Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 2: ONC HEALTH IT CERTIFICATION UPDATES – NEW AND REVISED CERTIFICATION CRITERIA

May 31, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Oracle Health	Member
Jim Jirjis	HCA Healthcare	Member
Anna McCollister	Individual	Member
Deven McGraw	Invitae Corporation	Member
Aaron Miri	Baptist Health	Member
Kikelomo Adedayo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Sara McGhee	Office of the National Coordinator for Health Information Technology	ONC Program Lead

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. All of our Task Force meetings are open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled towards the end of our meeting this morning. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate if you are here, and I will start with our cochairs. Steven Lane?

Steven Lane
Good morning, and welcome.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Medell Briggs-Malonson? Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Jim Jirjis? Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Aaron Miri? Kikelomo Oshunkentan? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning, here.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Good morning, everyone. I know Sheryl Turney is out this week and next week, so she will not be able to join us. Now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge & Update and Revise Draft Recommendations (00:01:19)

Steven Eichner
Good morning and welcome, all. Welcome to our Task Force members and welcome to members of the public. We will have an opportunity for public comment towards the end of our meeting. We do encourage folks from the public to make comments at that time. You may also make comments in our chat functionality, although we may not respond to comments in the chat until that public comment period. We have a good agenda set out for today, where we are going to be spending our morning working on the worksheet to finalize our recommendations for submission to the HITAC, and then onwards to ONC.

Just to give you an update as to where we stand in our process, we are going to work on recommendations this week, and for next week, we are going to be inviting Task Force members from each workgroup to all the Task Force meetings to contribute and review recommendations at that point and provide a capstone review of the entirety of the recommendations package later next week in preparation to present the entire recommendation package to the full HITAC at the meeting in person in D.C., so we do encourage Task Force members to participate in as many Task Force meetings as they want to next week. Please review the existing worksheets not just for the workgroup in which you are participating, but the other workgroups as well, to identify if there are areas for recommendations that you are interested in commenting on because we are getting to the end of our process, and will have limited opportunity to make further modifications in the next week or so, so I want folks to be able to take advantage of it. Steven, do you have anything to add to that?

Steven Lane
No, that is a great overview. Let's jump right in.

Steven Eichner
Okay. Well, we are going to have a quick review of our charge and then really get into it. Next slide, please. Again, just as a reminder for everybody, our general charge is for the Task Force to prepare recommendations for HITAC review for submission to ONC regarding HTI-1, which is a proposed rule that implements a variety of different activities across data exchange and health technology. Next slide. This goes down a little bit into the specific charges. We are not going to go line by line this morning. The content is available in your packets for further review. Next slide. This slide is just reminding us of the areas that were specific to our workgroup, and we are going to move forward and review recommendations. So, we are going to shift over to the worksheet and look first at the first area of recommendation, which was looking at DSI, and we have a number of recommendations in that space. Let's move over to Column I, please.

Steven Lane
Can you get I and J to show up as best you can? Anna, I definitely recommend you also pull up the spreadsheet on your own, if you can.

Anna McCollister

I just wanted to say I have added a bunch of stuff. They are all noted with my initials, but I did not touch the cochair responsibility ones.

Steven Eichner
So, what Steven and I did was reviewed all of the content in earlier columns and attempted to draft in consistent language recommendations that could be included in the Task Force's report to HITAC and then subsequent submission to ONC, so we want to use this meeting as an opportunity to make changes, add, augment, delete, etc. to this recommendation language.

Steven Lane
Ike, Anna did add eight additional comments in G. Did you have a chance to look at those as you prepared your content in J?

Steven Eichner
I looked at some of them. I may not have been as complete.

Steven Lane
Okay, well, let's go with what we have. Notably, we have next week to finish this work, but as much of this as we can get through today, the better.

Steven Eichner
So, one of the recommendations that came out of Task Force discussions was recommending that ONC conduct robust testing of initial and ongoing DSIs to assess for unintended differences and outcomes across different patient demographics and health conditions. Is that a recommendation that we want to put forward?

Anna McCollister
Yes.

Steven Eichner
Is there any dissent or any recommended changes?

Anna McCollister
There are some nuanced recommendations embedded, and I have not gone through what you guys have digested and made into recommendations.

Steven Lane
Anna, why don't we go through the ones that Ike pulled forward and see if there is anything missing? That might be most efficient.

Anna McCollister
Okay.

Steven Eichner

"Recommending that ONC require that relevant information regarding a particular patient be presented in the context of the data model used to develop a particular DSI module so that patient can easily visualize where they stand or their data stands in relationship to the DSI tool and understand the relevance of the DSI output in the context of that particular patient." Part of the rationale for that is there is significant risk that DSI modules may not accommodate or account for the variety of patients that a particular provider may see, and there may be some conditions where the DSI output may be clinically inappropriate for a particular patient, and catching those early would be useful and helpful and avoid putting additional responsibility or negative patient impacts on having to potentially pursue issues with payers and other components to get exceptions from what might be a recommended course of treatment from a DSI module.

Fillipe Southerland
Ike, this is Fil. With this one, I wonder if it is also a context issue with the DSI, potentially, where we look at the clinical decision support and what context we are sending over for the DSI to make the decision, and somehow ensuring that the context is relevant and complete for the DSI, where we make sure we study that we are delivering the proper context.

Steven Eichner
Can you elaborate a little bit further?

Fillipe Southerland
Well, I think of it as if the patient does have some type of a rare diagnosis, that is certainly something we would not want to leave out if we are transmitting a set of information over to the DSI, so ensuring that, as we enable these predictive models, there is some type of framework for presenting the correct context, which I think we have the baseline for that with the CDS Hooks, but I do not know if we have considered CDS Hooks in the full context of the ever-broadening DSI models that are out there.

Steven Eichner
Right. I think a challenge here is looking at trying to successfully define what might be the inputs for a DSI. It sounds like you are suggesting that there be a core set of required inputs that a DSI module might need to consider. I am not saying that is necessarily a bad idea, but is that the direction that you were thinking?

Fillipe Southerland
Right. I think potentially looking at that as a consideration… I totally agree that that is a really broad ask for all of the various conditions that are out there, but if we are sticking with more of a static model of "Here is the context that we are providing to the DSI" and that model does not include all of the relevant context on the patient data, the DSI is potentially going to make a bad decision based on that.

Steven Eichner
I think it is a good idea, and we can talk about a parallel piece as we are looking at patient consent information and looking at piloting or focusing, perhaps initially, on a selected set of data classes or data elements.

Anna McCollister
One of the recommendations that I made was that perhaps if not all of the relevant information is there, so if there are any variables in the DSI, that would be unknown, but the DSI does not work. It is not usable. If

we stipulate that some of the variables be diagnoses, a developer could say, “Is there a mechanism through which if there are specific diagnoses in which this DSI has not been tested, then it just does not let the DSI work?”

Steven Eichner
Right, and I appreciate the point. My question is are there other criteria than diagnoses where it would be related? Diagnosis is certainly a good place to start, but are there other related fields that should also be included? I could easily imagine, for example, a patient’s mass or weight, diagnosis-unspecific, if a patient were a significant outlier from the data used to model the DSI, and that might result in an output that is not compatible.

Anna McCollister
Correct, yes, depending on… To state the incredibly obvious fact, it is difficult to do this in the abstract when there are so many potential DSIs that could be developed.

Steven Eichner
Right. I can support that concept as a recommendation. I think it becomes a stronger recommendation if we can also include at least an initial set on which to build in similar fashion to recommendations about patient consent in terms of looking at disclosure, looking at an initial set of selected fields that might be selectable, and that as a foundation on which to build.

Anna McCollister
I am not following the patient consent element of this.

Steven Eichner
It is not in this particular recommendation, but there is a later recommendation regarding implementing patient disclosures where there is discussion about starting with an initial set of USCDI classes rather than looking at absorbing selections across every particular field. In that same vein, can we start by saying, “Hey, this is the initial set of criteria that a DSI should consider as inputs?”

Anna McCollister
So, restrict them to data that is in the USCDI?

Steven Eichner
No, with respect to the DSI recommendation, is there an opportunity to put some guidelines about what input fields initially help identify where a particular DSI could not be applied from an input perspective?

Anna McCollister
I think it would be difficult for us to prescribe that across the board, but by all means, please let me know if I am undercaffeinated and missing something. I think it would be difficult for us to proactively define all the fields that would be needed for all of the potential DSIs ahead of time. What I would think might be more manageable would be to have the developer list out all of the data elements that need to be present for this DSI to work as part of its submission for approval or whatever process has to be set up.

Steven Eichner

But listing out the fields does not help identify where that particular module should not be applied. To give an example, diagnosis is an element that is included for processing a DSI response and says, "Oh, you should not apply this DSI to this particular diagnosis."

Anna McCollister
I think that is going to have to be written up by the developer, and there should be mechanisms for challenging that, and that is part of some of the recommendations that I could not recently suggest, that there has to be a mechanism for feedback for clinicians and patients to be able to say, "This DSI as written does not work for my patient group or for me" so that there is a feedback loop for the developers so that they can improve it. But at a minimum, as part of the coding of the DSI, if there are specific data elements that need to be present for that DSI to work appropriate as tested, if all of those elements are not present with a variable specific to that patient, then it trips something so that the DSI cannot be deployed, or it trips some sort of a flag or warning saying, "This DSI does not have all the data elements that are required for this DSI to work as developed for testing."

Steven Eichner
But isn't that kind of inherent in the development of any particular DSI?

Anna McCollister
I do not know. Is it? If it is, then awesome.

Steven Eichner
I cannot imagine writing a return that would not say, "Hey, there is a missing variable, I cannot calculate a response" or "Hey, this response is returned, but you did not include this, so it affected the return either way."

Anna McCollister
I have not personally written a DSI, so I do not know. I was going through and putting in my recommendations, I said this all sounds great in terms of protecting patients from potential risk that could be introduced by the DSI, but I also recognize as a patient that there are many risks that are mitigated through improvements in these kinds of things, and it is difficult to write in a vacuum without getting input from the potential consequences of slowing innovation might be.

Steven Eichner
I think we can include it. Do other Task Force members have a viewpoint or experience? Is this a necessary or useful recommendation?

Hans Buitendijk
Ike, this is Hans. Generally, I think that having insight into the data being used or the data context where it should not be used as a general framing would be helpful, but I am trying to dive into the details as to which data specifically would fit into one category or the other beyond a couple of examples, and generally, there are already statements about DSI and USCDI interaction, but DSI might be against that, but it might also be against data not yet in the USCDI to be viable, so I think we should be careful to get into the details of what data should or should not be included in the details of such statements, rather, clarify what data is used and what context it might not be appropriate to be used. It is kind of like medications and adverse

events. Where do you not use it, and where is it? That needs to be clear, but exactly where it is depends on the context of the DSI.

Anna McCollister
But there also needs to be some sort of a feedback mechanism because any developer… Assume they are the best developer out there and they have the best of intentions. Let's just start there with our baseline assumptions. They are going to miss something. When you start thinking about applying, just like with drugs, to use that same analogy, you are going to miss something because there are so many differences, so many different diseases, so many different idiosyncratic presentations within each disease category, and complexities of people with comorbid conditions and different medications.

They are going to miss something, so we need to have some mechanism to find out what the variables are, how those variables are integrated, and to have somebody who is an expert in a rare disease, or in endocrinology, or a particular type give feedback to the DSI developer to say, "This does not work and this creates a dangerous situation in this particular patient population," and allow them to be able to fix it in future versions of the DSI, and to be able to flag it for populations in that version of DSI. It is kind of like the app store. Otherwise, we are going to have least-common-denominator DSIs that are not going to work in certain people with no established mechanism for getting feedback.

Steven Eichner
Okay. I think I have gotten there. I have added some text. "Recommend that ONC require that HIT developers include as an attribute associated with a DSI a list of all data elements in the expected range of each value required for the successful processing of a submission to the DSI module."

Anna McCollister
Are you writing that in the sheet now, Ike?

Steven Eichner
Yes, I just typed it.

Hans Buitendijk
Which column?

Steven Lane
Yes, make sure it sticks, Ike. Someone else might have been in there when you were trying to type.

Steven Eichner
It is currently the third recommendation.

Steven Lane
"List all data elements and the expected range of values required for the successful processing of a submission to a DSI module."

Steven Eichner
Oh, you have somebody in the worksheet.

Steven Lane
I cannot see who is there.

Hans Buitendijk
Somebody is typing zeroes.

Steven Lane
Did what you wrote get in there, Ike?

Steven Eichner
I will retype it.

Steven Lane
Okay, let's come back. We have spent a lot of time on this. So, we got general agreement on your first one. What about the second? The third needs to be redone, right? Did we agree on the second?

Hans Buitendijk
I thought with the updated edition that I created, that could be merged with No. 2 because the current second rule is that relevant information is available. I think that can be blended with what Ike just described, so that might just be a touchup area, and I agree with Anna's comment that ONC should work towards what a feedback loop could or would look like so that experiences can be shared around that from a DSI perspective. So, somewhere, that needs to be blended in there. I think it needs to be clear that when we talk about DSI developers, it is truly the ones that developed the DSI because they know what is needed and what is not needed versus those that integrate into their systems need to be aware of that so they integrate into the right place.

Anna McCollister
I also want to say that for the first recommendation, we cannot just say "robust," we need to have ONC stipulate exactly what that includes because one person's definition of "robust" is not going to suffice for somebody else, and rarely do those integrate input from diverse patient populations.

Steven Eichner
What language would you suggest?

Anna McCollister
"Develop guidelines for specific elements for robust testing that incorporates input from a diverse set of patients and providers that represent the populations that will be impacted by the DSI," or demonstrates how this works across diverse data sets not included in the original training data.

Steven Eichner
If we add "ONC to work with stakeholders to develop testing criteria," that means that there will not be inclusion of testing criteria in this release of a final rule.

Anna McCollister

I did not say “ONC work with stakeholders,” I said “ONC stipulate specific types of feedback that needs to be included within the concept of robust testing.”

Steven Eichner
So, how do you operationalize that?

Anna McCollister
I would stipulate that the DSI needs to be tested using training data that would represent all of the settings in which the potential DSI might be used, and that the assumptions about both inputs that are relevant and outputs should be tested or should be exposed to stake…

Steven Lane
Ike, how would you feel about letting Anna draft this offline and incorporate it?

Steven Eichner
That would be fine.

Steven Lane
We do not have time for this.

Steven Eichner
We need to move on.

Steven Lane
Sorry, Anna, but we have so many to go through here.

Anna McCollister
I completely agree, but I think this is incredibly complex, and I am not sure that it makes sense to embed this particular thing in a 500-page rule with a whole bunch of other stuff.

Steven Lane
Which one are you on now, Ike?

Steven Eichner
I think we are looking at module developers to provide access to DSI attribute information in a standard format.

Steven Lane
Ike, may I raise a question? On the one just before that about how DSI certification can best be presented, there is a reference there to noncertified health IT, and I am not sure what the intent really is by this. Is the intent that we want to recommend a way so that those that are typically not certified can use that information and it becomes challenging? Because the second sentence says “to meaningfully attest to DSI,” but I think if you only attest to it, it might be interpreted as part of certification, so I am not sure how this is meant to be focused. I think I have an idea of what the overall intent is, but that recommendation is not coming through clearly.

Steven Eichner
Right. I think the goal here is to look at supporting access to DSI attribute information, not solely for certified health information technology, but for other consumers or other users of DSI.

Jim Jirjis
Ike, it is Jim Jirjis. Can I comment on that?

Steven Eichner
Please.

Jim Jirjis
It seems like part of the intent of this is that we can require certified technology to have certain requirements to be able to show the attributes of the DSI, but also, when they are interfacing with third-party apps, they need to actually have those third-party apps provide that information to then display in certified technology, so I read this as just making sure that those standards are available for third-party developers so that they know how to construct it so that it can be shown in the EMR. These standards are going to be published, right? So any noncovered or noncertified technology would have access to those standards. Do we need to call that out?

Steven Eichner
So, the noncertified technology can also consume or utilize a DSI that is certified?

Jim Jirjis
No. Let's say we are using Meditech, and Meditech has the ability within its own DSI to have a link that shows the attributes of the algorithm, what population it is tested on, but we may also be interested in the vendor who has created some AI that then interfaces with certified technology, and as we are using that, there needs to be a place in the certified technology to show those same attributes for that algorithm that was developed by a noncertified company, right? That noncertified company may want to get them to comply. So, I read this as those noncertified companies that create value-added services for DSI need to understand the requirements so that they can actually create a little baseball card or whatever we would call it so they can send to the certified technology those details so the user can click on it and learn the same information about those algorithms. Are other people understanding this differently?

Steven Lane
Did we lose you, Jim?

Jim Jirjis
Oh, sorry, I did go on mute. My understanding here is if we are HCA, example, we use Meditech. We and Meditech may develop DSI that we then want to be able to have a link that shows the different attributes we have been talking about, what population, what bias, and so forth, but increasingly, there may be a noncertified technology company that develops sophisticated algorithms that needs to be able to also publish to the certified technology through an interface that same information so that when our doctors or providers are using the AI that is generated by a noncertified entity, that entity can still send to Meditech and display that same set of attributes. Do you see what I am saying? That is what I thought this meant,

that third parties may be developing DSI that is then integrated, the results of which may be as simple as service, where we provide data, there is an algorithm, and then an answer is provided back. Well, with that answer ought to be a standard, formatted, and structured baseball card that indicates all these aspects of that algorithm that the noncertified technology has developed.

Steven Eichner
So, to restate, basically enabling developers that are not producing certified technology to build a DSI module that is compatible with certified technology using the same interface criteria?

Jim Jirjis
Correct.

Steven Eichner
I think that is certainly sensible. There are a variety of entities, including public health, as an example, with vaccine forecasting that is not a certified technology or offered as a certified technology, but there certainly…

Jim Jirjis
Yes, we have a long line of AI companies that, if they only had their data and we formed an agreement with them, could take that data and do sophisticated sepsis monitoring. It is not all going to be developed by the provider and the certified technology companies. There is a whole marketplace of advanced analytics and predictive and prescriptive model services, and what I am saying is they need to be able to also send all this information about what their bias is, who the intended user is, and what population, so for those noncertified technology companies, there are a ton of use cases where we would tap into them and maybe integrate them into the EMR, and they would need to also provide all this information for the user, or at least they need the ability to. That is all I am saying. I think that is what this is trying to say.

Steven Eichner
Yes, and then, a method of demonstrating that they are compliant with the DSI requirements.

Jim Jirjis
Yes, because those are not forced to be compliant now. That may come from their customer base. We may say, "Hey, look, you are not compliant. Well, I know you are not a certified technology, but we are not even going to have a deal with you if you guys cannot even provide the stuff that the…"

Steven Eichner
Right, so, as kind of a mini-certification for the DSI.

Jim Jirjis
Well, I would just say the tool has to be certified. The rule itself says that the results can be a service. We just need the ability to let those third parties understand what other information they need to send along with the results so that it can be displayed in the EMR so the user can understand the limitations.

Anna McCollister
I thought the point of this was that if a DSI developer did not meet these criteria, they would not be able to be integrated into the EHR. Is that not what we are talking about here? What you are raising is also a concern of mine, as somebody who has done two health tech startups, it's one thing to be super cautious and say this is the ideal in terms of how it would work, getting input from our stakeholders, etc., but that also means you are creating a really big barrier to entry for people who could be doing innovating things that could be lifesaving, and it is difficult to consider the potential benefit/risks in the abstract across so many different disease areas or real-world scenarios.

Jim Jirjis
Anna, you are right, but I think that has already been litigated, if you will, by the FDA's guidance document, which does not just focus on certified technology, it is expecting that any DSI that is being used by a clinician or a patient would have an FDA approval process, and all this rule is saying is what the certified technology needs to do to make sure that that can be displayed in the EMR for the user, but the whole notion of do noncertified technology companies have to go through FDA certification, etc., the answer is yes. This rule is just to make sure the tool is able to receive that. The certified tools can actually set it up for the provider to see that.

Steven Eichner
I am going to ask that you look at the drafted recommendation and make comments on the worksheet. We will revisit it next week. We need to move on.

Hans Buitendijk
Ike, this is Hans. I have a question, and I put in a suggestion. I have put a note in Column K for the one we were just talking about where that might be reflecting some of the discussion, and whether, in that context, the second sentence is still needed, so I struck it through for now, so I am getting the sense that it is focused on the DSI developer, where they make appropriate attributes available so that where the HIT is going to be incorporated, they have the ability to understand what it is and can, in a way, redisclose that information as appropriate under the requirements to provide that, and maybe that could reflect what the discussion was about.

Steven Eichner
Sounds good. Please look and make comments in Column K, and we will reintegrate them next week.

Fillipe Southerland
Hans, I was going to say that is very close to recommendation. I just added that in Column G, so I should move it into Column K.

Hans Buitendijk
At least we were working in two different columns, and not overwriting.

Steven Eichner
I would like to thank all the workgroup members for their concentrated effort. I really appreciate it. I think we are going to end up with a really good product coming out.

Anna McCollister
Just to be clear, if I have comments about what the recommendations are, I should put them in Column K?

Steven Eichner
Yes, please.

Steven Lane
Ike, what is next?

Steven Eichner
In the same kind of vein, this connects in: Looking at a requirement that ONC require HIT module developers to provide access to DSI attribute information in a standardized format, a publicly searchable webpage, without logging and without providing a blog's limited indexing by external entities. The concept here is that members of the public and other developers can understand what DSI modules may be available and the descriptive attributes around or necessary for using that DSI module. It is not intended to provide actual access to the DSI module itself, and part of the goal here is so that patients can understand what the relevant DSI modules may be in advance of their working with a physician or other care provider on the specific DSI module that their provider may be using.

Hans Buitendijk
Ike, if I understand you correctly, that would be that not only to the users, the provider, patient, or whomever, the data of the HIT module is being made available on what is being used and that they have access to it, but that it is generally cumulatively available in a public-facing environment on what is being used.

Steven Eichner
Right, another benefit of providers being able to identify DSI modules that they may not currently be using.

Hans Buitendijk
I am somewhat hesitating from a floor line perspective, and that is that in decision making on care, there is a wide variety of knowledge that is being used by a variety of participants. This is a subset of the knowledge that is being used to contribute towards decision making where it is decision support. Are we suggesting that all the knowledge that is being used is starting to be summarized this way, and particularly where it is interpretations of what is being presented on the screen? I am trying to figure out how this leads to a potential under- or overrepresentation, but particularly underrepresentation, of what all goes into decision making. This is certainly one of them, but what else would a provider have to start to disclose?

Steven Eichner
I think the goal here is to help build a catalogue of DSI modules that may be available that is HIT developer-agnostic.

Anna McCollister
That ONC would maintain?

Steven Eichner

It is not even maintained as a directory. It is requiring that the developer publish the information on their website and let Google or whomever index it so it can be found through a search, not creating a new catalogue of information.

Hans Buitendijk
So, it would be the original DSI capability developer that provides that information?

Steven Eichner
Right.

Anna McCollister
And ONC would set the standards for what had to be included in that information?

Steven Eichner
Correct. It basically needs the attributes that are already in the list, so we are not creating new information, it is just making that information publicly available, findable, or searchable.

Anna McCollister
Right. That seems like a pretty reasonable minimum standard.

Steven Eichner
Because it helps everybody identify a module that may be useful to them. "Oh hey, I was looking for a module to help evaluate a patient for X." Well, if I can do a Google search using the keywords "HIT module" or whatever, it is more likely to turn up than if it is hidden behind a firewall somewhere. It does not mean I can use it, it just means I know where it exists and I can inquire with the owner about getting access.

Anna McCollister
I think that seems pretty reasonable as a minimum standard.

Hans Buitendijk
So, would that mean that this way, it currently says "require HIT module developers." Is that meant to be "required DSI developers to provide access to DSI attribute information," etc.?

Anna McCollister
I would think so.

Steven Eichner
Yes.

Fillipe Southerland
And this would be preferable to a directory maintained by ONC?

Steven Eichner

Yes. If ONC wanted to use an indexing tool to collect it, it certainly could, as could Google, a provider, or any entity, but the goal here is not to require developers to have to actively register their tool with a particular entity.

Fillipe Southerland
That makes sense.

Steven Eichner
Again, we are trying to reduce administrative burden, but still improve access to content.

Anna McCollister
So, if ONC or a private entity wanted to create some sort of an index, these parameters that are listed here would be sufficient to make sure that they would be able to pull that up.

Steven Eichner
Or at least locate the information. They may still need to spider the relevant websites, but the information would be findable and locatable.

Anna McCollister
Right. I think that makes perfect sense, then.

Steven Eichner
Available XML tags or something so it is both human readable and machine usable, right? If you want to build a report out of it, you can.

Hans Buitendijk
Would this be in collaboration with the FDA as it ties into overall definitions of decision support, where it fits in, etc., aligned with the guidance that FDA provides us to provide what information?

Steven Eichner
I would think so. Again, the focus here was not to create another directory per se. It might facilitate the development of a directory.

Anna McCollister
I think this makes perfect sense.

Steven Eichner
But it is just to help people be able to find the information they may be looking for.

Fillipe Southerland
It sounds somewhat equivalent to the Lantern Project, but I think with that, we had to at least provide the endpoint to ONC so that they could get it into that directory. I do not think they were actively scraping the web for FHIR endpoints.

Steven Eichner

This approach is not attempting to create an extra project or extra activity on the developer. I guess there is nothing prohibiting them from voluntarily contributing the information somewhere, but again, not as a requirement. In the same vein, looking at the next recommendation, providing guidance to HIT developers, providing a list of all DSI modules and their attribute data provided through the EHR implementation during patient care in support of transparency requirements.

Hans Buitendijk
Should that be "certified HIT" instead of "EHR"?

Steven Eichner
Yes.

Steven Lane
Ike, can I make a suggestion that we keep this in on the recommendations unless on their implementation? I really am worried that we are not going to get through these by the end of our meeting next week at the rate we are going.

Steven Eichner
Yes. So, looking at the next draft recommendation, looking at clarifying the distinction between "enables" and "interface," any concerns? Hans, I think this was initially a recommendation based on text that you had suggested. Does this meet your expectations?

Hans Buitendijk
I think so.

Steven Eichner
Okay. So, are we considering this one locked? I think this recommendation regarding USCDI is actually misplaced and belongs in the USCDI discussion, so we can either visit it now or come back to it.

Anna McCollister
Which one are you on? These are not numbered.

Steven Eichner
The issue of it is looking at what happens when the version of USCDI is updated through the SVAP process and what are the implications for that on DSI hooks.

Anna McCollister
I have nothing on that. I will let somebody who actually knows what they are talking about comment.

Steven Eichner
Hans, I think this is another one that came from your suggested text.

Hans Buitendijk
Yes. Here, the question is that there is a lot of DSI already being used under the header of CDS, not necessarily AI-based DSI, but other DSI. So, as you are updating USCDI, which is part of the scope, that

means that there is already deployed certified HIT that covers data that is currently not in USCDI that will come into it, etc., so it is creating a question of how you go back as USCDI expands on what the expectation is. That existing DSI that otherwise was not necessarily using that data yet now is using it. How does that flow, and can that be done in that as you update, you update the relevant documentation, or do you really need to go back to everything that you already had and document it at that point in time? So, can you spread the load, or does it all have to happen at the same point in time that now USCDI is expanded and the five more data elements were included that already existed in DSI are taking advantage of? Where does that fit? So, it is trying to smooth the process a little bit as USCDI expands.

Steven Eichner
If the assumption is that a USCDI change in version always either remains the same or expands data elements and classes and does not relocate a data element between classes, then a subsequent version of the USCDI should be backwards compatible with an older version.

Hans Buitendijk
That is not as much of a concern. The concern is that with DSI already in place, it has been there, it has been using data, and the documentation requirements change based on the USCDI scope. How do you manage that? Because that might put a requirement to go to already-deployed software to go back through and update to everything at the same point in time to the latest USCDI as part of SVAP.

Steven Eichner
Looking at the scope of SVAP, is that the SVAP module or looking at SVAP upgrade for the entire HIT module?

Hans Buitendijk
So, when you go through SVAP and you want to update to the latest FHIR US CORE and/or C-CDA, using G-10 as the example for that module, that means that you thereby are supporting the next USCDI version. Does that now mean that you have to go back to all your DSI, which you otherwise did not necessarily make changes to, that you have to also then, because you are now claiming conformance to a larger USCDI scope, that you also need to go back and update the DSI documentation that may not have been included at that point in time that there was DSI that was done against other capabilities that are included in USCDI. How does that relate? Or, if you are not working on that, you are updating FHIR US CORE to the USCDI latest version, you now have to go back and update the DSI, or is that as DSI updates? How is that done? That is the clarification request.

Steven Eichner
I think it is a good recommendation. Again, the challenge is that it is kind of unintended consequences, but if you do not, at a minimum, update your documentation, then you are not reflecting what you may be actually using to implement a particular tool. In other words, I am saying I am using USCDI Version 2, but in actuality, I am using Version 3 once I go through SVAP, correct? Is this a recommendation that we want to put forward at this time?

Anna McCollister
This is above my technical capability to comment, so I will defer to you guys.

Fillipe Southerland
I agree with your concern, Hans. I will say I did not get that. I did not understand what this paragraph was saying when I first read it, so perhaps we could simplify or reword slightly, but I agree with the concern.

Steven Eichner
Hans, can I ask you to revise for clarification?

Hans Buitendijk
Sure, and I will run it by Fil. I will send something to see whether that catches it better, if that is okay, Fil.

Fillipe Southerland
Thank you, yes.

Steven Eichner
I think it makes sense if you have the technical background. Without the technical background, it is difficult to follow.

Hans Buitendijk
Yes, there are some intricacies in SVAP on how that runs, and it is not everything in total.

Steven Eichner
Right, exactly. The final recommendation in this space is providing guidance to HIT developers regarding the contents and format of a DSI label, kind of consistent with the idea we talked about earlier about sharing information using something like the food nutrition label as a method of packaging information, so I think we can go through and collapse that recommendation with the earlier one about indexing. As a general comment on the report, looking at potentially asking the Annual Report Workgroup to undertake a recommendation that ONC more specifically clarify the role and expectation of patients and care partners as stakeholders, looking at the future development of DSI and looking at including diverse representation of patient voice in workgroups and Task Forces in the future, looking at future DSI work, and looking at consensus around faves definitions and the like in terms of defining minimum attributes. Is that acceptable?

Anna McCollister
I think that is acceptable. I would like for this specific recommendation that we have ONC include patients, individuals, consumers, or whatever word you want to use as a user because I just think that is a bare minimum to being put in our recommendations. More broadly, I know we will raise this in the HITAC meetings, but I think as ONC lists out specific things that they have to do to be considered for each of their actions and it includes burden on industry as well as diversity, equity, inclusion, etc., it needs to consider burden and impact on patients.

Steven Eichner
I believe patients are already included in the definition of “health IT user,” if that is what you are looking at.

Anna McCollister
Is it? I did not see that in the rule, but if that is defined elsewhere somewhere, that embeds that inherently within the rule, that is great.

Steven Eichner
I will validate in the next week, but I believe that is a core component of the underlying framework.

Hans Buitendijk
Is this meant to be similar to the other discussion where it is not in the context of DSI being performed, but a general understanding of what DSI is used, that we could combine that into how that information can be combined and made publicly available? I am looking at the complexity of this versus the complexity of a nutrition label. I understand the conceptual equivalents, but I am not sure whether, at this point in time, at the level of relative simplicity by which a nutritional label can be put together versus a DSI label that we understand what that is, how much information it is, and how it can be readable for the intended audience, so I think that would require a fair amount of work, particularly when the focus is not on the provider, but on the patient to make that informative and consumable.

Anna McCollister
Well, that is why I think it would be super helpful if ONC came up, like USDA does, with a standard label and then tested it to make sure, but you are correct, that is going to take a substantial amount of time and effort and people who are experts in information presentation, etc., but it is something that needs to be done, and they should probably start now and go towards the future, and part of the recommendations that I have put in there is this is something that should be updated on a regular basis because you do not want to have some sort of label that begins now that becomes so difficult to change that it is not something that could be updated as DSI becomes more sophisticated and this whole system evolves, but there needs to be some way of readily looking at this so that you do not…

It is not realistic to only rely on transparency in terms of having that information available for somebody to find it if they have the time, health literacy, and sophistication to be able to do it, but doctors are going to be applying this in the care setting, and it is already too much of a burden for them to input things in the EHR. They are not going to be searching out specific parameters. So, I think it would help if ONC came up with some sort of an easily digestible model so that if you want to dig into the details, you can dig into the details, and you know where to look for what it is you want to find.

Hans Buitendijk
Would this be something that is more of a next step as opposed to a final rule opportunity, considering that it requires a fair amount of development analysis to understand how that could be best be done with HIT developers in particular, DSI developers contributing the information for that to be able to plug that in, if that is the intent? I am not convinced that this is an actionable final rule recommendation or that it is an actionable next step recommendation.

Anna McCollister
I think we need to make a recommendation to ONC. With the specifics of the timeline and how it gets incorporated, I do not know. Perhaps we should recommend that for this rule, presumably, if it comes up this year, that it include specific data elements that need to be exposed and that ONC also begins this process of defining and developing an “information label.”

Steven Eichner
This is Ike. What happens if we include a suggestion/recommendation that the attributes include a patient-friendly description of the DSI module and…?

Anna McCollister
I do not mean this to sound mean, but that is a very vague description and it leaves a lot up to interpretation. My recommendation is that it needs to be tested to see if it is actually something that works, but USDA spends a lot of time and money developing the nutrition label, which I did some work on a long, long time ago, so this is not going to get done in two months. It is going to take time, research, testing, and all of that.

Steven Eichner
Where I was aiming was a twofold piece, maybe a threefold piece, 1). Looking at the contents of a label, 2). Looking at presentation, and if you look at the DSI attributes as being a content source for the label, that may be a good start.

Anna McCollister
Yes.

Steven Eichner
So, building on your concept, I was thinking whether there was an opportunity to change the recommendation to leveraging the contents of the attributes to develop a patient-friendly, interpretive document or interpretive resource.

Anna McCollister
Sure.

Steven Eichner
That gets you down that path. No, it is not going to happen in two months, but again, looking at the idea of a label, that potentially creates a bunch of issues down the line about how to implement that label across different technologies, apps, interfaces, and screen sizes, etc., and that is a complex issue, and whether it is accessible for screen readers, etc. That is a whole minefield of things that, in itself, is a deep project, a good project, but not to be implemented in the next couple of months. But at least if we say, “Hey, look at these attributes as a source” and augment the attributes to include additional patient-friendly data, it might be a good start.

Anna McCollister
I think that is great. Maybe we should suggest they do a design contest and award the top three designs of it at the end of the year as ONC works on their own version or a different version.

Steven Eichner
I will go ahead and make some changes in that. We will revisit it next week. We have a lot of work to do next week, I am afraid. We have barely gotten through the first group.

Steven Lane
We have spent two of our meetings on DSI. So, do you want to try to tackle ECR in the next four minutes before we go to public comment, Ike?

Steven Eichner
I think so.

Steven Lane
I am assuming on those ones above, Ike, that you are going to go back and reword them additionally based on our discussion, right?

Steven Eichner
Yes. The only one that we are leaving as is is the one that is in bold.

Anna McCollister
And then, if I have any comments to what you are recommending, I will put it in the next column over. I did not want to do it for anyone else because I did not want to screw up everybody else writing things.

Steven Lane
Okay, ECR.

Steven Eichner
Looking at a couple recommendations, "1). Recommend that ONC require that if an HIT module is certified only for CDA or FHIR, that there be an additional requirement that the HIT module developer identify and test a conversion service to the other transmission element, even though it is not integrated into that particular HIT module, the concern being that a healthcare provider does not need to face challenges in connecting to a public health authority that only supports one of the two options. There are a number of third-party entities that are capable of ingesting either resource so that we are not looking at creating new technology for the service, but again, looking at end-to-end testing and implementation so that the interoperability can occur with minimal effort on the provider side at implementation.

Steven Lane
Hans has a hand up.

Hans Buitendijk
I generally agree with this, but I would think that the first and third bullets should be in sync so that that same capability of outbound from a provider perspective can be converted or mapped into the other format, APHL AIMS having been used as a primary example, can be done on the inbound so that from a provider/HIT/EHR perspective, you support both the submission and the responsibility response, either CDA-based or FHIR-based, though if you want to do both, fine, but you only need to do one, and that it is a pair.

Steven Eichner
If you can identify a third party that is capable of translation.

Hans Buitendijk
The thing is, on the first bullet that is identified, where you have that, it should be the equivalent on the third bullet.

Steven Eichner
Yes, we can make that change.

Hans Buitendijk
Or you can combine it and say that the initial case report and the responsibility response choose one or the other where there is the opportunity to convert in the other one using those available capabilities.

Steven Eichner
Yes. We will knock out two really quickly, recommending that ONC replace the existing…

Steven Lane
Actually, Ike, let's do public comments and then come back.

Steven Eichner
ONC staff, can we open the lines for public comment?

Public Comment (01:18:39)

Michael Berry
Sure. We are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause just for a moment to see if any members of the public raise their hand. I am not seeing any hands raised, so let's turn it back to Steve to continue the conversation. Thank you.

Steven Eichner
Okay. To continue our discussion on electronic case reporting, looking at the second recommendation, it is that ONC replace the current real-world testing approach that enables HIT developers to self-certify that they have completed real-world testing or ECR to require real-world testing with live public health information systems, as identified or recommended by the public health community so that there is actually validation that there is true ability to exchange information between HIT modules and public health entities receiving the data, and that testing does not occur only in test bed situations.

This will help alleviate some of the issues that we have seen in the past in terms of implementing actual exchange between certified systems and public health systems that are not necessarily certified to ensure that there is a warm handoff and reduce the amount of effort and customization or subsequent effort after implementation. This particular issue has been addressed or identified in previous HITAC reports, including the HITAC Public Health Data System Task Force report that was produced fairly recently. Are there any suggestions in that space? Is this a recommendation that we can move forward?

Steven Lane
I like it.

Steven Eichner
Wonderful.

Steven Lane
Did we actually approve all three of those, Ike?

Steven Eichner
We approved two. The third has a modification.

Steven Lane
Sorry, has it been modified, or is that yet to come?

Steven Eichner
I will do the modification after the call. I have not yet done it.

Steven Lane
Okay, so we have seven minutes. Shall we keep going?

Steven Eichner
Absolutely.

Steven Lane
You are on a roll here!

Steven Eichner
It took us a while to get started.

Steven Lane
That is okay. That slide was important.

Steven Eichner
We got there. Looking at privacy rule and consent, looking at recommending that ONC adopt certification criteria that allows patients to request limits to disclosure of information using terminology like diagnoses, with which patients are familiar, to facilitate a clear understanding of choices made by patients.

Steven Lane
Can we scroll down a little bit? I think we are missing the bottom of the field there. Thanks.

Steven Eichner
The goal here is really looking at the adoption of language that is patient-friendly so that patients are not being asked to make decisions about disclosure using terminology that they are unfamiliar with.

Steven Lane
Who proposed this recommendation? Was this yours, Ike?

Steven Eichner
I would have to go back, but this is not me. Are there any concerns with that recommendation?

Hans Buitendijk
I am trying to digest it in the context of the renaming and discontinuing year-themed editions.

Steven Lane
Yes, what exactly does this have to do with what we were asked to comment on? That was where I was going.

Steven Eichner
I think the concern was looking at patient-friendly language. It may not be specific feedback looking at the technical framework, but looking at an environmental consideration.

Steven Lane
So, I do not see this in Column G in the member recommendations.

Hans Buitendijk
That might be a couple rows below. I think we may have skipped in a way that we are sitting on different rows. We are looking at 4, and Ike, you might be looking at Row 7.

Steven Eichner
I jumped down, sorry. I was in a different place. My mistake. "Recommending that ONC establish and maintain internet-accessible human/machine-readable language regarding each particular standard," but…

Steven Lane
In the certification requirement. Is that what we are getting at here?

Steven Eichner
Yes. So, as we are looking at evolving from name standards in terms of looking at things like 2015 edition and the like to a more flexible framework for adoption, creating a standardized method or table of identifying what the relevant standards are becomes rather important for providers and other entities in understanding what their technology is currently supporting, what it may need to support in the future, and not looking at certified technology, but looking at what trading partners that are not using certified technology are expecting.

Steven Lane
So, I just want to make sure that we phrase this in a way that makes sense. So, we are talking about a table that looks at each relevant certification requirement, because we call it a requirement, we call it a regulation, we call it a standard, so we are using a lot of different terms here.

Hans Buitendijk
It is the criterion that encompasses some of this information, so, currently, when you go to CHPL, that is where you effectively see for each product that is certified which criterion they have been certified to, and

there is optionality, so you might not see everything for every solution, but just a criterion that is the link to say what you are certified to, and then, in the criterion, it may or may not specify a standard or whatever other kind of thing in there, but the criterion is the one that is the building block of certification.

So, I think we should consistently use that, that as you go through, I agree generally that this is the kind of information that you need that you can then backtrack us to what it is, and particularly, since they want to move into an editionless direction, it becomes important that I can track each of these things at the individual criterion level because they may have different dates that they are active, and as a result, you may start to be certified to it at different times, etc., so we need to be able to keep easy track of which one is in effect, which one is applied, and for what timing. So, I agree with the intent behind this, that we need to have that clarity, but it is the criterion that we need to track, not the edition.

Steven Lane
So, I just changed all those words to "criterion." Does it still make sense?

Hans Buitendijk
I think it would start to. So, for each relative criterion, and drop the word "requirement," that includes the regulation number because that is 170.315(g)(10), for example, so that is known. It has a name already, typically, so I think we just want to tie it in. They are all elements that are actually sitting on the criterion. The parts that need to be tracked additionally are dates and effective expiry, etc.

Steven Eichner
You cannot necessarily replace each use of the word "standard" with "criterion" because, for example, the immediate past standard is not the criterion, it is the label of what was being used.

Hans Buitendijk
But the standard is referenced in the criterion, and it is the criterion that you certify to.

Steven Lane
Okay, we are out of time, so, Ike, again, I do not know who proposed this initially…

Steven Eichner
This one was mine.

Steven Lane
Okay, sorry. So, maybe try to reword this.

Steven Eichner
Yes, we will reword it.

Steven Lane
We will come back and pick it up here next week. We have a ton of work to do getting through the rest of these next week, so, thank you all for your time.

Steven Eichner

Thank you all, and we will see you next week.

Hans Buitendijk
Thank you. Take care.

Fillipe Southerland
Thank you.

Adjourn (01:29:25)