Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

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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
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Hung S. Luu	Children's Health	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Miri	Baptist Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
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Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
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Daniel Healy	Office of the National Coordinator for Health Information Technology	ONC Program Lead
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Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. Just a reminder that the focus of today's meeting will be primarily on Group 3 recommendations, and we only have a limited time to spend on each topic area so that we complete Group 3 recommendations today. 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 toward the end of our meeting. Let's begin rollcall of our Task Force members, so when I call your name, please indicate if you are here. I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Medell Briggs-Malonson? Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Hannah Galvin?

Hannah Galvin
Good morning.

Michael Berry
Adi Gundlapalli? Jim Jirjis? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Anna McCollister? Clem McDonald? Deven McGraw?

Deven McGraw
Good morning.

Michael Berry

Aaron Miri? Eliel Oliveira? Kikelomo Oshunkentan? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Sheryl Turney is on vacation, so she will not be able to join us. So now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:39)

Steven Lane
Well, thank you, everyone, for showing up for what is our last working meeting to pull together the recommendations. This is the last meeting of Group 3, and really, than you to Hung Luu for stepping forward to lead this group, and we are going to move quickly and try to finalize a set of recommendations that has been drafted on Tab 3, Column J. They are prenumbered this time, so we can hopefully get through them quickly. I see it was only Row 4 that we turned green last week, so we have a lot to do, so thank you for your focus here. Anything to add, Ike? Michael Wittie, can you stay out of Column J? I am going to be in there trying to work. Everyone stay out of Column J, and I will make it as pretty as possible.

Steven Eichner
That was about the only thing I had to add that was important. We again want to reemphasize our welcome to everybody. Let's get going so we can best use our time.

Steven Lane
Take it away, Hung.

Update and Revise Draft Recommendations (00:03:00)

Hung S. Luu
All right. Thank you, and reiterating once again, all members of the Task Force, that you are free to view the spreadsheet, but please stay out of the document. We are going to be editing it live, so if you are in the document, we will not be able to edit it.

Steven Lane
Actually, no.

Hung S. Luu
Column J.

Steven Lane
Yes. Feel free to put comments into K as we go. Hans has been really good about that, crafting language that I can then copy and paste into J.

Hung S. Luu
Thank you. With that, let's get started. We have a lot to cover today.

Steven Lane
So, 2J. Excel, can you get us over there? Perfect.

Hung S. Luu
All right. So, the first set of recommendations we will be working on is around the Insight reports or metrics that are proposed to give a view of the adoption and utilization of the certified technology. So, these are the recommendations proposed by the Task Force. The first overall is that the Task Force is supportive of the recommendation implementation of the CURES Act as the Insights condition main certification requirement, but we have some fine-tuned recommendations on how that can be accomplished. No. 2 is that we are recommending that due to the fact that some of the data that might be required of the vendors to provide as part of the Insight condition and maintenance of certification belong to the clients rather than to the actual vendors, so Recommendation 2 is to ask that the ONC coordinate with CMS as best as possible to make sure that that data is encouraged to be available to the vendors to specify the condition. So, I will pause there.

Steven Lane
Feel free to raise hands in the app, or speak up. We have a small group today. I think we just need to pause for 10 seconds and if nobody chimes in, keep moving.

Hung S. Luu
I am not seeing any discussion, so we will move on to 3. We recommend that ONC aligns the Insights program with the real-world testing program so that there is not duplicative work, so as to reuse applicable data as much as possible. I will pause. All right. And then, No. 4, recommend that ONC work with CMS to support alignment of definition of encounters between ONC's Insight program and quality measurement. So, this is around one of the metrics. We would like to recommend that there be consistency between how that is defined so that perhaps the same data can be utilized, but more importantly, that we are looking at the same benchmarks. It does not appear that there is discussion. And then, No. 5, recommend that ONC work with CMS to enhance the definition of encounters to address the inconsistent encounter types, a reference in the proposed definition, and then, cap types that are valid for FHIR US CORE and **[inaudible] [00:07:02]**. So, this is building onto the prior one.

Steven Lane
Should 4 and 5 be combined, given that they are dealing with the same issue?

Hung S. Luu
I think that is reasonable.

Steven Lane

Hans, these are largely your brainchildren.

Hans Buitendijk
I do not have any comments at the moment. I am good.

Steven Lane
But the question is do you think combining 4 and 5 is logical?

Hans Buitendijk
Yes, I think we can do that. That is just wordsmithing now.

Hung S. Luu
Okay. I do not see any discussion on 4 or 5, so, 6, recommend that ONC reference a limited scope of the FHIR measures by including only the FHIR API supporting the USDA version reference, the rationale being that the APIs may have application beyond what is supported in the USCDI, and so, this is to kind of limit it appropriately to what is in the USCDI version reference only.

Steven Lane
I just took a stab at combining 4 and 5. Hans, do you want to look at that and see if you are comfortable with it? We basically just slammed them together. Does that still hang together for you?

Hans Buitendijk
Yes, there is hardly a difference. One was expanded on the other, so that works.

Steven Lane
Perfect, okay.

Hung S. Luu
We really are moving at the speed of business!

Steven Lane
There you go. So, 6 is accepted.

Hung S. Luu
All right, moving on to 7, recommend that ONC, in the definition of Insights condition document exchange metrics, require that all documents are counted whether considered duplicates or not.

Steven Lane
This struck me as a pretty significant recommendation, Hans. It makes sense to me. It certainly is not one I would have come up with, but **[inaudible – crosstalk] [00:09:46]**.

Hans Buitendijk
The rationale is that every document that comes in needs to be “reviewed,” and therefore, it is work for a person and for the system, and it is managed, so excluding them seems to be odd.

Steven Lane
It does not give us credit for all the work we are doing.

Hans Buitendijk
Yes, it is a dual use of data and we need to manage it collectively, so if we count it, then we need to count everything.

Hung S. Luu
Seeing no discussion, I will move on to No. 8, recommend that ONC, in the definition of Insights condition volume measures, consider whether increases or decreases are truly indicative of desired advancements. So, I think this gets around the fact that there are other forces at play, and that not necessarily seeing an increase or decrease is necessarily applicable to the desirability of the advancement, but more the fact that there could be a shortage on resources or the fact that sharing a document could lead to duplicates, but at the same time, that could improve interoperability and the care of the patients.

Steven Lane
I think this is really kind of suggesting that we should not assume that more is always better, and that we should design metrics with that in mind and really be looking at the ultimate goal of improving care and outcomes, and you certainly do not want people gaming the system simply because they are being rewarded somehow based on higher volumes.

Hans Buitendijk
Yes. What we have seen is that in the beginning, starting volumes are good because you can see it trend upwards and say, “Hey, there is adoption,” but at some point in time, it does not matter anymore. It is now working, and it is hard to say whether more is better or less is worse.

Hung S. Luu
All right. No. 9, in the definition of Insights condition document reconciliation metrics, consider including documents reconciled not only by human use, but also recognize the use of automated tools which reduce the need for manual review and reconciliation of data already known. So, this gets around the credit. If tools have been developed to reconcile this automatically to benefit the human users, then that should still receive some credit.

Hans Buitendijk
Right, and we have seen an increasing number of tools to help with that and ease the burden on the individual.

Steven Lane
I just added an “e.g.” in there. All right, are we good with that one?

Hung S. Luu
I see no discussion, so if there are no last-minute objections, I think we can turn that box green.

Fillipe Southerland
I had added one on last Tuesday. It is at the bottom of Column G, if we can take a look at that.

Steven Lane
Let me just bring it over so we can look at that all in one place. Okay, there it is, Fil. You should be able to see it.

Fillipe Southerland
So, this one is that I think ONC made a good start at addressing the burden of the reporting criteria that may not be applicable to startup HIT developers, and I wanted to extend that consideration to specialty and non-EHR developers for these criteria as well as considering the same type of criteria for other base EHR.

Steven Lane
Seems reasonable to me. Does anybody feel differently?

Hans Buitendijk
No.

Hung S. Luu
Hearing no objections, I think we can accept that.

Steven Lane
Thanks, Fil.

Hung S. Luu
Going once, going twice?

Steven Lane
Gone. Turning green. Love it. All right, next.

Hung S. Luu
Let me get back into the same view. So, this is around our recommendations for setting USCDI Version 3 as named version moving forward, and so, the first recommendation is that the Task Force overall is supportive of moving USCDI Version 3. And then, Recommendation 2 is around the fact that we do recognize that there are specialty EHRs that do not necessarily serve all populations, and that there needs to be special consideration for those specialty EHRs in order to promote adoption of certification so that the patient population can benefit from certification without unduly burdening these small specialty developers that, right now, have to pretty much include everything that is in USCDI, even if it is not applicable to what it is that they do. I see Hannah.

Hannah Galvin
Yes, I would like to also just note that there are sensitive data elements, such as social determinants and others, in USCDI Version 3, and that there is some misunderstanding throughout the industry that once we move forward to a version, exchange of all these data elements is required in every situation, and I think that education around in what situations the data exchange is required versus that it is available will be helpful, as well as just an understanding that some of the data elements are sensitive and that, pending

some of the other pieces of this rule and the advancement of the ability to granularly segment sensitive data, there may be concerns about sharing some of those data elements in certain situations.

Hung S. Luu
Do you have concerns about wording of this recommendation? This is pretty much asking the ONC to consider establishing a framework whereby the specialty EHRs and other vendors can participate in certification, provided there is flexibility in how some of the data elements are handled. They might not need to manage or create all the data elements, but they certainly need to be able to transmit it in an interoperable way, so that is why we inserted the language of "flexibility."

Hannah Galvin
I think "flexibility" is good language. I do continue to say that once we go with the path of certification, there is concern specifically around some of the sensitive data elements and not having the technical capabilities yet, not just for the specialty EHRs, but across any EHR, to be flexible in that regard as well, so that would be the only thing that I might add here.

Steven Lane
Hannah, do you want to encapsulate that thought, maybe in Column K, if there is another sentence or something that you think gets at that? I am not going to do justice to your idea.

Hannah Galvin
Sure, I am happy to.

Steven Lane
Hans?

Hans Buitendijk
I like what Hannah mentioned because frequently, there is an everything/always type of expectation, and I think it is good to have clarity on the expectation that not every HIT has everything, and even with whatever they have, do not expect to get everything always, but that you get what is the right amount in the right context. That may be throttled, like for this purpose, you only need three elements, and for another purpose, you need everything, and it is throttled based on privacy and patient consent rules, what you can actually get and what you are not allowed to get, even though it is there.

Hung S. Luu
While we are waiting on Hannah, let's move forward to Row 4.

Steven Lane
Row 5.

Fillipe Southerland
Before we leave this one, can we change Recommendation 10 in the column above to align with the non-EHR language? I said "non-HIT," but I like the definition of "non-EHR" better.

Steven Lane

It says “non-EHR.”

Fillipe Southerland
Oh, okay, good.

Steven Lane
Okay, Hannah is still working, so do you want to go to Row 5?

Hung S. Luu
Yes, please.

Steven Lane
That was easy. Five is done. No objections there, right?

Hung S. Luu
So, the recommendation for Row 5 is the Task Force supports the proposed changes to the standard API for patient and population services. Okay, turn it green. Row 6’s recommendation is the Task Force supports the adoption of FHIR US CORE 6.0.0. However, we do recognize that that current standard will require additional critical updates and that the rule might actually be published before those updates are published, and so, the ONC should consider the most current version as part of the final rule…

Steven Lane
Michael Wittie, can you stay out of Column J, please?

Hung S. Luu
…and, if needed, update it to the more recent version with the critical update. That is a lot of updates. Any discussion around that?

Steven Lane
Thank you again, Hans, for keeping us honest here. Hannah, are you there? Not quite.

Hannah Galvin
Yes, I am done.

Steven Lane
Okay, you have to get out of the cell for us to see it.

Hannah Galvin
I am out. If you click on it, I think you can see my comment.

Steven Lane
Okay, I can see it. So, it says, “Would also recommend industry education that exchange of all USCDI V.3 elements should not be required in all circumstances, especially where deemed sensitive, until or unless mature standards to support granular segmentation are made available.”

Deven McGraw
Can we see that?

Hans Buitendijk
Now you can.

Steven Lane
I am not sure why it is not showing. Let me see if I can…

Hans Buitendijk
If you go back, it is a red and a top alignment.

Steven Lane
I am looking. I was just monkeying with those things.

Hans Buitendijk
It is there now.

Hung S. Luu
Oh, I am in the cell. That could be it.

Steven Lane
Here, I will tell you what. Let me copy it into chat, just in case that makes it easier for people. Okay, this is what she wrote.

Hans Buitendijk
Whoever is driving the screen, if you can go one cell above, to Row 3.

Steven Lane
Oh yes, you have to be on Row 3. That is the trick. There it is, at long last! Okay, so, this would go in the recommendation, not the rationale, correct?

Deven McGraw
This looks like an extra recommendation on education.

Hans Buitendijk
Agreed, which would be helpful.

Deven McGraw
It is not about establishing the standard, it is about accompanying the standard with education. I guess I do not see why updating the standard translates into a requirement to share all data elements.

Steven Lane
You are right, Deven. It is really not related to this particular…

Deven McGraw
I do not disagree with the sentiment, but I am not sure it fits. These are the standards for the data set. It does not translate into "You must share it all under all circumstances." There is a completely different set of rules that go into… Whether you can share or not is different from whether you have the capability to do it.

Hannah Galvin
Deven, I agree with you, but I have heard from vendors, at least, that they interpret it as such, and so, I think that is what I am trying to call out. But I agree that we understand that that's not the case.

Steven Lane
This is not about V.3, it is just about USCDI generally.

Hung S. Luu
Hans?

Hans Buitendijk
There is some language that, when you look at the criteria in general where this pops up, I agree that you must be capable of including everything, but the way that it is written and interpreted by many people is that you therefore must always include, say, in a discharge summary, everything always, even though for a discharge summary **[inaudible – crosstalk] [00:26:08]**.

Deven McGraw
Oh, interesting.

Hans Buitendijk
That is part of the educational element to make sure that at every time, you do not have to include everything. You need to include what is relevant, but if everything is relevant, you have to include everything. If some is relevant, you only need to include that. Over the last number of years, particularly with C-CDs, they are being fully loaded every time and being shared every time over and over again, or there are other documents that are being extra loaded that really do not need to be. Just tailor it to what you need, as long as you have the ability to include everything that is relevant. That is not clear to everybody. It is an educational topic that will be helpful. If this is the right **[audio cuts out] [00:26:54]** or not, fair point, but it is a good point that Hannah is bringing up, that there is confusion around that.

Hung S. Luu
I do not see that it fits anywhere else, or at least in Group 3.

Steven Lane
Yes, so one wonders whether it is within our scope, Hung. Does it perhaps fit into some of the data segmentation stuff? Could it go, perhaps, onto the Tab 1 item where they are asking for additional input on privacy controls? That is a thought that I have.

Hung S. Luu
Or is this another item to recommend to HITAC for…?

Steven Lane
Annual review?

Hung S. Luu
Yes.

Steven Lane
That is probably the most honest.

Deven McGraw
There is something to be said for a mention in the final rule preamble, when, even in the section around finalizing USCDI as a standard, understandably, this creates a mandate around capabilities, not a mandate to exchange all the data elements in every circumstance, so, as we have been talking about it, it is not completely out of the realm of something that we might suggest be part of the final rule, again, because remember, there are the rules, and then there are boatloads of preamble that help put the rules into context. So, I am fine either way. I do think it is worth mentioning. I suggested a modification in the chat to broaden the aperture a little bit, and maybe even broader than just focusing on sensitive data because the reality is in any circumstance of sharing, particularly sensitive data or not, you share what you should be sharing, and you do not have to send a whole boatload just because you can.

Steven Lane
Deven, could you just copy and paste your text into Column K, just because it is easier than me retyping?

Hung S. Luu
You read my mind.

Deven McGraw
I am not in the document. I can open it, but if somebody else…

Steven Lane
No, I can do it. It is not the end of the world. I do not think any of us have the ability to copy and paste from the chat.

Deven McGraw
Oh, okay. Fair enough. I will make a screenshot, and I will get it in. Technological limitations…

Steven Lane
I was sort of tweaking the text as we went along to reflect the discussion. Hannah, make sure you are comfortable with this.

Hung S. Luu
Okay, have we landed on where this recommendation should go? Are we comfortable including it as part of our USCDI Version 3 recommendation?

Hannah Galvin
That looks good to me, Steven.

Deven McGraw
What I am seeing is…

Steven Lane
I got it. Just because that was the only part we needed, "the capability to exchange exists."

Deven McGraw
I might have a slow uptake.

Steven Lane
I got it.

Deven McGraw
Okay.

Steven Lane
All right. So, there we go, and we think we are going to leave this here and consider it in scope. Aaron is not here, and it is not for him, so we will just do that. We will call that 3 under this one and see what Mike and Michael let us get away with. All right, shall we move on?

Hung S. Luu
Yes, please, down to Row 7.

Steven Lane
I am turning that one green. I just want to acknowledge how much fun I have turning things green.

Hung S. Luu
So, Row 7 is rather dense, but it might look familiar to some of our long-term HITAC members, and that is because I borrowed heavily from our prior recommendations to ONC on the ISA in terms of suggesting that in order to move laboratory interoperability forward, we really need a new data model, and also the technological infrastructure with the standards to accommodate the data model, in order to progress laboratory interoperability. So, it is listed out here what is needed, and also that there needs to be coordination between the different data standards in terms of HL7 LOI, LRI, and FHIR US CORE, and eventually FHIR LIVD, in order to be able to implement this new data model, which I think has increasingly been recognized as providing more granularity than what is currently available, and will also position us well in terms of supporting other applications of laboratory data such as real-world evidence.

So, that is 4.1, and No. 2 is that part of that new data model is that there are some data elements that are not mature and are not currently supported, and so, this is a recommendation for ONC to work with the FDA, and also standards developing organizations and manufacturers, to advance the UDI or, at the very least, some kind of identifier for the device, including kits and instruments, so that we can capture and transmit that information moving forward.

No. 3 is that there has to be a way of… Why laboratories struggle with accurate coding is because there is not an authoritative source of truth out there that they can refer to, and so, this recommendation is that we develop some kind of source of truth, such as what is being recommended by SHIELD, for the laboratory interoperability data repository, where that is a centralized repository of all the curated codes that have been provided by manufacturers for their offerings so that laboratories can go to that single site to look up their assay performed on the particular platform or with a particular kit and be able to know exactly what the recommended coding for that assay is. That is currently lacking, and so, this is one of the elements as needed to move interoperability forward, and definitely to support accurate coding in the LIS and EHR systems.

And then, Recommendation 4 is that we recommend that the ONC focus on the data model, with understanding that the data model by itself is not sufficient and does need the infrastructure, but just focusing on individual standards, such as LOI or LRI, and implementing them fully without the data model is not going to get us there. There might be things in the LOI and LRI that also are extraneous to the data model, and full-throated implementation may not achieve what we are looking for, but we do feel that LOI and LRI are fit for purpose for workflow, but it would require substantial investment for full implementation. Clem? You are on mute.

Clem McDonald
Where can one find the data model?

Hung S. Luu
The data model will be published in the… Well, actually, there are two places it is currently published, CLSI Auto 17 and also the Community Roadmap by SHIELD, which has been approved by the steering committee for publication and has been moving through the FDA for clearance. Once we find a suitable method for publication, that will also be another resource to find the data model.

Steven Lane
I must say, Hung, we have been trying to get these recommendations over the line for a number of years now. They keep coming back. Eventually, they are going to have to shut us up by just accepting it.

Hung S. Luu
Are there any objections to these recommendations?

Clem McDonald
Not really, but if you are specifying a data model that one cannot review, that is an issue.

Hung S. Luu
But we also included it as part of the recommendation.

Steven Lane
Yes, Clem, the recommendation says at the very top “further define an interoperable information model,” and then it provides a lot of the detail of what needs to go into that, but it is not specifying a completed data model.

Clem McDonald
Okay, thank you.

Hung S. Luu
I can summarize that LOINC needs to be there for the order and also for the performed test, but we need UCUM for units of measure for quantitative and we need SNOMED and coding for the qualitative, and we do need the test interpretation, such as high/low normal/abnormal, SNOMED for specimen information, and UDI for the test kit and relevant device data.

Clem McDonald
The high/low and stuff… I do not know about the codes for them, but the list for them is specified in HL7.

Steven Lane
He has it here, HL0078.

Clem McDonald
All right, thank you.

Steven Lane
I must say, each time we have gone through this, Hung, it has just gotten crisper and crisper, clearer and clearer what is needed. Okay, I turned that green. Any objections?

Hans Buitendijk
No.

Steven Lane
All right. Hung, you are killing it. This is wonderful.

Hans Buitendijk
We will never forget Table 78.

Hung S. Luu
Row 8? So, this is around pharmacy interoperability. Our initial recommendation is that we establish a certification criteria using the NCPDP Real-Time Prescription Benefit Version 13 rather than the named Version 12 because of the fact that Version 13 contains patient demographic information that may provide additional patient-matching utility, and also there is additional functionality not available in Version 12. Any objections to that?

Clem McDonald
For Recommendation 5, would the word “alternative” be as good as “complementary”?

Steven Lane
Let us get through them in order, Clem.

Hung S. Luu
Any objections on Recommendation 1? I am not seeing any. Recommendation 2, "recommend that ONC require health information technology support for both NDC and RxNorm." The rationale from our pharmacy interoperability colleagues is that the ECR standards are complementary and provide different information. Looks like there is no objection on that, so No. 2 passes. Recommendation 3, "recommend that ONC require health information technology to be supportive of either the XML or EDI formats as a transitional step until all users migrate to the final JSON format rather than requiring an intermediary migration." Any objections to that? Okay, seeing none, "recommend that ONC work with CDS and CMS to support prescription drug programs in being able to receive data utilizing the new standards." This recommendation came from Steve Eichner. I do not know if you have had an opportunity to further refine this or if you are now okay with this language.

Steven Eichner
I am good with the language as it stands. If other folks want to refine it, that is perfectly fine with me.

Steven Lane
I think it is fine.

Hung S. Luu
All right. Any discussions? If not, it looks like that passes. Recommendation 5, "recommend that ONC require use of ICD-10 as the primary diagnosis code set within SNOMED CT as an addition to and not a replacement for ICD-10." So, we are just striking "complementary."

Steven Lane
Clem, that was based on your earlier comment.

Clem McDonald
That is okay.

Hung S. Luu
Okay. Any objections on that?

Steven Eichner
Do we want to include "ICD-10 as maintained" or "as updated" so we are not stuck in time as the regular updates to ICD-10 are included, or is that understood?

Steven Lane
I think it is understood. If we say "require ICD-10…"

Clem McDonald
One last question on Recommendation 5. As written, it is "as an addition, not a replacement for ICD-10." Does that mean it must be added?

Hung S. Luu

That was the recommendation by our pharmacy colleagues because they do see utility in the SNOMED CT.

Clem McDonald
Maybe as an optional addition. Unless it is intended, it should always be there.

Steven Lane
Is it a required or optional addition?

Hung S. Luu
Their recommendation was that it be required.

Steven Eichner
This is Ike again. If both are included, you have potential different approaches to mapping implemented by different entities, and that could be an issue.

Steven Lane
But we are saying they need to send it. However they got to the SNOMED code, we are telling them to send it to us.

Steven Eichner
Right, but if IBM mapped SNOMED to ICD-10 differently from another entity, that could be an issue on the receiving end of it because they could use the different mapping.

Steven Lane
Yes, but that is a known problem with two code sets, right?

Steven Eichner
Yes, I am just not sure what it means on receipt and how to reconcile it.

Hung S. Luu
I guess I would return us to our initial introduction, where we are asked to concentrate on the recommendations, and not the implementation.

Steven Eichner
I am not saying we should not provide that implementation, but the back of my head is positing, “Okay, what does that mean for the utility of interoperability function?”

Steven Lane
Yes. Everyone is going to have to struggle with that issue. There is no standard mapping.

Hung S. Luu
Have we preemptively turned it green? Are there any objections to that?

Steven Lane

All right, let's move on.

Hung S. Luu
Okay. Actually, let's move on in order. Row 9 is around the CDS Hooks. There was a lot of discussion on this, and the two schools of thought are that CDS Hooks requires context in order to be utilized correctly. Otherwise, without context, two organizations or developers can implement the same hooks in an entirely different manner, and that could be a challenge for the receiver, and also, that might not be the intent of the certification process. And so, this is an attempt to reconcile that, so we are recommending to adopt implementation guides that can guide the use of the CDS Hooks and implementation guides such as the prior authorization use case when sufficiently mature and available. That is obviously recognized as a prime use case for CDS Hooks. Also, focus on implementation guides using high-value hooks such as patient view, order select, and order sign, and also encourage the use of hooks directed toward patients, as well as silent alerts that may function within an HIT system to drive workflows without the need to present alerts to a human.

Steven Lane
I just moved the rationale down below the recommendation.

Hung S. Luu
Okay. Any objections to that recommendation?

Steven Lane
We have this "such as prior authorization" in the core recommendation, and then we have some examples below. Can we move prior authorization down into the list of examples? I am not sure why it belongs in the core.

Hung S. Luu
Okay, that is fine. With that change, is everyone okay?

Hans Buitendijk
Yes.

Hung S. Luu
If there are no objections, I think that we can safely turn it green.

Steven Lane
So, just to be clear, patient view, order select, and order sign are hooks, whereas prior auth is a guide, correct?

Hung S. Luu
Yes.

Hans Buitendijk
And one or more of them could be used in prior auth, and that is where you would know how to actually use the right hook.

Steven Lane
Got it. So, how do you like how I did that? "Focus on implementation guides utilizing high-value hooks." Oh, "guides such as prior authorization." I did that wrong; I will fix that. "High-value guides such as prior authorization."

Hans Buitendijk
Right, that will work.

Steven Lane
"And utilizing high-value hooks." I think we have that. All right, going green.

Hung S. Luu
Okay, down to Row 10. "Recommend that ONC work with HL7 to determine that FHIR R.5 subscriptions can work with R.4 content, focusing on establishing implementation guides for high-value subscription use cases that benefit from certification." And so, the main concern around this recommendation is that there are different versions out there, and that we really need to ensure that we can align the R.5 subscription with the R.4 content, so if we focus on R.5, we can avoid costly rework as long as we can still use the R.4 content.

Steven Lane
I recall this discussion. Let's see, is Mark here? Mark is here. Okay, I think this came from Mark. Maybe we can get a public comment on this. If anybody in the public wants to chime in in the chat, you are welcome to do so as we go along. Is this ready to green?

Hans Buitendijk
There is a minor typo in "implementation guides." Other than that, no concerns.

Fillipe Southerland
The FAST identity use case was also part of the comments from the previous discussion here.

Steven Lane
Where do you want to plug that in, as a guide?

Fillipe Southerland
Right, so we have the shared care planning, but we could also include the identity matching, or FAST identity.

Steven Lane
Okay, "shared care planning and FAST identity use cases."

Fillipe Southerland
Right.

Steven Lane

All right, how do you like that?

Fillipe Southerland
Looks good to me.

Hung S. Luu
Mark approves as well.

Steven Lane
Yay! Thank you, Mark. We appreciate your positive feedback. All right, Row 11?

Hung S. Luu
Row 11. So, this recommendation is around the use of SMART Links, and we recommend that "the ONC track and support the development of standards and maturation of the SMART Scheduling Links implementation guide," but there was some reservation in that we do note the following barriers to widespread implementation when advancing standards, and that is that while we have seen increasing providers use FHIR, not all providers are FHIR enabled and not all providers have been able to adopt interoperative health IT, including those with limited resources, and also those that were not included in prior EHR incentive programs, and that scheduling systems are not universally integrated into EHRs, and lastly, multiple approaches currently exist, and that certifying a single approach may not be beneficial while these multiple approaches exist because there has not been a clear demonstration that one approach is superior to another in all circumstances.

Steven Lane
Wait, the wording of this last sentence, the "thus" sentence, is a little awkward. "Thus, certification to a single approach would not be beneficial while adoption to data for HIT that does not work…" I do not know what this is trying to say. Hans, was this you?

Hans Buitendijk
Partially. Let me take that sentence to Column K and do some reconstruction. Would that work?

Hung S. Luu
Yes. While he is hammering that out, let's move to 12. So, 12 was on the SMART Health Links, and so, in this case, "we recommend that ONC identify high-value use cases where a common QR code is valuable and recognize the limitations on what can be included in the QR code directly versus what can be accessible based on the QR code provided as the current limitations on the quantity of data that can be encoded when the QRS code may limit usability and diminish the advantages over other technologies for certain use cases."

So, the main concern here is the use of the QRS code is definitely valuable, but the fact that there are limitations on what can be encoded as part of that data gives us pause due to the fact that valuable data such as clinical conditions that may impact the patient's vaccination status may not be able to be included despite the fact that this would be essential information in a lot of circumstances where a medical condition precludes the patient from being fully vaccinated, but they may be discriminated against due to the fact that that is not being conveyed. And so, there should be investigation into seeing if the data can be expanded,

but also, the QRS code could be used to direct the receiver to a resource that may not be as limited in terms of the amount of data it can convey.

Steven Lane
I am sort of wordsmithing as we go. I will substantively accept that I changed that one word to "utility." It was "usability," which I do not think is what we were getting at.

Hung S. Luu
Any objections to that recommendation?

Deven McGraw
No objections, Hung, but there is something in the chat from Julie around maybe a potential typo.

Steven Lane
"QRS in Line 2 should just be QR."

Hung S. Luu
Oh yes, the second "QR code" in that line.

Steven Lane
Oh, the third, the fourth. It depends on how you have that. Yes, I was wondering what "QRS" was too. Thank you, Julie, for keeping us honest. Maybe somebody knows something I do not. I am just going to let it slide. All right, that one is green. Hans, are we ready to move back up to you?

Hans Buitendijk
Yes, have a look at Column K.

Steven Lane
So, slide us over, Row 11, Columns J and K, if you will.

Hans Buitendijk
The red is where I made the adjustments that hopefully are clearer. I need to drop the word "to support." That can be gone. There you go.

Steven Lane
That makes sense now. Is everybody comfortable with that? Are we happy now?

Steven Eichner
This is Ike. There is probably a minor wordsmith somewhere, looking at "tracking to support the development of standards and maturation of the guide," so it is probably "the development of and maturation of the guide, but not the standards of the guide," if that is what we really mean.

Steven Lane
Sorry, which line are you in?

Steven Eichner
The first line, "recommend that ONC track and support the development of standards and maturation." In other words, we are saying literally the standards of the SMART Scheduling Links implementation guide the way that it is worded at the moment.

Hung S. Luu
Okay. So, we can probably remove "standards."

Steven Eichner
Right.

Steven Lane
Just "the development and maturation of the SMART Scheduling Links implementation guide."

Steven Eichner
Yes, or "SMART Scheduling Link standards and implementation guide." In other words, not just the development of the guide, but looking at the standards within the guide.

Steven Lane
Got it.

Steven Eichner
And maybe "Scheduling" and "Links" both get decapitalized because you are no longer at the title of the document, but I am being overly picky.

Steven Lane
Wait, decapitalize which words?

Steven Eichner
"Scheduling" and "Links" in IG.

Hans Buitendijk
I think you should keep "Scheduling Links," but "implementation guide" can be decapitalize.

Steven Lane
That is a standard. Right, exactly, perfect. Got it.

Steven Eichner
That works for me. I am just saving having to do it in the Word document because I made a few of those changes as I was going through.

Hung S. Luu
Any discussions on that as written?

Steven Lane

Julie, are we good? All right, I seem to see that all of Column J is now green. Hung, you are a master of ceremonies. What do you say, should we go to public comment?

Hung S. Luu
I think so.

Steven Lane
Rock and roll.

Michael Berry
I just wanted to check first. Do you want to go to anything else on the spreadsheet or the Word document before we move to public comment?

Steven Lane
Let's see. Good point, Mike. Thank you. We did not do the green on the Group 2 tab. I am not sure we need to, but…

Steven Eichner
It might be good because as I am looking in the Word document, I would like to touch on one particular recommendation where there was a need to do some clarification of text, and it was…

Steven Lane
You want the text document?

Steven Eichner
Yes, please.

Steven Lane
Let's switch over to that.

Steven Eichner
Can we go to Page 5? It is the second one. Are you on Page 5? There we go. It is the one that has a lot of purple at the top, so let's scroll up a little bit further. Wonderful. This was a recommendation that was reviewed during yesterday's call towards the end of the meeting. As I was rereading it last night, it looked like there needed to potentially be a little more work on it because it looked like it was trying to do a couple of different things, and I want to make sure we are reflecting what we really need. The issue is that the way certification has worked in the past has been looking at certifying the entirety of electronic health records.

On the CMS side, they are calling it certified electronic health record technology, CEHRT, or certified health IT as part of programs like Promoting Interoperability in MIPS and other systems, and that creates a challenge for health IT that is not fully certified or does not meet all certification requirements across the board because then they cannot be used to meet things like MIPS program requirements and potentially are a conflict or are not fully compatible with some of the requirements in some state and local jurisdictions, which, based on the Promoting Interoperability requirements, also use the term "certified health information technology."

So, at a base level, we are recommending that ONC needs to reconcile terminology with CMS for consistency, with the secondary implication as to whether there really is an intent to have certified technology meet every certification requirement to be certified, or does it count as being certified if it meets some, but not all, requirements? In other words, if a certified technology is meeting the exchange requirements for a cancer registry exchange, how does that count in the real world from a specialized piece of health information technology? Does that make sense?

Fillipe Southerland
It does to me, Ike.

Steven Eichner
Did I capture your concern appropriately, Fil? I was thinking of you as I was looking at it.

Fillipe Southerland
Right. The core concern for me was that we have CMS potentially inadvertently excluding certain certified EHRs, per ONC's definition, for incentives because they are using the CEHRT definition. So, to your point, can we align incentives to a modularly certified EHR, or does it require full-base EHR certification plus additional modules, as what CEHRT currently requires? If that is the case, if we are saying that for incentives to be available, it needs to meet the base EHR definition, then the base EHR definition should consider applicability to specialty and non-EHRs of that base criteria.

Steven Eichner
So, does the language onscreen currently capture your concepts of what changes need to be made?

Fillipe Southerland
One minute here, Ike, I am reading.

Steven Eichner
I appreciate it. It is a complex concept, and as I was looking at it last night, I realized the text drafted yesterday did not fully convey some of your concerns, or at least what I interpreted as some of your concerns.

Fillipe Southerland
I like it. The last sentence, "Health IT certification indicates that messages are properly generated by the provider," what were we driving at there?

Steven Eichner
From a public health perspective, it is not necessarily critical from a local public health or state public health department that the sending EHR system is fully certified from a functional standpoint. What we are most concerned about is that it is sending a message that has been certified in terms of its accuracy of producing the right data. Does that make sense? In other words, looking at cancer reporting or immunization reporting, the focus from the public health end of it on receiving the data is was it sent from a system that is certified to send that message?

Fillipe Southerland
Right, okay.

Steven Eichner
It does not impact public health if the sending system was certified for something else if that is not the activity related to the transaction with public health.

Fillipe Southerland
Correct.

Steven Eichner
But under the current public labeling, there is not a good way for public health to say it is certified to specific immunization message exchange standards because that does not really exist in the way certifications work.

Fillipe Southerland
Right, I agree with that statement. I am struggling a little bit to extract that from what was written here, so maybe we need a little more wordsmithing on calling out that specific use case. I agree that we need a way to call out modular versus overall certification, and that is a good use case for it. I just did not quite get that from the last two sentences there.

Steven Eichner
Yes, that was my intention for the last two sentences.

Fillipe Southerland
Okay, "specialty care to public health…"

Steven Eichner
So, if we provide an example, "e.g., message types, immunization, or cancer reporting…"

Hans Buitendijk
Would that be a limited set of data exchange use cases, "e.g.," and then fill in some? It is not only going to be messages. There is a variety of techniques that are going to be used.

Steven Eichner
Well, transport mechanism is a separate issue, but it is related, and Hans, it is not the universe of those transactions. In other words, depending on what the provider is doing… If the provider does not diagnose or treat cancer, from the public health end of it, there is no requirement to report data for cancer, so they do not need the technology. If they administer immunizations or vaccinations, they need that technology. Does that make sense?

Hans Buitendijk
I completely agree with that. I was looking at the term "message types," which presumes a particular exchange technique, as opposed to just being about data exchange, which is necessary, if that makes sense.

Steven Eichner
Okay.

Hans Buitendijk
[Inaudible – crosstalk] [01:12:16] at some point in time, could be document exchange, could be messages in V.2, or whatever it is going to be.

Steven Eichner
"Properly formatted content or generated and transmissible by the provider." Does that work?

Hans Buitendijk
Yes, something like that. The main thing is that we not limit it to "messages."

Fillipe Southerland
Right, and I feel like public health is one good example, but we have other examples out there, like home- and community-based services, where a specific modular certification makes sense and covers the required use case, but the base EHR definition is not necessary.

Hans Buitendijk
Agreed, as well as that some of those examples are actually already modularized. It is the USCDI-related exchanges, particularly C-CDA and FHIR, that are not yet modularized based on what it actually supports in HIT. In other ones, you may or may not support immunization, you may or may not support ELR based on your context, so there is more modularization already there in the criteria. USCDI is the one that is not yet modularized enough.

Steven Eichner
So, should we provide an example in addition to public health? I am happy to do so, if we can get some suggested text.

Fillipe Southerland
I am wondering if maybe we should have "the functions needed by a system that meet every certification criterion," period, and then we go into some specific examples around public health and home- and community-based services that would benefit from this modularized approach versus the current CMS all-in approach with the CEHRT definition. I can provide some text here, Ike, in the chat.

Steven Eichner
That would be fantastic.

Steven Lane
Do all Task Force members have suggesting access to this document?

Hans Buitendijk
I have not seen it come through yet, but it might be in the email somewhere. I was just looking further and could not find it.

Steven Lane
It looks like you all have commenter access, Hans, which I assume is the same as suggesting.

Hans Buitendijk
Who did it come from? Maybe you can drop it in the chat.

Steven Lane
No, we cannot do it. Actually, I can send it to you in a private chat.

Michael Berry
It came from Accel. I believe they gave all the Task Force members access to this on Friday, I believe.

Steven Lane
It is coming in a private chat.

Hans Buitendijk
Thank you. Oh, "unauthorized."

Steven Lane
That is weird, because I can see you on there. Maybe I spelled it wrong. B-U-I-T-E-N-D-I-J-K at Oracle.com?

Hans Buitendijk
Yes, let me see whether I am different.

Michael Berry
Sometimes you have to open this in Gmail because I get that same error message when I am opening it from an email.

Hans Buitendijk
Yes, and I had to switch from Chrome to Edge to get it. I think I know why. This is my problem.

Steven Lane
Okay, we have not done public comment yet, have we?

Steven Eichner
No. We need to.

Steven Lane
Yes, it is time.

Public Comment (01:16:54)

Michael Berry
All right, can we pull up the public comment slide? 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 happen to be 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 for a moment to see if any members of the public raise their hand. I am not seeing any hands raised yet, so we can turn it back to the conversation.

Steven Lane
Mike and others on the team, just a question. There is an ONC brief overview Q&A coming up in an hour. That is on HTI-1, correct?

Michael Berry
Correct.

Steven Lane
Okay. Do you know what is on the agenda for that? Is it just a short slide deck?

Michael Berry
I am not sure.

Steven Lane
Okay, so is anyone on the phone involved in that today? All right. It conflicts with the Carequality steering committee, so I am just trying to decide what I am going to do. I assume it is going to be recorded, though, right?

Michael Berry
Yes.

Steven Eichner
I do want to just come back to that issue we were talking about before we broke for public comment. With the changes that Fil is recommending, are we good to move forward with that? I do want to pose that out as a concept, making sure we are reflecting…

Steven Lane
Sorry, which page are you on, again?

Steven Eichner
That was on Page 5.

Steven Lane
Right at the top. Can you bring it back up on the screen? Hannah, I just sent you the link.

Hannah Galvin
Thank you.

Steven Eichner

Fil is going to graciously add some suggested text regarding a nonpublic health example looking at community-based care or long-term care.

Steven Lane
Do you have time to do that now, Fil, just so we can sign off on it?

Fillipe Southerland
I did just put some comments into the Zoom chat, but let me…

Steven Lane
Make sure that if you touch the document, you are suggesting.

Fillipe Southerland
Okay, it looks like it is set to suggesting mode.

Steven Lane
"Use cases that may benefit from modular ONC certification." Is that the comment?

Hans Buitendijk
I guess the key, which I agree with, is that is really then on the CMS side, which defines CEHRT, in many ways on what is acceptable. There is a definition by ONC on some basic abilities, but I believe it is CMS that really determines what is the minimum required, and that should be potentially **[audio cuts out] [01:20:28]** to be able to allow for others.

Steven Eichner
Right, because at the moment, CMS typically uses something like certified electronic health record technology with its definition that is not quite lined up with ONC's. CMS is focusing more on holistic certification than on modular or elemental certification.

Hans Buitendijk
We might have used the word "monolithic" rather than "holistic." It is still holistic, but the terms are a little bit too coarse.

Fillipe Southerland
My suggestion is coming through there.

Steven Lane
You have to leave the cell to allow others to see them. No, you are not in the cell, right. You are in the Word document.

Steven Eichner
Does the Word document behave differently?

Steven Lane
Yes.

Fillipe Southerland
There we go, in red.

Steven Eichner
It is not so much providers that would benefit from CMS alignment between… It is not public health as providers, it is providers using specialty EHRs that are interfacing with these other types of entities.

Fillipe Southerland
So, how could we broaden that? "Populations," perhaps, or "elements of the care continuum"?

Steven Eichner
Right, again, because the beneficiary here is the EHR user, not public health directly, as an example. In other words, the beneficiary is the user of the specialty system and whoever it is exchanging data with. That is what it comes down to, rather than that the recipient of the exchange is public health, a user of a fully certified EHR, or whatever else. The real beneficiary, which is great, is the ability for the user of the specialty EHR to actually have technology that is certified.

Fillipe Southerland
I agree with that, Ike, if you want to make some modifications there. Also, I think Julie had a great suggestion in the comments.

Steven Eichner
Julie, do you want to make those edits?

Steven Lane
I do not think Julie has the capability. She is a member of the public.

Steven Eichner
ONC folks, can you capture the chat and send it as text, since copying out of the chat is difficult?

Michael Berry
Sure, we can do that.

Steven Lane
Okay, I think we are close to time. Anything else for today? So, just for everyone's benefit, the three workgroup leads will be toiling away in this document today in hopes of doing our best possible editing. The ONC will be copying over from our Group 3 recommendations, getting them into the document. We will be meeting tomorrow morning, same time, same station, in hopes of reviewing the document. I do not think we need to bother with the slides for this group. The slides will simply be a reflection of the text in the document.

And then, I think we have a contingency meeting scheduled on Monday the 12th, but I do not think we will need that for the whole Task Force. I think we will have plenty of time tomorrow to go through the document, go through the recommendations, and finalize anything, and then, I think we will use the time on the 12th

to go over the slides with probably just the workgroup leads. I do not think we are going to need Task Force members there. So, we will plan to see all of you, hopefully, in D.C., either in person or online, for our presentation on Thursday the 15th, and our presentation has been extended, I think, to 75 minutes. Is that right, Mike?

Michael Berry
Right.

Steven Eichner
And for Task Force members, when you do get a copy and electronic access to the Google doc, please feel free to make suggestions. Steven and I will be working with ONC to incorporate any last-minute elements. Really, at this point, we are looking at grammatical corrections, abbreviations, and those types of things, rather than looking at content changes.

Steven Lane
While I am booked solid all day today with meetings and patients, I am going to do my best to get any edits into the ONC team in plenty of time for our meeting tomorrow morning.

Steven Eichner
Hans, do you have a related question? I see your hand up.

Hans Buitendijk
A very brief one. Later today, will you have a clean version of the Google doc that we can then go into, or will it remain in its current markup mode through tomorrow?

Steven Lane
Realistically, I think a clean version is going to be tomorrow morning before our meeting.

Hans Buitendijk
Okeydoke, sounds fair. Thank you.

Steven Lane
All right, thank you all. We are at the top of the hour. Thank you in particular, Hung, for your hard work of leading us through Workgroup 3, and we will see some of you tomorrow.

Hung S. Luu
It was a team effort. Thank you.

Adjourn (01:28:35)