Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

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

March 18, 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
Okay. Thank you. Good afternoon, everybody. I'm Mike Berry. I'm with ONC. And I'm happy to kick off our Meeting No. 2 of the interoperability standards priorities task force. I'm going to start with roll call and then, we'll get started. I'll start with our co-chairs. Arien Malec.

Arien Malec
Good morning and/or afternoon.

Michael Berry
David McCallie.

David McCallie
Likewise. Good afternoon.

Michael Berry
Ricky Bloomfield. I see Ricky on but he might be muted. Cynthia Fisher. Valerie Grey. Jim Jirjis. Edward Juhn. Ken Kawamoto.

Ken Kawamoto
Hello.

Michael Berry
Victor Lee. Les Lenert. Clem McDonald. Jack Po.

Ming Jack Po
Here.

Michael Berry
Raj Ratwani. Ram Sriram.

Ram Sriram
Present.

Michael Berry
Sasha TerMaat. Andy Truscott.

Andy Truscott
Good afternoon.

Michael Berry

And Scott Weingarten. Okay. If I didn't hear your name, we'll keep an eye out for you and I'll take note as the call goes one. Thank you all. And I'll turn it over to Arien and David.

Introductions (00:01:38)

Arien Malec
Great. So, Ricky says he's here but not on audio yet. And, hopefully, Ricky will not repeat his timing where we called on him and then, he left just in time not to get called on. So, we'll make sure to call on Ricky early. We've got a pretty packed agenda today. So, we collected a bunch of input in last call. Our goal is to go broad and then, start putting together prioritization recommendation framework so that we can start to narrow and go deep. So, David is going to walk us through the going broad framework. And then, I'll walk us through the proposed prioritization framework and proposed recommendations framework and we'll get feedback on both of those. There is a lot of information on the go broad section. So, the request when David walks through that is let's make sure we got completeness and not dive into any of the topics at this point. Let's just make sure that we've got the territory and the map covered before we start drawing in all of the blue, squiggly lines.

And then, let's make sure we reserve some time to think about the prioritization framework and the recommendation framework, again, from the point of view of thinking about how we narrow down the very large list that we have down to a smaller and manageable list that allows ONC to get the kinds of recommendations that are useful for the national agenda.

Review of Mandate (00:03:15)

Arien Malec
So, turn to the next slide. And the next one. So, again, our goal is priority uses, identifying existing standards and implementations, specifications, make appropriate recommendations. As usual, that's inside the coloring lines. As a federal advisory committee, we get tasked but sometimes, we draw outside of the coloring lines. And in particular, I think what we saw for orders and results was that, in many cases, when we did a deep dive of the standards, there were some cases where we had all of the standards in place but we weren't using them. And in other cases, we didn't have the standards needed to keep evolving them. So, in the cases where you have standards and keeping using them, often times, we've got policy alignment issues.

And I think it's useful to point out those areas where good news, we've got all of the standards but we may have some policy or system alignment uses. But our must have for this task force is to identify priority uses for existing standards and specification and recommendations for future ones are right. Next slide. And over to David.

Review of Ideas from March 11 Meeting (00:04:36)

David McCallie
Thanks, Arien. Before we dive into this overwhelming list of topics, I just want to add one comment on the tail end of what Arien just said about the notion of making recommendations. In this list you'll see, as we dive into it, we cover recommendations. We cover areas that are not strictly limited to ONC's purview but include CDC, FDA, and CMS and possibly other agencies. And Arien and I both got feedback that recommendations that are broader than just ONC's mandate are valued by ONC because they participate

in these interagency meetings frequently. And hearing from an ONC FACA that something is important, is useful, even if it's, strictly speaking, broader than ONC. So, I don't think we should shy away from thinking about some of these areas that are maybe a little bit broader than a strict ONC purview. Arien, do you agree with that?

Arien Malec
Yeah. I completely agree. Although, as usual, all of our recommendations need to be formulated in the master phrase we recommend that ONC coordinate as opposed to we recommend that FDA to X, Y, and Z. But because ONC is the national coordinator then, that coordination role is vital and essential. And it's useful, for example, for FDA to know that standards alignment between FDA and clinical interoperability is a good thing just to pick a rando example.

David McCallie
Great. Thanks for that reminder. Okay. So, what I did here on this slide, what Arien and I did, is go through our notes from the first meeting and a couple of outside conversations and follow up to that first meeting where people clarified their thoughts and tried to put a top down view of the domains that surfaced and came up in the meeting. So, I tried to get everything that was mentioned enough to attract the groups attention. There are a couple of things that just got mentioned in passing that we decided to drop. Although, you guys should feel free to bring them back up in the later part of our session today where we solicit for additional ideas. So, let me just walk through these to tell you what I mean by the titles here. And then, each on of these has a slide coming up that goes into more of the bullet points that we, actually, discussed. And as Arien suggested at the beginning, the goal of this call is not to refine these but to make sure we didn't miss something completely or misinterpret or misunderstand.

So, these categories are somewhat arbitrary and maybe they overlap a little bit. It's the nature of what we do. First, improving syndromic surveillance. 1.) The ability for early detection of emerging problems in public health or in routine healthcare. And 2.) improving situational awareness for public health emergencies. Situational awareness is targeted more at the actual mechanisms for delivering public health such as status of ventilators and beds and facilities. 3.) Address gaps in vaccination reporting data flow. We had quite an extensive conversation on what parts of that current data flow work and which parts don't work. 4.) Is a broad topic that we've rolled up into just the notion of health equity issues that can be both access issues and failure to capture critical information to help us understand health equity gaps and so forth. 5.) Better usage of EHR data for public health and other purposes. The broad theme there is we are now capturing a tremendous amount of digital data.

Not all of it is being put to good use yet for things like public health. 6.) Gaps in adverse event reporting. This was mentioned. We didn't put a lot of time into it but it came up that some of the adverse event tracking is not computable and perhaps is fragmented in ways that we could spend some time thinking about improving. 7.) Contact and exposure tracking. Can we manage pandemics better if we improve systems that enable contact and exposure tracking? 8.) A bit of a holdover from an unfinished part of our 2019 agenda, care plans and chronic disease burden. We didn't talk much about it in our last call but we did highlight that it was sort of unfinished business from the previous incarnation of our task force. 9.) Better and easier binding between persons and their digital devices. We didn't go deep on this one but it got mentioned. 10.) Better integration of clinical and administrative data. It's a broad domain where there is a

recognition that some of the emerging API's, in particular, derivative of and implementation guides around FHIR have had splits between clinical workflows and administrative workflows.

And we put this on the list to see if we want to think about maybe doing better integration between those two. 11.) Suggested to us from the outside but a topic that has come up a number of times is improving the data sharing across DA, DOD, and non-governmental systems, in particular, security issues that make API's more flowing across those boundaries problematic. And then, lastly 12.) vaccination passports. I put this in parentheses and put it last because ONC had clarified for us that they already have active work int that space and requested that we not put additional effort into that space. So, it came up in our conversation last week. But we're going to take it off of our table since it's already being aggressively worked by ONC. So, let me stop there.

Arien Malec
If you do not have your phone on mute, please put your phone on mute if you're not talking.

David McCallie
Or it may be that you've got your speakers turned on. Whatever. So, while whoever was trying to say something figures that out, Arien, do you have anything to add to this overview?

Arien Malec
No. I just would request people, if they can, raise their hands before they tag in. And David, I'll help you watch hands and run interference for you.

David McCallie
Okay. Is everybody comfortable with what we're doing? We're going to just go through these one by one and maybe get one level deeper than the high level summary I gave. Let's just get started and if it doesn't work, we'll fix it. So, next slide, please. So, on the topic of syndromic surveillance, there was a general notion that there is still too much siloing of data, in particular, lab data that's getting abandoned from a public health awareness point of view. In particular, Bullet Point No. 2, we had discussions to address gaps in the roll up of data to state and local aggregators. There is still some excessive variability in lab messages despite a lot of work to try to homogenize in that space. Early detection and reporting of novel variance was mentioned. We didn't go deep on it. Electronic case reporting was brought up just in passing that we should maybe spend few minutes thinking about whether that's working as well as it could. And then, revisit TMS's decision to drop quality measures for lab reporting, which has, essentially, took away an incentive that was helping address some of the siloing of data.

So, those were the topics that we got in our notes for syndromic surveillance. Does anybody have things to add or critique? We're going to go in our later sessions and put some of this online in a spreadsheet and allow for a lot more flushing out of details. So, if you've got a hot, burning detail, save it and we'll have plenty of time to address it later. But if there is a high level thing, raise your hand and we'll go. But not seeing anything on that one, let's move to the next slide.

Arien Malec
Clem and Ram have their hands up.

David McCallie
Okay, great. Clem, I'll go first with you since Arien said your name first.

Clem McDonald
Are you talking to Clem?

Arien Malec
Talking to Clem.

Clem McDonald
Yeah. I think the original process focused an awful lot on x-rays and they were planning on doing text reporting. I think we ought to investigate a little bit more about what they really did with them and whether they ran into trouble with the surveillance studies. They were looking for pneumonias.

Arien Malec
Just to be really clear, most of the surveillance that's done at this level is reportable condition surveillance. So, that's the CDA templates where hospitals send out reportable conditions and then, ADT notifications. So, most of the ILI syndromic surveillance gets done via ADT. One of the things that we discovered when we looked at the work here was that we had good ADT coverage but some states were sort of off the grid. And then, we were missing cases of hospitalization because the ADT feed only looked at ED based use cases. But we were missing ambulatory ILI and then, also missing hospitalized ILI. And once we had the ILI feeds through ADT adding additional filters for COVID-like symptoms was relatively simple. So, I think, Clem, what you're suggesting is, in addition to the ADT and reportable conditions CDA based syndromic surveillance, we might want to consider adding radiological findings based on syndromic surveillance.

Clem McDonald
Well, I wasn't, actually, suggesting what to add. My understanding is that's what they asked for in the beginning. And there is a message specified in HL7B2 for lab tests and, I think, something about radiology stuff. The initial stimulus is anthrax and bioterrorism and some kind of pulmonary phenomenon. Of course, they could find it at the lab. But I don't know what they, actually, did or whether they dropped that, whether they're seriously using it, and how they use it. So, I think it would be helpful to understand what went on from the beginning until now. The ADT is clearly a good one but that wasn't what they started with I don't think.

Arien Malec
Got you. All that I'm reporting, Clem, is what's in the meaningful use or what's in the ONC certification criteria. So, we have certification criteria for ADT based syndromic surveillance, reportable conditions via CDA and then, ELR as the main certification.

Clem McDonald
Well, ELR was HL7B2, the one I was thinking of.

Arien Malec
That's right. Cool. Ram?

David McCallie
Good point.

Ram Sriram
This is Ram here. I have a question about we were talking about data transfer and things like that and protocols. What about the test procedures for those? How do you test that it's, actually, being done the way that it should be done?

David McCallie
Are you referring to testing of the actual interfaces, the system test?

Ram Sriram
Yeah. That needs to be taken into account.

David McCallie
Yeah. I don't think there is a robust mechanism for many of these where it's up to the sending system to decide that it's got a reportable incident. We don't know how they miss.

Arien Malec
For the ones that are ONC certification criteria, they're associated test criteria. Whether they work or not is a different question.

David McCallie
Yeah. There is, obviously, success of the API itself, the technical test. And then, there is the does it work in the workflow of the real world test.

Arien Malec
And Mike or somebody else from the ONC team, can you confirm? As I think about it, I'm not sure that ADT event notification is a certified health IT criterion, even though it is fairly broadly adopted through CDC. So, that might be an area where there is a gap. Maybe if we can do some investigation there and report back that would be useful. And then, David, you have ECR as a question mark. Let me just give you a little background on ECR. So, ECR is a CDC standard or a CDC interoperability initiative that is electronic case retrieval. And so, the goal is to create a trigger based mechanism to report out cases of interest started with some of the early work that was done on Zika putting in place Smart on FHIR decision support books app and to collect additional information on Zika. And there are now two flavors of this ECR, which is a CDA based reporting mechanism. It is adopted by a number of Epic hospitals as well as a number of Cerner based hospitals.

And I think it is somewhere in the deployment cycle nationally for both Epic and Cerner and do not know where it is for the other EHR's. And then, there is ECR Now, which is a digital support Smart on FHIR app that does much the same thing. It pulls information and reports back to CDC. And the goal was to replace the paper based case reports that were being done for COVID. Health systems that were connected to ECR reported that they were, actually, getting the ECR case reports before they were getting ELR information. So, they were able to fast track investigations in areas where they were but I just wanted to provide a background for why that one is on the list.

David McCallie
Okay. Let's go on. We've got a lot to cover. And, again, we'll have time when we identify our priority items to go much deeper than we're going right now. So, let's go to the next slide. I should have numbered these but I'm sorry. This is 2.) improving situational awareness for health emergencies. So, the core thought that has bounced around in some of the discussions here is probably going to turn out to be looking at the emerging profile of FHIR called SANER, it's down there next to the last bullet point, which proposes to address some of the reporting variations that are currently accomplished in non-computable ways and with lots of variation and turn it into something that can be made more computable and on demand. So, I'll just maybe jump ahead of the game and say there is a notion that if we choose to prioritize on this area and probably get someone to come and walk us through what SANER is trying to do. Some of the related concepts that we discussed briefly in our first call was whether or not there was a role for TEFCA as it emerges to address some of the access to this data.

And then, there was a lot of talk about the problem of non-computable and state by state variation that makes this a challenging problem for systems to deal with. So, I would say this is the SANER topic if you want. Whether or not SANER is something we decide to push on, we have to decide coming forth in future meetings. Arien, you have comments, broader ones and then, let me see if there are hands. Are there any comments on this one from the team? It's pretty straight forward. Okay. Let's go to the next slide. 3.) Address gaps in vaccine reporting data flow. I guess I wasn't thinking about it when I put that title up. There is a flow of the vaccines and the flow of the vaccinations. And they really are different. I know, Arien, you have been spending a fair amount of time analyzing the flow of the actual supply chain in California. So, this slide is probably not accurately titled. But what we heard, I think, in the meeting, let me summarize –

Arien Malec
I think that's really looking at the vaccination reporting, which is really the vaccine supply chain piece of this. I think it's sort of out of scope for health IT but definitely vaccination reporting reconciliation is in scope.

David McCallie
And what we heard in the discussion, I think, Les Lenert was one of the drivers of this part of the discussion was that some of the data flows inbound from EHR and established vaccination administration systems into local public health is well supported with standards and, actually, works pretty well in many settings. But getting the data out of the public health facility, particularly in group level access to the data like countywide statistics was lacking. And it didn't exist in some ways. And then, there was a secondary concern that, as we ramp up things like mass immunization events, wondering whether those events are generating flow of data to local public health officials or not. And I put out some queries to my colleagues at Cerner, for example, and they said that they know in some of the settings, the data does flow but they weren't sure about all of the settings.

Like we're having a big one in Kansas City at Arrowhead Stadium with 6,000 people or so will get vaccinated. Is that data going to flow to the right places is an open question. So, are there any comments on this one? Hands, let's see. Clem, go ahead.

Arien Malec

Just before Clem jumps in, data flow inbound is state dependent. So, it really depends on where we are. Sorry, Clem.

Clem McDonald
I don't think the flow is the problem. I think the problem is there is no strict identification about who the person is who got it. So, if they're going to be using this for a passport or really to be sure what's going on, we've got to get that fixed. I got my shot. They asked me if I had insurance but they didn't ask the insurance company. They didn't ask my social security number. I don't know how when it gets to public health they'll know who is who. The mass ones are worse. They can drive through. They get 10 seconds. They're not picking up much detail about who the individual is. So, I think we're screwed if we don't get that part fixed.

David McCallie
Noted. I don't think you'll get a whole lot of argument about the value of knowing who the patient is from this group. Any other comments? I will do an anecdotal comment. Every one of us is going through this process and has some story to tell about their own experience. But here in Kansas in Johnson County, I've been inundated with messages from the County Health Department to verify whether or not I've had my vaccine. And I don't know how I got on their list but they found me. And so, there are processes that are not perfect but that do help deal with this.

Ming Jack Po
So, at the last meeting when I mentioned this topic, I wanted to talk about something that was slightly broader than just the reporting data flow, even though it might be, potentially, out of scope. But I mentioned that it's, actually, private companies globally are now setting up these travel passports that were just mentioned. And they are, essentially, just making up standards on the fly. If we can somehow standardize this, this will be a tremendous advance in HIT like globally all at once because there is no question that these passports are going to get built for COVID.

Arien Malec
Just a clarification there because I'm involved in some of that work, there is standard work going on. There is coordination with HL7 around the FHIR based protocol for doing this. If you go to VCI, Vaccine Credential Initiative, you'll see links to the underlying standards work. There is an international, WHO international cred. So, there is some work to align some of the proposed standards for international creds with the proposed standards for local. And then, as we'll see, this is the scenario that ONC is already going deep on and doing standards coordination. So, I think the request for us is no further prioritization effort needed from us because this is an area that ONC is already pushing hard on.

Clem McDonald
Well, I'd argue against that. I think this is the most important step on the whole ship because it's time urgency. And we're not going to do it but I think it's a very high priority. The highest, I think.

David McCallie
And Clem, I think ONC would agree with you and say they've already prioritized it. And they have, apparently, dedicated considerable resources to actively working on it. So, we don't need to surface it as a priority because they've already done that is the message we got. We would be telling them –

Clem McDonald
So, it's through ONC, is that the –

David McCallie
Yeah. We're trying to identify areas, in a sense, that have been missed or need additional attention as opposed to areas that are already being addressed. So, that was the message we got. Let's keep moving because we've got a lot to cover. Next slide, please. Okay. Health equity. I will admit that this is not a strong point for me to wrangle this space. It's complicated and I haven't spent a lot of time thinking about it I'm sorry to admit. Broadly speaking, there are a couple of areas that we highlighted. One was the social determinants of health data that needs to be captured. Are the standards that should capture it adequate? Are they being used where they should be being used? And then, in the real world, are people doing it? Let's say it's well deployed but it's just not being captured at the point of care for reasons that might include cultural issues, training issues, complexity of the user experience, and so forth.

Then, there is an access axis of this where if you have electronic systems that are crucial for delivery of critical care, crucial care I should say, do the people who need to know have a way to get at that information? If everything is on a smart phone and they don't have a smart phone, is that a problem? Should we have standards that address minimum access capabilities such as web browsers in a library or something like that? Those are some of the issues that got raised. Ken, you've got your hand up.

Ken Kawamoto
Yeah. Thanks. I do think this is a pretty important issue. So, just a few comments or some things that may not have been thought about. I think the SDOH and race ethnicity information is kind of related. And I don't know if folks have seen the article in *New England Journal* last fall, basically, saying we use so many algorithms in clinical care built into EHR's and such that have unintended consequences. Essentially, for example, we might say because this patient is black, we're going to assume that these negative outcomes are going to occur. And, therefore, we will not provide clinical treatment to them where we're completing issues of the effects of racism versus biological differences. So, I think that's an area where the notion of capturing social determinants of health can make a difference because if we capture things like educational attainment consistently and have them available, if we capture things like homelessness then, we are using actual factors rather than proxies.

Assuming that because you are a black female who is 55 years old that your education level is this and etc. I think that's just one thing to keep in mind where this can be really a direct addressing and doesn't get into the whole details of what we do with that information necessarily but would be important. I think another really important issue that I started getting more aware of is the lack of digital access for vulnerable populations like the elderly and certain population groups where I was just shocked to learn if you're over a certain age, one-third of those folks don't have internet access. And especially as we start thinking about the need for patient engagement to deal with a lot of these issues, that's another potential area where thinking of what do we do when the patient doesn't have internet access and are there standards and policies around it that can help. And, specifically, I'm looking at things like those folks, typically, have phones but there are a lot of regulations around you may not contact patients using automated phone call based technologies.

And it's just like the regulations where even though you can text them and those kinds of things. And I think there are issues like that where if you have a smart phone and can open an app, maybe that's fine. And that's an exciting area. But I think this is an area where there is a real potential to help address this.

Arien Malec
Ken, just a couple of questions there. I think your last point is the bottom two points that we're listing under health equity. And it's more than just disadvantaged, homeless, digital divide, aged, etc. There was a really good study, I think, with University of Michigan that did the underlying reporting. It was reported out in a Politico somewhere and I'll see if I can dig it up. But the gist of it was that only 60% of people over I think it was 65 had portal access. But then, when you dug one level deeper, there was a huge educational attainment gap where if you looked at high school and below versus some college and above, there is a 20% gap. And that's, actually, the same race based divide gap, which indicates that probably the contributing factor is educational attainment. But it was pretty sobering that if we're looking at portal based access as our vaccine enrollment mechanism then, by definition, we've got a 20% attainment gap or 20% outreach gap. Let me just restate what I think their first topic is, which is the general topic as we're using machine learning and AI to learn appropriateness of care or clinical decision support.

It's very important that we not unintentionally learn pre-existing bias. Is that the point there?

Ken Kawamoto
That's exactly right where we might be systematizing the impact of bias rather than anything biologic related to race.

David McCallie
That's a good point. And I also have a concern. Just sort of almost the irony that as we try to become race and gender blind in the sense of being blind to the biases or eliminating our biases to force people to ask these questions and capture the data is a conflict. And I think there may be some cultural issues that affect how people are trained at points of care to capture some of this information that I get a sense hasn't been really thought through. Let me ask if anybody on the call or anybody in our group is aware of or participating in the HL7 FHIR Gravity Project, which, apparently, is working on profiling FHIR for SDOH.

Arien Malec
Ricky has got his hand up.

Clem McDonald
I've had a little involvement.

David McCallie
Ricky?

Arien Malec
Clem, if you can just raise your hand and we'll get Ricky first and then, Clem, we'll drop you in.

Ricky Bloomfield

Yeah. Thanks. I have not been involved in Gravity. But I just wanted to make a comment that on the bullet here why it's sensitive to data and so often not being captured. One of the things that comes up and I think it's been touched on a little bit is concern about privacy and how that data could be misused and could, potentially, result in additional bias. Obviously, from a healthcare perspective, having that information is really, really important so we can have the complete data. One of the examples that has come up recently, and there have been some articles about it that you may be aware of, is how GFR is often reported as having two different versions, a high version and a low version. And I think there was a *New England Journal* perspective on this that the underlying data that they found that the black population that they were using to measure, actually, had worse function. It wasn't a genetic thing or an ethnicity thing. It was just that that population had worse function.

And then, that was built into downstream use cases of being eligible for a real transplant and they were being denied access because of this GFR value that was being reported erroneously. And so, now more organizations are moving to remove that distinction. And so, it's just one anecdote that shows how sometimes, there are good intentions in trying to find information and distinctions there but it can, actually, lead to a lot of significant unintended consequences.

Arien Malec
Right. And that's probably secondary to systematic undertreatment of hypertension for black Americans.

David McCallie
Yeah.

Arien Malec
And, again, just a central point that Ken was noting about our algorithms are learning bias as opposed to learning essential differences. Clem.

Clem McDonald
Well, there are a couple of things. I have a little bit of a connection with Gravity. And they really worked through a pretty darn good set of questions and they've gotten standardized and everything. So, I think it's moving well. And there is a lot of support from it. The second thing is about smart phones. So, it's really an age thing maybe in addition to mostly age rather than a race thing. So, 96% of people in the US up to age 30, I just found out on the web, have smart phones. Something like 94% up to age 50 and then, it drops off fast. So, old people don't have them. Maybe old blacks have fewer of them. I don't know that. But I think we have to pay attention to the age cut offs on these kinds of things. And then, there was a third thing but I think I lost it that I wanted to add, too. Never mind.

Arien Malec
Okay.

David McCallie
Well, one of the things that I thought about when I read about the Gravity Project and I was impressed with at least the scope of what they are trying to address is that we might invite someone from that group to address our group if we think this is a priority item because it may well be that much of the work that we

would argue should be being done is being done. And we might just endorse it. So, that's something we'll have to consider as we plan our future meetings is whether to invite someone to help dive in.

Arien Malec
Just something I've been thinking about as we've been having these conversations to call out to ONC staff that I think it's going to be really important for us to hear from the people who – the makeup of this particular task force is pretty heavily white and Asian. And I think it's going to be really important for us to learn from and hear from people of color who are working to address some of these topics. So, I think we're talking about big things. I think we're going to need to hear more perspectives as we work our way through this area.

Clem McDonald
If I can come back to one of the questions about the lack of collecting the data, to emphasize that and the call of the data from CDC, over 40% had no racial data. And at my hospital when I was in the hospital, there was a real reluctance of clerks, whether they're black or white, in fact I think it was more often they were black, to ask a person that data because it made them feel like they were being racist.

David McCallie
That was my point about the cultural issues here is that we can have all of the standards in the world and good implementations and people just don't want to capture it. I get offended when people ask me those question in surveys and things like that. Why do you need to know what I am? I think in EU, it's illegal. You can't even ask it. Okay. Let's move on. Next slide. Hang on a second. Is that out of order? No, no, that's right. I'm looking at my notes wrong. Better usage of EHR data. The broad thought here is there is digital data on the table that is not necessarily being utilized, particularly in urgent situations where you need access to that data. For example, in hypothesis generation at the beginning of the pandemic, I was watching back in March on Twitter and people were fretting that we didn't know what drugs to try and whether people were trying drugs and nobody knew whether they worked or not. And there was a thought that there was a lot of EHR data that could have helped with those questions.

And I think over the course of 2020, some of that data started to flow. Vendors started doing vendor specifics amongst their clients, aggregation, identification, and serving up the data. But it took a long time. And it occurred to me that maybe with the bulk API's that are now coming into required implementation for EHR's and with the stabilizing around things like OMOP and OHSDI, not that that's the only choice, maybe we could do a better job of responding urgently to aggregation of data for purposes of helping understand what's happening in a pandemic. That's as opposed to clinical trial use of the data and real world evidence use of the data, which are also on this slide as broadly part of the notion of better capitalizing on existing EHR data. This one strikes me as something that is in the purview of ONC and could be a really useful area. Personal preference there. But what do others think? Any ideas? Are there any hands up?

Arien Malec
Clem has got his hand up.

David McCallie
Clem? We're not hearing you, Clem. You might be muted.

Clem McDonald
Why we're not focusing more on health information exchanges which have already aggregated data. And one of the problems with data that's not pre-processed is it's often crummy. It helps when they run it through some filters before they put it together. And when you grab it once that need is overlooked. But in any case, we just seem to ignore the health information exchange as a source of aggregated data, which is often organized in an easier way than going to 10 different hospitals. Or maybe sending it to those health information exchanges.

David McCallie
Okay, good point. Not to debate it at the moment, we'll come back to it if it gets our – any other comments on this one?

Arien Malec
Yeah. I just think we should look at the UK recovery experience. I think most of the data that we have, for example, on dexamethasone use anticoagulant therapy, the rule out trials for hydroxychloroquine and ivermectin were all done in the UK in the recovery trial framework. And I think we've got equivalent electronic health infrastructure in the US but we don't have the mechanism for doing that level of call it comparative effectiveness research. So, I think we should just look at what was it in the UK that made the recovery trial framework effective that's a missing element in the US.

Clem McDonald
Good idea.

David McCallie
Yeah. Great idea. Okay. Given that we've got a lot to cover still, let's go to the next slide. Gaps in adverse event reporting. Arien, I think you may have been the one that brought this one up. Do you want to explain what the opportunities here might be?

Arien Malec
Yeah. So, FDA has set up a set of electronic adverse event reporting structures. FDA requires adverse event reporting. There's a VAERS form for vaccines. There's equivalent forms for drugs, biologics, and medical devices. There's a singular reporting structure. That reporting structure requires accessing the portal and typing information into a portal. So, it doesn't have the ability to extract information out of an EHR and send it to FDA. And then, there is, actually, an electronic safety reporting system but it uses clinical trials terminology like MedDRA as opposed to clinical terminology like SNOMED and ICD-10 for the underlying terminology. This is a standards gap state. The ideal state here is that there is an easy to use safety reporting mechanism that works across drugs, biologics, vaccines, and medical devices and allows for easy generation of adverse events out of EHR's for signal detection into FDA that isn't tied into the FDA clinical trial standards.

And that might also require FDA to, I know this is kind of shocking if you're FDA, map MedDRA over to SNOMED. And for all I know, ILM may already have done this.

David McCallie

Are there any comments on this broad topic? If not, let's move to the next slide, please. Contact and exposure tracking. I think the self-evident topic. There were some early gaps. Early in the pandemic of 2020, the Duke Margolis work group put out some recommendations about gaps in outbound lab data that was missing demographic data that made contact tracing more difficult. So, that's one point. Another one is there have been a number of experiments, probably a dozen, of using smart phones to track exposure based on proximity with blue tooth and/or other proximity detection measures, GPS, etc. Maybe there is something that's emerging from the learning in that space that we could focus on. And it occurred to me, I put this one on the list, is that the NBA and the NFL were reasonably successful in their bubble management and is there anything to learn from that.

Did they do something or figure out something that we could leverage from? Comments on this one? Clem, your hand is up.

Arien Malec
Clem is on the list. One other thing to add here is, as we go to rapid testing approaches, how do we make sure that we have case reporting tied into rapid testing. Clem?

David McCallie
You are muted, Clem.

Clem McDonald
Extreme resistance to conceding that the virus could be transmitted by error to us all, which I think is finally relaxed. But nobody has studied the ventilation systems in nursing homes, the ventilation systems in ships, which are known to have poor filters. Nobody is filtering the air in these places to figure out where the risk is and the details about it. It's all been the businesses who have, actually, even highlighted the area by doing the flow of little droplets around. So, I think it's almost sinful that we've missed that point. And I don't know whether that's an informatics thing. It probably isn't.

David McCallie
Yeah. I know they did some amazing experiments in Germany. I think I was reading about a massive study with ventilation in a theater with careful tracking of how the exposure was affected by outside air versus air, where you sat in the theater, how close you sat. It was a remarkable, massive study. So, it's been addressed by some people.

Clem McDonald
I've seen some of those but they haven't, actually, measured the sampling. There are air sampler devices for viruses. Although, you've got to be careful of **[inaudible] [00:49:59]**. Anyway, I think we really screwed up on that one.

David McCallie
Okay. Ricky, are you still on? I was going to ask do you feel that the Apple, Google, smart phone exposure tracking is worth our attention? I don't mean to put you on the spot. You may not feel like you're allowed to respond.

Ricky Bloomfield

Sure. I'd be happy to share a little bit. I think there have been a lot of conversations on this topic mostly with public health authorities. And given that this needs to be driven by them and their implementation, it's also been implemented around the world. And perhaps there is something that we can learn. I just put a link in here to the UK government. They've done a lot of research on this topic to know how effective it has been. And based on their analytics, they predict that 600,000 cases have been prevented. Obviously, there are differences between how things work in the US and how things work in other countries that we need to be mindful of. To your question as to whether this should be an area of focus, it seems, to me, that there are a number of conversations with the CDC and others in the US on how to do this. And I'm not sure if there is an explicit role of DONC to do more here or to offer standards since that's our charge beyond what's already there.

But, certainly, it's worth at least considering here. And if there is something specific that someone can think about that might be worth exploring, we should definitely discuss it.

David McCallie
Thanks. Okay. Let's go to the next slide, please. Care plans and the burden of chronic disease. This is, as I mentioned, sort of an unfinished area from our 2019 discussion. I think, Arien, maybe you were the one who raised this in our first meeting's discussion. And I know, Ken, obviously, you were very involved in driving the 2019 conversation. Do either of you want to say anything about this one?

Ken Kawamoto
Sure, I can comment. I think related to this also the notion of how can we provide higher value, lower cost care. I think it's sort of related to that. But the challenging part is it's a very big topic. And it's very hard when it's a big topic on how we're going to address these things. One way to, potentially, narrow this down is to say what are specific data elements needed for things that we, specifically, are trying to address. So, one example might be new lung cancer screening guidelines just came out last week. And as it turns out, FHIR doesn't include a few key data elements in there. And the current USCDI process, the way I'm reading it, it might take another five or ten years to move it forward. So, looking at it from that perspective and as we think about what are the things we probably should do that we're not doing, one of them might be a process that's going to take 10 years to address screening and preventing the No. 1 cause of cancer deaths in this country.

So, that might be one way to sort of narrow it down to say if we're trying to address these kinds of issues, where are the gaps and what's going to happen if we leave it to status quo. So, that's my thought there.

Arien Malec
Ken, thank you. And then, I would just add to that that the basic notion is sort of in the should category, which is that patients, providers, nurse care managers should access a shared plan of care that is prioritized and rank ordered and salient for the patient. I think there are some standards in this place for plan of care. It might be worthwhile just looking at the scenario where there are early success stories that we can lean on. Is this a standards gap or a clinical practice gap issue? And I think we'll get into this when we think about the prioritization framework. I think if we think about our own lives, we would note that plan of care often happens in the conversation with a physician or the nurse. They're scribbled notes. They're scribbled discharge documents. And so, there seems to be a gap here but maybe some network stickiness in terms of addressing the gap.

David McCallie
Go ahead, Clem.

Arien Malec
Clem, check your mute button first before you start talking.

Clem McDonald
Well, I worry a little bit about focusing on more documentation rather than more health. I think that Ken's idea is good. We should focus on actual things that we could gather instead of documentation that would, actually, be actionable and useful. Physicians are already hating computers because of the amount of documentation they have to do. And they don't really feel it's doing a lot of good for health. So, that's my only concern. If we focus down and pick the things that can have an effect or we know have an effect, those are the things we should do.

David McCallie
Yeah. Clem, that was what I was going to say as well. I have been in a conversation outside of this group with a couple of folks who are working on the FHIR care plan refinement. And I have looked at some of their early work. And it's beautifully elaborate and detailed and logical. But the burden of capturing all of that information in the process of giving care strikes me as overwhelming. So, I have serious fear that we could have a beautiful theoretical model for what a plan of care should look like but no one would ever touch it because it doesn't degrade gracefully into the real world of actual decision making. That might be a topic.

Arien Malec
I think it would have to be some prioritization framework data because I think this is conflated prioritization framework of how do we think about jobs that want to get done but aren't getting currently done by the health system or getting done by the healthcare system or getting done in a way that is patient friendly but getting it done more friendly, actually, as documentation burdens. But we can talk about that in the context of the prioritization framework.

David McCallie
Okay. So, let's move to the next one. Better and easier binding between persons and their digital devices. I think this was Les Lenert's topic and I don't see him on the call today. I didn't gather in my notes a lot of information.

Arien Malec
I'll just sort of do an editorial. I think there are two things here. One is medical devices. So, how do we better tie medical devices into the interoperability notions that we have and the basic notion. And I think the HIT Standards Committee called for EDI to be included in USCDI. And there has been a long running call for EDI to be included in claims. As far as I know, neither of those two things have been done and universally collected. And then, I think Les's point was, or whoever raised this topic, how do we better tie patient identity into the digital devices that they currently carry and can we use those digital devices as tokens for identity and authentication and authorization. And Ricky might have something to say about this topic. But there is

a pretty obvious point that the device that people carry around is, in many cases, one of the best tokens that we have for who they are and what they've authorized.

I don't know, Ricky, if you want to comment.

Ricky Bloomfield
Yeah. I don't have too much to say. I agree with what you just said. I think the key here would be to do this in an open standards based way, of course, and see the alignment across the ecosystem and defining the specific use case exactly what you want to achieve with it and then, which standards could be used or could be created for that purpose.

David McCallie
It strikes me that maybe some of the work that's being done on the vaccination passport and that uses some of the W3C sovereign identity management or personal identity management standards might have some relevance here. But it's beyond my knowledge level. Maybe there is some spin out from that work.

Arien Malec
How are we doing on time?

David McCallie
We're at the top of the hour. So, we have 30 minutes. And we only have –

Arien Malec
I think we have 20 minutes because we've got to give open time for public comment.

David McCallie
Right. And we've only got two more topics here so let's buzz through them. Next slide. Integration of clinical and administrative data. I'll just reference that there are several efforts underway outside of the strict EHR clinical use of FHIR to profile administrative data, electronic prior authorization, the DaVinci work, some of the groups that are trying to leverage fast FHIR or bulk FHIR is a better way to describe that for aggregating data for other purposes besides direct patient care. So, this is just a broad place holder. Are there any suggested areas? I think, Arien, you were the one who brought this up.

Arien Malec
Yeah. The ICAD recommendations in the space, David, where the ICAD task –

David McCallie
Which one?

Arien Malec
ICAD.

David McCallie
I don't know that.

Arien Malec
Yeah. It's the Intersection of Clinical and Administrative Data Task Force that submitted recommendations to ONC. So, there is a pretty good baseline of recommendations that we could look at. Clem has his hand up.

Clem McDonald
I just want to know how it's coming. These areas that are very active now but I've not been able to keep connected. But somebody somewhere along the line could give us a summary of how it's moving. Is it happening? Is it getting there?

Arien Malec
Yeah. So, maybe I'll give the status here, which is that the DaVinci PA recommendations were called in to CMS regulation for, I believe, QHP's but not MA plans if my memory serves correctly. I wasn't sure why that distinction was made. The ICAD task force made a broader call that looks at ePA as the first use case but notes that the intersection of clinically adjudicated claims or clinically adjudicated authorizations, use of attachments and the like is becoming more prevalent and that there are no attachment standards named by CMS. And broadly, just based on the slow progress of administrative standards relative to clinical standards, even though the rest of us are tearing our hair out at the slow pace of clinical standards, the recommendation was for ONC to align the standards evolution framework and to set a road map for aligning clinical administrative standards.

And the natural implication of that is we probably should align all of our standards around FHIR but also just make sure that we've got harmonization of clinical models and administrative models to make sure that we're asking for consistent data and data sets and can represent them in consistent ways. So, that there isn't such a divide between administrative standards and clinical standards. So, the summary, Clem, to your request is the ePA recommendations that were made by DaVinci are enshrined in regulation at this point. And then, there is a broader call for broader alignment between administrative and clinical transactions. And even though the ICAD task force was a sub task force under the HITAC, about half of the membership with NCVHS as well, which is the socket that makes recommendations on administrative standards to CMS. So, there is also, potentially, another recommendation that we start to align the work at NCVHS and the HITAC.

Clem McDonald
Thank you, Arien. That's very helpful.

David McCallie
The next slide, I think this is our last one. Better data sharing between the systems that are inside of the military standard security layer of the VA and DOD and outside community of care.

Arien Malec
Maybe I'll make some editorial comments to frame it and then, we can decide in our prioritization framework whether to pick it up. But this is a recurring need. And it shows up in some of the TEFCA work. It shows up in some of the work that VA and DOD, if they're adopting a new EHR and thinking about joining national networks, is wrestling with. I've come across this work in administrative networks as well. And the systematic issue is that VA and DOD are held by FISMA and NIST RMF standards to a certain security

posture for VA and DOD owned data. There are security classifications, for example, in the DOD. Health data is considered critical readiness data. So, as an example, if you've got COVID infecting a large number of service members that could be a sign of military readiness. And so, that data is classified at a fairly high level of sensitivity.

And that's all great when you're inside the DOD boundary or inside of the VHA boundary. But when you start thinking about, as an example, VA trying to interoperate data on the veteran's behalf with health systems using national networks, you think about DOD doing the same thing for service members that are cared for by Tri Care and are receiving care in the community, most VA vets primarily receive care in the community, have primary insurance that is commercial insurance and then, use VHA benefits a secondary insurance for certain conditions. Often, for example, doing med renewals through the VHA. And so, when you think about trying to apply the DOD and VA security boundaries and the Fed Ramp requirements for cloud based services, you start thinking about where is the service boundary between VA and DOD and where is the commercial land.

And one level of absurdity says that we just apply all of the VA and DOD security controls and mandate Fed Ramp CUI for everybody. And that's the minimum security standard for everybody. And if you do that, you're probably raising the security bar for the US healthcare system but you're effectively, running all of the US healthcare system on a federal standard as opposed to addressing the federal commercial standard mismatch. We saw this also in Direct with the level of assurance that was required for signing certificates and authentication certificates. It's been a persistent issue of how does the VA and DOD interchange data with the rest of the US healthcare sector.

David McCallie
Okay. Are there any comments on that broad topic other than Arien's thorough review? Clem?

Arien Malec
Clem has his hand up.

David McCallie
But not his mic. Clem, go ahead. Open mic.

Clem McDonald
It's a regulator thing rather than a technical thing. And it's been killing them. It's been killing us in a lot of spaces where we're not cohesive in that area. So, in Indianapolis, all of the hospitals participate in IHE. VA couldn't. I think I heard rumors that they can now. I don't know if that could be true. But there are all of these things and they're so privacy conscious excessively beyond any reasonable use. And much of it might come from these regulatory legislative things I don't know about. But they've got to deal with those things.

David McCallie
Yeah. That's why it got on our list. I think that's the scope of our existing domains. The last domain is the vaccination passports, which we've said that we are not going to dive into any deeper since ONC is already running with that one and has groups already running with that one. So, Arien, I think our plan is to shift over and talk about how we might think through the prioritization of these domains and anything else that we add in. So, the show is yours.

Framework and Prioritization Discussion (01:08:47)

Arien Malec
All right. So, we're just going to walk through some proposed prioritization and recommendation frameworks looking for feedback from this group about whether the approach for prioritization makes sense and the approach for recommendations make sense. We're going to do a hard stop at 12:25 to open up for public comment. So, let's go to the first slide. All right. So, the first proposed framework for prioritization. We're just going to assume that given the list we walked through, we're going to have more that wants to get done than is going to get done. And so, we need to put a framework in place for prioritization. So, the proposed framework here is let's prioritize areas that align with ONC declared priority areas. That's COVID-19, health equity, 21st Century Cures enablement, and unmet needs on the existing ONC road map. Let's avoid areas already being covered through existing ONC initiatives. So, our commentary on the vaccine passport initiatives sort of falls in this area.

And then, once we've thought about our priority areas, let's prefer foundational and/or leveraged areas. So, where is the solution that unlocks other solutions as opposed to a solution that is what's in the trunk versus what's the least in my computer science graph theory way of thinking about it. Similar prioritization framework. Let's prioritize areas that have general solution areas or general solution domains over something that is specific and solves just one thing. Obviously, if that gets trumped by overall prioritization, so be it. But in the context that we have a choice, let's prefer things that have general applicability as opposed to specific applicability. Existence of well defined policy levers over novel policy levers required. So, it's nice to want to advance an area. And we'll see this in the next slide in terms of how we think about the recommendation. But if it requires completely new policy leverage to go get done that might be a reason to shy away. It might not.

And then, as we were discussing in the plan of care conversation, we should prefer areas where the jobs are already being done but inefficiently over areas where we want the health system to do better. And, again, that's a little bit of a double edged sword. But we're likely to have more traction where something is being done already. But if it's being done in a dumb and inefficient way then, we are going to get traction in a case where we want something to get done but it's just not getting done right now. So, I'm going to pause and see if these prioritization framework concepts make sense and if there are prioritization items that we're missing as we think about how we prioritize these items. So, in general to repeat, it's let's look for need first lined up against ONC objectives, striking out anything that ONC is already addressing. Let's look at generality and leverage second. And then, down in kind of a third tier priority, let's think about areas where there is express need already as opposed to need that wants to happen in areas where there is already some policy guide rails or ground rules. Are there any comments?

If you have to noodle on this because it's the first time you've seen it, this is not your last crack at it. But please do noodle on it and think about whether this is an appropriate mechanism for prioritization. Seeing no hands up, let us go –

David McCallie
I think it's good, Arien. I like it.

Arien Malec

Seeing no hands up, let's go to the next one, which is how do we think about recommendations? And so, this came out of some conversation with ONC about some of the feedback from the last ISP task force. It's useful to chunk recommendations into timeframes. So, in some cases, there is work that can be done immediately. In other cases, there is some timeframe implications that may be medium term or long term. And this is useful to set expectations for ONC that we didn't deliver 50,000 recommendations and there is a pregnant assumption that they all need to get done right now. In many cases, we have prioritizations that are easy wins and other areas that are going to require some more foundational work. And it's useful to call up the foundational work. And then, we also want to consider the type of action required just from easiest to hardest. There are areas where there is industry alignment and voluntary action around existing standards.

So, as an example, when we looked at this from the Duke Margolis task force on COVID, we saw that the standards for ELR and the standards for lab orders was already there. And there was better alignment needed around what data is required to collect. In many cases, that just required people to stand up and raise their hand and say, "Yeah. I'm going to go, actually, wire the wires that aren't yet wired together." I think a lot of the finding was that this data was in EHR's but it wasn't flowing over to labs. And from labs, it wasn't flowing over to public health. And so, this may just be an area of wiring of things around existing standards. We have a standards gap but there is clear alignment that we need to address. We have standards but we have a gap relative to adoption of the standard. But there is clear alignment that we must need to go do and put in the hard work. Everyone agrees we should put in the hard work and so, we just go do it.

Second is we don't have the standard or the standard isn't yet where it's ready. And so, therefore, there is some standards work that is required. And this is an area where ONC aligns with industry and with SDO's following the playbook that ONC has gotten very good at, which is to define priority, get the SDO's in place, get industry in place and go work through some of the nitty gritty standards work to make sure that we have standards readiness. And then, the third set of actions are harder. In my experience, they are sets of actions that end up being more leveraged. So, it's unfortunate that the hard thing also is the more leveraged thing. But we discover a lot of times we have all of the standards we need but they're just not all getting used. And so, that's an incentive alignment problem. And, again, striking from easiest to hardest that might be that we need to line up ONC certification requirements with other HHS rule making requirements. The classic one there is making sure that we get CMS leverage for adoption along with ONC leverage for adoption.

It's slightly harder as incorporated in CLEA and FDA, IHS, other areas where there are other non HHS factors like FEP or DOD and VHA. So, that's an example where the federal government just needs to line up incentives to point in a consistent direction. That's easy. The second area are areas where there is literal acts of congress that are required. So, as an example here, Patty Murray is part of the health committee and has proposed a bill for creating consistent funding for public health and tying that funding to standards. We may or may not want to endorse that overall approach but that's an approach that requires literal acts of congress and appropriation. And then, down at the hardest level are cases where, in the classic area here, is HIPAA alignment or health privacy alignment where if only states, generally, did more or less the same things, we'd, actually, get more interoperability. And that's been a time in memorial issue that we've been working on.

And we keep saying the same thing. So, I just want to be very clear. It's hard but still needful if we believe that multistate alignment is required. So, again, just to repeat the prioritization framework for recommendations on the top, let's consider the timeframe for recommendations and also, let's consider the type of policy alignment or the type of work that's required to advance the ball. Whether this is we got the standards and we need to use them and there is, actually, alignment we need to use then, this is more of a project management, national coordinator bully pulpit role. Second is we, actually, need to develop some standards and test them and put them through the standards evolution or whatever we called the standards evolution framework, which we've now got a good one on ONC. And the third one is where we require more incentives and more incentive alignment. And that requires some hard regulatory work. So, I'll pause there and see if this makes sense as a proposed framework for recommendations.

Please raise your hands. And, again, also feel free to noodle if this is throwing a lot at you and you need to think about it and add something. You'll get another crack at it.

David McCallie
Arien, when is your textbook on how does government work coming out?

Arien Malec
I've also been calling for Steve Posnack to do his recurring podcast on take a gritty bit of regulation that you think has no business being there and trace it up the stack to what congress asked for and how does the APA work. And there is just so much nitty gritty that's involved in getting this stuff done. It's fun stuff but it's also mind boggling.

David McCallie
So, what I think our challenge might be is a little bit of offline challenge for Arien and I and the ONC team and then, it comes back to the group for refinement would be how to collapse these I would say profound and deep thoughts into something that could be put into columns of a spreadsheet where we have check boxes and ways to capture at a high level how to score some of these ideas and then, apply some kind of a scoring algorithm that we could generate a rank.

Arien Malec
Agreed. And I think, David, you have alluded to this in the beginning that there are some cases where, even though something is hard, it is worth saying and, again, let's look at the MedDRA case, we recommend that ONC work with FDA to create a standard for safety reporting that aligns with clinical standards and not just clinical trial standards. It's useful for other federal agencies to hear that a FACA lined up and said yeah, this is important, go do it because if you think about ONC and their long list of things that want to get done, FDA and CMS and IHS and FEP and DOD and VHA all have their long lists of things that need to get done. And it's useful to hear that at least some congressionally mandated federal advisory committee said, "Yeah, this is important. Go get it." We should open up for public comment.

David McCallie
Mike are you going to –

Public Comment (01:21:04)

Michael Berry
I'm just getting myself off mute, thank you. Operator, can you please open up the public comment line?

Operator
Yes. If you would like to make a comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press star 2 if you would like to remove your line from the cue. And for participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment while we poll for comments.

Michael Berry
Great. And while we're waiting, I just wanted to note our next call will be this time next Thursday, March 25 from 2:00 to 3:30 Eastern Time. And we sure appreciate you joining us today. Operator, are there any public comments?

Operator
There are no comments at this time.

Michael Berry
Okay. Thank you.

Arien Malec
All right. Well, we definitely welcome public comments. And the future of standards evolution is worthy of public comment. But hearing no public comment, I think it's probably worthwhile giving the five minutes to prepare for the next meeting.

Solicit Additional Ideas (01:22:22)

David McCallie
One question, Arien, and maybe to Mike and ONC team. We were going to spend a little time soliciting for additional ideas. Obviously, we ran out of time not surprisingly given how much we had to cover. But would it be appropriate if members want to send us emails with suggestions to cue up for the next meeting that they could do so? Is that an allowable approach?

Michael Berry
Yeah, sure. That's no problem.

David McCallie
Okay. So, hopefully, the remaining members heard that. If there was something that we lighted over or something we just completely missed that occurred to you in the discussion today or between the two meetings, just put a little, brief description and send it in an email to Arien and I and we'll make sure it gets on the agenda for future conversation.

Arien Malec

Yeah. And we'll make sure that anything that comes in through that channel gets exposed through the public forum.

David McCallie
Yeah.

Arien Malec
All right.

David McCallie
Very good. Thanks for hanging in there.

Arien Malec
Thanks, everybody.

Adjourn (01:23:49)