien put it, and if we get into something and discover that we should be driving in a different direction, as long as we have time to do it, we should feel free to do so. We are not under a rigid requirement to produce X number of items, and things that we do not go into in depth do not have to be left off our list of recommendations, so let's try to learn from what each of us is interested in and feels strongly about and come up with a way to prioritize our energy and our limited time.

#### Arien Malec

Yup.



# **Review of Ideas from March 11 Meeting (00:04:13)**

#### **David McCallie**

Next slide. I think everybody knows who everybody is. I think we have a couple of people on the call this week that were not on the call last week, so if you are confused by a term we are throwing around or one of the categories and you just do not know what the heck we are talking about, feel free to speak up on that. I will do a quick review of them here in a second. Next slide. We will not review our mandate. I think we all understand what ONC expects of us, at least broadly. Next slide.

So, here is the current list of the high-level items. We have conveniently resorted them from the last time you saw those through some sorting mechanism that I do not know what it was, so let's just call it a random resort to make sure we do not get seduced into thinking that everything at the bottom is unimportant and everything at the top is important.

So, a brief one or two sentences on each of these just to catch you back up: No. 1 on our list here in row order, not rank, is clinical and administrative data standards harmonization and burden reduction. The thought there is if we can address, speed up, or put some pressure behind some of the reconciliation between clinical systems and administrative systems, such as claims processing. Next on our list is data sharing between federal and commercial healthcare entities. This has been in our discussion so far mostly as a security issue regarding mismatch between security policies on either side of the federal firewalls. This item came to us from a well-placed, important source, and so, at least some people outside of our committee also think it is an important issue to be addressed.

The next one on the list is vaccination and immunization registry reporting and, maybe broadly speaking, the data flows around maintenance and access to vaccine immunization registries. Next is heath equity standards: Social determinants of health, ethnicity, race, gender, and related issues, including access to healthcare systems and health information systems. Next on the list is real-world evidence, comparative effectiveness, recovery type, and data use, which I generalize broadly into taking better leverage of data that is in EHRs, particularly to the degree that that might leverage some of the new data-blocking APIs, like bulk FHIR access.

Next is one of several public-health-related priorities. This one is on situational awareness, which involves the required reporting of healthcare facilities to their state and to the national public health networks regarding their status to deal with something like an epidemic or pandemic, including things like bed availability, ventilator status, et cetera. Next is another public-health-related item on syndromic surveillance. There is a certain amount of syndromic surveillance that works today, but it has been suggested that perhaps we can do better. That is basically trying to detect the emergence of a public health issue or public health emergency.

Next on the list is a carryover from 2019 instantiation of our group, called care plans and the burden of chronic disease management. Next is adverse event reporting. It could be mostly around adverse drug event reporting, but not necessarily limited to drug adverse events. Next on the list is easier and more robust coupling between patients and devices associated with the patient. I think there is possible relevance in that one to things like virtual clinical trials, where a device is being used to monitor a patient's progress outside of a formal trial setting.

Next is another public-health-related issue, which we have summarized as "contact and exposure notification." That should probably be "contact tracing and exposure notification." The idea here is what value we should place and prioritize on things like devices that can detect when you have been in proximity to someone who has a positive test and if that is something useful to put our standards priority ointment on. And, the last is one we carried forward even though we do not intend to address it any further, which is the so-called vaccine passport or vaccine credential proofing, and the reason that we have been asked not to put any more of our time into it is that ONC has already prioritized this and has active work under way that they felt our input would be redundant. So, you will see that on this list, but I think it will disappear from our lists subsequent to this one. Arien, did I leave anything out or misrepresent anything of those from your point of view? Then, we will ask the group if they have any broad comments.

# Framework and Prioritization Discussion (00:09:51)

# Arien Malec

I think we are good. Was anybody surprised by this list or by what is not on this list? Seeing no hands up, why don't we go on to the prioritization section? So, we put together a prioritization framework. Let's go to the next slide. Generally, we are looking to see that we are doing prioritization because I think we are more than happy to pass on recommendations for a bunch of areas. We know that we can go more deeply into fewer areas, particularly given the time that we have allotted to us. And, our general prioritization framework was prioritizing areas that align with ONC-declared or national priority areas, particularly related to COVID-19 and future pandemic preparedness, health equity, 21<sup>st</sup> Century CURES enablement, and unmet needs on the existing ONC roadmap.

We want to avoid areas being covered through the existing ONC initiatives as far as we know. Vaccine credentials is the only item that we are striking off the list of that criteria. And then, a set of criteria related to the generality versus specificity of solutions and general criteria related to the salience of policy levers and criteria related to the express need in the market with a preference for jobs that are being done inefficiently currently over jobs that just currently are not getting done, and again, there is a tradeoff there. Sometimes the job is not getting done because we do not have the standard that enables the job to get done efficiently, so we need to balance that criteria.

With that as our framework, we are going to pause and see if there is any feedback on the framework. I am not hearing any. We have a set of slides where we took the incredibly complex spreadsheet that I put together in the middle of feeling very odd that David actually took a look at and immediately improved by simplifying, so if we go on to the next slide, we have recommendation frameworks. We are going to end up using the previous spreadsheet that we created for orders and results and for some of the other items that we did in the ISP task force because it was a really well-organized spreadsheet to help us frame up recommendations. We are going to go on to the prioritization section right now, so let's go on to the next slide.

So, we are going to do four levers and score each one as high, medium, or low. Again, the simplicity of this is all thanks to David. No. 1 is priority area, high, medium, or low. No. 2 is what the potential impact is, foundational, general, or specific. The difference between "foundational" and "general" is that a foundational standard unlocks a lot of other data uses or interoperability uses. As an example, if you figure out identity and security for data exchange, it is pretty foundational because you can do a whole lot with it, whereas

there are just a whole lot of things you cannot do if you do not have identity and access management figured out. "General" is where you have a solution that you can plug into a whole bunch of different use cases, and then, "specific" is how we solve a particular problem by addressing this. Again, we can trade that off against priorities.

With "applicable policy levers," do we have well-defined policy levers, do we have policy levers but the policies are unclear, or do we need new policies, new regulations, new legislations, or new state action in order to get the policy across the door? And then, with "current burden," "high" would be that there are jobs that are already getting done, but getting done incredibly inefficiently and are driving clinical or clinician burden, administrative burden, and high U.S. healthcare costs, and "low" is either the job is not getting done or it is getting done by hook or by crook, but not in ways that drive significant burden for patients, providers, and other actors.

I will pause there. By the way, we have adopted an order-of-magnitude prioritization so that we overweight "high" relative to "medium" relative to "low," so it is just a useful way of generating separation when we think about the priority scoring areas. Our first tack would be not to equally weight each of these columns. If we see surprises and a magic weighting makes things less surprising, I think we are more than happy to put in some weightings that we can defend, but as I noted, when you do these exercises, the simpler they are, the better, and you can do a lot of damage and harm by getting super sophisticated with weighting. I will pause there to see if the prioritization framework **[inaudible] [00:15:48]**, and again, super thanks to David for taking order-of-magnitude simplicity on the original framework that I put together. Jack has his hand up, and then, Clem, I think I heard you wanted to get in as well.

# Ming Jack Po

Arien, this might be tangential to some of the things you have mentioned, but I wanted to at least bring it up. It's like a meta-priority thing. I'm curious if there is a way to build a website that lists these standards as well as some sample ways of using them. Of course, Change Healthcare does that with their APIs, as do Microsoft and Google Cloud. Everybody typically does it. The reason why I mentioned that is one of the things I find very educational about **[inaudible] [00:16:39]** I did not even know about, and I cannot imagine most people would know if even I have not heard of some of them, some way to even just list "For these types of areas, these types of APIs currently exist, these types of standards currently exist." It is a very meta thing, but I am curious.

# Arien Malec

That is a great point. So, David, let me repeat what I heard Jack say, which is that it would be useful for each of these areas to do a survey of what is available, both from a standards from a perspective and also from an existing API perspective, to see how the ecosystem needs are currently getting met.

#### Ming Jack Po

And actually, just if the ONC is flat-out willing to maintain a site like that because frankly, most people are googling if there is a standard, and I tried it just now. Typically, the first page is full of random startup vendors who have their own sites. It does not occur to you that there would be standards on these sites.

#### Arien Malec

I want to do a plug for the ONC internet...Dave, remind me.



#### David McCallie

The ISP.

#### Arien Malec

It is the same name as our task force, which is what was throwing me. So, there is a standards list that ONC maintains that is really well done. It is organized by area, it lists all of the standards, and then, Mike or Wanda, I do not know if this still exists, but there was the OPP, and I forget what that means because I only have this particular tweet that Steve Posnack did once on it, but there used to be a list of people who implemented those standards. We will put a link in the notes to the existing ONC standards listing, which I think was really well done. Jack, great point, and we will do a survey, and we will make sure **[inaudible – crosstalk] [00:19:03]**.

#### **Clement McDonald**

**[Inaudible]** under the first bullet, you have "high," "medium," and "low" as a priority area, and then you have four other choices. I do not understand how they interact.

#### Arien Malec

Clem, even though I am normally a lumper, this is part of the David-lumper versus Arien-splitter framework. We went down a path where I could independently prioritize COVID-19 health equity, 21<sup>st</sup> Century CURES, and ONC roadmap as high, medium, and low, and then you have the question of what the overall rating is, so we decided to collapse it all and give it an overall rating. We may need to get a little more finely grained, but the thought is we would test it against if it addresses COVID-19 health equity, 21<sup>st</sup> Century CURES, and other health items on the ONC roadmap, and based on that assessment, we would declare it high, medium, or low from a priority perspective. So, it would jump over prioritizing individual columns and then figuring out how to lump them together and then just get to an overall priority level. Does that make sense?

#### **Clement McDonald**

I do not know what the "it" is in that first question. Is it one of those four, or all of them?

#### Arien Malec

So, you would typically rate something highly if it was really, really important for one of these priority areas or it was important for multiple priority areas, but again, we are going to leave it to the task force to figure out what "high," "medium," and "low" mean relative to this. As I said, the alternative is to get really detailed in each of the columns, and then you have the same problem of how to combine them all.

#### **Clement McDonald**

Okay, cool. Thank you.

#### David McCallie

Clem, we thought about just having everybody log into a web page and vote for what their favorite topics were, but that does not give us any insight into who cares about what and why they care about it, so I hope this process will illuminate why each thing is important to you when you speak up about it and argue for a particular prioritization. We still might end up voting if we do not feel like we identified a clear set of leaders, but at least we will know who is behind it and why.



#### **Clement McDonald**

Yeah, I did not have any confusion about the last three. The first one seemed like... I am still not crystal clear what "it" is, but I think I will figure it out as we go along.

#### **David McCallie**

That was probably poorly worded on our part. Sorry. Also, Jack, to your question, I put a link in the chat to the ISA web page, which is ONC's current attempt at defining what standards are out there and categorizing them in half a dozen different ways based on whether they have widespread use or whether or not they are free. That list has links to the standards themselves, so if there is something that strikes your curiosity or strikes your interest, you can follow through to the standard itself. I think that if you browse that website and find it wanting or missing something, ONC would be happy to hear us weigh in on that as well because some of us were on the committee that helped design that website a while ago, maybe 10 years. Clem, you were on it. So, I am sure that process is still open for improvement.

#### Arien Malec

I have to say it has gotten so much better, though. It was good work when it started, but we have made a lot of recommendations, and it has gotten really useful. To Jack's point, what it does not do is list all the APIs or alternative ways of getting the job done, other than standards-based ways of getting the job done, so you can at least survey what is out there, but it is a really useful survey for looking at vocabulary standards, vocabulary subsets, transport standards, content standards, structural standards, et cetera. Let's go into the exercise, and then we will either decide halfway through the exercise that we have to change course and do it a slightly different way because everyone is confused or we will figure out what we mean by going through the exercise. Next slide.

So, we will start with clinical admin data and standards relative to priorities. David has already helpfully filled in that health equity is high with respect to health equity. Boy, I do not know how we are going to get through everybody. I wonder if we could just do a Delphi rating approach here and ask people for a discussion. I can propose out some thought processes or framings that people can agree or disagree with, and then we will do a Delphi rating where we have people vote in the chat as to high, medium, or low. I wonder if that works for people if they can access the chat.

#### **Clement McDonald**

I do not remember what "21CC" is.

#### Arien Malec

That is 21<sup>st</sup> Century CURES enablement.

#### David McCallie

This page is less about opinions and more about...I will not call them facts, but it seems pretty clear, for example, that working on situational awareness is relevant to the COVID-19 pandemic crisis. Maybe we should have filled this in for discussion and that would have made it a little faster, but we just wanted to ask if, of the 11-ish topics we have, are there some that are clearly aligned with ONC's priority items? If so, maybe that would buoy us upward.



That is right. So, for example, if we look at the first item, "clinical and administrative data and standards," you would have a hard time making a case for COVID-19, a hard time making a case for health equity, which is, again, at the margin. 21<sup>st</sup> Century CURES is part of the burden reduction, and the ONC roadmap is a continuation of the work that ONC was engaged in under Don Rucker, so you would probably highlight both those columns in terms of clinical and administrative data and standards.

#### **David McCallie**

I am wondering if we can get editing access to this. Is that possible? It would be nice to take notes as we go through it. I do not know if that is possible. Maybe someone from the ONC team could put a mark in the section here.

#### Arien Malec

I think it is going to be logistically difficult given that I think it is Excel doing the data screen sharing. David, I wonder if what we could do instead is have you or somebody from the ONC team maintain notes, and then we swap out a different version of the slide once we have completed the exercise.

#### **David McCallie**

Yeah, we could do that. I have a copy of the slide that I can live edit, but you will not be able to see it until we swap it out.

#### Arien Malec

Right, so we will just do discussion.

#### **David McCallie**

So, on Row 1, then, just to make sure I captured it, I am not going to fill in the non-applicables. For "clinical and administrative data 21<sup>st</sup> Century CURES," are you giving that an M?

# Arien Malec

An M for 21<sup>st</sup> Century CURES and an H for ONC roadmap.

#### **David McCallie**

H for roadmap, okay. Go on. I will take notes.

#### Arien Malec

We will pause at the end, but if people violently disagree, please chime in and raise your hand. We will get you into the discussion. I want to drive this efficiently, but not in an authoritarian way. I recognize that I am doing this for the sake of putting something on the board, not for the sake of putting bias on the outcomes. Again, for federal and commercial data sharing, I think you would say COVID-19, eh, health equity, eh, 21<sup>st</sup> Century CURES, yes, relative to TEFCA and the national strategy for data sharing, and yes relative to ONC roadmap. Whether "yes" translates to medium or high… I guess I put "high" for 21<sup>st</sup> Century CURES and "medium" for ONC roadmap, or the reverse, or "high" for both.

#### **Clement McDonald**

Could you just clarify what the data-sharing is? Is this clinical data or health data? What is the output?



Clem, for background, the particular challenge here is that federal partners, particularly IHS, VHA, and DOD, DOJ, prison services, et cetera, are all beholden to FISMA, the NIST framework, and to FedRAMP, so the federal actors have a set of federal data-sharing requirements that they are obligated to engage in as federal providers, and almost 100% of the time, when you are talking about data sharing between a federal actor and a non-federal actor, you have the problem of whether you adopt a commercial standard or the federal standard.

When federal actors separately negotiate agreements with a commercial provider, they can often get that addressed through contractual requirements, but when we are talking about a data-sharing framework, we have not solved what the security boundary is for federal actors relative to the commercial boundary. So, as an example, do you require that any care quality implementer must have a FedRAMP ATO in order for VA and DOD to engage in data sharing via national networks? That would be one extreme that would basically hold everybody to federal standards. The other way you could cut it is to say, "Hey, federal government, your boundary extends up to the point where you are exchanging data with commercial parties," and that point, we go to a HIPPA and commercial standard relative to information security and other controls. Does that make sense?

#### **Clement McDonald**

In general, federals are tougher and really are going to be severely limiting, right?

#### Arien Malec

Correct. Some of us have been there and done that and have all the scars. All right, let's go to vaccination data flows. In particular, this would be the ability to get vaccination lot information. This is not vaccine logistical tracking, this is vaccination data flows, particularly the set of standards that are associated with IISes, but in general, the flows by which vaccinations flow to either the state or CDC, including lot information, other clinical information, and the flows that allow for actors to query the current immunization status of a patient, and I think as Les was saying before, potentially **[inaudible] [00:31:36]** location so that you could line up who you actually need to do outreach for. Pretty clearly, that would be high for COVID-19 and maybe medium for health equity in the sense that...

#### David McCallie

There are a lot of health equity issues with vaccines.

#### Arien Malec

Yeah, that is why I said medium for health equity, low for 21<sup>st</sup> Century CURES, and low for ONC roadmap, which existed prior to COVID-19. Again, health equity is high relative to health equity, it is probably medium with respect to COVID-19 given that health equity issues are significant relative to COVID-19, and then, again, this is a separate column relative to ONC priority for health equity, so we can talk about 21<sup>st</sup> Century CURES or ONC roadmap, but it gets a "high" at the health equity/health equity level.

EHR data issues would be flat FHIR, bulk FHIR, real-world evidence, or the U.K. recovery-type trials in the U.S. Clearly, they are medium or high relative to COVID-19, medium with respect to health equity in the sense that at least part of the things you can do when you have population data sets is look at health





disparity and outcome disparity. It was already an item for 21<sup>st</sup> Century CURES and the ONC roadmap, so it is at least medium or high across the board. I see Andy and Ed have their hands raised. Andy go ahead. Andy, that is the mute button. All right, we will go to Ed, and then back to Andy when he figures out his mute situation.

# Edward Juhn

Thanks so much, Arien. I just have a quick question of clarity. When you are looking at the ONC priority area for the column, are we talking about social determinants of health when we think about the health equity in the first column, or are we thinking about it distinctly from the social determinants of health datasets that are available?

# Arien Malec

Thank you for that. When we put the slide up that had all the details in the last round, I think we intended both to look at the coverage area, for example, with the Da Vinci Gravity Project, which is around social determinants of health in particular, but also the data flows by which data and analytics could be used to look for disparities outcomes, for example, routine collection of appropriate demographic information on race and ethnicity to look for disproportionate impacts relative to, for example, COVID-19 or vaccination rates.

# Edward Juhn

Okay, great. So, it would include race, ethnicity, and language in the way that you are defining that.

# Arien Malec

Exactly.

# Edward Juhn

I just wanted to clarify that. Thank you.

# Arien Malec

Thank you. Okay. Public situational health awareness? Oh, sorry. Is Andy back on?

# David McCallie

It looks like his hand went down. Oh, he is still trying to log in.

# Arien Malec

Andy, when you get back in, we will figure it out. Just pipe up. Okay, public health situational awareness. This is a proxy for the SANER Project, which is, in many ways, the ability to do summary metrics that are calculated at a setting of care, and then aggregate those summary metrics out, so the original use case for SANER was looking at bed fill rates, ventilator fill rates or availability rates, and the variety of metrics that hospitals were required to report out to the federal government relative to COVID readiness tracking. I think you'd say it is high relative to COVID, low relative to health equity rather than N/A in the sense that you could then sub-segment relative to healthy population areas or other disproportionate share metrics, and then, probably low or N/A for 21st Century CURES or ONC roadmap.





Syndromic surveillance: Again, this is outbound data feeds related to ADT for ED, related to lab **[inaudible] [00:36:37]** for reportable labs, reportable condition feeds, and then, things like...ECR. Sorry, the acronym took a little while to come to me. So, ECR is a CDC standard for pulling case report information electronically on a trigger basis out of EHRs, and there is a FHIR Decision Support Hooks flavor called ECR Now. Some of these things are actually in meaningful use...

# Andrew Truscott

...or the ONC task force call.

<u>Arien Malec</u> Sorry, Andy. Go ahead.

<u>Andrew Truscott</u> Oh, you can hear me now?

Arien Malec We got you now.

# Andrew Truscott

I was listening to the hold music and saying something completely different. Carry on, please.

# Arien Malec

Okay. We will come back to you, Andy, because you had your hand up, and we will get to your comment. So, syndromic surveillance would be the existing things that already have standards and certification criteria, but also, some of the areas that CDC was promoting, for example, ADT, feeds in EDs, and ECR Now, which do not have standard certification requirements in them. Again, I think you would say it is high for COVID-19, low for health equity, and maybe N/A for the other two categories. Andy, back to you.

# Andrew Truscott

A minor point. I just wanted to check on the vaccination data flows. You do mean from providers and administrators of vaccines to IISes as well as from IISes to state and/or CDC?

# Arien Malec

Correct, and from IISes or equivalent back to providers or points of vaccination.

# Andrew Truscott

Okay, cool. I think we need to be holistic.

# Arien Malec

Right, but the big thing this would exclude is drug supply chain tracking.

# Andrew Truscott

Yes, I agree. I think you said this was previously not on the ONC roadmap.

# Arien Malec

It was. It has been a low-lying ONC/CDC set of activities, so maybe it is a low relative to ONC roadmap in the sense that ONC and CDC have been working on areas or standards, but as we know, most of the art here is not actually in the standards work, it is in the IIS arena and the provider arena.

# Andrew Truscott

I agree, and there is a renewed sense of urgency.

# Arien Malec

Yes, I agree. Care plans and chronic disease management: So, again, here, this is the ability to share a plan of care, prioritize that plan of care, engage in a plan of care with a multidisciplinary set of actors, the care team, and the individual patient. This has been a long-running activity, and was one of the items that was the fourth priority out of the ISP task force previously and punted back or picked up here in this group. It is low relative to COVID-19. You can imagine that care planning for COVID-19 is pretty high up in Maslow's hierarchy of needs relative to where we have been at with COVID-19. It is medium for health equity, and probably low on the ONC roadmap.

#### David McCallie

Arien, what was your score on the COVID-19 intersection with care plans?

#### Arien Malec

I would say N/A in the sense that it is general, but it is not particularly specific and relevant for COVID-19. It would not change the trajectory for the pandemic if we had a national care plan standard.

# David McCallie

I agree.

# **Clement McDonald**

The other thing I worry about with care plans is the extra work burden to put it in a structured form.

#### Arien Malec

Right, and Clem, I think we are going to pick that up when we look at the burden. It is going to be hard to make a burden reduction case for care planning. You could, but it is going to be harder to make a burden reduction argument there. As you say, it is likely to be an increased burden to capture it in a structured way.

#### **David McCallie**

It probably depends on whose burden you are talking about.

#### Arien Malec

Right, exactly. Did we **[inaudible – crosstalk] [00:40:58]** for the patient in the U.S. healthcare system? That would be silly. Adverse events: So, again, this would be the ability to use clinical terminology as opposed to FDA clinical trials terminology to capture and report adverse events into the post-market surveillance system that FDA manages, so there is some relevance for COVID-19, maybe medium or high relative to vaccine AE tracking. Again, maybe high because it has been a relatively hot topic, for example, with clotting disorders or anaphylaxis related to vaccination. It is probably N/A relative to health equity and



21st Century CURES, and again, this has been one of those items that has been kicking around as an ONC/FDA collaboration item for years. It is probably low there. Clem?

# **Clement McDonald**

It is the same thing. This is a funny space. Firstly, the ability to translate is not important for the recording because they need to come down this main list, so I want to keep it separate whether we have a common approach or we just want to capture, but it could be a real burden, and some adverse events are so... They know that already because they are just so common. It is not a discovery process. So, some sorting down or characterization is what they need to hear from because they are going to be asking physicians to do this during the practice plan, which might be easier than it is now and more likely to be done, but I still think we need to dissect the need and the when. The when is important. If someone tells me for the 1,900<sup>th</sup> time that aspirin irritates their stomach, that is not very useful.

#### Arien Malec

Right, and this may actually fall more naturally into the real-world evidence piece of this, so there is an online MedWatch form, or whatever FDA calls it these days, that I can go and fill out if I really want to report an SAE. I think FDA would tell us that SAEs are underreported relative to their frequency because there is a significant burden for reporting SAEs. And then, maybe a way of framing the question is would it be better to have a single-click button to report an SAE, which would go into a single detection system at FDA, and they would filter out the opioid-caused constipation adverse events, but could do signal detection, or to put this in the "real-world evidence" category and build mechanisms to do signal detection out of drug exposure and problem lists that we get out of EHRs?

#### **Clement McDonald**

I would like that better to put extra effort on.

Arien Malec

Thanks, Clem.

# **David McCallie**

I think you need to deal with causality at some point.

#### Arien Malec

Yeah, that is where signal detection gets into this. Is there a signal? When there is, you need to do additional work to see if there is... Sorry, this is an area I used to be in with the clinical trials world, and I did pharmacovigilance technology systems for a while.

# David McCallie

That is one level of it. The other side is when you report an adverse event, you do need to distinguish between a pharmacological effect which causes an adverse event versus an unanticipated adverse event. Since we almost never do re-challenge, the causality analysis for the symptom and the drug is usually uncertain, and we need to represent that.

#### Arien Malec



That is exactly right, and we typically default in the clinical trial setting to report everything, and then do some work with the DSMBs to disambiguate whether we believe it is a linked adverse event or not. But, signal detection setting is useful sometimes to see if there is a signal here, and then you have to do the work to establish causality or not. All right. Patient device linking: So, we talked about this both in terms of using mobile devices as proxies for patient identity and also for better linking implanted or wearable medical devices to the patient, and then, this also encompasses things like UDI, which has been a standard forever, but is almost entirely unused. Again, I do not know if we completed an AE row...

# David McCallie

It is probably high for COVID.

# Arien Malec

Probably high for COVID, right, low for ONC roadmap, and N/A for the rest. Patient device linking has been on the ONC roadmap. The standards committee made recommendations relative to UDI back in the day. It is probably not that relevant for COVID-19 or for health equity. I do not think it is a 21st Century CURES item, so maybe it would be a low or medium on the ONC roadmap.

# David McCallie

Arien, my memory of CURES is fading, but was there not a device implant/real-world evidence tracking item in CURES? Maybe I am misremembering that.

# Arien Malec

Wanda or Mike, maybe you can help us with that one.

# David McCallie

I will put it as a question, and we can look into it.

# Arien Malec

Contact exposure tracking: So, the major smartphone systems vendors put in place a contact tracing API that they embedded into the OS for their devices. They have been enabled for a number of regions in conjunction with public health departments. I have zero data in the U.S. as to whether any of that has been at all useful or impactful, and I think there is evidence in other regions that more comprehensive device-based electronic contact tracing has been useful, and if you really wanted to do this, you would need to be able to interoperate reportable labs, reportable conditions, and hospitalization with the device so that you could actually generate the triggers for exposure. Any comments here, particularly Ricky or Jack? Maybe you have comments to add.

# David McCallie

Arien, would you rate it as a medium or a high for COVID?

# Arien Malec

I would rate it as a medium at best.

# Leslie Lenert

Really? Why would you say that? It was invented for COVID.



So, if we are talking about true contact tracing, we should put it as a high. If we are talking about devicebased contact tracing... This may just be my personal bias, and I will shut up.

#### Leslie Lenert

Having built these, I would say there is a need for standards, particularly for the data integration with COVID testing results, as you said, and with issuing the keys to allow people to release that.

#### Arien Malec

Sure. Let's put a high for COVID-19. I will withdraw any of my grumpiness. Certainly, contact tracing is a high for COVID-19. It is hard to make a health equity case, a 21st Century CURES case, or an ONC roadmap case.

#### Leslie Lenert

Yeah, I do not think they were applicable to any of those.

#### **Ricky Bloomfield**

And, just one nuance there. One of the reasons this was called "exposure notification" was because it is not actually doing contact tracing, which is a very different public health function, so I do not know if we want to update the language here to reflect that it is not actually contact tracing.

#### Arien Malec

That is right. We have to go back to the slide because I think in this slide, we contemplated both digital exposure notification and data standards for contact tracing, most of which have to do with **[inaudible – crosstalk] [00:49:52]**.

# **Ricky Bloomfield**

There could certainly be separate efforts there, for sure.

#### Leslie Lenert

There are quite a variety of software platforms for contact tracing, and there is almost no standardization across them.

#### Arien Malec

Right, and when we were doing work at the Duke Margolis Center, the big issue that we noted and that Sasha TerMaat noted with respect to EHR data flows was that even when demographic and contact information were captured in EHRs, they were not flowing upstream to commercial labs and then flowing into public health, so at least there is a data standards area there in terms of how that data flows. It might overlap, for example, with some of the health equity data sharing items like, again, significant SDOH linkages on race or ethnicity, principal language, location, et cetera. All right. Dave, we got through the rapid run. Are you in a position where we can talk about the composite score?

#### David McCallie

We could, but I think it would be better to go and put our time into the next slide, which is probably more useful to us, and I have some question marks that we are going to have to trace down, and it will probably change the composites, so I would say we should do that as an offline distribution of what it looks like after we have chased down the question marks.

# Arien Malec

Sounds good. The Delphi rating can be our homework.

# David McCallie

Yeah. I want to make sure we do not run out of time on the next slide, which I think is probably going to be more impactful for opinions about what people think we should pursue.

# Arien Malec

Cool. All right, let's go. So, here, we are looking at impact, applicable policy levers, and current burden. Ignore the composite score at this point. Impact scores would be the foundational standard, these general-purpose standards for something specific to a particular use case. Let's go down that category. I have opinions, but I am going to shut up and see if anybody wants to volunteer their opinions in terms of which of the areas here are more foundational relative to general-purpose. Maybe people can make the case that X item or row on this list is foundational and/or general-purpose. Hearing none...

# David McCallie

Arien, let me just test your notion of "foundational." Take health equity as a use case. Getting robust agreement on how to codify the various issues that roll up into this broad category of health equity seems pretty fundamental to me, so I would be tempted to call that one foundational.

# Arien Malec

I guess I would look at EHR data use as foundational in the sense that if you could get population-based exports of clinical data, there are a crazy number of things that you could do with that, whereas health equity standards would be more general-purpose in the sense that you could put health equity standards into a bunch of different workflows, but it unlocks analytics and analyses in a particular area of healthcare. Does that make sense?

# David McCallie

Yes, I just wanted to double-check on how you were thinking about it. So, do we want to go by column and ask if there are any of these categories that are foundational? Maybe we will flag the EHR data use. There are some broadly applicable tools there, as you said. Health equity is general-purpose. We are codifying that as medium. Maybe I should use different letters here.

# Arien Malec

Clinical and administrative data standards would probably be general or foundational. You can make the argument either way.

# David McCallie

I will go with medium. Federal/commercial data sharing is a pretty specific problem. For example, do we want to go with resolving the security mismatch as a specific?





Yeah, that is one that is on the border in the sense that it affects a lot of servicemembers, veterans, and members of travel organizations, so it affects a significant sub-population in its broad effect for a sub-population, but is definitely not general in the sense that it impacts all Americans, but it is an important set of groups, so it is on the cusp of medium and **[inaudible] [00:55:25]** there.

#### **David McCallie**

Okay, I will call it medium...or, general-purpose.

#### Arien Malec

It seems like everything else is low.

#### David McCallie

In the impact column?

#### Arien Malec

Yup. I am just trying to keep up with the comments. Okay, got it. As I said, I think what we are going to do here is assign some of this as Delphi ratings, getting each person to individually assign, and then we will look at the composite and see if there are any patterns. Valerie?

#### Valerie Grey

Hi, thanks. Could we talk a little bit more about health equity and how it ranks? When I was listening about the federal/commercial data sharing discussion and we were talking about how many affects, to me, the health equity issues in social determinants of health affect a ton of people, if that is the way we are thinking about things.

#### Arien Malec

I think we agree. Where we were going was federal/commercial data sharing was on the low/medium boundary area and health equity is on the medium/high boundary area.

#### Valerie Grey

Thank you for the clarification.

#### Arien Malec

All right. "Policy levers" is going to be a fun one. "Clinical and administrative data standards" is one where, between ONC and CMS, HHS has all the levers. Whether they use them or not is a different question. Again, with federal/commercial data sharing, the federal government has all the decisions here. With vaccination data flows, you have a mix of CDC, states, and EHR, so CDC and ONC clearly hold a good number of the levers, but then, states and localities hold some of the levers as well, so that feels more like a stretch for new policies.

I think ONC holds all or most of the applicable levers for health equity. I think ONC holds all or most of the applicable levers for EHR data usage in the sense that ONC already has the policy framework to establish certification criteria and incorporate it, and CMS has the ability to incorporate into programmatics.



Situational awareness, syndromic surveillance, and contact and exposure tracking all feel like the same argument for vaccination data flows. You have ONC and CDC, but then, you also have states and localities.

#### David McCallie

Let me just take a shot. Would you call those low because of the federated approach, where there is not top-down lever control?

#### Arien Malec

The dialogue in my head... This will not happen tomorrow, but in the next few weeks, there could be a consensus on legislative action relative to this area that would establish policy frameworks that do not currently exist, but if you did not have those, you would basically be in the same trench fighting that you currently are of promulgating standards and having states not take them up, so I think calling them low is appropriate.

#### **David McCallie**

Yeah. It is a disadvantage of making a recommendation in one of those spaces because there is not a clear way to see it through.

#### Arien Malec

That is right. So, there is a health committee proposal from Senator Murray; there have been a number of proposals that would establish ongoing pools of money for public health preparedness, but then tie those pools of money to adoption standards, in which case, a low suddenly turns into a high.

# David McCallie

Yup.

<u>Arien Malec</u> Have we talked about adverse events?

# David McCallie

Care plan, adverse events, and patient device linking.

#### Arien Malec

Again, in these areas, I think ONC holds most of the levers, except for adverse events, where ONC and FDA hold most of the levers. The only issue here is getting FDA to accept that something other than MedDRA could be used for adverse event reporting.

#### David McCallie

Yup. I am going to call that a low again on the split control problem.

#### Arien Malec

Yeah, I would argue for a medium. We will get Delphi ratings, but I would argue for a medium in the sense that it is only a low if you believe that the FDA will never adopt anything that looks anything like the rest of the world.





# **David McCallie**

Clem, go ahead.

#### **Clement McDonald**

I think it is going to be tough to get that changed. If there is any other process to make it easier... They are pretty rigid on that stuff, and they are slow, and they get flak for whatever they do, so they are really sensitive. Dave, are you thinking the same thing? You were kind of hemming.

#### **David McCallie**

Yeah, I agree that it is pretty easy to define how the world ought to be, but I do not know that there is any way to force the world into that situation.

#### Arien Malec

That being said, part of the feedback we got on this taskforce was that there are areas where it would be useful to give ONC a recommendation to explain to FDA why what they are doing is actually not productive for the nation **[inaudible – crosstalk] [01:01:50]** useful.

#### **Clement McDonald**

You might be able to work this better by pushing on the surveillance or looking at real-world data. There are a whole bunch of variables in MedDRA that are sodium high, sodium low, glucose high, glucose low... Those could be generated by looking at lab data. It would be more reliable, and they could actually put magnitudes on it, and maybe that would encourage them to get rid of some categories and just not do it that way.

#### Arien Malec

On the other hand, I remember the great COSTART/MedDRA swap-over, and so, let me just tell you that things could be worse. There was a time when you had WHO-ART, COSTART, and MedDRA all vying for stuff, and boy, that was...

#### **Clement McDonald**

Were any of you guys at the AMIA meeting when they first presented MedDRA?

#### Arien Malec

As I said, I was deep in those weeds with WHO-ART, COSTART, and MedDRA way back when.

# **Clement McDonald**

There was a little chuckle because they got up and said, "But, we cannot tell you what is in it because it is a secret." People were falling out of their chairs laughing.

#### David McCallie

I think it is still proprietary.

#### Arien Malec

I think we got a bunch of the applicable policy levers done. Let's go to "burden." Again, the key thing here is if it drives large amounts of clinician burden, large amounts of patient burden, and if the job is currently





getting done in ways that are driving high burden or just not getting done. So, if the job is already getting done, it is getting done in ways that are problematic, and it is getting done in ways that drive high burden, and you would mark it a high if the job is getting done and maybe not as elegantly as we want it to, but is already getting done, or if the job is not getting done but no one is going out of their way to do something terrible, you would mark it low, and something in between. Go ahead.

# David McCallie

I am looking just to clarify because I think Clem was using "burden" in a slightly different way in our earlier conversation, and I realize that it is a word that we probably should have put a few more qualifiers on. We are talking about a high burden as a high problem that should be solved, right?

#### Arien Malec

Yes. A high burden is either something that leads to significant health cost effects and is not getting solved or something that is already getting solved in ways that generate high burden for patients, providers, or other actors, or is currently driving high costs in the U.S. healthcare system.

#### **Clement McDonald**

I had not understood that correctly. Thanks.

#### **David McCallie**

Good, Clem. I am glad to see the clarification. I wish we had been a little bit more precise, but it is what it is. Here we go.

#### Arien Malec

That is why you get into these things. So, I do not think you could argue that "clinical and administrative data standards" is anything other than a high burden. This is ePA, medical necessity, claims attachments, and everything to do with benefit eligibility for complex care.

#### **Clement McDonald**

It did not sound like that to me. I thought it was just the ability to get that stuff **[inaudible] [01:05:41]** the standard forms.

#### Arien Malec

Yeah. We can go over and review the Clinical and Administrative Standards task force output recommendation, but we particularly focused on ePA, medical necessity, and attachments, but generally, it was the notion that clinical data is increasingly required to adjudicate administrative transactions.

# **Clement McDonald**

If you could get that phrase in there, I think it would help us remember what we are really talking about.

# Arien Malec

Got it, sorry. It is shorthand from previous task force work. I saw somebody's hand go up and down. Andy, your hand was up or down. Maybe not. Okay, federal/commercial data sharing is a medium burden. I think we have heard from the group that vaccination data flows are a high burden.





# David McCallie

And high impact.

#### Arien Malec

Yeah. Let's call health equity high burden in terms of the impact to populations. I would have to think about EHR data uses. I would love to hear other people's perspectives. This feels like a job that is getting done through other means, such as proprietary data extracts, through consortia coming together and hammering out data-sharing agreements, data export agreements, and yada yada yada. Is this an area where if only we had flat FHIR, everything would be 10,000% easier, or would this be an area where if only we had flat FHIR with the current work we are of doing columnar data exports, and then, working on that would be reduced, but we would still have all the other data-sharing yuck that we still have?

#### David McCallie

Arien, my take would be to call it a medium.

#### Leslie Lenert

This is Les. I do a lot of work with PCORI and at PCORnet, the CD2H, and other networks for provisioning of data. I think that a lot of this is getting done. For large-scale data production resources, I am not really sure if flat FHIR is the answer to that, and again, there are all these issues about what it means to centralize this data versus doing it with a distributed query, which might be much better to protect data confidentiality, security, and those types of things. If you want to talk about standards for this, you probably need to think about that kind of approach, and again, flat FHIR is not an analytic model. Common analytic models are OMA, PCORnet, and ITB2.

#### Arien Malec

Yeah. I think we are exposing that we are going to need to get some public testimony in this area. Let's call it medium. That feels appropriate. The hard bits of this work are data sharing, data use, and figuring out the analytics model, and the data extracts are actually just work that we could harmonize and make smoother, but they are just work. Situational awareness: For folks who are managing hospitals that are needing to report out to the federal actors, is this a high, medium, or low burden right now?

#### **David McCallie**

I heard it was high in some of our earlier discussions on this.

# Arien Malec

My sense was that six months ago, it was terrible, and now it is like, "Whatever, we know how to do it."

# David McCallie

Do you want to call it medium?

#### Arien Malec

Yeah. We will go through a homework round where we ask you to independently rate after the exercise. Syndromic surveillance: I would say the current burden is low. It is just that you cannot get done what you need to get done. Any objections? Care plans: Again, I would argue for low. I am sure other people would argue for high. This is classic. It depends on whose burden you are talking about. If I am talking about



myself as a patient, my plan of care is notes that I get scribbled and assemble and keep in my head. It would be super useful for me as a patient to have an integrated plan of care that I could refer to that was sitting on my device of choice. Again, Jack or Ricky, maybe you have comments on this.

#### **David McCallie**

This is David. We did not talk about the details on that one as much because it had gotten some discussion on the previous task force, but I would say that care coordination is still quite a burden.

#### Arien Malec

It is a burden for patients. It is one of the classic areas of healthcare where it is a pain in the butt for patients at the very least, or even life-threatening, and the reason it is such a low burden for hospitals and providers is because they do not do it, or they do the minimum necessary for joint commission requirements.

#### Ming Jack Po

Sorry, I am giving a bunch of feedback in the chat.

#### Arien Malec

I am looking at the chat, Jack.

#### Ming Jack Po

It is just because my phone is not always working very well. I would say that actually, in the last year or two, basically everybody from CVS to Google is entering care coordination, so I think standards would be really great to get aligned right now.

#### **Ricky Bloomfield**

This is Ricky. I would echo that. I think especially as we have seen in the last year, many more entities are having more of a virtual care environment, and trying to get ahead of that and having concrete and standardized ways to improve the communication between physicians and patients can potentially have a big impact.

#### Arien Malec

Yeah. And again, just thinking out loud, it would be so cool if the work that is currently getting done in terms of discharge plan requirements, et cetera could just get published. Anyway, on to adverse event reporting. I think there is a low current burden because nobody is really doing it. Okay, patient device linking: Low current burden because nobody is doing it.

#### **David McCallie**

Probably.

# Arien Malec

Contact exposure tracing... Boy, traditional contact tracing is a high burden and digital contact tracing is a low burden. I have turned on my exposure notification; I am just not sure it actually does anything.

#### **David McCallie**

I would argue for high in that it is a very process and not standardized well.



Yes. Traditional feet-on-the-street contact tracing is a high-burden activity, and you can tell it is because it is not getting done at the level that it needs to because it is just so expensive.

#### **Ricky Bloomfield**

This is basically a scenario where...

#### Leslie Lenert

Key-sharing is a pretty high-burden activity too. Once you have a positive test, giving you a key to share your exposures to other people or share your device as associated with a person who is infected is pretty...

#### Arien Malec

That is all now built into current-generation operating systems.

#### Leslie Lenert

No, it is not, actually.

#### Arien Malec

How does a positive test get in and trigger the exposure notification part? The traditional contact tracing of getting lab data or ECR data over to contact tracers to actually work phones is a manual activity with high burden.

#### Leslie Lenert

Yeah, and when that happens and you want to trigger an exposure notification based on that, you need to reach out currently to the infected person and give them a digital key so that they can volunteer to upload their exposure.

# Arien Malec

Cool. That is awesome. I hope it works really well. Clem?

#### Leslie Lenert

That is one of the burdens. There is too much delay, and it is too hard for people to volunteer their status.

#### **Ricky Bloomfield**

This is Ricky. Just a comment on that. This is one of the reasons why I think it may be helpful to divide this one into both contact tracing and exposure notification. I think the burden in each one of those could be very different, as well as the other columns here might apply differently to in-person contact tracing versus exposure notification. I would echo the comment around exposure notification that from the end user perspective, the burden is low. From the public health authority perspective, most of the burden is around making sure that the user has their test confirmation, and that somehow makes it for them... Once they have that test confirmation, there is nothing else that they need. They can just go ahead and submit their keys because that is all locally on the device, but they need that confirmation to avoid potential fraud because anyone could submit their keys whether they are actually positive or not.





Clem, we are going to go to you, and then we are going to go to homework, and then we are going to go to public comment. Clem, that is the mute button or the audio issue.

#### **Clement McDonald**

It is very complicated, but it would not be so bad if we did it like a few other countries do. We just got so tangled. We build these things, and no one remembers to get them, they do not remember to use them, they do not want anybody to know, and it goes on and on like that. The newer twist is that the six-foot limit is probably goofy. It is not just droplets. If you are in a restaurant, the whole place can get full in the air. So, we may not even have a good way to define the distance. Maybe you could measure the persistence in an area or something, or the phone could tell you that you are inside a building. I think there are a lot of issues, and it is very important, but I think we should try to get some technology on it somehow, but be aware that the distance by itself was not an accurate definition from what we know now.

#### Arien Malec

I am going to trust Apple, Google, and some of the device manufacturers for figuring out if we have better algorithms for how long I am loitering in a particular area and whether I am indoors or outdoors. The big burden is getting positive information to the device to trigger any of the exposure notification, and I also agree with the sentiment that we should bucket traditional contact tracing and exposure notification as two separate items, and not conflate them. All right, we are going to go to homework. What I am going to ask the team to do... David, did you want to get in?

#### **David McCallie**

No, do the homework, but I would like us to review our expert testimony slide just to get thoughts on whether we have missed somebody. Do your homework.

# Arien Malec

Given our history of getting public comment, we probably will have some time at the end. So, if we go up one slide, what I would like people to do...other slide, other "up." So, if we look at the priority area slide, please fill out the composite score as opposed to the sub-scores here, and we will do a Delphi rating, so we will just take all your scores, figure out the distribution, and pick something that is relatively modal in the distribution, and then, for the next slide, just fill out the first three columns. Do not worry about the composite score. So, potential impact, applicable policy levers, and current burden, high, medium, and low, and again, we will do the same thing. So, we will have four columns where we will look at the distribution and modality and use that as a framing for overall prioritization, and as I said, I think our inclination is to equally weight, unless when we do the rank/sort, we decide that it is just wonky and that some obvious weighting would help the wonkiness. David, back over to you. Is that homework? We will provide instructions.

# David McCallie

We will send the slides out with a little bit of instruction, so hopefully it will be clear what Arien said. Next slide. Shifting focus here for a couple of minutes before we have public comment, we have had some discussions with our ONC partners about getting additional input from subject matter experts in some of these domains. Some of this may or may not be as important based on our ranking, but let's just assume at the moment that we have pursued all of these things. Here is our current approach, and if you guys have

strong feelings about something that should be added or taken away, let us know. If we do not have time on this call, you can certainly do it in the email, and we will share it in the next meeting.

On the health equity topic, there is a major project underway called Project Gravity at HL7, and they have agreed to come and explain that work, which is quite relevant. That would tentatively be on April 8<sup>th</sup>. On public health situational awareness, the project that we are aware of that has the most overlap is the SANER Project, and we are pretty confident we can get someone from Audacious Inquiry to come and explain that work. For public health data flows broadly, which is several of these domains, the name Jim Daniel at CDC was suggested so we could get an overview of what is working and what is not working in public health data flows.

On clinical and administrative data and standards, the task force that Arien has mentioned several times, we could get a readout from that task force chair or perhaps someone from Da Vinci or one of the other groups that has been working on this. Data sharing across federal and non-federal boundaries: The thought was we could approach CommonWell, Direct Trust, or e-Health Exchange, some of the groups that are already struggling to solve this problem and get their perspective on what is working and what is not working. And then, on the topic of real-world evidence and leveraging EHR data, the OHDSI and HL7 collaboration that I think George Hripcsak is heavily involved in was an example of what we might want to focus on here in terms of just getting a clearer understanding of what the issues are. Any comments on these topics and/or experts? Actually, while you are thinking about it, do we want to do public comment? I think we are right at the time.

#### Arien Malec

I think we can do public comment. Let's go to public comment and then come back. Like I said, we will get the homework out via email.

# Public Comment (01:23:12)

#### Michael Berry

Operator, can you please open up the public comment?

#### **Operator**

Yes. 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 yourself from the queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing \*. One moment while we poll for comments.

#### Michael Berry

Okay, and while we are waiting, I just wanted to remind everybody our next ISP task force call is Thursday, April 1<sup>st</sup> from 2:00 to 3:30 Eastern Time, and also, I will plug our annual ONC meeting, which is Monday and Tuesday next week from 12:00 to 5:00 p.m. Eastern Time, so if you have not already registered, you can just search our website for the annual ONC meeting, and there is a registration there, and you are free to register. All right. Operator, do we have any comments?

# **Operator**

There are no comments at this time.



#### Michael Berry

Thank you.

# Homework (01:24:14)

#### Arien Malec

In addition to the homework on filling out the form, which we will provide ample instruction on out to the group in a more consolidated way of filling out the data, if you also have people in addition to the list that David mentioned that you think would be important to listen to or hear from, that would be fantastic. We will give homework to people to solicit other ideas for people to hear from. Any other questions or comments? Cool. All right, let's give people back two minutes. This was a pretty rapid-fire meeting. I am hoping we come to the next meeting with a proposed prioritization and spend most of the time worrying about the stuff on the margin, and then get down to actually focusing on standards and needs in the priority area. I want to thank everybody for their engagement. I thought we accomplished a lot, and I look forward to next week.

# David McCallie

Thanks, everybody.

Adjourn (01:25:47)

