



Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE 2021 MEETING

May 6, 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
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
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

Thank you. All lines are now bridged.

Michael Berry

All right, thank you very much, and hello, everyone. I am Mike Berry, I am with ONC, and I would like to welcome you to the Interoperability Standards Priorities Task Force. We really appreciate you joining us today. I will open up the meeting today with roll call, and I will start with our co-chairs. Arien Malec?

Arien Malec

Good morning.

Michael Berry

David McCallie?

David McCallie

Hello.

Michael Berry

Ricky Bloomfield? Cynthia Fisher? Valerie Grey? Jim Jirjis? Edward Juhn?

Edward Juhn

Here.

Michael Berry

Ken Kawamoto? Victor Lee? Leslie Lenert?

Leslie Lenert

Here.

Michael Berry

Jack Po? Raj Ratwani? I know Ram Sriram has a conflict. He will be absent today. Sasha TerMaat? And, Andy Truscott? Okay, if I missed anyone or you join late, I will catch your name in the roster later. I would like to turn it over to our co-chairs, Arien and David.

Introductions, ISP Task Force Timeline 2021 & Proposal, ISP Task Force Work Timeline (00:01:19)

Arien Malec

All right. I think we have an action-packed agenda today, mostly focused on putting together draft high-level recommendations for the HITAC meeting next week. The HITAC meeting is primarily going to be focused on public health data systems, but for us to meet our June deliverable for recommendations, we need to put something in front of the HITAC for them to at least say we are on the right track or wrong track, and then follow up with more detailed recommendations for the HITAC meeting in June. Can we go on to the next slide, and the next one after that?





So, here is our overall timeline. It may surprise people, but we are actually in May, and we have until the HITAC meeting in June to get to recommendations. I think the good news is we have a lot of really good input. We have heard from a bunch of good testimony in terms of standards readiness, and I think we are in a great position to be able to offer recommendations. We just need to operate expeditiously between now and then to get those recommendations in place. Go on to the next slide.

As a reminder, we lined up to make recommendations on health equity standards, real-world comparative effectiveness, recovery-type EHR data use, and clinical/administrative data and standards harmonization burden reduction, and then to consider recommendations on these three activities. Based on the input of folks from the task force, we managed to put together a set of draft recommendations, so we are going to review those today. We also decided to defer public health recommendations to the Public Health Data Systems Task Force, which is hard at work, and actually is publishing recommendations by July, which will be a good sprint there, as well. Go on to the next slide.

This is how we thought about the timeline working through. Today, we are presenting high-level recommendation drafts and getting input and discussion from the task force. We will do some offline homework between now and May 10th and 11th in order to get to draft recommendations to present to the HITAC, so if you have not been able to get your input in, we will have another turn of the crank Friday, over the weekend, and Monday and Tuesday for the Thursday HITAC meeting. And then, based on the feedback from the HITAC on May 13th, we have three other meetings, May 20th, 27th, and June 3rd, to do homework and get to detailed recommendations in a formalized recommendations letter, and then, on June 9th, at the HITAC meeting, we will present our final recommendations. David, any comments on the timeline or any comments from the task force in terms of working through this timeline?

David McCallie

No. I think that is a nice summary. I will reinforce the notion that what we need to get through today is the high-level stuff because we have enough time to flesh out all the details, so I think as we discuss what we have in the slides for high-level, it is a good idea to surface some of the low-level stuff, but let's not worry too much about getting all of that captured in these slides. This is basically a test of whether we are headed in the right direction for HITAC, if I understand it.

Draft High Level Recommendations Review and Discussion (00:05:26)

Arien Malec

Exactly. Any comments from the task force in terms of the overall timeline before we get right to the meat of this meeting? Coolio. Let's go to the next slide, and the next one after that. Okeydoke. So, here is the actual meat of the discussion. We are going to present each slide. I will give a brief overview of the slide content. I am not going to read and drain all the words from the slide, but I am looking for the task force to provide feedback as to whether this appropriately addresses task force input and is an appropriate recommendation.

So, the first three slides really focus on foundational standards, and if you remember when we thought about prioritization, we thought about making recommendations relative to foundational standards and then making recommendations on specific high-priority areas. So, you might wonder where these foundational standards came from, and these are really the foundations behind the specifics: Public health, EHR data





use, and clinical/administrative burden reduction standards that we talked about. So, I think FHIR Hooks in general is best positioned to provide a standard way to publish a triggered workflow in an EHR that is triggered by some event.

So, as an example, in the ePA use case, it is triggered by an order or referral, in the public health use case, it is triggered by documentation for a travel history, for example, for Zika, and then, for the recovery-type trial, it could be triggered by registration or initiation of an encounter to trigger, for example, a randomization event. FHIR questionnaires are heavily used by the Gravity Project as a standards-based way of collecting information that is not captured in the EHR.

One could also, again, imagine this in a research use case to be able to collect non-EHR data. And then, FHIR consent directives are foundational standards used in the Gravity Project through questionnaires, but also have more generic use in a recovery-type trial usage to be able to capture consent directives or authorizations relative to research, and our recommendation here is that ONC should invest in testing and development activities to track these standards and related implementation guidance for broader maturity to incorporate new certification criteria. And, I will pause to collect task force feedback on this recommendation.

Ricky Bloomfield

This is Ricky. I think that makes sense. One thing that we might consider as well is the FHIR subscription, which is one of those foundational pieces that allows for reduction in the polling that happens today because there is no notification when new data is present, so it requires any connection to poll for updates, and it has one implementation guide, and there is additional work going on this year within Argonaut to further flesh that out, so I think there is a question as to whether it is mature enough to be included here, but it could be considered one of the foundational pieces of FHIR.

Arien Malec

Fantastic, yes. So, way back when in the ATI Task Force, David and I contemplated Pub/Sub as a foundational piece for an interoperability mechanism, and it sounds like FHIR subscriptions are the Pub/Sub.

Ricky Bloomfield

Yes.

Arien Malec

We will definitely take that feedback into advisement, and I think it makes sense to include it in this list, potentially at a lower level of maturity.

David McCallie

Arien, there is one thing that we can work out with ONC's input. We could express these as particular standards and have the use cases that we envision underneath them, but an alternate would be to position it as standards priorities or interoperability priorities and then list the standards under them, so the priority might be to capture consent in a more fluid way for sharing of sensitive data, et cetera.

Arien Malec





Yeah. So, basically, flip the order of the “in order to” and list the “in order to” as primary and the actual enabling standard as secondary. That makes sense. Any other folks from the task force?

Leslie Lenert

This is Les. I have a couple comments. Some of these are actually relatively mature compared to other things we have already pushed out into USCDI or other things like that. Second, I would like the last sentence to be a little bit more forceful. “...should prioritize the standards for incorporation of certification criteria.” You could fit in evaluation and testing of the standards for incorporation criteria. And then, under the consent directive, I would urge you to change... So, I think clinical research is good, but I think you should add advance directives as an area for consent because [inaudible – crosstalk] [00:12:02] interest of patients in limiting care and the difficulty of getting that inserted. I think that would make it more... When you say “consents and authorization,” that is usually administrative. Advance directives are more clinical.

Arien Malec

Got it.

David McCallie

Good suggestion.

Leslie Lenert

To add to that, that was along the lines of my suggestion. This is Ed. Maybe in the last bullet, “ONC should advance,” it should be “advancing [inaudible – crosstalk] [00:12:35] development,” but also the adoption of actual engagement just so that this tracks the movement forward. So, I echo the comments. Thank you.

Arien Malec

Great feedback, thank you. Other comments? Let me just capture what I heard. 1). We want to make sure that we note FHIR subscriptions as a foundational standard, 2). Rather than the wishy-washy language, “track these standards for broader maturity and incorporate into the certification criteria.” We really want to talk about testing toward production use and incorporation of the certification criteria as the language in the recommendation. And then, lastly, we want to make sure that we call out advance directives in the consent directives use case section. All right.

David McCallie

That is what I have.

Arien Malec

Other comments? Otherwise, we will go on to the next slide. This has been fantastic. So, common data model. We have heard...

Leslie Lenert

Let me just say one more thing. It says, “Usual context for CDS Hooks is decision support.” I would put that at the front of that paragraph there on CDS Hooks.

Arien Malec





Yeah. The thought process that I have, which is the reason for my comment that CDS Hooks is probably better thought of as Hooks, is that what CDS Hooks actually does is trigger a workflow based on some underlying event, and the predominant or initial reason for doing that was plugging in CDS, but you can also plug non-decision-support workflows, and it is foundational for the capability for ePA. But, you are right, we definitely should list decision support as the primary use case for CDS Hooks because “CDS” stands for “clinical decision support.”

Leslie Lenert

People are going to ask, “What happened to decision support?”

Arien Malec

“What happened to decision support in the decision support standard?”, yes. Okay, so, we heard a bunch in the research section on common data models, and it actually came out in the ICAD Task Force’s recommendations relative to standards for administrative and clinical, and it is really a substrate of the overall recommendations, which is to harmonize administrative and clinical use cases. So, we proposed a set of recommendations on this slide that ONC should identify common staging data models and should map USCDI to those staging data models.

Sorry, I have a recommendation in each of these bullets, and I am confusing myself. There is garbled grammar here, but ONC should continue to map USCDI to HL7 FHIR and other foundational standards, such as V.2 and CDA, should build a clear and rapid roadmap to expand USCDI, which should incorporate research and administrative needs, and should identify common staging data models and map USCDI to those staging data models, as well as HL7 FHIR and other concrete interoperable representations.

There are a lot of words here, but the intent is that we should take USCDI, which is a clinical data set that is associated with API use and transparency and access for patients right now, and continue to advance it to make sure that it is maximally useful for research as well as for driving administrative needs around the primary premise that even if the data capture in EHRs is not sufficient for research or administrative purposes, it should be primary for the core data that is used in both those purposes, and the language here may be a little garbled, but hopefully, it communicates the intent. As I read it out, I realized that the language was not as clear on paper as it seemed to be in my head, but I am definitely looking for feedback here on these recommendations and whether they make sense and communicate the intent of the workgroup. Please raise your hand if you are able to do that so we can make sure to call on you in order, and if you cannot, then feel free to call out as soon as we drain the people in the queue. Les is first.

Leslie Lenert

I have a quick question. Did you mean OMOP rather than OMAP?

Arien Malec

I meant OMOP, yes, thank you.

Leslie Lenert

Oftentimes, it is /OHDSI. And, I do not know why you are calling it a staging data model as opposed to a research data model or an analytical, longitudinal... It is a longitudinal data analysis model.





David McCallie

Les, I think I may have been the one who put that phrase in here, and I took it from maybe Chris Chute or his co-presenter, whose name I am blanking on right now, with the notion that if you look at it from an ETL point of view, getting the data into the common data model is often step 1 before it is processed in the second stage to more use-case-specific data models, perhaps a data warehouse model or some other kind of optimization for whatever the researcher's needs are. So, the thought was that the common data model does not necessarily have to be the core of the deliverable, but it could be a staging area to downstream uses. That was the language in one of our presenter's slides. So, that is where that came from, but maybe we should have something about ETL in there, or something a little bit clearer.

Arien Malec

I think ETL is a little specific, so maybe we should just talk about high-priority common data models.

Leslie Lenert

I would say "research common data models." You do not want to exclude PCORnet at this point yet. Maybe you do. There is a whole group of people who do i2b2-related stuff who are going to get mad at you eventually.

David McCallie

Well, that is why I said "data models," plural. I did make that explicit change because I do not think there is just one.

Leslie Lenert

I would say "research data models."

Arien Malec

We will get into the specifics of the actual data models in the research section because we do call out... I think we even heard from PCORnet that most settings are mapping to OMOP, and then, secondarily mapping to the PCORnet data model that was derived from the FDA Sentinel data model, so we actually make some specific recommendations there, which may be controversial, and we can get into them when we get there, but I definitely take the point that we talk about research data models here. I will correct my typo here.

Leslie Lenert

I could be very happy with the language "broadly disseminated research data models."

Arien Malec

Yup.

David McCallie

I think putting a couple of the other ones in the EG, such as OMOP, i2b2, PCORnet, is not a bad idea at this stage of our recommendation. I do not know that we are in a position to pick the best one, but this notion that there should be expansion of USCDI accompanied by mappings would be the core models.

Arien Malec





Again, I think we will get into it when we get into the research section, but I think we did hear that it is a pain in the butt for organizations to do multiple mapping, and in many cases, they are just dealing with different representations of the same underlying data rather than some particular great reason to go from this model to that model. On the other hand, I think we also heard that the terminology questions that are the topic of the next slide are much higher in the priority list and are more salient. So, first of all, on the previous slide, are there any other comments from the task force? Cool, let's keep going before I confuse the team. Let's go on to the next terminology section.

So, what we heard is both from our research hearing and from our administrative burden reduction hearing that A). We are not doing a good job of source-normalizing data, and that requires secondary normalization, and B). Particularly to procedural codes, we are letting administrative standards drive data collection instead of clinical needs and research needs, and that the particular administrative standards that we are using are heavily U.S.-centric and not open and freely available.

So, our No. 1 recommendation is that ONC should use its direct levers to continue to standardize terminology while working with other related agencies at HHS, primarily FDA for analyte machines and CMS for CLIA, to correctly originate codes at the source for laboratory and other similar data to LOINC. That was the biggest problem that I think we heard. And then, ONC should, directly and through coordination with CMS, harmonize procedural coding standards to open freely available standards that are either international or clearly cross-mapped international standards and are optimized for clinical care, research, and administrative data use.

So, we thought about creating a recommendation about RxNorm, and maybe we should. The particular issue here is NDC to RxNorm and making sure that we have clear alignment around RxNorm as well as international work to promulgate RxNorm as an international standard as opposed to a U.S. standard. The issue with international standards for medications is that approved formulations in the pharmacopeia are different in each nation or each administrative region under separate regulatory control, and so, it is complex to map medications internationally, but it is a useful thing to do, and I think RxNorm probably has the best ontology in terms of being able to map active ingredients to generic names to brand names. FDA already does work at creating internationally recognized generic names for medications, and it would be useful to harmonize there. I am talking myself into the need for a third bullet here, but Victor has his hand up, so we will go to comment from the task force.

Victor Lee

Thank you. I was not the one who submitted this comment, although as I read it, it specifically mentions procedural coding standards, and I wonder if that is in specific reference to CPT, which I know is complex because it is in legislation, and so, therefore, we had to have regs for it. While I wholeheartedly agree with the RxNorm comment and agree with some of the limitations you mentioned, I do not see that as being so much of an issue as the proprietary ones that require licensure.

Arien Malec

Yup, that is why continued normalization under RxNorm actually is not a recommendation, but I do think it would be useful for ONC to work with FDA to harmonize NDC to RxNorm or continue to reconcile NDC and RxNorm so that we have a single standardized terminology set, but yes, the non-open, non-freely-available U.S.-only standard for procedural codes is CPT, so I think you are reading that comment correctly.





Victor Lee

Right, and if I recall correctly from USCDI, I believe that SNOMED is also a first-line recommended code system for representing procedures, and then, I believe ICD-10-PCS is listed as an alternate [inaudible – crosstalk] [00:26:55] as well.

Arien Malec

Yeah. I think that is right. I think the logical procedural terminology for administrative use would be ICD-10 or ICD-11, and then, the logical clinical procedural terminology would be SNOMED CT, and this is actually consistent with, for example, standards committee recommendations from back in the day. I believe John Halamka and Stan Huff published an article in *JAMIA* making recommendations for harmonizing to clinical terminology settings for procedural terminologies, so I do not think this will be a surprising recommendation, and I have said it is consistent with both the feedback that we have heard from the research data use team as well as the feedback we heard on the ICAD Task Force.

Victor Lee

Thank you.

David McCallie

We can put some of those bullet recommendations in a more granular version of this.

Arien Malec

Yeah, when we get to detailed recommendations rather than the high-level recommendations, it is appropriate to make those cross references. I try not to wave red flags all that often, but I think people know what they will do...

David McCallie

When did that happen?

Arien Malec

Maybe I could wave the red flag harder than I sometimes do. Okay, any other comments on this slide? All right, let's go on to the next one. So, foundational standards... Oh, wait, I do have it. We just split it across two slides. Good. So, in the transition to ICD-11, ONC should work with CMS and NLM to ensure SNOMED CT and ICD-11 harmonization to ensure a single source of capturing clinical data for multiple workflows. This is pointing out that with all the work that we did for ICD-10, we are going to do it again for ICD-11. And, here is the comment on RxNorm. The note on clinical on RxNorm and administrative workflows is that NDC is actually the coding system that is used for NCPDP transactions as opposed to RxNorm, so we have FDA and NLM doing what one might call dual warring standards out of HHS. Okeydoke. Any other comments on this slide? Cool, let's go on to the next one.

Health equity. So, David, unfortunately, I was not at the Gravity presentation, but this is David and my synthesis out of what we heard. I think we want to double down on the USCDI Task Force recommendations relative to Gravity. We want to make sure that for sex, race, ethnicity, and address information, No. 1, that we expand it for gender identity and sexual preference in accordance with the USCDI Task Force





recommendations and that we should ensure associated interoperability standards and EHR certification requirements, prioritizing the capture and exchange of this data for multiple purposes.

The gloss here is that if you actually look at the race/ethnicity coding standard, it uses the OMB standard with the CDC's terminology set, which allows for capture at CDC of fairly granular levels of race and ethnicity information and, at the OMB level, at the standard categorizations that we are all used to for administrative purposes. But, for example, when we looked at some of the work that we did early on in the pandemic, it had data flows for reportable labs all the way to public health. We discovered that in many cases, the information was getting lost in transit because it was not flowing all the way from the EHR to the lab to the public health authority. I am going to pause here.

Sorry, with ONC, on the work to harmonize address models, we heard from the At Health Task Force, I think it was called, looking at the Postal Service standard relative to standardization of address information, and that this is foundational information for geolocation information, and geolocation information is foundational for health equity in looking at, for example, food deserts, or vaccination pharmacy deserts, as I just heard today, or pollution data, or some of the other cross-correlates that we need to longitudinally map and geolocate and map health outcomes to the specific communities of interest. David, it looks like you had your hand virtually up.

David McCallie

Yeah, and I even clicked the button. It can go in our detailed slide, but my memory from the Gravity presentation is that I thought of it as three levels of work that roughly correspond to the staging that I think makes sense for ONC's pushes. Level 1 is the expansion of the nomenclatures to capture the social determinants. Level 2 was the design and promulgation of specific FHIR questionnaires designed to capture those expanded vocabularies in some kind of workflow. Level 3, which was the furthest out there, was the thought that there would be an API exchange possible between systems that could share SDOH and related data in an unattended fashion. Clearly, that API requirement is much more fragile than the first two, so we may want to break those out in our details as a staging, which I think is how Gravity is already doing it, but I think it makes a lot of sense to do it that way.

Arien Malec

Okay. I am also happy, obviously, to change the words on the slide for the recommendations. Any other comments from the task force? Okeydoke. Let's go on to the next slide. This one will be fun. And then, Les, this may be where I am waving another red flag. Clearly, I had OMOP wrongly done in my brain, so all the issues here are mine.

David McCallie

And, I reviewed and missed them all, too, so I am at fault for bad proofreading.

Leslie Lenert

I think you are going to run into a wall by saying that OMOP is the preferred model. So, I would say...

Arien Malec

Another way to formulate this would be the recommendation that we converge on a preferred data model. In my career in healthcare, we have often rolled into political sensitivities about everybody's standard and





everybody believing that we should converge on a single standard, but everybody wanting to converge on their own standard, and what that leaves us with is at the risk of wanting to avoid making people uncomfortable or unhappy, we soft-pedal the need to get to a single standard. I am more than happy here to soft-pedal OMOP as the preferred data model, but I do think it would be appropriate for us to say...

I think we heard from the research group that everybody is mapping their data multiple times, and that there was not a lot of value in that multiple mapping, and in some cases, those mappings were lossy because they had to downmap and upmap in order to get to, for example, the PCORnet data model. So, rather than talk about standardizing on OMOP, perhaps we should talk about standardizing on a research data model as the target for the country, and then align... I think we can look at FDA Sentinel, CDC, and some of the work that is going on in the VA and DOD as federal actors who have an interest in a single aligned research data model. Les, does that make sense to you?

Leslie Lenert

I think what you should probably say is that it should work to conduct comparative analyses of existing models with the view of converging on a single model.

Arien Malec

Yup, agreed.

Leslie Lenert

So, there has not been a comparison of the analytics performed by PCORnet and OMOP, to my knowledge, on the same thing, so somebody should probably say, "Well, this one is more prone to coding, this one is more error, this one has got these granularity issues." So, I think what you heard from Chris Chute was an interest in OMOP being the model, as you might have heard from other people who were involved heavily in OMOP.

Arien Malec

Yeah. So, I think I am reacting more to...

Leslie Lenert

There are some issues with OMOP as a standardized model.

Arien Malec

That is right. If I am being honest, I am in no position to compare the OMOP data model to the PCORnet data model to the i2b2 implied model, et cetera. What I was referring to primarily was some of the feedback that we heard that many of the large health systems are doing multiple mappings to multiple models, and that that mapping is lossy. That is really the problem that we want to solve: The need for multiple mapping that creates excess work and lossy conversion, and in order to solve that, we really should converge on a single model. Les, to your point, the logical way to do that would be to do the comparative analysis that you suggest, aligned at the federal level on research data use models for the organizations like FDA, VA, and...

Leslie Lenert

If you had allowed me to testify, I would have told you to map to FHIR as a representation language.





Arien Malec

No doubt.

Leslie Lenert

And, to PCORnet because FHIR is the closest thing we have to a detailed clinical data model, like Stan Huff said.

Arien Malec

Yeah. So, I guess FHIR would be the representational model for the underlying detailed model, and I think we already made recommendations that we should align the representational model for FHIR to the research data model, so I think we are saying the same thing, but we can go back and forth on the wording of this slide between now and Tuesday, if that works.

Leslie Lenert

That sounds fine. Again, we want to minimize the controversy. So, you will have problems with the first one.

Arien Malec

Okay. To your point, I think we want to say that ONC should conduct work to comparatively assess existing data models in order to converge on a single data model, which should be harmonized to the USCDI and cross-mapped to FHIR. David?

David McCallie

This goes back to why I put the language of a staging model in. I think people get a little bit more proprietary if they feel like they are being told they have to use a particular data model for their particular research. The question is can you get the data out of the EHRs and other administrative sources into your preferred data model with a minimum of extra work, and the use of FHIR is a huge step in that direction, but at least from what we heard from the presenters, they all put FHIR into something before they put it into their final clinical model, so this notion of a staging pipeline is what I think makes sense. You cannot make somebody use OMOP if they do not want to. Les, I am sorry, I cut you off.

Leslie Lenert

The point is that OMOP and PCORnet are relational models optimized for longitudinal data analysis, and that is not a good representation.

David McCallie

Right, and the data coming out of them...

Leslie Lenert

That is not a good representation because you do not have all the relations that could be represented in there. For example, you do not have an object-oriented view of blood pressure, for example, such as systolic/diastolic. They are single events. You would have to introduce a table that modeled that, whereas in FHIR, there is an explicit representation because they are all part of a single measurement.

Arien Malec





Okay. So, I think we have gotten what we want relatively clear. I think we are going to work through a couple of iterations on this particular slide, and Les, I am happy to see you volunteering to help David and me converge on the language between now and Tuesday to get this clear.

Leslie Lenert

We want to get through this. We do not want to be sent back home.

Arien Malec

That is exactly right. We do not want to wave the red flags too hard, and we want to make sure that the language is clear for this whole task force. I completely agree. Are there other folks on the task force who have commentary here? I see that Adele has some public commentary, which we will make sure gets incorporated as part of our public feedback. All right, that was exciting. Let me just do a quick time check. So, I think we are doing fine. I think we are actually doing quite well at going through these recommendations. Let us go to the next slide. All right. So, on harmonization of clinical and administrative data for burden reduction, I am saying that we endorse the ICAD Task Force recommendations...

David McCallie

Arien, before we dive into burden reduction/ICAD stuff, can we go back one to the EHR? I have a question for Les. Thank you for the material that you submitted. In that material, you had a particular bullet point that I was interested in that we did not pull forward into this slide about, to put it in my language, enhancing the ability of EHRs to perform core functions of a randomized trial, particularly randomized drug choice, et cetera. I took it to be something like what the U.K. recovery trial was able to do: A lightweight randomization. Did I get that right, and do you think we should add that at the high-level point?

Arien Malec

Let's look at Bullet 2, which is intended to address Les's comment, and make sure it has the right content there.

Leslie Lenert

I would say no. So, if you use Epic or Cerner, which I have to mention because of David...

David McCallie

No, you do not. I do not work there.

Leslie Lenert

You have clinical research packages for your EHRs, and they have certain functions, and they all currently exist outside of the scope of meaningful use regulation. There are no standards for how trials are representative within electronic records, and there is not a standard for representation of experimental medications that allows one to prescribe X and prescribe a placebo-controlled drug as part of Study X. We have to invent the name of that every time we deploy one of those inside of our EHR, and the lack of standardized clinical trial functionality inside EHRs does really slow things down quite a bit.

David McCallie





I agree, so I would like to call that out for more attention. I do not think it is something that gets solved overnight, obviously. I missed it in your bullet point there, Arien. I see the word “randomization” now, but I think that is burying the lead.

Arien Malec

Randomization is a specific... And, I completely agree with everything Les just said. Just so you know the thought process that was going through my head, it is relative to recovery, where we are trying to source EHR data use for emergent comparative effectiveness research, so the biggest missing feature is the ability to randomize. Everything Les says is exactly right. How do you document research use medication in the EHR? I also took notes that among the candidate data models that we should be looking to harmonize on, CDISC really should be in the mix as well.

Leslie Lenert

To some extent, yeah.

David McCallie

So, let’s just take it that we need to refine that point and maybe make it a little bit stronger around the ability to support clinical trials in a more standard way across EHRs. What I was struck by in the recovery trial was that it was pretty simple what they did, but they got very powerful and quick results. It was not a formal, deep, complex, FDA-worthy clinical trial, but it answered really important questions.

Arien Malec

That is right. So, there is the observational retrospective, or the observational trial, or real-world evidence trial where you are looking at random exposures to a compound and looking at outcomes associated with that, and you have all the usual issues that you have with retrospective. On the other end of this, you have the investigational, Phase 2/Phase 3, highly controlled trial with the clinical **[inaudible – crosstalk]** **[00:48:19]** well-defined randomization.

Leslie Lenert

This is a pragmatic trial.

Arien Malec

We need to have something in the middle...

Leslie Lenert

I think the technical term for what you were trying to say with the recovery trial was a pragmatic trial.

Arien Malec

Pragmatic, yup.

Leslie Lenert

[Inaudible – crosstalk] randomized to an improved agent at two different doses. Now, there is another large one called ADAPTABLE that was for aspirin dose.

Arien Malec





Yeah. The other term for this is comparative effectiveness research, where you are randomizing to a real-world treatment as opposed to a well-defined protocol, but at least, you are doing prospective randomization to the natural history and real-world model for that segment.

David McCallie

So, is it the sense that both the pragmatic trial and the comparative effectiveness research are things that we would eventually push for consideration to be a part of EHR technology to go all the way?

Arien Malec

Mm-hmm.

Leslie Lenert

Yes.

David McCallie

Can I get a sense of the group? Are you comfortable with that? That is a big deal.

Arien Malec

And, this is not a national competition, but I think it is fair to say that the U.K. did the lion's share of research that was used by the global community, and that I think the U.S. has the largest deployment of the electronic health records in the nation, and our ability to provide a true learning health system is compromised by our ability, not our inability, to be able to do something that is sub...industry-sponsored clinical trials.

Leslie Lenert

Again, the big difference between the U.K. and here was the ability to do randomization at a country-wide level for a very simple trial.

Arien Malec

Yeah, and that is why I called out randomization as the critical element. I think it is worthwhile, Les, to note the modeling issues in the research modeling section and also call out the standards for non-approved agents incorporated into the EHR, or for research agents.

Leslie Lenert

Talking about how to develop standards for representation of pragmatic research within a trial or pragmatic trials within an EHR would be great.

Arien Malec

I definitely took the "pragmatic trials" label, and will be sure to incorporate that.

Leslie Lenert

That is more what we would call it here because you are really channeling... Who was the FDA head in the last part of the Obama Administration?

Arien Malec

Janet Woodcock, or was it...?





Leslie Lenert

The one before her.

Arien Malec

Oh, the FDA administrator?

Leslie Lenert

Yeah. Doggone it. Anyway, “pragmatic trial” is fine.

Arien Malec

Perfect, okay.

David McCallie

I like adding that and bringing it to a higher level, Arien. I think that is something that there should be a discussion about. That is an important concept.

Arien Malec

That is exactly right. The “why” here is really critical, and I think it is implied but missing as a particularly called-out section.

David McCallie

We have been motherhood and apple pie so far, but this one pushes the boundaries a little bit more.

Arien Malec

That is right. Okay, cool, let’s go on to the next slide. So, now, we talk about harmonization of clinical and administrative data. So, we have done a lot of the heavy lifting already in previous slides, particularly relative to terminology and modeling, so here, we call out how we need to track administrative standards and create items for relevant Da Vinci, Fast FHIR, X12, NCPDP, and other related administrative standards in the implementation guides. The ONC should harmonize the implied administrative data model expressed in X12 and NCPDP to USCDI in order to ensure that EHR clinical data captures, maximally available, yada yada. And then, cross-reference our recommendations and terminology. Any comments here?

David McCallie

Let me explain that first bullet point because it came from me. I think that there are a number of groups like Da Vinci and Fast FHIR solving problems, and they have acronyms to represent their proposed solution to that problem. What I am saying here is that we should make sure that broader context of what interoperability priority is being addressed by these acronyms is captured in the ISA so that you can then track the progress of those efforts against the broad principle of what problem they are trying to solve because there may be other competitive solutions out there, so we want to organize it around what problem we are trying to solve, and there are a bunch of acronyms that I have never heard of before, such as PDex and some others, that we should invert into asking what problem this thing is trying to address and make sure that it gets a heading in the ISA.

Arien Malec





Yes, and again, relative to our foundational standard, as an example, PDex is really a decision support function, but it is decision support for administrative items for whether a procedure is going to get paid for as opposed to clinical decision support, but to your point, we really should be up-leveling it and addressing the need first, and then the standards that fall under that.

David McCallie

Right, just invert it to start with the problem, and then consider what choices you have as solutions.

Arien Malec

Yup. So, that is such a good point that it really should be in the bullet points. When you have to explain a bullet point, it is probably a good sign that your bullet point is insufficient.

David McCallie

Alix made a comment, Arien, which you can see there, referring to HL7 and HL7 accelerators. Again, I think those are things that can be nested under asking what problem you are trying to solve, so a national directory of patient assignments is a problem. A national directory of providers and their associated organizations is a problem. What standard is being proposed to address it? And, "X12" is capitalized. No, we meant "times 12."

Arien Malec

X12 is capitalized. I should know that. Thanks. All right, good. Any other commentary here? Awesome. Just as an aside, it is hilarious to me sometimes that with the length of my career in interoperability, there are standards and standards efforts that precede my time in healthcare and were just being formed back when I was in clinical research, so that just shows you sometimes how long the trail has been to drive standardization in healthcare. All right, let's go on to the next slide.

David McCallie

Can you say "claims attachment"?

Arien Malec

Claims attachment! Yes, maybe we should have a standard for claims attachments. That might be a useful thing.

David McCallie

Or, maybe we can just bypass it completely.

Arien Malec

Exactly. We will wait so long for a claims attachment standard that we will not need one because we will have national interoperability. Situational awareness: So, I think the Public Health Data Systems Task Force is going to take on situational awareness as well. We have a ridiculously ambitious agenda there, and not much time, so, given that we heard from the SANER work... I certainly found that the SANER work was an upgrade over the legacy standards that had previously been in place, and it would be super useful to have situational awareness on scarce resource availability, both in the context of a public health emergency, a natural disaster, or, as we have seen in other areas, just in the cases of health systems being overwhelmed by a terrorist attack, et cetera.





So, No. 1, we should make sure that SANER is listed in the ISA and should be worked through pilots in early implementation toward broader adoption, but most importantly, my No. 1 finding or observation out of that hearing was that, as often happens in healthcare, we do not so much have a standards problem as we do an ecosystem, funding, and policy harmonization problem, and it would be useful for ONC to work with its counterparts at HHS, primarily ASPR and other parts of the human services portion of HHS, to create policy funding mechanisms and aligned adoption. I am going to pause there and see if there are comments from the task force.

David McCallie

I will make the same comment that may go into our bullets with respect to SANER. You could look at it as stages of difficulty and initially getting some consensus around the actual FHIR resources that could capture that information and move on from there to API implementations for server-to-server communications. So, it is a detail, but you make the mistake of trying to boil the ocean sometimes, and we might miss a valuable head start just by getting the FHIR resources clarified, and that might be sufficient to trigger a lot of downstream stuff even if you do not implement the APIs on day one.

Leslie Lenert

I think it is a pretty tough API to implement because you are asking for bed availability... Again, as you say, if we get the FHIR objects represented, then people can start to work to **[inaudible] [01:00:29]**.

Arien Malec

Yeah, and David, to your previous point, our first bullet here really should list situational awareness in the ISA, with SANER and the legacy standards as standards under situational awareness. That is probably the real comment, and then, to your point, it would be useful to have the underlying FHIR representation standardized and made available, and that can often be an important precursor to the stakeholder alignment and policy and funding mechanisms. Les, to your point, this is not so much an EHR certification program, it is going to be an HRIS standardization program and a scheduling system standardization, and an ERP alignment standardization process, yada yada. There are just so many other systems than we traditionally think about in terms of interoperable standards.

David McCallie

But, they will be difficult to implement, I agree.

Leslie Lenert

I thought SANER was actually such a small step. There are probably better ways to do this from what they were talking about. Back when I was doing Biosense, the foundation of this was if the hospital's lights are on? Is it open? Has it been destroyed by an earthquake, tidal wave, or bomb? Is the emergency department open? Are the CT scanners open? Is the OR open and functional? There is a very fundamental level of things that could be actually assessed in the EHR just by the evidence of traffic within the EHR.

Arien Malec

Sure, okay. I think we have the marching orders here relative to the detailed bullet points. I think that is it relative to our high-level recommendations. I want to acknowledge that we have gotten more detailed recommendations. Jim sent us some very detailed recommendations, Les, you sent additional





recommendations that have not yet been captured in these high-level recommendations, but I wanted to make sure relative to the HITAC that we have the highest-order bits flipped first before we go to the lower-order bits. I think that is the last slide here. Should we go to the next one? Yeah, homework and next steps.

So, first of all, we want to poll the task force to make sure that we have not missed anything relative to high-level recommendations, and for these high-level recommendations, we should ask if we have the right categories, the right high-level points made, and the natural places for some more detailed commentary and recommendations to fall under these high-level points. I am going to pause there and just poll for the task force to make sure that we have the right high-level points captured and are not missing something.

David McCallie

Of the two categories that we had on our high-level proposal for soliciting that input, we had the care plan/chronic disease management carry forward from a previous task force and the data-sharing federal commercial entities, for which we decided on the side that a lot of the problems that had once been barriers have actually been worked around, and that that may be less of a concern than we thought at the beginning. So, those are the two that we left...

Arien Malec

Yeah. I do not want to presuppose that. In both of those activities, we just ran out of steam relative to collecting testimony and deliberation and getting to recommendations, so in some sense, that is going to be a pass-forward to the next incarnation of this task force, and it is probably worthwhile to mention that there are just some activities that we did not get to.

David McCallie

Yeah, that is kind of where I was headed. Let's at least acknowledge that we did not have time and bandwidth to address so they do not get completely lost.

Arien Malec

Right, or ignored, or that there is a predictable comment of "Why did you not address this? You probably should have done it." By the way, I see that Mike has a comment that in my timeline, I completely forgot the Friday meeting that we have after the HITAC, so we actually have four meetings between the HITAC and the next HITAC in order to... Maybe there are five meetings. We have plenty of meetings between now and the June HITAC meetings to get to a detailed recommendation draft or detailed recommendation final letter for the full HITAC consideration, so I think we are in relatively good shape with getting to recommendations.

So, with that, let's discuss homework. I think everybody has this draft of recommendations. Where I think we have some work to do is on the wording of the research section, and then, we captured some updates relative to FHIR subscriptions, the language on adoption of the foundational FHIR standards, and then, some minor tweaks, but I think we have some rewording to do, not foundational, but wholesale rewording, on the research use. So, in terms of homework, I will take the action of doing a quick turn on the easy content and publishing out the presentation material to the full task force.

Les, I was joking that you pre-volunteered to help us work on the research section, but I am hoping that that was not a joke and you would be happy to work with David and me to do some rapid turns on the research language so we can at least get to some consensus there for consideration from the full task force.





The request from the task force members is to check your email and provide commentary Friday, over the weekend, Monday, and Tuesday so that we can finalize the deck by Tuesday for the Thursday HITAC meeting, which I think should be sufficient time to flip out and get to the full HITAC for consideration. I think we tried to get the meeting materials two days in advance so that the HITAC members can review it prior to the meeting. So, if that homework makes sense to folks... I will pause there.

David McCallie

I think the next stage after this quick turn for the HITAC meeting would be that we would probably go to a Google document bullet-point spreadsheet model for the detailed recommendations that we...

Arien Malec

I would rather go straight to the recommendations letter, but we can work that out next meeting. It is nice to draft out the recommendations letter and then have people edit and work on the actual recommendations letter. My experience is there are a lot of things that seem like they make sense when you list them on an offline document, but when you actually say, "We recommend that ONC...", that sometimes takes some work and is the art of the recommendations.

David McCallie

Well, that is fine. You just have an online recommendation letter for editing.

Arien Malec

Right.

David McCallie

Yeah, that makes sense, particularly if you write it.

Arien Malec

Yeah. I've got certain skills, one of which is writing copious amounts of recommendation text that everybody finds all of the flaw and typos in.

David McCallie

We are happy to play the copy editor role.

Arien Malec

Exactly, the copy editor and "What the hell were you thinking?" role.

David McCallie

"What do these words actually mean?"

Arien Malec

Good. Well, if it is okay with ONC, I think I am hearing from the sense of the task force that we have completed the work that we have here, and I wonder whether it would be appropriate to go early to public comment.





Public Comment (01:10:33)

Michael Berry

Sure, we can do that. Operator, could we open up the line for public comments?

Operator

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

Michael Berry

While we are waiting for comments, I just want to note, as Arien has mentioned a few times, that our HITAC meeting is next Thursday. It is a full-day meeting. Most of that is going to be a public health data systems hearing, so there will be lots of presenters and lots of testimony given, so I encourage you to look on the HITAC calendar and join that call. Also, as Arien mentioned, next week's call that is usually on Thursday is pushed to Friday, so just check off your calendar there and join us then. Do we have any comments?

Operator

We currently have no comments.

Michael Berry

Thank you. Arien?

David McCallie

Mike, we did get one chat section comment. I could just read it. Is that okay protocol-wise? I think it is a useful comment.

Michael Berry

Yeah, please.

David McCallie

It was from Adele Stewart, and it says, "Would it be appropriate to recommend standardized capture of information that originates with the patient as part of the health equity conversation? For example, terminology associated with patient-reported outcomes measures as part of patient-centered care." And, she makes note that this is granular, and I agree, it might be a granular recommendation, but I thought it was worth surfacing for the record.

Arien Malec

Indeed, and thank you for the comments. All right. I think with that, we can give everybody 15 minutes back in their day. Hearing no objection, thanks, everybody, and I will look for your email for our homework.

David McCallie

Good work.





Michael Berry

Thank you, everybody.

Arien Malec

Thank you.

David McCallie

Bye-bye.

Adjourn (01:12:54)

