Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

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

May 19, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

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

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Michael Berry with ONC, and we would like to thank you for joining us today. We do have a guest presenter today and we have a couple ONC subject matter experts joining us, and I would like to thank them for their participation. 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 this morning. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate that you are here, and 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
Jim Jirjis?

Jim Jirjis
Good morning.

Michael Berry
Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Aaron Miri? Kikelomo Oshunkentan? Naresh Sundar Rajan? Fil Southerland? Sheryl Turney? All right, hopefully some of those other people will join us shortly, and now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:22)

Steven Eichner
Good morning and welcome to our Task Force members, and a special welcome to public attendees, and of course, welcome to our presenters as well. We have a really good special edition for our off-cycle meeting of Task Force Group 2 working on the HTI-1 comments and recommendations from HITAC to ONC. We have, again, a couple of presenters, as was mentioned earlier. We are focusing today largely on electronic case reporting, and I will walk through what exactly that means and the impact of how that is going to be effected by some of the language in the proposed rule. Steven, do you have anything to add?

Steven Lane
No, I just wanted to welcome everybody to the meeting. I see we have a lot of public attendees. The meeting materials are all available online. I will put the link into the chat in a way that the public can see it, and you are all welcome to enter your thoughts in the webinar chat throughout the meeting, and as we have time, we can put voice to those, and then we do have verbal public comment 10 minutes before the end of the meeting, and we invite people to participate in that.

Steven Eichner
We enthusiastically invite people to participate. It is really important and valuable to the Task Force to receive public comment and help inform our discussion and any recommendation that we may draft and put forward. Let's do a quick review of things we have done before and a quick review of our mission, and we will then get into it. Next slide, please. So, just as a quick reminder of the Task Force charge, on the next slide, the overarching charge is to evaluate and provide draft recommendations to the HITAC on the health data technology and interoperability certification program updates, algorithm transparency, and information-sharing proposed rule, otherwise known as HTI-1. The Task Force was subdivided into three separate groups to really look at different aspects of HTI-1, and then we will take information from all three groups and condense it into a single draft report for HITAC to review, modify, approve, or disprove, and, if it does approve it, submit it on to ONC. So, these are all the charges overall, and what is in yellow, the electronic case reporting, is what we are going to be looking at today. Next slide.

This is the focus area of what Group 2 has had on its plate. We are coming down to the end of our areas of comment. We will then be working on discussions about what our recommendations may be and then putting that together in a more formal document for transmission. Next slide. That concludes the overview of where we are at. Let's shift into presentation, and I will turn the floor over to our ONC presenters.

Jeff Smith
All right, thank you much. Can you hear me okay?

Steven Eichner
Yes, sir.

Electronic Case Reporting Certification Criteria (00:05:55)

Jeff Smith
Thanks, Ike. Okay, so, as is the norm for these things, just a few housekeeping disclaimers. We are in a public comment period, so we are going to try and convey what we can via these slides, the information

that is in the proposed rule, but please know that the proposed rule is the source, and all of the comments that we receive over the line today are valuable, but they are unofficial, so if you want to convey official sentiments and recommendations, those need to go through the *Federal Register*. Last but not least, we cannot really interpret the information, clarify, or provide any further guidance than what is in the proposed rule, so these slides are really a distillation of what we put in the proposed rule. Odds are fairly good that if you ask us a question that is complex or ask us to elaborate beyond what is in the proposed rule, we are not going to be able to do that. Anyway, I know that is old hat for this group. We can go to the next slide, please.

All right, we are going to talk about electronic case reporting, as was previously stated. Next slide. So, here is the high level of what we are proposing. Electronic case reporting has heretofore not been underwritten by standards. This is one of those rare certification criteria these days that was more or less just a verbal, written-down kind of description of what we wanted the technology to do. We had not really pointed to standards up until this proposal, and so, we are actually looking to rely on HL7 balloted standards, and as it turns out, there are both CDAs and FHIR-based standards to support electronic case reporting that HL7 has blessed and balloted.

So, given the fact that there are two ways to do this, both CDA and FHIR, we are actually proposing that health IT modules could be certified to F5 for both, and we are interested in feedback on whether CDA or FHIR would be better or if we should just go ahead and let health IT modules certify to this criterion with either standard. The last bullet point there is on developers will have… Sorry. Essentially, what we are saying is that in terms of the timeline, this is one of the regulatory tricks that we can pull, which is to say we are proposing that modules could be certified to either the CDA or the FHIR standard as soon as 60 days following the rule, but then they would have until January 1st to choose one of those standards, so that is the proposal at a high level, and we will dig into the details on subsequent slides. Next slide.

Also, as we try to do here, we try to outline the benefits of our proposals. In this case, I think it is fairly clear that not having standards has led to variable implementation, and what we are trying to do is what we try to do across our criteria, which is to harmonize implementation by pointing to standards that different companies can look at and say, “Yes, I can build my technology to that.” We think this will improve interoperability and implementation consistency. It will hopefully improve how public authorities can understand where in space and when in time outbreaks are occurring, as well as promote bidirectional exchange between public health authorities and clinical care delivery.

And then, also, this will enable us to put F5 or electronic case reporting on the same track that we are able to put other health criteria in terms of the standards advancement process. Previously, we were unable to enable developers to advance standards because there was not one, so I think that is going to be one of the fundamental benefits here, that we will be able to point to a standard, and as standards evolve and merge and as new versions come out, we will be able to list F5 among the other criteria for standards version advancement. Next slide, please.

So, we are going to start with some details on the FHIR-based approach, and then we are going to talk about the CDA-based approach. So, there is an implementation guide for electronic case reporting that has been balloted by HL7 for FHIR. It includes three profiles that we are pointing to. One is the electronic initial case report, the other is the reportability response, and then, the electronic reporting and surveillance

distribution, or eRSD, is the third, and we will take a little bit of time to talk through that. These really do mirror the CDA implementation guides, except for the eRSD. That is something that exists outside of or maybe crosses both the CDA and FHIR approach. The eRSD exists in both of those worlds, according to the standards, but essentially, this is meant to be a picture of how electronic case reporting ought to happen in a standards landscape.

So, what I will focus on next is really the fact that we would be relying pretty heavily on these standards to identify the mandatory and must-support data elements. We do also specify that in the eRSD, the specification library and the supplemental library would be expected to be supported, as well as the reportable conditions trigger code value set. Now, we do point to what we call a regulatory baseline for the RCTC, and that is from March 29, 2022. We do, of course, know that there are newer versions of the RCTC, and what we would intend to do is point to those newer versions in the final rule if we do finalize as proposed, and I will talk about that in just a second in terms of the minimum standard code set. Next slide, please.

Here is the CDA approach, and, as I mentioned, it has an implementation guide that includes the eICR and the reportability response. Those are two different implementation guides, but they work in tandem, and again, we would be relying on those implementation guides to determine the mandatory and must-support data elements. Interestingly, the CDA basic guide also says that modules looking to use the CDA-based approach should rely on the eRSD profile in the FHIR implementation guide. That is literally in the CDA guide, so we are following the instructions that are part of the CDA-based approach, and we would require a module that takes the CDA-based approach to also take the FHIR eRSD profile, and again, it includes mandatory and must-support data elements. We specify that the eRSD supplemental library, as well as the specification library and the reportable conditions trigger code set, would have to be supported out of the eRSD profile in specific. Okay, next slide, please.

So, just a word on what I mentioned earlier, the regulatory baseline. So, you may or may not be aware of the fact that ONC has a construct called the minimum standard code set, and this pertains to a lot of the terminology standards, like ICD-10, or more like SNOMED, LOINC, and RxNorm, less ICD-10 because that updates less frequently, but generally speaking, we have a construct called the minimum standard code set, and essentially, what this is…

For most of our standards that we point to in regulation, in order to allow health IT modules to use newer standards, especially before SVAP, when it was not possible, but now that we have SVAP, we can actually enable modules to certify using newer standards, but we have long had the minimum standard code set concept, which allows modules to use newer versions of standards, especially those that update frequently, and were really just additions to vocabulary concepts, not wholesale different standards. So, the RCTC is kind of a conglomeration of these vocabulary standards, and we were able to convince those who needed convincing that the RCTC was very similar to a minimum standard code set. It updates several times per year, so while we have to point to a distinct version, there is an expectation that developers would want to use the newest version of the RCTC value sets. So, this is something that we have questions about and would love your feedback on. Next slide, please.

So, these are the revisions to F5, more or less the regulation text, pulled into a slide. Essentially, what we would ask developers to do in order to be certified to the revised version of this criterion is consume and process electronic case reporting trigger codes and parameters and identify reportable patient visits or

encounters based on a match from the RCTC value set received through the eRSD profile, and then create a case report consistent with at least one of the following standards, the FHIR implementation guide or the CDA eICR implementation guide, and then receive, consume, and process a case report response that is formatted to either the reportability response profile in the FHIR IG or the HL7 CDA reportability response implementation guide, and then transmit a case report electronically to a system capable of receiving an electronic case report.

So, just to spotlight a couple things, “at least one” means, in regulatory speak, either/or or both. If you are lucky enough to have clients that would want both and who see value in certifying to both, and then transmit a case report electronically to a system capable of receiving an electronic case report, we will talk about that in just a minute. Next slide.

So, ONC is proposing that the functional requirements for health IT modules remain agnostic to which reporting platform the electronic case is transmitted. Rather, we propose to require that a health IT module be capable of transmitting electronic case reports consistent with the reporting requirements established by a public health authority. So, essentially, we know that case reports are primarily flying towards APHL AIMS, but not exclusively. There are state-based registries that are receiving case reports, there are health information exchanges that are receiving case reports, and so, we think it is important that health IT modules be able to send not just to a single source, but really to any source that a public health agency wants it to be sent to, which very well could include APHL AIMS.

What we are trying to do here is just make sure that the technology is capable of sending cases wherever it needs to go. We certainly do seek feedback on the option to use either CDA, FHIR, or both. We know that having two standards is not as good as having one standard, but it was unclear to us in the research that we did that one was preferred by industry and users over another, so we would love your feedback on whether we should have just one standard or whether we should continue to allow for both standards. We also have questions on whether the ERC profile is appropriate for those that want to do CDA as the CDA implementation guide suggests. We take it at face value that it does work, but we would love to get confirmation and feedback on that front. And then, we did constrain the aspects of the eRSD profile, and we are interested in receiving feedback on whether or not we have appropriately constrained the profile. Next slide, please.

Okay, just a word on the deadline for transitioning, and then we will open it up for questions and comments. As I mentioned at the beginning, there is the opportunity for health IT modules to certify to either the CDA, the FHIR, or both as soon as the final rule would be live, which is usually 60 days after the fact, after it publishes, but we would set in stone the requirement that developers update and provide their clients with the revised version of this technology by December 31st, 2024, or rather, the time period up to and including December 31st, 2024, if we want to be specific. Really, the implications of this construct are to allow developers who are ready to certify the ability to do so, or basically, as soon as the rule is final, and for those developers who want and need a little bit more time, they would have until January 1st, 2025 to update and provide **[inaudible] [00:21:49]**. All right. Johnny, I went through all that without acknowledging and asking for your color commentary. Do you have any color commentary you want to provide at this point?

Johnny Bender

No, I think you covered everything, and we tried to make the slides pretty comprehensive, so I think we are good so far.

Steven Lane
Go ahead, finish up.

Jeff Smith
I was just going to say thanks, Johnny, and if you want more, I suggest you read the rule. There is a lot more history, background, and context that could be pertinent to some of your questions and some of your comments. Do not forget to read the rule. Thank you.

Steven Lane
So, we had a hand up and now it is gone, but Dr. John Loonsk would like to ask a question.

John Loonsk
Hi, Steven. Thanks for the invitation to join you today. There has been a very active commentary in the chat, but I think there were a number of points that were teased out there that could use some clarification. If I could just comment, ONC really did an excellent job in preparing the eCR part of the HTI-1 NPRM, and representing the eCR program, I just want to commend them on that and also suggest that the vast majority of what is there needs to be supported. We are trying to operate the program on the basis of functional certification, and as Jeff alluded to, that is almost impossible to do, and so, the movement to the eCR-specific standards is critical for the program to move forward.

There is a discussion point around CDA and FHIR. Both standards were developed with specific eCR implementations, and both of them have the kind of specificity that we are seeking in terms of getting the kind of data out to public health agencies that is really necessary. eCR is built on a hub-and-spoke model, in broad terms, and I think there are references in the NPRM to the fact that there are needs for decision support to get the right case reports to the right public health agencies, and the way that that is done is a combination of triggering out of the EHR and more advanced decision support logic that is implemented in the hub, if you will, to pass on the appropriate reports to the appropriate public health agencies, and all the public health agencies author their rules in that hub to see that the reporting abides by their state laws.

And so, a point there is that there is a need for that decision logic to have the appropriate case reports be carried and delivered to the right public health agencies, but I will just make one or two more comments that in the concept of a hub, too, is the opportunity to provide additional services to the public health agencies, and the one that I want to allude to that I think came up in the chat is that there has been extensive work done on transforms between CDA, FHIR eICR standards, and reportability response standards, and the goal of this is to enable the public health agency to be able to support eCR in the way that they want regardless of the format in which the eICR was submitted.

We think that is a great benefit to the public health agencies because most of them have not wrapped their minds around, and certainly not technically implemented, FHIR in implementations, but there is an opportunity in this hub-and-spoke model to take in electronic initial case reports in CDA and share them in FHIR and take them in in FHIR and share them in CDA using the public health agency's progression to the

new standards. So, there is a lot more under the covers here. I am happy to bring it out. I do not want to dominate the conversation too early, though, and would stop here for the committee.

Steven Eichner
John, thank you so much for that. This is Ike. I do think you brought up a very vital point, which is looking at public health's flexibility or choices about how to receive data, whether it be using CDA or using FHIR, and you are entirely correct that PHAs have not gone down one particular path down that venue. I think it is important that we are not creating an environment where providers run into challenges in exchanging data with the public health authorities serving their jurisdiction that there be some consideration, whether it is support for both or either within the health IT modules or in collaboration with another module or another provider to support conversion services. I think it does become an important consideration, again, so that we are looking at ease of interface between providers and public health on both ends, and there are not unrealized expectations. Hans?

Hans Buitendijk
Sorry, double muted and needed to move the cursor. Thank you, Ike. If it is time for some questions or comments, I wanted to highlight one in the chat going back and forth, which I think there is a fair amount of clarity that was achieved as well. Thank you, Laura, for confirming that mapping is available, and that is around the variety of PHAs that obviously not all are going to support CDA, not all are going to be ready for FHIR, and similarly, on the reporting side, the source side, is that depending on where different EHRs are at, the next step is more logically CDA and others are ready for FHIR. Generally, I suspect and believe that FHIR is the general long-term direction, but having a choice is good. But now, how do we align between the choice that the certification provides and the reality that not all PHAs would be able to receive whatever the source is going to choose? Yet, choice is still important, that certification is focused and not overburdened, and that we can support as much as possible a singular solution.

So, the notion of the mapping capabilities is important, and it needs to be recognized that they are available, are used, and are appropriate to be used in combination with certified software so that the certification is to, one, the mapping tools, where appropriate in the flow, can be inserted and taken advantage of so that the PHA can receive it on the other side in the appropriate format, and in the reverse, the responsibility response can do the same thing. I think we want to make sure that, throughout the process, that is recognized and acknowledged as a valid way to go about it so that everybody on the respective edges can focus in on a particular approach, yet have the ability in the middle to make the adjustments and map accordingly.

Steven Eichner
Wonderful. John Loonsk, can you walk us through the slides so we can do a little bit of a level set of what the eCR process actually looks like?

Steps Involved in Electronic Case Reporting (00:30:52)

John Loonsk
Sure. Just one comment before starting that. Currently, all the state-level and large local public health agencies are receiving CDA content. That happened during COVID, and they are at least getting case reports for COVID-19 electronically, just as a supplement to Hans's comments. This graphic that is on the screen that Jim Jirjis helped develop is helpful…

Jim Jirjis
"Jirjis."

John Loonsk
"Jirjis," sorry. I did not mean to malign that.

Jim Jirjis
No worries.

John Loonsk
There is a setup step which involves the eRSD, electronic reporting and surveillance distribution, and that is the specification that Jeff talked about earlier. It is made available for download from a website, and the goal of this is to have that be as consumable as possible by the certified health IT module so that trigger codes, which is a large part of what it conveys, can be implemented as quickly as possible in an emergency use case. In every emergency that I have been involved in in my many years in public health, there are new codes that come out that are relevant to that emergency. It happened during COVID and it happened previously, and the ability to electronically consume that specification, or a specification, in that regard is critical to getting the appropriate surveillance done out of the healthcare organizations in the process. So, the setup step is the eRSD. It is alerted and then downloadable or pullable for retrieval for implementation in the health IT module.

Jim Jirjis
Who manages that website in the content? Is that the CDC? Is that AIMS? I am guessing that all the detail for the different states is in there. Who manages that content?

John Loonsk
Good question. So, the electronic case reporting is a joint project of the CDC, the Council of State and Territorial Epidemiologists, or CSTE, and the Association of Public Health Labs, or APHL. The content, the trigger code list, that is shared is supported off of a system, the eRSD site, on the APHL AIMS platform.

Jim Jirjis
That is what I thought, okay.

John Loonsk
That is publicly available. There is more to the story, though, Jim. It is publicly available, it is a registration site only to get the communication information from the users so that they can be alerted when there is a new version, but otherwise, it is publicly available information to get the eRSD specification. The trigger codes themselves are developed as part of the RCKMS project, so that list is actually developed through work that the Council of State and Territorial Epidemiologists does, and I just want to make sure to call that out in this picture, and those trigger codes are loaded into the eRSD specification, and that is what is made shareable.

Jim Jirjis

And is the scope of what is shared…? Because there, it says FHIR format, also usable as XML. Are the rules and the trigger codes machine understandable, but the rest of it is human understandable? When you said the goal is to try to get as much as possible to be machine understandable and automated, what is the status of these eRSD files now? Is there human effort in the certified technology that needs to set up rules, or is it all automated, or is it variable?

John Loonsk
So, the content that is put out now is trigger codes and guidance on the timing for triggering and creation of eICRs. There is capacity in a second bundle of the eRSD to eventually convey rules, but there are not rules per se being shared explicitly because there is not a common standard for how those rules can be implemented in the certified health IT module for processing, but we believe that is an important growth direction over time, but for now, the eRSD conveys trigger codes and guidance on the timing of when the triggering should be done.

Jim Jirjis
Got it.

John Loonsk
So, when that is shared and there is a certified health IT module that receives that, there is a manual signoff on that. It is not generally automated that it is ingested, but we have been seeking to have it be as easily ingested as possible so that there is not a huge burden in including these trigger codes and in an emergency, that can be done as quickly as possible, but when the trigger codes are in place, then eICRs, or electronic initial case reports, are created, and it is important to indicate that there could be more than one eICR that is created. If you think about what is reported, the goal here is to report on a likely reportable condition that is identified during the course of a current encounter. It is not to represent legacy information here or historical information on the patient, it is to try to identify a current reportable condition and to establish and then send an initial case report.

Some state laws actually require reporting on suspicion, before even the lab results are back or before other clinical diagnostic information is back and the case report needs to be transmitted, to comply with state laws, and the architecture here is seeking to do that, to implement case reporting in such a way that it meets state laws and that the burden of manual reporting can be alleviated as those public health agencies accept this electronic process as the alternative. So, the initial electronic initial case reports, if you will, are transmitted in close proximity to the start of an encounter to cover reporting on suspicion and to be very timely around critical conditions that need to be reported in that regard, but obviously, some data is not accumulated until the encounter is carried out and data are added to the chart, so there is guidance that suggests that there should be subsequent eICRs that are sent, and those follow in time, and I can go into the specifics of that, but I will not go into great detail now.

Jim Jirjis
I just want clarification there, if you do not mind. This may be simple terminology, but obviously, there is an initial case report, but for anything subsequent that is on the same condition or set of triggers, there is just a symphony of non-initial but follow-up case reports that occur as more data comes in. Is that accurate? And we keep calling them subsequent initial case reports. That is a little confusing…or am I getting it wrong?

John Loonsk
That is incorrect, but it is my fault. The naming of the eICR is confusing in this regard, and there can be multiple eICRs sent, and there are multiple eICRs sent. There is a desire on the public health side to get the right amount of them, and not too many, and not too little, a kind of Goldilocks effect, but the second eICR that is sent is still called an eICR, and in HL7 standards parlance, it is an update to the first eICR, but that is the naming structure. So, I understand it is confusing, Jim, but in fact, the subsequent eICRs represent updates to the initial one that was sent.

Jim Jirjis
Thank you.

John Loonsk
And then, just a little bit more, for every eICR that is transmitted out, there is a reportability response that is conveyed back, and this is a one-to-one basis. Those reportability responses were actually created on the hub, but the content is authored by the public health agency, and so, the reportability responses convey information about what was reported, what was found to be reportable, but also can convey information about the condition coming from the public health agency and delivering it back to clinical care, and as many of you know, clinical care has been seeking such bidirectional communications from public health for some time. The reportability response is one conduit for putting that information back. It also serves as the conduit for conveying information, for substantiating that reporting is carried out properly, and for healthcare organizations to accumulate them and use them for aggregate reporting on reporting that has been done.

Jim Jirjis
I have two quick questions there. First, are those automated? The reportability responses… I am guessing that by "the hub," you mean the AIMS platform. Secondly, do humans still need to receive those and do something, or is it automated as it interacts with the EMR?

John Loonsk
I am talking about the APHL AIMS hub platform with the RCKMS system on top of it that contributes to determining reportability to which public health agencies, and then returns the reportability response with that information in them that has been authored by the public health agency, but also identifying which public health agency it came from back to clinical care. In CDA, it is a clinical document, it is renderable by itself, it is standalone, and it can be used in that way, but it can also be parsed on the EHR side to work with aggregate data, to accumulate data, to potentially put data into the EHR in a more integrated way, and there are a lot of details into how that can be done, but it can also just be used as a return document. What we do not recommend is that all reportability responses are presented back to the provider. What we recommend is only those reportability responses that represent a reportable condition in them, or what we call a "maybe" reportable condition, are presented to the provider so that they do not receive the noise of "not reportable" or "no rule met" reportability responses. So, there is a lot of information there, but I will stop there.

Jim Jirjis
One clarification to make sure everyone understands is this is the one area, as I understand it, where the rule is asking should it not be either FHIR or CDA, but should it be a requirement that certified technology do both? What I do not understand is if everything is going through the hub, are there some public health

agencies that do not? Why would it be a pretty standard CDA? Why is the question coming up of should certified HIT modules do both for the reportability response?

John Loonsk
Good question. I have identified the fact that transforming the data is one of the things that can be done on the hub to ease the transition for public health agencies. I think what ONC pointed out previously was a question that they have about whether all EHRs are using that hub in terms of doing reporting. What the NPRM does identify and what we strongly believe is that there is the need to have that decision logic to ensure that something is actually reportable. From the standpoint of the eICR that is sent out, we understand that ONC is suggesting that FHIR is the direction of the industry. We certainly see that as the direction as well, and so, we understand them wanting to express the eICR in FHIR format as an option in addition to CDA. CDA is how all of the implementations have been done to this point.

From the standpoint of the reportability response going back, we do not necessarily think that it has to support both, that what the guidance now says and what the NPRM now says is that the health IT module be able to support both the FHIR and the CDA version of the reportability response. It would be a little more EHR-sensitive if the health IT module was only expected to process the same format as the eICR that was put out. That is what would be responded to by the hub in this regard, and so, it is a tweak, if you will, that I think the EHR vendors would find appealing, and is just a subtle variation on the language that is in the NPRM. Did that make sense, Jim?

Jim Jirjis
Well, it sounds like what you are saying is that the industry has basically been CDA, and most agencies and EMRs are working through the hub. With the first couple of A and B, or at least B, where they are giving a choice of CDA or FHIR, I am guessing that is because the AIMS system can do either, and the EMRs may or may not be able to do either, so they are giving the flexibility. What I do not understand is why in the reportability response the ONC is asking us differently than the others whether we should require both. Isn't it the same situation that the EMRs may or may not be able to do FHIR yet, and so, why would we call that out? I guess that is where I am a little confused.

John Loonsk
What I was trying to say is that I think there is an opportunity for that reportability response going back and for that health IT module not to have to do both formats of the reportability response, but to only do the format of the reportability response that matches the format of the eICR that they send out.

Steven Lane
At a minimum, as opposed to only.

John Loonsk
At a minimum, yes.

Steven Lane
Hans, your hand has been up for some time. I want to let you get in here.

Discussion (00:47:46)

Hans Buitendijk
Thank you. I have a couple of comments in response to the last discussion, but then I have three questions, two small and one maybe a little bit larger. On the prior one, I think I agree with Jim that there can be the choice, and based on the feedback that we got from Laura in the chat and John confirming, there is mapping opportunity back and forth, so there is not really a need to support both, and that is where, in the comments and in the recommendation, to clarify that the reporting source has the option to do one or the other. They may do both, but they have to do at least one or the other in a pair, so it is CDA report out, responsibility response in CDA back, or it is FHIR report and FHIR responsibility response back, from their perspective. I think that goes a little bit to the question on this slide.

This actually is a great slide, but it gives an implication that certain aspects that are being discussed are part of the certified HIT modules, and it actually would be very helpful to have this chart. It becomes a little bit more complicated, but to recognize the potential, because it is not required, to use eCR Now and/or APHL AIMS as a mechanism in between, and this picture implied that those are actually to be certified, they are going to be certified so that we can all rely on them, and where you want to use them to provide that mapping and rounding capability, you can do so, and that simplifies on the reporting side. On the other hand, there might be reasons to do it directly point to point or orchestrate it yourself. So, I think this diagram is helpful, but it implies that the capability of mapping and otherwise are part of the certified HIT modules where, in fact, we can use APHL AIMS, eCR Now, and perhaps another alternative at some point in time, to sit in the middle, and they sit outside the certified eCR.

Jim Jirjis
Hans, can I comment on that real quick? I completely agree we need to add the AIMS platform into this diagram. In my head, it was more like an extension of the public health agency that all these certified technologies were interfacing with the AIMS platform, and in my head, that was part of the public health agencies' kit.

Hans Buitendijk
Yes. Since they are not required to use either APHL or AIMS right now, it sits in the middle, and it can be used, and there is value in it, and maybe others say there is not and they want to do it on their own, that is all fine, but there is something in the middle. Is that going to be certified? Can we rely on it? Is that clear? And I think that will be helpful to identify. So, that is just a suggestion request.

Jim Jirjis
Before you move on, Hans, do we know for sure that there are public health agencies in EMRs that, in fact, do not use the AIMS platform?

Hans Buitendijk
I believe there are. I cannot name them, but John and Laura might be able to name anybody who is going directly.

Jeff Smith

This is Jeff, and yes, we have spoken to public health agencies that are not connected… Let me rephrase that. We have spoken to public health agencies and authorities that receive case reports outside of the dynamic that we are discussing with AIMS.

Jim Jirjis
Just before we leave the point, though I know you have another comment, as John and I adjust the figure, it would include both. It would include a public health agency and certified HIT module interacting directly, but also with the potential of an intermediary hub platform. Is that correct?

Hans Buitendijk
I think that will be helpful to depict so it is clear to understand what is being certified to. I only need to do it against either a FHIR or CDA pair, whichever one, and then I use APHL AIMS or eCR Now in combination with APHL AIMS to achieve that the right agency gets the right format, and that means that as part of certification, I only need to certify against one, and I am relying on or taking advantage of those other capabilities. If I do not, then I probably have a little bit more responsibility to set aside the variety of public health agencies in the reporting requirements because ultimately, they can state what that is, and if that is the responsibility that I as a reporter want to take on, that should be okay. It is everybody's decision to do that. If I do not, I am going to go through APHL AIMS and possibly eCR Now.

Steven Lane
Ike, you have had your hand up for quite some time.

Hans Buitendijk
I had two additional questions, if I can go back in line.

Steven Lane
Okay. No, go ahead, Hans.

Steven Eichner
Actually, I was going to glom onto Hans's last comment, and then we can come back to you, Hans. I do think it is important, as you just suggested, that we ensure there is good availability and good exchange between providers and public health, whether that be directly or use of an intermediary to convert data between the two. My concern is that if we look at enabling certification to either, a provider may end up in a position where the technology that they have adopted is not compatible with the tool set that the public health agency in which they are cannot receive data in the choice that they made about CDA versus FHIR, and figuring out a way around that or through that might be if you want to seek certification for a single component, you also need to identify a method for conversion that would be acceptable to a PHA that is not necessarily involved in AIMS so that there is an escape hatch, if you will, to maintain compatibility.

Hans Buitendijk
I think that will be a helpful clarification for ONC to consider on how that can be done in a predictable, dependable way for everybody, so I will second that.

Steven Eichner
That was my only addition. I will let you ask your next question, Hans.

Hans Buitendijk
There are just small questions that I had. Can you expand a little bit more on the methods that eRSD is available? And a question for ONC: We have talked a little bit about the responsibility response, on it going back. What is the intended meaning of the use of the words “consuming” and “process” in the NPRM? Those are the two open questions.

John Loonsk
Sorry, Hans, was that directed at me?

Hans Buitendijk
The first was to you, John. On eRSD, what methods of distribution, like notification, subscription, email, look it up yourself, or whatever, are currently available and what are the plans there? That is an area where it appears that not everything has been built out yet on clearly how that can be obtained. So, that was a question for you and a question for ONC. What is the intended meaning of “consuming” and “process” of the responsibility response?

John Loonsk
So, the eRSD is accessible for download or for being pulled and downloaded to the health IT module. So, we actually had developed subscription methodology for distribution as well, but there are a number of technical issues with the recipient side of that, so while we may go back to that over time, what we have found is that the way people wanted to get this was through download, and what happens is there is an email list of those who have registered for this site, which is why registration is there, and they register for the site, and then they receive notice when there is an updated version to retrieve. Some health IT modules have implemented automatic polling to retrieve it as well, and that is supported also.

Hans Buitendijk
That is a FHIR endpoint, correct?

John Loonsk
No, it is not a FHIR endpoint. It is in FHIR format, but it is retrievable as XML or JSON, and that is the context of it being usable in both CDA and FHIR worlds. It is FHIR format, but you can map it and you can process it even if you do not use a FHIR server to retrieve it.

Hans Buitendijk
Is it an API, or is it a button that I download?

John Loonsk
It is a button that you download, or there is a method for doing a secure polling to retrieve it as well.

Hans Buitendijk
Okay, thank you. That helps. And then, the other question was for ONC. What were “consume and process” intended to mean?

Johnny Bender

We provided some clarification in the preamble around "consume and process." We cannot really provide much color beyond what is in the preamble for "consume and process," but the preamble states that for the proposal, requiring a system to consume and process trigger codes, we propose that a certified health IT module identify a reportable patient visit or encounter based on a match from the RTCT contained in the eRSD specification library, and then we also just provide some additional clarity and examples.

Jim Jirjis
This is Jim Jirjis. My understanding on this question, having talked to our own public health folks here at HCA, is that when they consume that, there is a table that the EHR hits. Is that what you mean, like the documents are consumable so that an automated process can occur? Is that the intent of "consume and process"?

Johnny Bender
Let me see if I can find it, sorry. We understand that some systems use a manual process to consume and process the eRSD, so I think we were looking to not preclude that and leave it up to the health IT modules.

Hans Buitendijk
And it was not really as much about the eRSD, it was more about the responsibility response.

Johnny Bender
The reportability response?

Hans Buitendijk
Yes, that is the one that the "consume and process" is more… The other one is clear what you mean.

Johnny Bender
Got it, okay, perfect. I think for the reportability response, I would have to take a look, and I will see if I can find the language that we use there, but I think we did provide just a little clarity on that, but I would say that we are not expecting health IT modules to do anything beyond what is proposed. So, I do not think we proposed any requirements on acting on the reportability response or any required follow-up, but the language we have proposed is "consume and process," but if it is bad language or unclear, that is the kind of thing we would want to hear in comments.

Hans Buitendijk
Thank you.

Steven Lane
Was that it, Hans?

Hans Buitendijk
That is it, thank you.

Steven Lane
Okay. John?

John Loonsk
Thank you. So, there were a number of comments in the chat about the involvement of health information exchanges, and I just wanted to clarify that there are and can be health information exchanges that play an active role in this that are implemented currently. The challenge is that the health information exchanges cannot trigger the eICRs and meet the currency of data, for example, for a suspect condition report. So, from the standpoint of eCR to date, we have welcomed the involvement of health information exchanges in terms of exchanging the data, but it is important that the health IT module actually be the place where the data are triggered from to get the data that are needed to support accurate and particularly current case reports as part of the flow. So, hopefully, that was clarifying.

Steven Eichner
Just to elaborate that, looking at the AIMS platform as an example, there are multiple paths that healthcare providers can use to connect to the AIMS platform. There is not a single path, and it does not have to be a direct connection.

John Loonsk
That is correct. So, there are HIEs in the middle of that that are part of the flow right now that are supporting eCR in the context of connecting the healthcare environment to the APHL AIMS platform, and from there to the public health agency.

Jim Jirjis
Can you give an example of one of those?

John Loonsk
So, I think KHIE was teased out in the chat. MiHIN is another information exchange that is involved as well, and there are some others too.

Steven Eichner
As well as national networks in the space. Can you talk for just a moment about the distribution of RR responses through the HIEs on the return end of it? Is that occurring, or is that looking for a return back to the submitting provider?

John Loonsk
So, whenever an eICR is received, a reportability response is pushed back to the healthcare organization in the same format as the eICR that was received, and that goes back the same way that the eICR came in, and so, let's say the flow is healthcare organization sends to HIE, HIE sends at times to the eHealth Exchange hub and then to the APHL AIMS platform. The reportability response goes back in the reverse path on that.

Steven Eichner
I was wondering, for Task Force members in particular, as to whether there might be an opportunity or need to provide some feedback to ONC looking at real-world testing and inclusion of health information exchanges and the like as a component for that real-world testing, again, trying to make it easier for everybody, both providers as data senders and public health agencies as data receivers, to look at it all the

way through and the different scenarios that might be involved, and I will make a note of that in the worksheet. Jim?

Jim Jirjis
I think there is another step here that the rule comments on that is not really depicted here, and that is that in the end, this requirement to be able to send a case report to some other entity, but to not have standards, but instead require the certified technology to distribute it in the manner in which those entities can receive it. I wanted to ask who they are talking about. If things are either going directly to the public health department or through the AIMS platform, who are these other entities, and doesn't that create burden to the provider to come up with a variety of different ways to deliver that? Can you comment a little bit about that?

John Loonsk
Jim, was that directed at me?

Jim Jirjis
I am not quite sure because I think the people I wanted to direct it to, the ONC, cannot really comment, right? I guess I am pointing out two concerns. The first is I would like examples of such organizations, and the other is how do we not get to where now, everyone has a different interface and the rule does not land in a place where now, providers have to create all these interfaces?

Jeff Smith
Jim, this is Jeff. I can comment. Let me just see because I think my colleague Johnny just sent me a link that takes me to the part of the preamble where we actually do talk about this. In terms of the nonstandard or nonspecific requirement around transmitting to any entity capable of receiving it. We very much wanted to make sure that we were not requiring only the transmission of case reports to AIMS. I think it is really important to understand that the genesis and the overwhelming need for this criterion has been to support CMS, and that remains the focus.

Jim Jirjis
But if that is the case, I completely agree that we do not want to have the rule inadvertently require it to be the AIMS platform or direct to public health, but perhaps there is an opportunity to reword the document because still, even though we may not report to AIMS or somebody else, shouldn't we still constrain the reporting and be clear that it ought to be in a CDA format no matter who we are sending the case report to? There should be a standard there so we do not end up with everyone thinking it means they can have their own API.

Hans Buitendijk
Or FHIR.

Jeff Smith
Yes, that would be really helpful feedback if there is confusion. That would be great.

Steven Eichner

That would be excellent. I know you made a comment close to that in the existing worksheet. If you could go revise it a little bit or make it a little bit clearer, I think that would be a great subject for discussion and potential inclusion in the recommendation. Because we have so many folks from the public involved in this meeting, I want to make sure we have sufficient time for public comment, so I would like to turn the floor back to Mike and our ONC colleagues to conduct public comment, and then we can come back to our discussion if we do not have sufficient public comment to consume the rest of our time. Mike, can you take us to public comment?

Public Comment (01:09:42)

Michael Berry
Sure, we can do that. We can put the slide up for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause just for a moment to see if any members of the public raise their hand.

Steven Lane
I think we had at least one public participant who tried to raise their hand earlier and put it back down, so this is your chance.

Michael Berry
I am not seeing any hands raised at this time, so we can return to our conversation.

Steven Eichner
Okay, thank you for that. I wanted to make sure we had plenty of time if there were comments.

Jim Jirjis
Ike, to your comment before we went on there about clarity in this space, it sounds like the ONC wants to make sure that there are transport and content standards, but not wanting to restrict which entities are used to accomplish the reporting, and so, maybe that can be an opportunity to clarify that in all instances, we believe case reporting information should be either FHIR, standard, or CDA, but we do not want to constrain it to a single platform.

Steven Eichner
Right, perhaps somewhere in the line of looking at saying the transmission standards should be A or B, but the routing of that standardized format or standardized message may differ based on circumstance.

Jim Jirjis
Yes, otherwise it could inadvertently increase complexity enormously.

Steven Eichner
Right, and then elaborate enough about circumstance so there are still some kind of constraints.

Jim Jirjis
Yes.

Steven Eichner
Hans?

Hans Buitendijk
I have a quick note on the last part of discussion. When we use the term "transmission," I think as we develop our recommendations, we need to be careful to distinguish between the format of the payload, CDA/FHIR, or the transport, and currently with APHL AIMS, that is XDR or direct messaging, in which you put the content, or at some point in time, which I do not think many are ready for, you can use FHIR endpoints to submit it, too. So, I just think we want to be careful about what we mean when we say "transmission."

Jim Jirjis
We mean transmission format. Good callout.

Steven Eichner
Steven?

Steven Lane
John Loonsk is up first.

Steven Eichner
Okay. John?

John Loonsk
I just wanted to tease out what I alluded to previously. I understand the comments about not focusing on a particular platform, but I think it is important to understand that what is triggered out of clinical care does not necessarily meet the reportability laws in each state, and that the guidance currently identifies the fact that there is additional decision logic that is needed regardless of the platform, and I think that is really important because otherwise, the health IT modules, companies that support them, or the healthcare organization may not understand that to meet this state law, there is more than just what gets triggered out.

Steven Lane
I was just going to say that while we all appreciate the potential value of supporting diversity in these dataflows, we can go too far, and there are a lot of well-meaning folks that want to help make this work, and there is a lot of local creativity, history, and stakeholders, but we should not create so much diversity that we never get to a standard. I think at every step along this evolution, we should be driving more and more toward standards, and of course, just including technical standards, as has been recommended in the NPRM, is clearly a step in that direction, but in our efforts to support each other, we should not inadvertently keep ourselves from moving toward standards.

Steven Eichner
Absolutely. I think it is important that we keep a focus on making sure that the messages we send in exchange are meaningful, have useful content, and are not just full of noise that is not useful because that creates a burden on everybody as well in sending, receiving, and processing content that is not helpful. Hans?

Hans Buitendijk
Perhaps we should consider that standards-based diversity in that we want to be standards-based from a format perspective, we want to be standards-based from a transport perspective, there might be some variety, like we have choices that are transitional or permanent, but I think that also goes to the discussion point of what other kinds of networks, hubs, or otherwise could potentially do it, or that it is done at the source right there, kind of effectively, it looks like a point-to-point at that point, and that is that the knowledge that is to be used, and Annie made a comment in the chat as well, that that knowledge is shared, and therefore can be applied so that the knowledge about when, what, and how to send it is standardized knowledge that can then be used by the appropriate party that is doing it so that we end up with a variety of different ways in which it could flow, but at the end, it still flows in a standard fashion, in a standard format, understood, and to the right place.

One of the questions earlier on in the chat was also what are some of the flows from eRSD to full encoding and availability standardization of the RCKMS part. John did indicate that there is potential for that, but in this context, I am kind of curious around that to better understand what that might mean and how that could help here, and that might be a forward-looking recommendation to ONC as well, to work with CDC to define that level of standardization of knowledge, not just the content, but knowledge on where what should go.

Steven Eichner
Thank you for that. I think another piece that you mentioned earlier, Hans, is looking at the role of USCDI in the space. Do you want to talk to that a little bit as well?

Hans Buitendijk
That might be a little bit more detailed, but today, case reporting does not have a standard, other than that there is an expectation that it can contain USCDI effectively. There is some regulatory guidance that indicates that what that really means is that it is appropriate to send what is needed, which may not always be, or in many cases, is not the full USCDI. So, while we are looking at what is going to be in certification, the final rule comes out, and what is the amount of time, 24 months or whatever, after that that we have a standards-based certification, in the meantime, there is the opportunity to already more formally acknowledge that the scope is what everybody is effectively using when they are supporting eICR, which is not exactly the same as USCDI, to bring that in alignment, but that is a much more detailed component of the discussion.

Steven Eichner
Agreed. I think another piece kind of related to that is looking at the adoption schedule and transition schedule between standards and ensuring that the data receivers, not the producing health IT modules, are capable of supporting receipt of the data in a modernized format in a timely manner as well so we are not bumping up against a conflict on requirements to send in a format and the ability to receive in that same format. Are there any other questions?

Hans Buitendijk
What could that be?

Steven Eichner

Well, I think this has been a really intriguing discussion. I think we have come up with some good points. We have made some notes in the worksheet. I do encourage Task Force members to visit the Google doc worksheet, make additional comments, and begin to develop recommendations. I will spend some time after our meeting going through and developing some recommendations in the worksheet. We will try to get those out or updated in the worksheet, and please look at it before our meeting next week to provide additional input. We now have on the screen our schedule for the next few meetings, looking at patient-requested restriction criterion, and then shifting into working on our recommendations and moving into a draft report for HITAC.

Steven Lane
Yes, and I am not sure we are going to need the full time next week to go through patient-requested restrictions, despite the fact that it is a topic near and dear to my heart, so, as much as possible, I am encouraging workgroup members to get into the worksheet, to refine your recommendations, to make observations from our discussion if there are topics you want to raise to make sure we come back to, because I am hoping we can start with more detailed crafting of our recommendations next week. With that, and seeing no hands, I think we can end a few minutes early. Thank you all for your time and participation. Thank you especially to our ONC team, Dr. Loonsk, Laura Conn, who was helping out in the chat, and all the folks from CDC. We are most appreciative of your engagement here. I really do think this is a very positive piece of the NPRM that is going to help us all move forward in a good direction, so, thanks again.

Steven Eichner
And as a reminder for the public, there is a comment period open through June 20th. There is a comment template available on the ONC webpage, as well as links to the full rule in the *Register*, as well as a version in Microsoft Word.

Steven Lane
All right, thank you all. Have a great day.

Steven Eichner
We will see you all next time out.

Hans Buitendijk
Thank you. Take care.

Johnny Bender
Thank you.

Adjourn (01:21:47)