

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) ADOPTED STANDARDS TASK FORCE 2022 MEETING

June 28, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Hans Buitendijk	ORACLE Cerner	Co-Chair
Steven (Ike) Eichner	Texas Department of State Health Services	Co-Chair
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Jim Jirjis	HCA Healthcare	Member
John Kilbourne	Department of Veterans Health Affair	Member
Hung S. Luu	Children's Health	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae	Member
Lisa Nicolaou	Michigan Health Information Network	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Vassil Peytchev	Epic	Member
Samantha Pitts	Johns Hopkins University School of Medicine	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Ram Sriram	National Institute of Standards and Technology	Member
Raymonde Uy	National Association of Community Health Centers (NACHC)	Member
Debi Willis	PatientLink Enterprises	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Josianne Charles	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Liz Turi	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Scott Bohon	Office of the National Coordinator for Health Information Technology	ONC Staff Lead



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

Michael Berry

And hello, everyone, and thank you for joining the new Adopted Standards Taskforce. I am Mike Berry with ONC, and I serve as a designated federal officer of the HITAC and this taskforce. On behalf of ONC, I would like to thank all the taskforce members for volunteering their time and expertise, but also thank the members of the public for joining us as well. As a reminder, your feedback is always welcomed, which can be typed in the chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at about 11:50 Eastern Time this morning. So, I am going to begin roll call of our taskforce members, so when I call your name, please indicate that you are here. And, I will start with our cochairs. Steven Eichner?

Steven Eichner

Present, good morning.

Michael Berry

I think Hans Buitendijk is going to be joining us in a minute. I do not see him online. Raj Godavarthi?

Rajesh Godavarthi I am here.

Michael Berry Jim Jirjis?

Jim Jirjis Present.

Michael Berry John Kilbourne? Hung Luu?

Hung S. Luu Good morning.

<u>Michael Berry</u> Clem McDonald? Deven McGraw? Lisa Nicolaou?

Lisa Nicolaou I am here.

Michael Berry Eliel Oliveira?

Eliel Oliveira Good morning. HITAC Adopted Standards Task Force 2022 Transcript June 28, 2022

Michael Berry Vassil Peytchev?

Vassil Peytchev Here.

Michael Berry Samantha Pitts?

<u>Samantha Pitts</u> Present. Good morning.

Michael Berry Alexis Snyder?

Alexis Snyder Good morning.

Michael Berry Fil Southerland?

Fillipe Southerland Good morning.

Michael Berry Ram Sriram?

Ram Sriram Good morning.

Michael Berry Raymonde Uy? And, Debi Willis?

Debi Willis Here.

John Kilbourne John Kilbourne is here too. Sorry I missed my name.

<u>Michael Berry</u> Great, John. Thank you so much. I appreciate everyone's...

Ram Sriram I may have been on mute. This is Ram Sriram.





Michael Berry

Okay, great. Thank you so much. And now, please join me in welcoming Steve for his opening remarks. Steve?

Task Force Introductions (00:02:00)

Steven Eichner

Good morning, and thank you all for joining us this morning. Thank you to the taskforce members for being willing to commit your time, interest, and expertise in helping complete the important work of reviewing standards that have been included in regulation to determine if they need to be maintained or if they need to be retired. We have got some exciting work ahead of us in the next few weeks, with the goal of completing our work at the end of August to submit a report to the full HITAC for their consideration, and then submission to the Office of the National Coordinator.

Hans and I have had several meetings with the wonderful team from ONC and the support team to help create a framework and develop some documentation to help us through the process, but before we get into that, we would like to spend just a couple of minutes with introductions around the table, providing your name, where you work or what organizations you work with, and some of your areas of expertise.

My name is Steve Eichner. I am the Health Information Technology Lead for the Texas Department of State Health Services here in Austin, and I work on a variety of health information exchange and standards activities, providing resources to help providers connect and submit data to public health, provide opportunities for healthcare providers and other entities to retrieve data from the Department of State Health Services, and work with public health agencies across the country and public health agency organizations such as the Council of State and Territorial Epidemiologists and the Association of Territorial Health Officials. Hans is now with us. Hans, we were just starting to do some introductions, if you would like to introduce yourself, and we will proceed in the same order as roll call.

Hans Buitendijk

All right. Good morning, and my apologies for the delay. I got stuck somewhere that I could not get to the phone quickly enough. My name is Hans Buitendijk. I am with Oracle Cerner, the Director of Interoperability Strategy, and I am also currently a member of HITAC and had the pleasure to work with Steve and others on this call today on the prior workgroup activities and taskforce activities earlier this year, and I am looking forward to work with you on this charge that we have. It is a slightly different role, so I am trying to get used to that and see what it is like. I have seen some very great folks, like Steven Lane and others, that have provided some guidance on how to do this, so we will see how that goes, but I thank you very much for joining, and I am looking forward to it.

Steven Eichner

Rajesh?

Rajesh Godavarthi

Thank you very much. Good morning, everyone. Raj from MCG Health. I have been with MCG Health since 2003, primarily in clinical decision support, where we provide evidence-based guidelines for clinical decision support. I have been part of the HITAC committee since the last term, and I also actually co-lead the HL7 interoperability groups around the prior authorization use cases, participating in several industry events



related to interoperability initiatives. Thank you for allowing me to take part in this conversation. I am very much looking forward to it.

Steven Eichner

Thank you so much for being here. John Kilbourne?

John Kilbourne

Hi. I am John Kilbourne. I am with the VA, and I was also involved with the HITAC work, to a degree, recently as well. I enjoyed working with everybody there. My background is primarily in terminology such as SNOMED, RxNorm, and UMLS in my role at the National Library of Medicine prior to the VA, and I just want to say I work at the VA, it is a very large organization, very complicated, a lot of moving parts, a lot of parts that are moving that should probably be still and parts that are still that would probably be good if they moved, and so, I hope that I can contribute here more than I have been able to in the past, and I am looking forward to helping with what we are doing here. Thank you.

Steven Eichner

Thank you. Hung Luu?

Hung S. Luu

Hi, Steve. We seemed to have skipped somebody. Do you want to go back to them first?

Steven Eichner

Excuse me?

Hung S. Luu

You seem to have skipped over Jim Jirjis. Do you want to go back to him?

Steven Eichner

Oh, sorry, Jim.

Jim Jirjis

No, I know you were trying to save the best for last, so you were waiting. Just kidding. I am Jim Jirjis, a physician. I am the Chief Health Information Officer for HCA, and we are in about 22 states, 44 markets, and we deal with a variety of data and culture across multiple different care environments. I have been with HITAC for one term thus far. I am glad to be here and participate.

Steven Eichner

Thank you for that. And now, Hung Luu.

Hung S. Luu

Yes. This is Hung Luu. I am an Associate Professor of Pathology at UT Southwestern Medical Center in North Texas, and I am also the Director of Clinical Pathology for Children's Health, a pediatric healthcare system, and my interest in informatics is actually in laboratory interoperability. I served on the standards committee and also the informatics committee for the College of American Pathologists, and through that, I have been associated with the SHIELD Initiative, which is promoting laboratory interoperability, and so, I look forward to serving on this taskforce and hopefully contributing. Thank you.

Steven Eichner

Thank you. We are very happy to have you. Clem McDonald? Clem, do you want to introduce yourself?

Michael Berry

He said there was something wrong with the sound a minute ago.

Steven Eichner

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Okay. Let's go to Deven McGraw. Then, let's go to Lisa.

Lisa Nicolaou

Hi there. My name is Lisa Nicolaou. I am with the Michigan Health Information Network, and I am their Social Determinants of Health Program Director there. My areas of expertise are really in community information exchange and the development of those community information exchanges, baseline work, as well as how we move data across sectors of care in that cross-sector data-sharing capacity, where we are not just adding more technology where it is not beneficial, and making sure that we get to something that is an equitable solution. That is me, and I look forward to participating.

Steven Eichner

Thank you so much for being here. Eliel?

Eliel Oliveira

Hey, everyone. Good morning. My name is Eliel Oliveira. I am the Director of Research and Innovation at Dell Medical School in Austin, and I have been in this place for about 20 years or so. I lead several research projects here at the medical school in our health informatics corps, some of them funded by ONC itself. I have a long history of working with ONC in standards development and extraction of data from EHRs, but most recently on patient engagement technologies and social determinants of health referral management systems. The other part of my work here is supporting our health information exchange here in central Texas, and before the medical school, I was also the Chief Information Officer for the Louisiana Public Health Institute, where I also did manage our HIE **[inaudible] [00:11:01]** wellness area, and have a long history working in cancer research as well. It is a pleasure being here.

Steven Eichner

Thank you so much. Vassil?

Vassil Peytchev

Good morning. My name is Vassil Peytchev. I am with Epic. I have been working in the standards area for quite a few years now. I have experience with implementing and creating specifications for HL7 Version 2, FHIR, X-12, CDA, and different types of IHE specifications. I am looking forward to contributing to updating the list of supported standards for certification. Thank you.

Steven Eichner

Thank you. Samantha?

Samantha Pitts

Good morning, everyone. I am Samantha Pitts, a general internist and faculty at the Johns Hopkins University School of Medicine. At Hopkins, I work primarily in quality and safety and have been involved in decision support and use of data for a quality and safety promotion and evaluation, as well as in implementation around e-prescribing, specifically CancelRx and a script standard at Hopkins.

Steven Eichner

Thank you. Alexis?

Alexis Snyder

Hi, good morning, everybody. I am Alexis Snyder, a Patient and Stakeholder Engagement Specialist located in the Boston area. I work with providers, health systems, researchers, patients, and other stakeholders on best practices for engaging patients and stakeholders in this work, with a focus on patient-centered outcomes research and health IT. I also advise on a number of advisory committees and councils that are health-related, including the HITAC, so I am happy to be here this morning.

Steven Eichner

Very happy to have you. Fillipe?

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Fillipe Southerland

Hi, good morning. Fil Southerland. This is my first year here on HITAC, so I am excited to be participating in this workgroup. I am Director of Healthcare Solutions at Yardi Systems. We are a long-term care EMR. So, I lead up our interoperability team in that sector and work with a number of long-term care pharmacies, integrating via FHIR and HL7 standards, as well as lab providers and medical device vendors, etc. So, I am happy to be part of the committee, and good morning, everyone.

Steven Eichner

Thank you. Ram?

Ram Sriram

This is Ram Sriram. I am the Chief of the Software and Systems Division at NISD, and I am also the Program Manager for the Health Information Technology. And, we have been working in this space for a long time, and my people have actually developed a number of test methods that have been used in the meaningful use satisfaction when EHS came around almost a decade ago, and actually, EHS is a much longer story, but the meaningful use test methods were developed by my people. And, my main research area is actually artificial intelligence, which I have been working in for about four decades, and now I am passionate about how you can apply AI in the healthcare field and what kinds of standards you require to implement.

Steven Eichner

Wonderful, thank you. I do not believe Raymonde is with us this morning, but just in case... And, Debi Willis?

Debi Willis

Hi. I am the CEO of PatientLink, and we focus mainly on patient engagement. We have a long history of taking data from a patient and sending it into an EHR as structured data using a variety of standards, but we now have a consumer FHIR application called MyLinks, and we have worked with several of the EHRs in helping to test their API when the APIs first came out, and we are now involved in helping them test their R4. We are connected to over 42,000 different locations in the United States, and really look at the impact of standards on patients and how data flows, whether or not it is consistent between the EHRs, and if the data is full. I am also on the Vulcan Steering Committee. Vulcan is focused on data for research.

Steven Eichner

Wonderful, thank you. And, Mike, can you introduce yourself and then the rest of the ONC and support team?

Michael Berry

Sure. I am Mike Berry with ONC. I am the designated federal officer of the HITAC, and I look forward to meeting those of you I do not know yet, and we appreciate your time. I know that Josianne Charles is one of the program leads here at ONC. She is off today, but she will be joining us next time we meet, which is in two weeks, and Liz Turi is another person from the Office of Technology that is supporting this taskforce. She is also off this week, and will be joining us in a couple weeks, and Scott Bohon is another program lead that is supporting this taskforce, so they will be our subject matter experts to support our cochairs and this taskforce going forward. So, that is the core team, and we look forward to getting started. Hans, Steve, I will turn it back to you.

Steven Eichner

Thank you for that. And, I am going to turn the floor over to Hans to talk about our charge.

Task Force Charge, Planning (00:17:40)

Hans Buitendijk



All right. Thank you, and let's go to the next slide there and introduce the charge that we have for this effort. It stems back to the 21st Century CURES Act itself, which has a requirement that on a frequent basis, but starting after five years of the act having been put in place, to begin to look at which of the standards and implementation specifications that are being referenced we should continue to maintain and which ones we should start to phase out. We are now at the five-year mark and this is the first time it is occurring, and then, from this point on, every three years thereafter, we will review that to help ensure that the standards are still applicable and still relevant, that they progress where they need to, and that they take that path. So, for anybody who wants to go back to the original language, you can go to the code that is highlighted there.

So, that is what this is really about, and this being the first time, the question is how we are going to go about that, what we are going to do. So, in the next couple of slides and steps, we are going to be looking at that, identify what exactly can look at, and what we need to keep on the side outside of scope. So, in that context, we are going to review the current set of ONC-adopted standards. And so, we are looking at ONC's adopted standards in the 21st Century CURES Act final rule, and we are going to look at that and understand whether each one of those is a candidate to be maintained, whether it is a candidate to be phased out, or possibly replaced. So, we have a couple different choices that we can look at.

They also can all be found in the ONC standards hub, but we will have some spreadsheets that the team put together that can help focus in on the ones that are in scope. What is not in scope is that we are going to be looking at new standards that are otherwise not referenced or not applicable to the use cases for which there are standards. So, for example, if we are looking at the current FHIR, C-CDA, or TIME setting protocols, then we can look at those and say hey, there is an opportunity to replace, move forward, or phase it out altogether, but if there is another area that is not covered in the current rule for which there might be standards, then at that point in time, it would be out of scope. An example of that might be for laboratory orders or radiology orders that are currently not put in there, so that is why we are not going to be looking at that.

So, through the process, as we are getting used to it, we will have a couple times that we may have to pause and make sure that we stay on track there. That does not mean that there are not other opportunities to provide feedback on that, but that is not the charge for this taskforce in these next couple of weeks. So, that is what we are going to aim for, and then we are going to look in a moment to how we actually are going to go about that. Steve, from your perspective, anything that we want to highlight here?

Steven Eichner

I think you did a great job. The only thing I would add is just information about some of the other opportunities for submitting additional standards or addressing topics that are not currently included in federal regulations, such as the Interoperability Standards Advisory, United States Core Data for Interoperability, and the opportunity to provide public comments when ONC and other federal agencies release proposed regulations for comments. There are ongoing opportunities to submit information for both the USCDI and for the ISA, and information about those opportunities are available on the ONC's website, and when there are opportunities for comment on regulation, those are also released by the respective federal agencies and available through the appropriate websites. Back to you, Hans.

Hans Buitendijk

Right, and I see a question from Vassil on the chat. A couple of notes on the chat, and then I will address the question. If you want to respond, we want everybody to see your feedback, not only the taskforce members, so please use "everyone," and that is perfectly appropriate. That will be capped as part of the record as well. But, the question that Vassil raises is about updated versions of current standards. So, as an example, currently, FHIR US CORE Version 3.1.1 is named, and you will see it later on in the list. If we believe that there is an opportunity or time that there are more current versions out there, we certainly have the opportunity to address that, including considering what a possible version might be. That is where it starts to get into the edge of the scope as to how far we go with needing to arrive at a common agreement and recommendation, say, Version 5.1.0, which just came out.



So, do we have to get to that level of specificity? Not necessarily. We can have just an indication and say hey, it is a good time to start to consider a more current version, and then we have some options there. But, we do not have to totally be as specific about that. But, if it is, for example, something that is totally new, then that would be out of bounds. So, that is where we are trying to find the balance. Vassil, does that help address your question?

Vassil Peytchev

Yes, thank you.

Standards Review Process (00:24:50)

Hans Buitendijk

Okeydoke. And, as we go through it, we will figure that out a little bit more as well. So, let's go to the next slide there, and we are going to start with the methodology that we are going to be able to use. So, there are two spreadsheets that you should have received, and we are going to step through each one of those to get a better understanding of how we are going to do this. If you can open up the reference material spreadsheet, that would be great.

In that list, we are going to see the total list of standards that are in scope of our discussion. We are going to keep out anything that is not on the list for other purposes, but for any of the lines that we are going to see, we are going to have the opportunity to determine if we need to recommend either of those actions. So, for the first line, I am going to go from left to right. We have our Network Time Protocol, Version 4 that is being referenced. In the next column, you will see the regulatory text citation, and as we start to scroll to the right a little bit and I move my display of cameras to another screen so you can see it, you can see the publisher there.

So, that is what we have in scope, and as you scroll down, we have a list of about 60 standards, if I recall correctly, that are in play as a result of that, and they are a combination of code sets, they are some syntax, they are data concepts, like USCDI, so you will see the wide spectrum that we have, as well as, on Rows 55 and 56, we see two standards that are particularly applicable to certification testing, so they are named as well. So, it is not only about the standards that are used to certify systems, but it is also about the process according to which they are being certified as they are being named.

So, that is the list. We have all the links in here if you would like to go into detail with these for some that you may not be as familiar with. We also have the opportunity as needed if we are in a particular area where there is need for more background, more information to help inform our recommendation, we have the opportunity to invite guest speakers to provide some context and considerations and take that into account as we move forward. Before moving from this spreadsheet to the next one, which is the recommendation spreadsheet, any questions here that we should address? We can always come back, obviously, but that is Spreadsheet No. 1.

Let's jump to the other spreadsheet, and that is where we are going to concentrate a little bit more on our work. Let's see. Is the recommendation spreadsheet that we have done available as well, where we are asking everybody to comment? Let's go to this one. This is fine, to go there. Let's jump back to the other one because there is a little bit more information that is visible there. If you would like to, if you go to cycle grouping, we have grouped standards into a number of categories that are alike or we believe are best discussed and considered together, so we have made a selection there around care coordination. That is a very large group, so we split that in two. And then, we have a number that are around public health reporting, clinical quality measures, privacy/security, patient data access, prescription, etc. So, that is a little bit more of a combination of a number of smaller groups that only had two or three there.

Steven Eichner

Just to interject quickly there, there are lots of different ways of separating things out into different groupings. We recognize that there are crossover functions in some cases or multiple uses for the different standards,



but we wanted to have some core way of grouping them so we could track activity and put things in manageable groups.

Hans Buitendijk

Yup, and you can see that back on the first tab when you scroll to the right a little bit, where we have Columns G and H. That is where we categorized each of these standards accordingly, and then, we do not need to do that right now, but if you go to the individual tabs, Groups 1, 2, and 3, that is where they are then collected together so that you have these different types of organizations in mind. But, it is Group 1, 2, and 3, etc. that we are going to use to step through the sessions. An additional piece of information that is here is that you will see the approved SVAP versions, so while, on the left-hand side, we see what is in the rule that is currently in place, you see that the SVAP versions are noted as well. They may be considerations to say hey, that would be a good next version for regulation to go to, so it is in part to have a sense of that and in part to really recognize that we have the regulatory track, and then, until the next regulation comes out, we have the SVAP to allow the standards version adoption process by which we can enable parties to certify to a more current version if they so choose.

Clearly, in the next couple months, if not weeks or days, we believe that SVAP will come out with another version, so if that happens while we are in flight with the conversations, we will probably have a good opportunity to update that as well and have the latest versions available there, but we will let everybody know when that happens. So, that is the next one, so that allows us to define the scope of what we are going to look at.

You will note that while the 2015 certification edition rules are effectively still in effect, so there was a little bit of a discussion if we should look at that as well, but since the 21st Century CURES Act final rule is the one that is in play right now, to which the end of this year we are really in a switchover mode, we are not looking at any standards or versions that are in the 2015 certification edition since they effectively already being addressed by either being replaced with more current versions or a new standard that is being put in place, so that is why we are looking at the 21st Century CURES Act final rule only. Any questions or clarifications up to this point? And, particularly from the ONC team, as we review these up front, if you see anything that we missed and should highlight further as we are getting up to speed with this. Okeydoke. I see a question from John Kilbourne. Go ahead.

Discussion (00:33:22)

John Kilbourne

I just thought of a question. Do we have an explicit reasoning for why we would want to remove a standard? And, I am not arguing against the idea, and I do not think we should just keep accumulating standards into perpetuity, but what would be the criteria? Maybe one by one, we will look at each standard, and there is not a general set of criteria, but I am interested if there is a sense of what would qualify a standard for removal. Maybe this is two early to ask that, but in general, I am asking that.

Hans Buitendijk

It is a great question, and I think we are going to discover that if there is any standard in here for which one would say there is no need to have a standard anymore. It is hard to think that perhaps we will see that going through the list. It is more likely that we will say there is a newer version out there. Perhaps there is an alternative standard that is better suited for what is attempted to be achieved that could become a consideration, but to actually totally drop the standard, we will have to discover that, and we will have to go line by line through these, and that is a great setup for the next topic in a moment on the spreadsheet we are going to look at on how we are going to go through that, and if somebody has a good argument to make to say, "This standard was a great idea, but for these reasons, we really should not perpetuate that," it is in bounds to bring that up. So, it is more at this point in time that it is valid to bring up, not necessarily that we are going to find anything that would meet that, but we are going to discover it.

Steven Eichner



This is Steve. Just to add onto that concept, it is really looking at two aspects of retiring a standard, one potentially retiring a standard because there is a better replacement available, and then, a second condition about whether there is no need for a standard to continue to be in regulation. In some sense, it is a parallel to some of the things that have occurred in promoting interoperability, with some things being initially required and being measured in promoting interoperability, but then, when they became a plateaued service, they were no longer included in certification criteria.

Hans Buitendijk

That is a good example, Steve, because the example that interestingly actually was suggested to go back into by the Interoperability Standards Workgroup is the lab results interface, LRI, that was initially in a while ago, then it was taken out, and the recommendations in the Interoperability Standards Workgroup are to consider that it might be a good idea to bring it back in. That would actually be an area that is outside of the scope of this taskforce because it is currently not in, but at the time, that might have been the argument used, to say we can retire this because we achieved our objectives. It is there, no need to worry about it anymore, it is adopted, and nobody is going to change it. I think I saw something in the chat come in. Vassil, you have a question about the definition of replacements being available. Can you clarify what you are looking at that we need to clarify?

Vassil Peytchev

Well, it was stated just now that one way to look at whether we can retire a standard is if there is a different standard replacement being available, and I was wondering what the definition is. Would it be something that is already considered for rulemaking, something that is just in the list of standards, and as we suggest an existing standard to be retired, we specify what it will be replaced with? What are we looking at here?

Hans Buitendijk

I think there are two examples, possibly a third, of replacement that are valid that we can look at. That is going to be a hard one, but let's look at FHIR US CORE. Currently, we are at 3.1.1, and one replacement will be a more current version. That is the clear replacement of the current reference standard. So, it is not that we are looking at the standard overall and saying that is the level at which we operate. We are operating at the level of the version, and that entry is that if you change the version, that is a replacement. I am going to pick another one as an example, which, again, might not be totally true, but Time Protocol Version 4. There is no need to go to a more current version. It works perfectly fine, so that one would be maintained.

At the same point in time, though it would be a little bit hard to find something, but it is fair game, there was another standard outside of FHIR that would be very suitable to support data-element-level APIs, etc., and it would exist. It is valid to consider and bring up that this Standard X, whatever that is, would be a better approach to what we have for FHIR US CORE, and suggest that that is the appropriate replacement, and retire FHIR US CORE. Now, you see me wrangling a little bit because that is hard to consider in that particular example, but I am just using that to indicate that it is valid to consider that as a replacement because we have the same capability that we are looking at, but using a different standard that is more with the times, a better growth path, or whatever direction it might be.

Steven Eichner

I would add in a certain maturity level. It is not a conceptual "Hey, we could draft some other standard that did all these other things that were already served by the existing standard," but again, some level of maturity and adoption that says as the standard is already...I am not going to quite say fully developed, but is well on its way in a position that could be adopted and put in practical application in a reasonable time period.

Hans Buitendijk

Yeah, we have not defined clearly the three, five, or six criteria which it must meet to be a valid replacement. I think that is going to be part of our discovery and our discussions, and if, along the way, we need to look at that, that is okay, but at the same point in time, we can reference some of the earlier work of the HITAC and related work to look at what were some of the criteria to get into a regulation, and that is where we can



reference and point to as well. Well, it needs to be good enough and strong enough to get into regulation, so we can and should consider those criteria that were used at the time and are still being referenced to make sure we are including something that can work and that can be adopted, is scalable, etc.

Steven Eichner

And, one of the complicating factors is making a specific recommendation and/or a specific timeline, or looking at all the costs or implications of shifting standards that may not have the expertise, and it is really pretty far out of scope in terms of saying, "Okay, what does it take to implement Standard B?"

Hans Buitendijk

Right. Does it clarify, Vassil, what is fair game and where we need to tread carefully?

Vassil Peytchev

Yeah, I think it clarifies. Thank you.

Hans Buitendijk

And then, the debate will get us to a consensus recommendation on whether we are comfortable with that and if we are to go that way or not. Okeydoke, then let's take that jump to the recommendation spreadsheet and have a look at that because that is where we want to do some prep work and get ready for our next meeting. So, you will see now at this point in time the list of standards, organized by groups, so in Column C, as you scroll down, you will see the variety of topics in sequence. So, our intent is to begin focusing on Group 1, then 2, then onto 6 at the end, and we are trying to group them around our upcoming meetings. We will find out whether we will be exactly able to get exactly one group in one meeting, but the aim is to focus around that.

And, what we are going to be looking at, and if you can click on the drop-down there, there is a column for everybody on the taskforce, and we are going to be asking everybody to make a choice on whether you believe and would suggest that the standard at hand should be maintained, no change is required in the foreseeable future, it is all going fine, there is nothing else out there that you could recommend to jump to, or if we are going to be looking at a phase-out where we looking at a replace/update, a full retirement, or "I don't know, I need more information to provide."

Now, it is not only going to be these four choices, but this will help us then organize and pool things together on where to focus discussion. If we all have "maintain" behind one of them, it is probably going to be a very short discussion. If, on the other hand, it is one of the phase-outs and some argue it needs to be retired and others argue to replace it, then we will have to spend more time on it and we can help organize our time together on that. If it seems inconclusive, then it might be a good indication that we might need somebody to present a little bit more on it. Steve, I think I heard you or someone else. Clem?

Clem McDonald

So, Hans, one problem or question...

Hans Buitendijk There is an echo, unfortunately, Clem.

Clem McDonald

Better?

<u>Hans Buitendijk</u> A little bit better, but there is still an echo there somewhere.

Clem McDonald

Well, the question is are we dealing with the version changes within the coding systems?



Hans Buitendijk

That is going to be an interesting topic. We talked about those. Those are probably more on the easier side because they already have a mechanism that you can adopt a more current version, so we probably are going to be able to have a more general discussion around code sets and how to manage that, and if we would suggest that retiring the current one needs to be adjusted in light of what we have learned, but in some ways, that is actually an easier one because yes, there is already a version in the regulation, but there is also guidance that indicates a more current version can be used as well that you can certify as well, so it would be a much more similar replacement and a general statement of "Yes, we like that method" or "No, we do not, and we think a better method of adopting a more current version is available." So, I suggest we think about it in those terms to handle that.

Clem McDonald

Okay.

Hans Buitendijk

And then, if you go all the way to the right, past the last person, you will see that there are two columns here. One is the draft disposition and determination. So, this is where we are going to be looking for that if you indicate particularly anything other than "maintain," though you can also put it in for "maintain" as well, put in your name, and then, behind that, the rationale as to why. Summarize why it is that you think this can be retired. What is it that you would like to see as information because it is inconclusive? So, that can help us also further determine how close we are with our initial ideas that we are to focus more of the discussion on. And then, Column V will be used to synthesize from there in our discussion what our actual recommendations will be that we are going to finalize and present to the HITAC full committee, and then, from there onwards to ONC. So, U is our working space where we can make our comments in between meetings, and Steve will step us through the timeline in a moment, and final is where Steve and I are going to synthesize our discussion into what the wording should be in the end.

Steven Eichner

I want to add that the synthesized material is certainly something for discussion and input. It is not a unilateral or closed-door discussion. We may do a little bit of work offline to prepare it for presentation and review, but we decidedly want the taskforce's input and consensus on any recommendation we might put forward.

Hans Buitendijk

And then, if you jump to the instructions of what we just talked about it, it is included in there, and they define what "maintain" is, that there is no change necessary. With "phase out," select this option if you recommend the standard be phased out and replaced or updated. We need not have a very specific timeline to it. It is more that that is a good, logical next step. John, you have your hand up.

John Kilbourne

Yes. When you showed the last screen, you showed USCDI as one of the standards up for consideration, and that made me think. To verify, we mean an all-or-nothing. USCDI is a data structure, almost. It has a lot of different pieces in it. It says, "Use this for this, use this for that, we want to use this, we want to use that." When we are talking about USCDI, do you mean we are saying either keep it as a whole, or would we be suggesting changes, for instance, to the USCDI collection of standards? In other words, USCDI is a collection of standards as opposed to other standards which are just a single standard, and do we treat the collection differently than we would treat an individual standard? I hope I am making sense with my question.

Hans Buitendijk

That is a great question, and USCDI is a good example to clarify that here, the objective would not be to suggest specific changes to USCDI that would result as part of USCDI Version 4, given that 3 is just about to come out and the comment and review period has lapsed, so it is not meant to do that. If you do have recommendations on how to better structure USCDI, what data might be missing, or what vocabulary





standards are referenced directly in there that may need some work, whatever that might be, there is the USCDI ONDEC capability where that feedback can be provide. So, that is not the scope and the purpose of this taskforce, so if anybody brings that up, we are going to gently remind them to take that path.

So, here, it is really more about assuming that right now, where we are, USCDI Version 1 is in regulation, USCDI Version 2 is not, USCDI Version 3 is about to come out, so if we were to make a recommendation today, I am not saying it is the right one, but just as an example, it could be "Well, we know that USCDI Version 3 is about to come out. That will be a better next option version than USCDI Version 1." So, our recommendation from a regulatory perspective is to start to consider Version 3 because it is more current, more complete, more comprehensive, etc., and we should consider that one.

An alternative, which is a great argument for that, might be that no matter what USCDI Version 3 is going to be, USCDI Version 2 is settled, out there, and in play, and that will be the right one. There is still a little bit more work to be done on Version 3, and that is not the right thing to go to. We do not want to go too deep into that because time changes and we are not fixed in time, so I think we have to be considerate that things can happen between now and whenever ONC might take action and actually move forward with an update or change, but that is the direction. It is USCDI as a whole, not the individual pieces that are in it. That is what we have to look at. Perhaps we can make some comments, but we have to be careful that we are not going into the ONDEC process.

Steven Eichner

And, the same thing would apply for any other standard that we are looking at. That is not what the taskforce's charge or scope is, to making edits within a standard, saying, "Oh, well, this standard would be great if it included this field additionally" or "Why is that field included in that particular standard?" It is really looking at the standard as its entirety.

Hans Buitendijk

Right, and that brings us to Dennis's question as well. USCDI points to vocabulary, clearly, but then, supporting standards, any one of the lists here, some more than others, would reference vocabulary as well on particular attributes in C-CDA or other standards that are in play. They will reference very specific bindings to value sets in there. Again, Steve's comment applies there as well. We are looking at the totality of that standard and whether it is appropriate. We still have Clem's question to address as well, that various code sets are being updated on a basis of every six months or one year continuously.

There is already a process to which we can adopt the most current one, so that general part is in the context of that advancement. SVAP may have a more current version of FHIR US CORE in there. It may have other ones in there over time. It is then about that standard with its bindings to the vocabulary that were relevant in that standard that we are referencing. We are not trying to provide feedback on the details inside the standard. It is either good enough in total or it is not good enough because of some reason, and that is why we would rather not do it. Does that help clarify, Dennis? Any other aspect that you were thinking of that needs to be addressed? Dennis, if you are talking, you are on mute. Okay.

Any other questions on how we want to go about organizing our thoughts around that? Okay, Steve is going to address the next steps on the timeline, but this will be the format in which we are going to start to collect data. As Steve indicated, it is not just enter the columns, Steve and I are going to go in the back room and come up with a suggested wording. That is going to be done during the sessions, give or take some prep to streamline the discussion, but other than that, that is what we are going to talk to, effectively line by line, some faster than others. A couple of them we might be able to do in groups because it applies to everything, and then we will work our way to the end.

Steven Eichner

Hans, do you want to talk for a moment about when and how we are going to identify subjects that we need to get some additional information about based on taskforce's knowledge **[inaudible – background noise] [00:56:25]** we need more information about?





Hans Buitendijk

Yeah, if you can open up the drop-down in Debi's column, this is not specific to Debi, but if somebody marks it as "inconclusive, we need more information," and you clarify then in Column U a little bit more what it is that you are looking for, that can help inform the team with ONC where we should invite some parties to further provide clarification or insight on that. So, for example, we might reach out to some of the SEOs that are responsible for these standards and provide insight into where you are at, where you are going, and if it is sufficiently different or not. We can look at that. Or, if there is a totally different alternative out there, Standard X, that might help provide some insight there. So then, it is a phase-out/replace. If you have a suggestion about another standard, that is probably a good candidate to bring somebody else into to help compare/contrast for everybody on the taskforce why that would be a good idea.

Steven Eichner

And, that helps inform the timeline, going to the next slide, I believe, back in the presentation deck. We have scheduled meetings pretty much for every week between now and the end of August, looking at Tuesday mornings 10:30 Eastern Time. We are skipping a meeting next week because of the 4th of July holiday, but are hoping that taskforce members will take the opportunity to review the material that has been distributed and make at least an initial set of recommendations or, at a minimum, identify the topics on which you need more information, and please complete that by a week from Friday, so, Friday the 8th, so that we have an opportunity to review that and begin to recruit speakers to fill in information that we need.

We are also looking at moving the meeting on August 30th to August 31st to accommodate some projected absences. Hans and I will be providing an update on the taskforce's progress at the August 17th HITAC meeting, and then our final recommendations will be presented to the HITAC on September 14th. So, that is an overview of the timeline. At each public meeting, there will be an opportunity for public comment, usually the last 10 minutes or so of the meeting. Hans and I encourage all taskforce members to be active participants in discussion, either using voice technologies or looking at using chat, and we are also available offline for additional questions through email or phone calls as needed.

Hans Buitendijk

Steve, I think Samantha and Jim have a question in chat about the deliverable from next Friday, to clarify that.

Steven Eichner

The deliverable for next Friday is to take the link for the worksheets and to supply additional information at a minimum about standards that you need more information about so that we can begin to identify speakers to help provide that information. If you could complete at least a portion of recommendations about whether a standard should be maintained or retired, that would be great. Again, focus initially on Group 1, since we have an initial plan to go in group order. Hans, do you have anything to add on that?

Hans Buitendijk

No, and particularly, the last point of emphasis is that we may not all get through the 55 lines all at once. Group sequence is important. If you can at least get through the first two or three groups, that will be very helpful, and then catch up along the way so that we can plan those meetings well in advance with speakers.

Steven Eichner

And, we will be sending a reminder out after the 4th of July to all participants regardless of whether you have completed or filled out the forms and the material or not, just as a courtesy, so that we do have good information when we meet in two weeks. Hans, anything else to add?

Hans Buitendijk

Nothing to add, other than the correction. Any questions on this? Does that clarify? Any other comments on the approach? Any clarifications, suggestions...?





Steven Eichner

Concerns?

Hans Buitendijk

Concerns? Anything you would like to raise before we start to dive in deep with everybody getting ready for the next meeting?

Steven Eichner

Well, we will open the floor for public comment, and then have another opportunity to provide any feedback based on those comments.

<u>Jim Jirjis</u>

Hey, it is Jim. I will raise my hand.

Hans Buitendijk

Go ahead.

<u>Jim Jirjis</u>

Just a quick question. Since this is an every-five-year thing and most of us have terms of HITAC on three years and maybe six total, did anybody on this call participate five years ago when this drill was done, or is this the first time under the HITAC statute that this exercise has been done? The reason I ask is if there are lessons learned about what worked and what did not five years ago.

Hans Buitendijk

We are the ones. We are going to learn first. It is the first time it is happening, and after this time, it is every three years, so that is when the cadence starts, every three years. But yes, we are exploring this task for the first time. We can help set how it could be done for the next time around.

<u>Jim Jirjis</u>

If we are looking to be done at the end of August, it seems like kind of a daunting task, so we have to stay high-level. Is that correct? There are details under each of these that could get wrapped around the axle. Go ahead, sorry, Hans.

Hans Buitendijk

No, you are totally right on. We have the potential of getting wrapped around the axle and opening all kinds of doors that we probably should not, and that is what we need to learn, so we hope to be as efficient as possible by having already a couple of those general guidelines fairly clear and crisp, like the example for USCDI, where we need to get that discussion in ONDEC, not here, so we are trying to limit it to USCDI Version 3, 4, 2, or whatever, and that level is where we are trying to do it. The other part is that we are also trying to avoid getting too precise about what this next version is. If it is very clear very quickly, it is Version 5, whatever. There was no implied reference to a particular standard there.

But, if that is the one, okay, we can do that, but if it starts to require a lot of discussion other than that we need to go to a more current version, then having a recommendation of "We need to go to a more current version," but by the time that you are going to write regulation, the landscape will have changed, so we really are indicating to you that you should explore the most current version at that point in time and not state what the version is, other than "the most current version" or some criteria around it. That hopefully will help us not to get any deeper than we need to, but it is going to be the first time, so we will have to learn and figure out how long it takes, how deep we are going to go, and how useful the end result will be for ONC to consider that in the next round. So, that is a little bit of a vague answer, but we have to learn this because we are the first.

Debi Willis



This is Debi Willis. I have a question/statement. I agree that this is a pretty daunting task with a lot of things we need to cover very quickly. I feel that a lot of these questions are going to be something I really know nothing about. I am really focused on the impact of standards on patients. I feel like that is more of my expertise. So, in all the other areas, I am going to really rely on people who are experts in those areas, so I will not trust my opinion because I do not know enough about it. So, how do we deal with that, when there is a line item that we feel is just not anything that we really understand or feel that we could contribute as an expert?

Hans Buitendijk

A fair and challenging point, and I think it is in part using the "inconclusive" that can help us guide how much more we want to provide that is introductory to these standards to make sure that everybody has the opportunity to provide perspective, and/or if we are in an area where somebody might not be as well versed to make sure for those who are that we are making crisp, clear arguments and criteria that can help raise the comfort levels for those that are less versed in it to say yes, they have thoroughly thought about it, and we are good with the reasoning without us having to go become an expert in that space.

So, I think it is going to be a little bit of that balance between those two, but certainly, do not hesitate to indicate that we would like to understand more about what this is so that we can have a better informed statement around it. You will find some of it if you go to the different standards links that are given in the introductory paragraphs. Some of them are very good at that, and I will readily admit and share the same experience that other ones are a bit obtuse as to what they are about. But, help us identify where that is so that we can figure out who to pull in and how to best get sufficient clarification for that.

Debi Willis

So, my understanding is our hallmark, though, is to start working on the spreadsheets to indicate if we feel the standards should be kept. Is that what we are supposed to do?

Hans Buitendijk

Correct.

Debi Willis

Okay. Is the focus on No. 1, or are we trying to go through the whole thing if we can?

Hans Buitendijk

If we can, go all the way. We need to end up there. But, for the next two weeks, looking at Groups 1 and 2 would be great. If I have it correctly in sequence, Group 1 is the code sets around care coordination, and Group 2 is the other standards around care coordination that use that vocabulary. That will be a good start to have because then we can gauge based on that how fast and how quick we are going to go. So, I would suggest at least those two, and the other ones shortly thereafter based on that, and not necessarily all at once, but for you, a good cadence to get them out.

Steven Eichner

This is Steve. I think there is...not an urgency, but if you can identify those areas about which you need more information early on, that would be great because the bigger window we have to identify where there are gaps, the more time we will have to bring in appropriate experts. Secondarily, it is not simply one vote and you are complete. As a taskforce member, you are certainly entitled to update your recommendation and your components as we go through the process as we gain more information. That being said, I think that there is an interest in not revising comments much more than a week after a particular subject has been discussed in meeting or as we have started to develop or finalize a recommendation around that particular standard.

Debi Willis

So, because we have so many standards to look at in a short period of time, would it make sense to add one more choice instead of saying "need more information"? I would rather have one that says "I would rely





on the opinions of the experts in this area" instead of clicking "need more information" for so many items because I do not think we would have enough time to bring people in. I believe probably a lot of us have very specific areas that we feel comfortable with. What is your thought on that? If you come up with 50 of those elements saying "we need more information," I do not know that you could accommodate that. "Out of scope or expertise" is what is recommended. I really feel that if I am really interested, I would want more information, but if I feel like this is really not anywhere in the scope of my understanding, I would rather say "out of scope" or "beyond my expertise."

Hans Buitendijk

I think that is a very reasonable suggestion, and looking at the ONC team, is that something that we can put in before we send out the spreadsheets after the meeting?

Michael Berry

We can, Hans. Another option could be to leave it blank until after the discussion because after the next meeting, where you talk about Group 1, maybe people can make an informed decision after that discussion and then fill it out then. Is that an option that could work as well? Otherwise, another choice we could add after, say, we have a discussion and people still do not feel like they can make a decision, we can put an "abstain," basically you are abstaining from picking one or another.

Hans Buitendijk

Debi, what is your thought?

Debi Willis

That would work for me, but for you, if I just left it blank, I do not know if you know that I have looked at it but do not feel I know enough information or if you would think I just did not even look at it. It is up to you and what you feel you need from us. Do you want us to say, "Yeah, I looked at it, but it is not in scope for me"?

Steven Eichner

I think the inclusion of a blank for "have not acted as yet" and then an abstention saying "I cannot act" are probably both good choices.

Hans Buitendijk

And, that would mean we add the choice, you could still leave it blank, which indicates you are still working on it, and an "abstain" or "I defer…" I think "abstain" encompasses the variety of ways you say, "I am okay with whatever the group is going to come up with." Mike, I think it might be a combination of the two. If you have the blank, it means you are still working on it, and "abstain" indicates "I am okay with where the group goes."

Steven Eichner

This is Steve. In companionship with that, I think there is probably a need for a third column about rationale rather than positioning on that particular standard so that we have a space that we can use that is not really looking at building the recommendation, but looking at building information about what additional information we need to provide because if we do not add a second column, we end up with only one column that has both "Hey, what information do I need?" and "What my recommendation is."

Hans Buitendijk

So, you would suggest including one between Columns U and V, or maybe between T and U, to indicate "This is the information I am looking for to help my decision"?

Steven Eichner

Yes.

Hans Buitendijk

And, if I am already more firm, then in Column U, based on whatever I learned, I am now going to put in "And this is my rationale for my choice."

Steven Eichner

Yes, because adding both to the same column will be difficult to untangle. Mike, is that possible?

Hans Buitendijk

Mike, does that work?

Michael Berry

Yeah, we can add whatever you feel is necessary.

Hans Buitendijk

Let's add that column, and then we have "add an abstain" and a clarification on the blank, that it means that it is still a work in progress, and the abstain should not be taken as the single and only final vote, if you will. You is totally allowed, as the discussion unfolds and new information becomes available, to change your perspective and input. So, until we get to Column V, where we conclude as we go through the meeting, everything is allowed to be fluid. It is only helping us get through the process and get to Column V to fill it out. Any other questions? Looking at the clock, we are about to have to go to public comment. Any other comments?

John Kilbourne

Just a quick question and comment. This is John Kilbourne. A lot of these code sets seem to fall under the SVAP scheme. The new version will come out pretty much as good as the old version, but better. Is there a Ctrl+Alt+Del+M, like a shorthand way of saying that? It seems like the majority of what I am looking at will be "Yes, let's just accept it, but with the latest version of the vocabulary," or should we all just figure out our own way of saying that? Maybe that is just as easy.

Hans Buitendijk

I think for now, it is probably just as easy to do that, and SVAP picks part of it up, but they are voluntarily not part of regulations, but actually, code sets have a very specific, agreed-to adoption scheme beyond what is listed in regulations, so I think that is going to be fairly straightforward, rather than adding a column with another drop-down for that specific purpose.

John Kilbourne

Right, thanks.

Hans Buitendijk

Right. Any other questions and comments before we go to public comment? Okeydoke. And, for any other questions along the way, as Steve indicates, please reach out for clarifications and otherwise, but now, we are going to open it up for public comments. For those on the line, if you can raise your hand, though we should have clarified that you could have participated in the chat along the way as well. Mike, you have better instructions than I do.

Public Comment (01:19:28)

Michael Berry

Yeah, I will open us up for public comment. So, if you are on Zoom and would like to make a comment, please use the hand raise function, which is 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. So, we will pause for a moment just to see if anyone raises their hand. I am not seeing any hands raised, Hans and Steve, so I will turn it back to you, but will continue to monitor. Thank you.

Hans Buitendijk



All right. Thank you, Mike. Steve, anything from your perspective that we need to address? Or, unless we have additional comments, we will have a slightly earlier close.

Steven Eichner

Yeah, we have one additional question that has been put in the chat box, looking at all the more current editions listed in the spreadsheet, and a comment saying the sheet contains all of the versions from SVAP. So, I want to bring that to everyone's attention.

Hans Buitendijk

And, if you want to find out the most current version that is available for a standard that is not in regulation because it is a couple of years old, it is not in SVAP because they do not necessarily address everything, there are ways to find out that lets us follow up to see whether there is a quick way in which we can add some of that information so not everybody needs to hunt and peck through to find them. For a couple of them, it is going to be fairly straightforward to find them, and for others, you need to know where it is. ISA has a lot of it, but not necessarily the most current, either, depending on where they are in their update cycle. So, the most current version published is not always going to be straightforward. We will discuss on how we can support that.

Steven Eichner

And, the other component there is looking at a version change as a different kind of update or current standard replacing a standard with something else, so there may be different implications in either case about what comes next. I am looking how at replacing Version 4 with Version 5 is a change, but it is a different kind of change than looking at replacing a standard with a different standard that has a different source, if that makes sense.

Hans Buitendijk

Yeah, and the bar for the recommendation criteria, etc. will be likely a little bit higher because that is typically the biggest switch. So, we will check whether we can get the latest versions fairly easily, and that information as well, and I guess that we are on to the next step, which is closing the meeting, and Steve, I guess that means that we are looking at reconvening two weeks from now.

Steven Eichner

Yes, sir. I do want to thank everyone for their time and attention today and their commitment to the taskforce's activities.

Hans Buitendijk

And, in the meantime, have a great July 4th weekend that will be in between, and we will talk again in two weeks. Thank you. Have a great day.

Michael Berry Thanks, everybody.

Adjourn (01:23:04)

