Health Information Technology Advisory Committee

HTI-2 Proposed Rule Task Force 2024 Virtual Meeting

Group 2: Standards and Certification

Transcript | August 28, 2024, 11 AM – 12:30 PM ET

Attendance

Members

Mark Sendak, Duke Institute for Health Innovation, Co-Chair
Hans Buitendijk, Oracle Health
Steven (Ike) Eichner, Texas Department of State Health Services
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Hung S. Luu, Children's Health
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services
Dan Riskin, Verantos
Naresh Sundar Rajan, CyncHealth

Members Not in Attendance

Suresh Balu, Duke Institute for Health Innovation (DIHI)
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Shantanu Nundy, Accolade
Fillipe Southerland, Yardi Systems, Inc.
Sheryl Turney, Elevance Health

ASTP Staff

Seth Pazinski, Designated Federal Officer
Maggie Zeng, Staff Lead
Sara McGhee, Overall Task Force Program Lead & Group 2 Lead

Presenters

Vaishali Patel, ASTP

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

Seth Pazinski
All right, good morning, everyone. Welcome to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force Group 2 meeting. I am Seth Pazinski. I will be serving as your Designated Federal Officer for today. As a reminder, all of our meetings are open to the public, and public feedback is welcome throughout using the Zoom chat feature. We will also have time scheduled at the end of our agenda for verbal public comments as well. We are going to get started with rollcall, so when I call your name, please indicate that you are present. Mark Sendak?

Mark Sendak
Present.

Seth Pazinski
Suresh Balu? Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Steve Eichner? Raj Godavarthi? Mary Beth Kurilo?

Mary Beth Kurilo
Good morning.

Seth Pazinski
Good morning. Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski
Good morning. Meg Marshall?

Meg Marshall
Good morning.

Seth Pazinski
Good morning. Alex Mugge?

Alex Mugge
Good morning.

Seth Pazinski
Good morning. Shantanu Nundy? Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski

Good morning. Fil Southerland? I got a message that Sheryl Turney will not be able to join today. Naresh Sundar Rajan?

Naresh Sundar Rajan

Good morning.

Seth Pazinski

Good morning. All right, is there anyone I missed or anyone who just joined us? Okay, then I am going to turn it over to you, Mark, to get into our agenda.

Opening Remarks (00:01:53)

Mark Sendak

Thank you, everybody. I think today is our last meeting, so, starting next week, we are going to be meeting with the other subgroups to go through everything, and then we are going to present to HITAC on the 12th, so I really appreciate the time everyone has put into this, and I especially appreciate ONC's help in shepherding us through the process. I am happy to jump into the presentation from ONC. Our next slide is reorienting around the charge. So, we are making recommendations to the HTI-2 Proposed Rule. This subgroup is focused on certification criteria. Next slide, please. Today, we are just going to go through a few of the last criteria, and then we are going to spend most of the discussion time wrapping up loose ends from earlier criteria, making sure that we draft language for the proposed recommendations for everything that we want to make sure to push forward to HITAC. Next slide. I am happy to hand it off to the ONC staff now.

Seth Pazinski

Vaishali, you are on mute.

Vaishali Patel

Okay. Can you hear me now?

Seth Pazinski

Yes.

Conditions and Maintenance of Certification Requirements (00:03:23)

Vaishali Patel

Okay, great. Hello, everybody. Thanks, Mark and the rest of the committee, for investing the time and providing us with input on various aspects of our rule. I am here specifically to discuss the Insights condition, which I guess is the last amongst the items that you have gone through. We can just jump to the next slide, I believe. I think you guys are all probably pretty familiar with this disclaimer and public comment guidance, which is that the information that I am sharing today, essentially, is not the final word on this, and that you all should also be looking at the… I will be discussing the Final Rule, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, Insights as well what was in the Proposed Rulemaking for HTI-2, so, those documents are the final word on this. Next slide, please.

So, in terms of the brief overview, I am just going to provide a brief overview of the Insights condition. I am sure not everybody is familiar with it, so I just wanted to share a brief overview of the Insights condition before going into what we have proposed related to that in HTI-1. As I just mentioned, the Insights condition was finalized in HTI-1, and we are proposing to make some modifications to it in HTI-2. There are three areas in which we are making

those modifications. The first relates to the reporting process, the second relates to the minimum qualifications for developers, and the third relates to updates to measures that we had finalized in HTI-1. Next slide, please.

The Insights condition was developed because the Cures Act called for the establishment of an electronic health record reporting program that would provide transparent reporting to measure the performance of certified health IT in a variety of domains, one of which included interoperability, but went beyond that to usability, privacy and security, as well as other areas. The legislation specified that the implementation of it should be within the condition and maintenance of certification for developers of certified health IT. We kind of renamed the electronic health record reporting program to the Insights condition because we wanted to avoid confusion with other past programs that were similarly named, and also because it reflects the goals that ONC sees in the program, which is to glean insights on health IT and how it is working. We hope that the reporting program, the Insights condition, will address information gaps in the health IT marketplace, provide insights on the use of specific certified health IT functionalities that we have measures on, and also provide information about consumers' experiences with certified health IT. Next slide.

So, in HTI-1, we finalized the Insights condition and operationalized our directive from the Cures Act to develop measures that really focus on interoperability, but across a variety of areas. These areas include individual access, clinical care information exchange, looking at standards adoption and conformance, and public health information exchange. Those four areas are their mains, and we developed measures in each one of those areas. Each of the measures has specific certification criteria that are associated with the measure, as it is part of the certification program. Within each of these measures, there are specific metrics to operationalize the measures, and those metrics are described. We have measure specification sheets that go into the details of the metrics, the definitions, and any implementation guidance, and that is on ONC's website.

I will not spend too much time in the weeds going into that, but I did want to provide a brief overview of the Insights conditions, highlight some of these measures, such as the measures for clinical care exchange, which really focus on the Consolidated Clinical Document Architecture (C-CDA) problems, medications, allergies, reconciliation, and incorporation, and look at the document-based exchange. The individual access really seeks to measure access of individuals' access to their electronic health information through certified health IT and looks at the methods that support it. And then, for standards adoption and conformance, we have a measure area that relates to the apps that connect to certified health IT. Looking at the use of Fast Healthcare Interoperability Resources (FHIR) is both in terms of requests for individual patient-level data as well as bulk data. And then, we have two measures that relate to public health information exchange, one that relates to the sending of immunization administration data, and the other that relates to the querying of immunization history and forecasts through certified health IT. Next slide, please.

In terms of the HTI proposals, in terms of the process for reporting, in HTI-1, we had finalized that certified health IT developers who are participating in the program would report on the percentage of total customers as represented by hospitals for products used in inpatient settings and clinician users for products used in outpatient settings, and they would submit that for each metric for which they are submitting a response. The rationale for us requesting this information was that this provides transparency regarding the degree to which the data underlying the metrics is complete. To what extent does it reflect the full breadth of data versus being partially reflective of it? This is because developers indicated to us that they would need the permission of their clients to report on the metrics data, and so, we understood that they might not be in a position to report on all of the data of their clients, but maybe report on a proportion of that, so we just wanted to know what proportion that was.

So, in HTI-2, we are proposing to require developers of certified health IT to provide healthcare provider identifiers for providers that are included in the data that is submitted, and that additional provider identifier information would allow us to link to other publicly available data, like National Plan and Provider Enumeration System (NPPES) and

other sources, and would help us determine the representativeness of the data. So, for example, to what extent are the providers that are included in the data largely from smaller systems versus larger systems? Does it primarily reflect physicians, or does it also include other kinds of clinician? So, it just tells us something about the representativeness of the data in addition to us having information on the completeness of the data.

So, that is our main proposal. We are also open to considering other alternatives that provide both transparency on the completeness and representativeness of the data. We could remove the requirement for developers to report the percentage if, instead, we only required the developers to provide the healthcare provider identifiers. That is a potential option. Also, we are requesting comments for alternative options that might be more patient-centered forms of reporting on the completeness and representativeness of the data rather than on providers. Next slide, please.

In terms of the process for reporting, we have a number of different clarifications that we have outlined in the process of reporting. I am not going to go through each one of these. These are relatively minor changes, but there are a couple of things to highlight. We are proposing that developers assess whether they meet the Insights requirements as of January 1st of the data collection period, which is about 18 months ahead of when they would actually be required to report, so that way, we have a date set in stone. I think it will just make it more clear for developers as to whether they need to report 18 months later or not, and that is similar to the real-world testing program requirements, so it sort of makes things consistent with it. Another minor update to highlight here is that we are suggesting that the documentation related to the methods that developers are using to report on the metrics should be available via a publicly accessible hyperlink as opposed to submitting the data directly to ONC, and then ONC hosting it. This is just a process that is consistent with other certification criteria. Next slide, please.

In terms of other updates related to the process of reporting, in HTI-1, we finalized that developers must have at least 50 hospital sites or 500 individual clinician users across the developer's certified health IT to report on the Insights measures, and that was to ensure that startup and small developers were not disadvantaged by this program. We are just proposing to revise the wording on this to remove the term "sites" because that was apparently confusing to some developers. The more important update here is that we also want to provide clarification on how we are defining hospitals and clinician users. Again, this was a question that was raised by developers, and so, we are just providing some definitions here to clarify, and we are also requesting comments on those definitions. Next slide, please.

So, this is sort of more of the meat, I would say, of the updates that we are proposing in HTI-2. For the individual access to electronic health information through certified health IT measure, we are proposing two updates. One is to expand measuring access to not only include measuring whether an individual accesses their electronic health information, but also whether an authorized representative accesses the information as well. That sounds good, Sara. I saw your note. I will move quickly. So, that is to kind of address that. On the immunization administration and immunization history side, what we are planning to propose is to separately count the number of immunizations electronically submitted to Immunization Information Systems (IIS) that return with an acknowledgement with an error severity level code, E, and then report that by IIS in each category, and also separately count the number of immunizations administered that were electronically submitted to the IIS where an acknowledgement was not received by certified health IT. So, basically, it is like a communication failure, so it just documents that and reports on the number of those, and that is similar between those two measures. Next slide.

On the C-CDA side of things, we are just updating the measure to align with the updates that were made in B2, and there are a number of updates associated with that that relate the new types of data that were specified in B2 and support for automatic reconciliation, and we are also revising one of the metrics as noted there. I will stop there. I hope I have not taken too much time away from you all for questions.

Discussion (00:20:24)

Sara McGhee

Thanks, Vaishali. This is Sara. Accel, could we go back to the previous slide? I want to touch quickly on this proposal. In the HTI-1 Final Rule, we finalized the adoption of the decision support intervention certification criterion, and we also finalized a supportive maintenance of certification requirement as part of the assurances condition for this certification criterion, and now we propose to add a conforming update to the attestation condition of certification, and that is to help address the assurance maintenance of certification requirements that we finalized in our previous rule. We believe that this will support and enhance transparency and accountability, and also help with developer compliance. All right, next slide. Thank you. All right, back to Mark.

Mark Sendak

I think we just gave ourselves five minutes. Is that a question, Vaishali, or just a clarification?

Vaishali Patel

I think Hans asked me a question, so I am just responding.

Hans Buitendijk

And that answer is clear.

Mark Sendak

Okay. Any other questions from Task Force members?

Steven Eichner

This is Steve Eichner. Thank you for the presentation. I do think we have some issues, though they may not be quite at the HTI-2 level, about some of the ways the Insight measures work with immunization registries and the error rate components. For example, in Texas, the IIS currently produces an error when a consent is not on file, but that is not really an error in transmission, nor is it an error in program. Actually, it is a notification to the healthcare provider that the consent has not been filed. Patients are perfectly within their rights to not submit a consent and to choose not to participate in the registry. Those kinds of errors are going to create problems as you look at the completeness and accuracy. I think another thing we need to address is looking at the anonymity of data reporting so that data is not traceable back to individual practices or individual facilities because that could give competitors insights into their business activities, looking at, for example, the number of immunizations they might administer, so that is something we need to be cognizant of about other uses for that data. We may want to put some of those in our comments and feedback, and I am happy to do so.

Vaishali Patel

Steve, one thing I want to address that is important for me to communicate is that these measures are at the product level, so there is no issue with Personally Identifiable Information (PII). This is not reporting at an individual practice or client level, it is at the product level. So, to the second point you were raising, I just wanted to make it clear that the Insights program is reporting these measures at the product level.

Steven Eichner

You had said one of the components of HTI-2 included a facility ID, so how is that then treated in aggregation?

Vaishali Patel

Yes. Give me one second. So, the list of providers is not linked to their responses to anything they have reported. For example, let's pick the immunization administration measure. We would get a count of the number of immunizations that were administered and then sent over to an IIS at the product level for a given product, and

then, there would be a list of providers associated whose data was included in that metric, but we do not know how any individual provider's count. It is just a list associated with that.

Steven Eichner

A list of entities that contributed data, but without any attribution to how much?

Vaishali Patel

Yes, it is not specific to their data. It is rolled up at the product level.

Steven Eichner

Thank you for the clarification. That helps.

Vaishali Patel

The first comment you had was about the Texas patient consent piece. You can put that in a comment. Obviously, there are going to be state-level variations in how all this is implemented, and the reporting is by IIS, so we will be able to track by IIS, and there is going to be a variation by IIS in terms of how things are implemented across the country.

Steven Eichner

What I indicated is specific to Texas, and I am sure there are other jurisdictions that will have problems, but again, from a data perspective, it is going to report out as an error, but it is not an error at all. It is not an error in transmission, so the data have very limited utility because you are not really seeing what you expect to see. It is a perfectly successful transmission of the data or the non-data, as the case may be, so it will impact your utility, and I think you need to be able to accommodate those components and figure out a way of managing those errors.

Vaishali Patel

I appreciate your comment, Steven. I know you and I are talking separately later this week about this, so we can get into more nitty-gritty detail on it. I think the error messages are things that are an at Health Level 7 (HL7) level, and that is not something that… We are trying to leverage information to provide greater insights and transparency, and I am talking at a high level, not specific to this comment, but we know that there are nuances to all of this, and I think it is important for us to be aware of the issues surrounding the data, but I guess the question is then whether you measure at all. I think there is a balancing act there in terms of being aware of all the nuances when interpreting the results versus not reporting on it at all.

Mark Sendak

I think we will take one more comment. Mary Beth, I see you have your hand up, and then we will need to move to the spreadsheet.

Mary Beth Kurilo

Thanks so much, Mark, and thanks, Vaishali, for a really great presentation. On behalf of IIS, I just want to mention that we are really supportive of these measures going forward, but we do appreciate what Steve is bringing up around some of the nuances for a state like Texas that has legislated direction around how to handle opt-outs. We do plan on commenting some thoughts on how to potentially address that issue, either with implementing Measure 1A or looking at exempting some of the opt-outs from Measures 2, 3, and 4, but I know we can get into that in more detail offline or later on in the call. I do want to say that overall, we do not want the perfect to be the enemy of the good with these measures because we think they will give some really great insight on how much reporting and querying is flowing back and forth between IIS and electronic health record (EHR) partners.

Task Force Recommendation Worksheet (00:30:12)

<u>Mark Sendak</u>
Thank you. I am looking at the spreadsheet. Can we pull that up, Sara?

<u>Sara McGhee</u>
Yes. Just one second. Sorry, I am having a bit of an issue. Just give me one second.

<u>Mark Sendak</u>
I have one question, too. I think today's topics are Rows 42 and 43.

<u>Sara McGhee</u>
Yes. Can you all see my screen?

<u>Mark Sendak</u>
Yes.

<u>Sara McGhee</u>
Let me get down to 42 and 43.

<u>Mark Sendak</u>
It was 100% accidental, but in Column E, if we need to, we may need to re-add the Proposed Rule language for the rows below, 44 through 47. They may have been written over, but we can do that later. For 42, Mary Beth, it looks like you had entered in some recommendations. Do you want to try to synthesize those for the workgroup? That way, we can see what we can move over to Column J, and I will just take notes.

<u>Mary Beth Kurilo</u>
Sure, absolutely. So, starting with the first comment, I know that the measures suggest reporting overall, and then, in Year 2, stratifying by IIS, but we have some concerns that that is going to really skew the numbers from some folks who participate in larger jurisdictions, so we wanted to explore the possibility of moving straight to stratifying by IIS in Year 1. We do not think that would put that much additional burden on EHR partners to report on their products, but would love to know if folks are open to that, so we feel like the data would be much more valuable if we just jumped directly into stratification by IIS in Year 1.

<u>Mark Sendak</u>
Just to make sure we are on the same page, what is IIS?

<u>Mary Beth Kurilo</u>
Sorry about that. It is an immunization information system. I will just mention that there is another conversation going on in Group 1 about terminology, and I think "immunization registry" and "immunization information system" are used interchangeably throughout HTI-2, so we are recommending consolidating around one of those terms, and the preferred term in public health is "immunization information system," as it is more representative of the broader functionality of these systems as opposed to "immunization registry," which is, I guess, an older term. So, we would opt to lean into "immunization information system," or IIS for short, as the preferred term over "immunization registries."

<u>Mark Sendak</u>
So, having that as a recommendation, does anyone have any alternate views, or are folks okay putting that in? I will take that as a yes. Are there any other recommendations you want to include for Row 42?

<u>Mary Beth Kurilo</u>

Yes. We also looked at something that I guess overlaps with the topic that Ike brought up earlier. Some of the optional measures, particularly the number of submissions that did not receive acknowledgement, overlap with Measure 4 for Year 1 or Measure 8 for Year 2, so we were wondering if there was any need to differentiate with any of those, if they are actually measuring something different, or, if not, if it makes sense to drop that measure from the optional list.

Mark Sendak
Let me just copy that. It looks like you have a third point here too about patients being able to opt out.

Mary Beth Kurilo
Yes, and this is directly the issue that Ike was bringing up. We believe patients who opt out should be excluded from Measure 3, and possibly Measures 2 and 4 as well, so that a jurisdiction like Texas, which has a lot of those opt-outs, would not necessarily look like they were sending messages in error, that they would just not be included overall. I do not know if this is the perfect solution or another alternative that we had talked about internally, but there is the possibility of adding a Metric 1A that would include immunizations that were administered and that were attempted to be submitted to the IIS, meaning that it would not include the opt-outs, but I think that may take more offline discussion, and I would love to hear from Ike, Vaishali, and others about whether that would resolve the concerns that a state like Texas has around opt-out patients.

Steven Eichner
Thanks for that, Mary Beth. Just for the sake of clarity, when we are talking about opting out or in, we are talking about opting into the registry, not opting out of data sharing or participating in Insights.

Mary Beth Kurilo
Right. Thanks, Ike.

Steven Eichner
I think the challenge here is that, at least in Texas, the "error message" is being generated when a record is not included in the registry because consent has not been submitted. So, we do not collect data about patients who are opting out of participation, so I am not quite sure how you would identify them as being part of a denominator or part of exclusion. There may be some portion of folks that had intended to participate, but did not have a consent on file or a previously submitted consent. We do not have a way of teasing that out, and either way, that is not a technical performance measure at all in terms of looking at the ability for successful or unsuccessful transmission. That may be a programmatic issue, but not a technological issue.

I think the focus of the Insight measures really needs to be on the technical performance, not looking at the programmatic performance of IIS and the like. So, if we are looking at a rule about meeting the validation criterion, we really should be looking at the validation criterion of that registry, but also looking at it on the IIS side about what modifications are necessary on the IIS side to report sufficient data back to the healthcare provider for inclusion into the measures in the first place. I am not sure how many registries have implemented standardized reporting of errors or used standardized code sets to report errors consistently between IISs back to the vendor. You would have much better insight into that than I would.

Mary Beth Kurilo
Yes, and we have seen great improvement across the IIS community for standardizing those acknowledgement messages, and that has been a huge area of our measurement efforts in collaboration with Centers for Disease Control and Prevention (CDC) to really line up around the standards around acknowledgment messages. On the IIS side, I think that is definitely improving.

Mark Sendak
Hung? We cannot hear you, Hung.

Hung S. Luu
Sorry, I was triple muted. This is related to what I put in the spreadsheet. Is there value in collecting end user feedback on the health information technology as well so that what you are measuring is what the functionality is and what the measurements of the functionality are? Are they actually useful to the end user, or are there barriers to being able to utilize them in the manner in which they are intended? My proposal in the spreadsheet is that end user feedback be incorporated as a measurement as well, so not only are you measuring whether you can transfer information from Point A to Point B, but whether the information actually comes across in a meaningful way that you can utilize and whether it inflicts frustration on either the person generating the data or the person trying to make use of it at the other end. I think that would be the important measurement because you can measure all you want on the ability of a system to perform what you ask of it on paper, but if it is not useful to the human trying to interact with it or trying to make use of the information derived from it, then I think that is a failing.

Mark Sendak
Hung, just to confirm, is this what you put in Row 48?

Hung S. Luu
I put it into the field that was especially allocated.

Mark Sendak
The one for global comments, I think.

Hung S. Luu
Yes.

Mark Sendak
I can move that over as a workgroup recommendation. Are folks okay with incorporating that? I feel like that is going to touch on a lot of these. So, that was 42. Steven, I did try to add a line at the very end on top of Mary Beth's comments about focusing the Insight measures on technical performance, not pragmatic performance. I do not know if I captured that correctly. What was the alternate?

Steven Eichner
Programmatic performance.

Mark Sendak
Programmatic, got it. Okay. And then, let's go to Row 43. I know that we are over time. For this one, there were no member recommendations. Is there anything people would want to include as a workgroup? If not, then we can start going through our backlog.

Sara McGhee
Mark, this is Sara. I am going to go up to the top. I think Mary Beth added some recommendations in Column J, so I am going to pull that up for everyone.

Mark Sendak
So, Row 3? Yes.

Mary Beth Kurilo

I can just quickly touch on that this was a conversation that we had early on in a workgroup about supporting the adoption of USCDI Version 4, but also using it as an opportunity to call out that there are some previous comments that have been made about USCDI and elements that we would ideally want included in future versions of USCDI. I know this is a little bit out of scope with what we are commenting on, which is that, overall, we support the move to USCDI Version 4, but it seems important to go on record that there are some outstanding recommendations that have been made that are on record for comments that would be good to include for future versions.

Mark Sendak
Something I do not see but which I know we have faced internally as a struggle with USCDI is medication administrations. Are folks okay with putting that in this list? Otherwise, I think this comment looks good.

Sara McGhee
Mark, this is Sara. Can we mark this text as green? Is it final?

Mark Sendak
Do you mean to just make it green, or do something different?

Sara McGhee
To make it green, just so we know that this group has discussed it and that we can take it to the full Task Force.

Mark Sendak
Okay. Let's go to Row 4. Mary Beth and Hans, it sounds like the two of you agreed to language here.

Mary Beth Kurilo
Yes. I will speak to this, and then, Hans, please jump in if you have more to add. So, this topic also came up on Group 1's work, and so, this was language that we crafted, so I do not know if it needs to appear in both places or in the final transmittal consolidated comments, though it will obviously be represented once, but this is language we came up with around the SMART Health Card and SMART Health Links. We are proposing it as an optional measure, given that those are still in the midst of going through the balloting process, but we support their use for consumer access to immunizations.

Hans Buitendijk
To add, this has been a little bit confusing because we were chasing down these standards. The latest update as of this morning, Mary Beth, is that there are three references in the rule to health cards. There are SMART Health Cards, SMART Health Cards: Vaccination and Testing, and HL7 FHIR SMART Health Cards and Testing. The first one is being confused in my and other folks' heads, EHRA or otherwise. We equated that somewhat more with the Health Cards and Links because there is an HL7 FHIR SMART Health Cards and Links implementation guide (IG) that incorporates the SMART Health Cards, so there is a bit of confusion going on. The SMART one, not the HL7 one of that, is published, so that actually is a correct reference.

However, the SMART Health Cards: Vaccination and Testing term is used in the preamble, but in the actual rule language, it uses HL7 FHIR SMART Health Cards and Testing. The latter one exists, but is not published, so it is still a challenge for vaccinations for F1, and I cannot find SMART Health Cards: Vaccination and Testing as referenced in the preamble. That terminology is not used in the actual rule language, so there is a bit of confusion around the Health Cards. The framework could start to be used because it is published, but the vaccination-specific capabilities are still seemingly in a document that was balloted a number of years ago, but has not been published. We would like to go there, but there is some guidance that has been referenced that it looks like it does not exist. If it is published before the Final Rule, that is a reasonable thing to do, though still optional, as Mary Beth indicated, but if it is not published for vaccinations specifically, then we have a little bit of a problem because we

have no guidance to point back to. So, that is filled with chasing down, and if somebody from ONC knows more about that, it would be great, but there is something out of sync. As of this morning, that the little twist that Mary Beth and I found out.

Mary Beth Kurilo
Thank you, Hans.

Hans Buitendijk
Sorry about that.

Mary Beth Kurilo
No, it is okay. I am guessing we should hold on to this language until we track down where the actual balloted piece is.

Hans Buitendijk
Yes, and I am just typing some things on that, but if someone from ASTP/ONC has insight to make sure that the SMART Health Cards: Vaccination and Testing language in the preamble is indeed linked to the HL7 FHIR SMART Health Cards and Testing in the actual draft final language, and if there is any clarification that can be shared, that would be great, while also noting that the last one, the HL7 version, is not published.

Sara McGhee
Hi, Hans. This is Sara. I do not think we have anybody from ONC on today to speak to that, but I will take it back to them.

Hans Buitendijk
Thank you, and then we can fine-tune one way or the other.

Sara McGhee
Sounds good.

Mark Sendak
So, if everyone is okay with it, I will make this text green, and I do see that it has the language about the unpublished guides. Okay, do we want to go to Row 5 next? Hans, is there anything you wanted to include here?

Hans Buitendijk
I think it shows what is there, but if you want me to talk through it if there is any additional discussion on Row 5, I thought it was all there, but I might have moved something to Row 10 because that is really where it was J2 about dynamic registration versus the comment on Row 5.

Mark Sendak
You have something in Column G about giving the example of Helios.

Hans Buitendijk
Sorry, I am in the wrong row here. Unless there needs to be further discussion, I think the comment could be that publication of the trust community details with endpoints… We are looking now into saying yes, if that is acceptable to be a comment, we can almost just copy it in there verbatim.

Mark Sendak
Perfect, so I will move that to J.

Hans Buitendijk

If it makes sense to others. In other words, that is part of Unified Data Access Profiles (UDAP) IG, which is used in dynamic registration, and if that is in, then at that point in time, this will be there. I guess that is where it is defined.

Mark Sendak

I will copy both of these over to Column J. Can you scroll to the right, Sara?

Hans Buitendijk

That is why I was looking at Row 10. In the context of the comment there about dynamic registration, if dynamic registration would not be there, then UDAP would not be there, and therefore, it would stand on its own, but I think that dynamic registration is suggested to be supported, so that is why we can remove the duplication.

Mark Sendak

Just to make sure I understand, what do we want to do? I just finalized 5 and 6. Did you want to go to 10?

Hans Buitendijk

The only reason would be that 5 relates to 10, because 10 is what is based on.

Mark Sendak

And in 10, we have the language in Column G. **[Inaudible] [00:52:41]**

Hans Buitendijk

That was originally up in Row 7, but given the comments that Sheryl was making there, it is more general, and there is J2, which is specific to dynamic registration. I just moved it into the row that is best in the context of J2, and then, Sheryl's comment in the context overall would fit better there. That is what I was actually suggesting by moving it down here. If that makes sense, then if that carries over into J, then Row 5 stays intact because it then works together.

Mark Sendak

Let me copy this over in Row 10 as well. Any other comments about 5, 6, or 10? This is all in Column J. So, I will finalize those three. Okay, let's do 7. It looks like there is a lot going on here, Hans, Sheryl, and potentially Rajesh. Let's start with Hans and Sheryl. If you have looked over each other's comments, are they compatible together? Hans, it looks like there is duplication of your comments here in what we put in Row 10. Is Sheryl here? It does not look like it. Hans, should we just remove your section from the workgroup recommendation in Row 7?

Hans Buitendijk

Yes, because it seems to be better fitting with J2 on that individual row. We should leave the comment on 7 more as the general one that Sheryl raised.

Mark Sendak

I know that Sheryl is not here, so are there any modifications we want to make to the language proposed by Sheryl?

Hans Buitendijk

Sheryl and I talked about it, and we are okay and in sync, so I do not have any further comments.

Mark Sendak

So, that is for 7. So, in 8 through 23, we are including the language in 10. Do we want to add anything for any of these other rows?

Hans Buitendijk

If you look at Rows 8 and 9, I put in two comments, though one is just a clarification. Generally, we do not need to make supportive comments, but in this case, because of the statement in combination with role-based criteria, where we do make other comments around it to make a more specific criteria based on payer, provider, laboratory, public health, etc., this might be helpful to have as a general statement, that modular, in combination with role-based, is very helpful. So, it is supportive, but we emphasize that we would like to see more of that wherever possible.

Mark Sendak

Got it. So, this is Row 8?

Hans Buitendijk

Yes.

Mark Sendak

I know that we have made that type of comment and recommendation elsewhere. Does anyone have any additional changes they want to make to that? Hans, I had skimmed over Column G, so I will move these others over.

Hans Buitendijk

You do not need to move over 8 and 9. That was just a general comment for awareness, to double check. Since we have comments on dynamic registration, I do not think we need anything on 1.

Mark Sendak

How about 12?

Hans Buitendijk

It is a request for clarification. I am not sure whether others agree with that, but it is asking for more clarification and making it a little bit easier on the user clinician in this regard.

Mark Sendak

Is there any other feedback for 12? If not, we will move that over. Let's go to 15. Hans, did you want to move that recommendation over from Column G?

Hans Buitendijk

If nobody objects, and if there is clarity, so we do not need to get too granular so we have too much. So, there is not an expectation that we are going to be… Let's say vital signs for laboratory. That makes sense, but if there is the intent to go further down to only vital signs on this day or something like that, that would not necessarily be helpful. It would make it more complicated to have too many choices. It is complicated from a usability perspective.

Mark Sendak

Is everyone good with that there? Okay, we will move that over. The next one is 17. Does anyone have any alterations to Hans's proposed text?

Hans Buitendijk

Just be certain I spelled it correctly. The last word, "context," is misspelled.

Mark Sendak

I will fix that. Nos. 18 and 19 have the same recommendation. Are there any adaptations folks would want to make?

Hans Buitendijk

It might be sufficient to comment in G34 on both 20 and 21 because they both reference J20 and J21, so it would not necessarily be needed here, as long as we have something in G34.

Mark Sendak

Oh, you are saying in 18 and 19?

Hans Buitendijk

Yes, in 18 and 19. G20 and 21 are being referenced by 34 in particular, so making the comment in the main criteria would be enough, but I just want to highlight that we want to stay in sync with that. We need to have it there, or we need to do it here.

Mark Sendak

Sorry, I need to orient myself in the spreadsheet. Where is G34?

Hans Buitendijk

It should be further down in Row 29.

Mark Sendak

Let's make sure. Does the recommendation in Column J…? It sounds like if we finalize this, it will address…

Hans Buitendijk

It effectively does, because then, the particular hooks that are being addressed are then flexible as well. As an example, in G34, there is a reference to a number of different hooks, like appointment hook and order hook, related to a number that I think is 6 or 7, and if there is flexibility on the guide, that would also allow somebody to say, "The main benefit that I can achieve with prior auth is in the appointment space, so support appointment books." Somebody else might say, "I do not have that capability, but I am focusing on orders. Do that, but do not require the use of appointment books." Currently, the language in G34 requires support, seemingly for all. If there is flexibility, you can focus on the ones that have the most impact, and then grow from there. That is why, if this one holds, it would then cover what would otherwise need to be stated in J20 and J21. So, I am okay if it is here and not elsewhere.

Mark Sendak

Let's go back up to Row 20. I will move your comment over, Hans. Are there any changes folks want to make to the recommendation? If not, I will finalize.

Hans Buitendijk

This also relates to the other comment that we talked about earlier with Mary Beth.

Mark Sendak

Row 21? It looks like this was the last one in this batch. Any feedback? Hans, are your comments in G and I in Row 21 now reflected in J, or do we need to make any changes? Okay, we will keep that.

Hans Buitendijk

I am okay with the way that you covered it. I think we talked about that in a couple places, to focus on subscription topics.

Mark Sendak
Perfect, okay. Row 22? I do not see anything, so we will move on. Does anyone have anything to add in Row 22? So, let's go. In Row 24, there are some notes from our discussion, but we do not have a recommendation yet. Is there anything people want to put in the workgroup recommendation for Row 24? Sara, maybe that is not needed because then we break it out into all the pieces below.

Sara McGhee
Yes, that is right. This is just an overview row. The specific proposals are broken out in 25 through 31.

Mark Sendak
Okay, so I will just delete those. Given that so many of the recommendations between 25 and 30 are similar, can we just finalize those together? So, in Column J, 25 through 30, does anyone have any changes they would want to propose making? If not, then we will turn those green. Row 31 is similar as well. Any comments? Otherwise, we will turn it green. We have eight minutes. Let's try to get through the ones that have recommendations. In Row 33, Hans and Ike, are you all right with this, just to confirm? Okay. Any comments on this recommendation, or are folks okay to finalize?

Hans Buitendijk
None, other than wordsmithing to make it flow with the rest.

Mark Sendak
Would you like to wordsmith?

Hans Buitendijk
By when do we need that?

Mark Sendak
Sara? Seth?

Steven Eichner
Hans, I can take up the lead for the Digital Imaging and Communications in Medicine (DICOM) element and send you some text.

Hans Buitendijk
Okay. I would start with "We recommend that ASTP/ONC address or clarify," or something like that. It is mostly just the beginning of the sentences.

Steven Eichner
We will get the language cleaned up and put in the next little bit in the next couple hours.

Seth Pazinski
Mark, I can speak to the overall timeline. We will be sending out the draft recommendations in this Google doc to the members of HITAC that are not participating on the Task Force, just so they have an opportunity to provide any questions or concerns in preparation for the full Task Force meeting next week.

Mark Sendak

Any changes in Row 34?

Steven Eichner
Again, we will polish the language in the next hour.

Mark Sendak
Was there something Sheryl wanted to add, or did we want to copy down something from above?

Steven Eichner
Sheryl, can you provide a little extra guidance?

Mark Sendak
I do not think she is here.

Steven Eichner
Can we scroll to Row 7?

Mark Sendak
I guess this is more of a question for ASTP. If something is already up here, do we need to copy it to somewhere else in the same document, or would it be passed along regardless?

Steven Eichner
It should be passed along, but I was thinking of something that could be relevant to the context of the item below, where we could use the same base idea and reflect it, so I think that is where she was going, calling attention to the applicability of our recommendation to the DICOM, as well as dynamic charts.

Mark Sendak
Should I just slightly change the language to say "align with the recommendation in Row 7," or do I need to be more specific?

Steven Eichner
"Incorporate language from…"

Mark Sendak
"Dynamic description."

Steven Eichner
Again, I will put some text together in the next hour and a half.

Mark Sendak
Hans, I will move the language over in 35 from G to J. Sara, what did we set a timer for?

Sara McGhee
We are setting a timer for five minutes. Public comment starts at 12:20.

Mark Sendak
No, I meant the one that just went off. Was that a transition to something?

Sara McGhee

Oh. It is for this section, so if you all need to finish discussing, that is fine.

Mark Sendak
For 36, is there anything we need to update in this, or just confirm the final around server site?

Hans Buitendijk
The question is whether "health IT storage" might be better. There are different terms floating around, like "database," "server site," "storage erase," and others, so that might be better, or to clarify whether it is for data at rest. But there is the server site versus the device, so I still like that one, as long as it has encompassed whatever infrastructure that is. It could be a combination of database servers, storage area network (SAN), storage arrays, etc. Somewhere in that environment is where you are going to encrypt. Each of the terms is going to create its own ambiguity.

Mark Sendak
So, are folks okay with 36? We will keep that. Hans, if it is support, can I just remove for Row 37?

Hans Buitendijk
I have to jump down to that.

Mark Sendak
Or I can just keep…

Hans Buitendijk
That can just be general.

Mark Sendak
In Row 38, Hans, you wrote something in Column G about the ePA, electronic prior auth.

Hans Buitendijk
Yes. This is the ePA for prescriptions, so it is not 34/35. Here, it is using NCPDP. The suggestion is to ensure that there is alignment of adoption. There have been some references to rules in which there is the capability as stated for payers to support that. The understanding that I have, and it would be helpful if others have better information, is that the actual implementations of those are not necessarily there, to say that if we build it from a provider side, there is something to connect to. I think this is a general statement to ask that those requirements and target dates are aligned so it is not that one party is ready and the other is not.

Mark Sendak
Do you want to recommend aligning target dates?

Hans Buitendijk
Yes, and availability on both sides, particularly with payers and providers. From our discussion, I believe pharmacies can play a role in that as well, or might have a role as well in the prior auth space, so that is why I listed payer pharmacy from a provider perspective.

Mark Sendak
So, does the language in 38 now look good?

Hans Buitendijk

I am okay with that. Maybe it could say "and possibly pharmacy" at the end. It depends on the role. I think there is, but some might argue that it is not as much or different.

Mark Sendak

So, we will take a brief pause to do public comments, and assuming we have a few minutes, we will wrap up finalization, so I will go back to Seth.

Public Comment (01:15:14)

Seth Pazinski

Thank you, Mark. So, we are going to transition into the public comment portion of the agenda. If you are on the Zoom and would like to make a comment, please use the raise hand function, which is located on the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press *9 to raise your hand, and once called upon, you can press *6 to mute and unmute your lines. Just as a reminder as we give folks a few seconds to queue up with any public comments that they have, as Mark mentioned, this is our last individual group meeting for Group 2, and we have a series of full Task Force meetings starting on Tuesday of next week and continuing on Wednesday and Thursday. Those meetings are going to be from 11:00 a.m. to 12:30 p.m. Eastern Time, and the purpose of those will be to wrap up the recommendations and get ready for the co-chairs to present the final work of this Task Force at the September 12th HITAC meeting. I am not seeing any hands raised on the Zoom at this time, so I will just check if we have anyone on the line. We do not, so I will turn it back to you, Mark.

Next Steps (01:16:31)

Mark Sendak

Okay. Let's wrap this up. We are almost done. Sara, can you pull the spreadsheet back up? The language in 39 and 40 is similar. Are folks okay finalizing both of these? I will just say "We recommend…" Okay, I will make those green. We talked about 42 already. Are folks okay with finalizing this one? I will make that green. Are folks okay with finalizing Hans's global comment in 48? Sara, could you scroll down to Row 48? Go ahead and make that green. We have some that are blank, which I assume will mean we support the language. Does anyone on the Task Force have any other recommendations they would like to include?

Sara McGhee

Real quickly, Mark, in Column D, I believe these are added as global comments, and they are not really tied to a proposal, so there is nothing to add in terms of summary, just so you know. I think that is what Sheryl was adding her comments to. She put them in the Proposed Rule summary section, but I do not think they were tied to anything.

Mark Sendak

Are you saying to remove it from Column J?

Sara McGhee

No, what I am saying is these particular topics in Rows 44 through 47… I do not think these are tied to any particular recommendation in the Proposed Rule. I think these were global comments that Sheryl wanted to add, and she added her comments in Column E, so it was just a little confusing. I wanted to point that out.

Mark Sendak

Got it.

Hans Buitendijk

I believe 44 was done in Row 7, so I think we covered that. I am double checking, but that one looks awfully familiar to 7. I believe that is the first part of 7.

Mark Sendak

Yes, I do **[inaudible] [01:19:43]**. Okay, how about 45? This also seems similar to Hung, but I will copy that over as well into Column J. And then, 46, increasing audit capacity… Any comments on making that a workgroup recommendation? If not, I will finalize that, and 47 as well.

Hans Buitendijk

The question is how much is that… The effect that we currently have is view, download, and transmit. That already indicates patient-initiated data sharing between providers, but it is the patient transmitting that. If it is where the patient asks the provider to share data with a particular other provider, then that seems, at least to me, to be a new criterion, not an existing one, and I am not sure where to tie it to in HTI-2 proposals so it would be a clear extension of that. I am wondering if this is really a general feature or we can tie it more clearly to the specific proposal so this then has an opportunity there.

Mark Sendak

Sara, can we make a follow-up item for Sheryl to try to address Hans's concern in this?

Sara McGhee

Yes, will do.

Mark Sendak

So, I will remove this from the workgroup recommendation. I know that Sheryl is not here right now, so we do not have what we need to finalize that one. I think this finalizes all workgroup recommendations we have at the moment. In the last two minutes, is there anything anyone would like to add to the workgroup recommendations? If not, thank you for the whirlwind at the finish line, and for all the work over the last few months.

Hans Buitendijk

Thank you for helping us get through that. We appreciate it.

Mark Sendak

Of course. So, the meeting is adjourned, and we will take this to the full Task Force next week. Seth, did you want to say anything?

Seth Pazinski

No, that is it. Thank you all.

Adjourn (01:23:23)

Questions and Comments Received Via Zoom Webinar Chat

Steven Eichner: I've joined the call.

Hans Buitendijk: Can you clarify that the "bulk data" measure is when FHIR Bulk Data is used, not when other FHIR based methods are used to share data on multiple patients, correct? Or is the focus on multi-patient use cases whether they use FHIR Bulk Data for format and technique, or other FHIR based techniques?

Vaishali Patel: The BULK FHIR is when Bulk is used

Vaishali Patel: Hello, Hung. Thanks for your comment.   We have provider surveys related to their experiences related to public health reporting, including immunization reporting.

Questions and Comments Received Via Email

No comments were received via email.

Resources

HTI-2 Proposed Rule Task Force 2024
HTI-2 Proposed Rule Task Force 2024 Group 2: Standards and Certification - August 28, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/30/24.