Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS WORKGROUP MEETING

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

VIRTUAL

Speakers

Name	Organization	Role
Steven Lane	**Sutter Health**	**Co-Chair**
Arien Malec	**Change Healthcare**	**Co-Chair**
Kelly Aldrich	Vanderbilt University School of Nursing	Member
Hans Buitendijk	Cerner	Member
Thomas Cantilina	Department of Defense	Member
Christina Caraballo	HIMSS	Member
Grace Cordovano	Enlightening Results	Member
Steven Eichner	Texas Department of State Health Services	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Kensaku Kawamoto	University of Utah Health	Member
John Kilbourne	Department of Veterans Health Affairs	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
David McCallie	Individual	Member
Clem McDonald	National Library of Medicine	Member
Mark Savage	Savage & Savage LLC	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Abby Sears	OCHIN	Member
Ram Sriram	National Institute of Standards and Technology	Member
Michelle Murray	Office of the National Coordinator for Health Information Technology	Acting Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Craig Newman	Altarum	Presenter

Laura Conn	Centers for Disease Control and Prevention	Presenter
John Loonsk	John Hopkins University	Presenter
Dave deBronkart	HL7 Patient Empowerment Workgroup	Presenter
Debi Willis	MyPatientLink.com	Discussant

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

Michelle Murray
So, hello, everyone, and thank you for joining the Interoperability Standards Workgroup. I am Michelle Murray with ONC, filling in for Mike Berry, who is on leave today, and we are pleased that you could join us. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting. Please remember to address everyone rather than only the hosts or panelists. Comments can also be made verbally during the public comment period that is scheduled the last five minutes of the meeting at approximately 11:55 Eastern Time this morning. Let's begin the roll call of our workgroup members. When I call your name, please indicate your presence, and let's start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michelle Murray
Arien Malec?

Arien Malec
Good morning.

Michelle Murray
Now to the rest of the members. Kelly Aldrich?

Kelly Aldrich
Hi, everyone.

Michelle Murray
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michelle Murray
Thomas Cantilina or Jeff Ford? Christina Caraballo?

Christina Caraballo

Good morning.

Michelle Murray
Grace Cordovano?

Grace Cordovano
Good morning.

Michelle Murray
Steve Eichner?

Steven Eichner
Good morning.

Michelle Murray
Adi Gundlapalli? Sanjeev Tandon? Raj Godavarthi?

Raj Godavarthi
Good morning.

Michelle Murray
Jim Jirjis?

Jim Jirjis
Good morning.

Michelle Murray
Ken Kawamoto? Les Lenert? Hung Luu? David McCallie?

David McCallie
Hello.

Michelle Murray
Clem McDonald? Mark Savage?

Mark Savage
Good morning.

Michelle Murray
Michelle Schreiber?

Michelle Schreiber
Good morning.

Michelle Murray

Abby Sears? Ram Sriram? Are there any other members I did not call or ONC staff who would like to identify themselves?

John Kilbourne
John Kilbourne is here.

Thomas Cantilina
Hey, this is Colonel Jeff Ford dialing in for Colonel Thomas Cantilina from the DOD.

Steven Lane
Wonderful, let's kick it off.

Michelle Murray
Go ahead. We are ready to go.

Co-Chair Remarks (00:02:32)

Steven Lane
Great, thank you, Michelle, and thank you, everyone, for your time and attention today. We really appreciate it. We have a packed agenda, so we are going to just blast right ahead. As you can see, we are going to dig deep into two of the items that have been presented as high priority for us to consider in crafting our recommendations to the HITAC and subsequently to ONC. We are going to focus on electronic case reporting and the state of that art, and potential improvements or advances to the ISA that could support that, as well as the HIPAA right to request corrections, so we are going to try to stay on time and we are excited to hear our speakers. Do you want to add anything to that, Arien? Arien is getting coffee, so we are going to go ahead.

So, just to start right in, just a quick reminder that this is, in fact, our 17th meeting of this workgroup. It has been quite impressive, and thank you all for all of your hard work. We are deep into our Phase 2 charge of identifying opportunities to update the ISA, the ONC's Interoperability Standards Advisory, to address HITAC priority use cases, and one of those use cases is public health interactions, and we have a great group of folks today. Craig Newman, who is a public health interoperability expert working with the ONC, John Loonsk from Johns Hopkins University, who has been the physician lead on the electronic case reporting project, and Laura Conn, who is a health scientist at the CDC, are all here to help us understand the ECR and how the ISA can help to support that. So, with that, Craig, I think you are going to start us off.

Electronic Case Reporting (eCR) Discussion (00:04:09)

Craig Newman
Yeah, I think so. So, thank you for having me here. I have been asked to start off today with a really quick overview of the lifecycle of HL7 standards. This will be review for many of you, but we wanted to make sure everyone was on the same page as to how HL7 works in developing standards. My role is cochair for the HL7 Public Health Workgroup. I am also one of the project managers with the HELIOS FHIR Accelerator for Public Health, and I will mention that towards the very end. Go ahead and go forward, please.

We are just going to start out with just a reminder that standards development is a very cyclical process. Content gets created within HL7 and then goes to ballot, which is a commenting period, usually for a month, where anyone who is an HL7 member that is signed up for the ballot is able to review the documentation and standards and provide feedback on it. That feedback is then resolved by the project team in collaboration with an HL7 workgroup, at which point, hopefully, the standard gets published.

Sometimes it is necessary to go back for reballoting, so sometimes there is a mini circle within that part of the circle, but once the standard has been balloted and published, we really enter that implementation and feedback phase where developers and implementers of all sorts, across spectrums, public health, EHR providers, pharmacies, and whoever is interested in implementing the standards get their hands on it and try it in the real world, and that results in feedback and then more updates, another round of balloting, and more implementation, and you go through this circle until ultimately, you have a stable standard that has received a lot of feedback from the people that are actually going to use it.

And, what is important to know is all of this happens within the context of an HL7 workgroup. There is always a sponsoring workgroup for most of the standards. We are going to talk about ECR, certainly, and that is the public health workgroup, but there may also be cosponsoring workgroups, and so, this happens within HL7, and those workgroups have significant input into how the comments are resolved and the changes implemented in the standards.

As far as ECR goes, which you will be hearing about here shortly, this whole process started back around September of 2015, so it is about seven years old, and the first ballot happened just a few months later, actually, in early 2016, and we have been going through this cycle with ECR ever since. Go to the next slide.

Just a reminder that change is expected. It is built into the development of standards at HL7. All standards start as a standard for trial use, and the vast majority of standards go through multiple versions. It is not uncommon. It is very common to see things evolve over time. This is really kind of by design. Typically, a lot of projects will start out with a smaller, more manageable scope. You do not want to boil the ocean at first, as there are way too many lessons to be learned, and you do not want to present something too imposing to implementers. You want to make sure that the people that are going to have to develop the tools and implement the standards are comfortable with the scope that they are starting with. You do not want to smack them upside the back of the head with a giant standard.

And then, finally, we change by learning. Implementer feedback is always an important part of the standard. What gets developed has to meet the needs of the people in the real world, and that feedback is how we fit the standard to the needs of the community, and that learning over time can also mean the scope expands over time. As we are successful in one area, we will sometimes add to the use cases, add to the standard, and enlarge it over time. Next slide, please.

HL7 does use the DURA-based comment process. You can actually click forward at least once, and at least every FHIR IG has a link built right into the standard to propose a change, and then it opens up a form where people can provide feedback against specific specifications, specific versions, and this is how the comments are collected. Part of the reason for going through this is because it is really important to capture

who is making the comment for tracking purposes and to work with them to resolve the issue, and so, there is a very formal process by which this happens. You can go to the next slide.

All sorts of feedback are typical for HL7 standards. Some things are simply technical corrections. They may be typos or inconsistencies. These things happen all the time, despite authors' best efforts, unfortunately. Terminology changes over time: The codes and the concepts that are needed for interoperability. Just recently, the vaccine credentialing smart card implementation guide has been wrestling with how to encode vaccines internationally, which is not quite as easy as you might think.

Sometimes, suggestions are alternative ways to achieve the use case. We have had examples where there have been a lot of questions about how immunization decision support recommendations should be presented within a FHIR IG to achieve the use case. Clarifications happen all the time. The author's intent of what they mean or the description of how they do it sometimes require clarification. Sometimes, scope is expanded with new data elements and new use cases. Laboratory orders and results in the V.2 space are a great example of this. They have been expanded many times over the years with new data elements and new use cases as the world evolves. We have seen a lot of work here just recently with the COVID pandemic where content has been greatly expanded in both of those IGs. Next slide.

There are a lot of ways that people can contribute feedback. I mentioned the HL7 workgroups, and that is really the primary forum for discussing standards. This is where the comments that are submitted are officially addressed. This is where the discussions happen. Those are always open calls, so everyone is welcome to attend those. There are HL7 listservs that announce when comments are going to be discussed and what the proposed dispositions are, so there are lots of ways to keep up on that. HL7 connectathons are a great place to have the hands-on experience. Those always generate a whole lot of comments and feedback.

The HL7 connectathons are not the only ones out there. Various groups sometimes will sponsor their own, and those are perfectly valid, good ways to get that feedback in the comment. FHIR accelerators are a growing way for people to participate. Accelerators operate really outside of workgroups. They are HL7-sponsored groups that are looking to make improvements in a little bit broader areas, so the HELIOS Accelerator is one of the newest ones. It was stood up just last fall, and we are in the process of developing the set of use cases that HELIOS is going to look at over the next 12 months. I will come back to that in just a second. But, there are a lot of other FHIR accelerators that are relevant for public health reporting. They include social determinants of health, payer and provider exchange, and oncology. There are a number of accelerators out there.

And then, finally, there are just a lot of different ways to get involved. We try and interact with trade associations where we can. EHRA, CSTE, and NACCHO all come to mind. I am sure you are all aware there is a very vibrant community on FHIR.chat.org. I will remind people that is not just about FHIR, despite the URL, but it also contains space to talk about CDA, V.2, and really anything having to do with interoperability. And then, there are just a lot of other projects going on that people can become involved with. One that comes to mind is Gender Harmony, where they are exploring sexual orientiation, gender identity, and related concepts. They are really all great places to get involved and contribute feedback into the standards.

I will end with one more slide, which is just really an overview of the FHIR accelerator. This is designed to be a very diverse team, including not only public health, but healthcare providers, philanthropic organizations, and private sector HIT vendors, all working together to tackle challenges in public health data sharing. The three areas that we are honing in on over the next 12 months are bulk data in IISs, which are immunization information systems, so we want to explore how to make public health data more accessible to authorized users. We are looking at aggregate data, demonstrating ways to provide mission-critical information, things like bed count, ventilator usage, and that sort of thing, to public health.

And then, more generally, we are doing something we call "align and optimize," which is really taking a closer look at the ways the FHIR offers new ways to exchange data. We have been using CDA and V.2 in the public health space for a long time. We have had some tremendous successes there, but FHIR offers a lot more tools that we can use in terms of pushing data, pulling data, and subscribing to data that maybe are not as easily done today, and so, we are going to really focus on that as well, and look at the way FHIR is being proposed to be used today and how we can use it in the future. I think that is most of what I had.

I know there was a question about how HL7 tracks maturity and adoption of standards, which is a really good question. Historically, there has not been a whole lot of tracking of maturity or adoption. We know that as things get included in regulation, that certainly drives adoption. One of the things FHIR has really tried hard to do is to actually track maturity, and so, they set out, in fact, what they call the FHIR maturity model, which is a set of criteria that you judge both the base standard by as well as implementation guides, depending on how much it has been tested and how much it has been implemented in the real world. Different standards are assigned different maturity levels all the way up to "normative." And so, with FHIR, there is an excellent framework in place to track maturity, and there are discussions going on about adopting similar things for the other product families, for CDA, and for V.2, but those are still very much in discussion. So, I hope that helps. If you have additional questions, I am happy to answer them.

Steven Lane
Thanks so much, Craig. That was a very helpful background. Arien, you wanted to provide some comment.

Arien Malec
Absolutely. So, I think we are going to hear in a little bit about the HIPAA right to correction, but we have been exploring in this update of the ISA a number of areas where HL7 accelerators are currently absent in the ISA, so I would welcome your thoughts about how HL7 and other SDOs in some of their accelerator work can have a faster path into the ISA so that the ISA appropriately tracks the latest version of standards. So, that is maybe my first comment, and I would appreciate your comments there. I think we are going to put in some recommendations to that effect.

Secondly, in your overview of the work that gets done through HL7 workgroups, real-world production testing… As you go through the FHIR maturity model, which was modeled after the IETF maturity model that is used for the internet, the ability to get feedback from production pilots and early production experience is really important, so I would love for you to be able to comment on how real-world implementers are able to get their feedback through to spec maturity.

And then, thirdly, with respect to ECR, if you look at the ISA, the entry in the ISA currently points to something called 1.0 STU, but if you click through, you get a reference to Version 2.0, and then, I think the

AIM platform and the work that CDC is doing is pointing at a slightly different version, so maybe some generalized feedback as we think about things like ECR that are going through heavy production testing, and this may be a subset of Idea No. 1, but things like ECR that are going through heavy production testing, and then, a slower and more deliberate process that goes through workgroups, how we are able to point implementers to the latest and most productive version of a standard.

I know that is a lot to throw at you, but those are the things that really arise as we are having these conversations. How do we better align the accelerator work with the ISA, and how do we better keep track of real-world production, usage, and the more rapid evolutions that sometimes happen with an implementation guide with the more methodical updates that happen in the workgroup process?

Craig Newman
Yeah, there is a lot there, and I may have to get you to remind me of a couple of them because I think I have forgotten the second one of them already. The accelerators are project teams that really push the boundaries, but ultimately, mostly what they produce are standards that go back through the HL7 process. So, the Da Vinci Accelerator is a good example. They work in a large number of different areas within the payer/provider space, and they have developed a large number of implementation guides that go through that process, so they find a home workgroup and they go through the balloting process just like any other standard. And so, I think my suggestion would be keeping in touch with the leads of the accelerators is a great way to understand the work that is going on, but ultimately, when it comes time to point to a standard, whether it came from an accelerator or some sort of standalone project, you may not notice a whole lot of difference, but I think it is that coordination aspect with the accelerators that is helpful.

In terms of how things evolve over time, you are right. There are usually multiple versions, and it can be difficult for implementers to know which one to start with. I think that is why being clear in the ISA about what is available and what is recommended for use is a great place to start. I know it is V.2 and not FHIR, but I will point out that really, I think the reportable results to public health is still using the very first V.2 implementation guide even though it has evolved a great deal over time, but it is hard to migrate the real world. When something is up in production, people are a little reluctant to change it because they do not want to introduce issues. So, I think one of the things you need to do is really coordinate with those accelerators or with the project team, and I think John will maybe mention versions of ECR that are out there. There are ones that are sort of in practical use. There are ones that exist largely because of the process and would not be recommended, and then there are the latest and greatest. It is tricky to know which one to point people to.

Arien Malec
Those are exactly the thoughts that arise about the ISA. We have the risk of having the ISA basically point to older and, frankly, worse versions of an implementation guide because that is the one that went through the formal balloting process. I am reminded that before OAUTH2 became an internet standard, it went through 37 revisions, and as OAUTH2 was getting matured, you had Google, I think, using V.12 and Facebook using V.14 in production, and I would say that is actually a really good experience for a standards development approach, that somebody is using the standard in production, learning from it, and getting value out of it, but then, it does leave implementers in a really confusing position to figure out which version to pick up, and as I said, I think there is a risk that the ISA points to a version that literally nobody is using, but even though it is the last one that went through a formal balloting process. So, if you have thoughts that

come to you later, we would just welcome your feedback, but I think we are going to make some recommendations in this area to make sure that the ISA is a better tool for implementers to be able to pick up real-world changes. Thank you.

Craig Newman
Yeah, and high-level work with the project teams and the accelerator leads. They are the ones in the community. They know what people are excited about, what they are nervous about. Worse is always in the eye of the beholder, and older and more stable may not be worse to everybody. Something newer with bells and whistles may be a risk, and so, there is going to be a lot of variation within the community that needs to be considered.

Steven Lane
Well, that is a great introduction to the next presentation. Thank you again, Craig. Now we are going to hear from Dr. John Loonsk about the ECR standard as it exists and advances that are being made. I have had the opportunity to work with John pretty extensively over the last couple of years, helping to support the ECR effort, so I am really excited to have him here to speak to us. John?

John Loonsk
Thank you, Steven, and thanks to the committee for an opportunity to talk about the interoperability and standards needs for electronic case reporting. If you can advance to the first slide, we are representing now 12,200-some facilities nationwide that are doing reporting for electronic case reporting, and most of those are doing COVID-19 because we pivoted to exclusive COVID-19 reporting during the pandemic. If you can move to the next slide, you will see the very rapid advancement during the pandemic, a very difficult time to do infrastructure advancement to get to this point. So, we are very excited. Steven and others from the physician community helped lead the charge on ECR, as we call it, because essentially, they were trying to do the right thing in terms of getting the data that public health agencies needed, but also, it offers the opportunity for them to eliminate manual reporting as things progress as well. Next slide, please.

So, at the same time, the public health agencies have been moving forward in being able to accept their electronic case reporting data, and this is significant parallel progress with the public health agencies. They all are accepting COVID-19 electronic case reports now, and that represents very significant progress from the start as well. Next slide, please.

There are several things about electronic case reporting that are unique, and this is a new approach for doing public health, and this is the slide that we use when we are onboarding folks to do electronic case reporting. What is notable about this slide is that it is really a start apology. In other words, it prevents a single interface for healthcare organizations and EHRs to report to the multitude of different public health agencies that exist on the right-hand side, and it achieves this by implementing a decision support engine in the middle that represents the reporting laws of the different public health agencies that receive, and this has been the complexity with doing electronic case reporting, is that the states have different laws for what is reportable.

There are certain commonalities, but then, there are also variations. The decision support engine in the middle here, RCKMS, allows for the public health agencies to author in accordance with their state laws and receive the case reports for what is reportable in their condition, and it really protects the healthcare

organizations and the EHR vendors from that multi-jurisdictional complexity. So, this is a start apology, and I am going to walk you through the standards needs to manifest this as we proceed through this presentation. At the end of the presentation in the appendix, there is a series of very specific recommendations for the ISA, down to the language recommendations as to what would support this. Next slide, please.

So, it is important to think about the public health agencies. I know not everyone has the exposure to what they do, but what public health agencies do at the end result of this is they need to support reportable condition case ascertainment, they need to investigate those cases to confirm, to classify, to manage, and to do further reporting, for example, reporting of notifications to the Centers for Disease Control and Prevention. That is done on a voluntary basis, but a core set of the reportable conditions is a very important part of our nationwide infrastructure. Electronic case reporting is the reporting from healthcare to state and local public health agencies to support these activities. To do this the surveillance systems in public health agencies need to track and manage cases, they support additional information retrieval, they have to facilitate things like contact tracing that became very prominent in the public eye during COVID, but also identify trends in changes in what is going on from a condition standpoint, and, as I said, report what are called anonymized notifications to the CDC as part of this as well.

These surveillance systems and the associated databases, of which there can be more than one at a given public health agency, need to electronically consume the data. The target here is not viewing the data. This is happening at an aggregate level. The target here is to process the data in the surveillance system, and they do this by using interface engines and some surveillance system technologies to map a data-element-by-data-element basis of the data that come into them into their surveillance systems so they can carry out these functions. To do that, the public health agencies really need consistent data structures to support that mapping, and they need those structures to support the consumption of the data so that they can use them.

No. 2, they really need reliable content and, ideally, desirably, coded content from the electronic processing moving forward. This is the end of the electronic case reporting process, is getting these data for what is reportable in a particular jurisdiction into the public health surveillance system that can manage and track them. Next slide, please.

I mentioned in the overall architecture that the variability in state laws induces a complexity here, and we have handled that complexity by a shared services platform at the Association of Public Health Laboratories with supports, among other things, a decision support engine called RCKMS, and it is that decision support engine in which the public health agencies author their reporting laws to ensure that what they get are the conditions that are reportable by law in those jurisdictions, not more, and not less, and the use of what we call the electronic initial case report, or EICR, in this context is to be processed in this decision support engine as well as mapped and consumed into the public health agency surveillance systems.

So, as you can see, a lot of emphasis on that standard because this infrastructure is built on the use of that standard that is operational constructs as well as the specific data for mapping and processing. Currently, this now supports 132 conditions. This is not a small task. The ability of the EICR to support the multitude of conditions also influences the single interface that is presented to healthcare organizations, and I will talk about that in a minute. So, RCKMS has rules, they are authored by the public health agencies, and consistently structured and coded data enables RCKMS to process the electronic initial case reports to

automate reporting through this process so that the healthcare providers do not need to manually report, and then, hence, to minimize reporting burden.

If you think about the permutations here, with the many public health agencies on the right, there are some 2,400-plus public health agencies if you consider locals on the right-hand side of this diagram. With those jurisdictional complexities, most of the laws reside at the state level, so that is a little bit simplifying, but the different states and territories have differing laws, as I have emphasized, but then, add to that the complexity of these 132 programs, many of which had individual surveillance systems when they started out that are now integrated into this picture and provide that single interface for the reporters on the healthcare organization side to automatically report without disrupting the clinical workflow. Next slide, please.

So, talking about finally that left-hand side of the screen, we have two different approaches for how we can implement. We implement with either the EHR-developed solution that is represented on the bottom lines, where the EHR developer will program in the reporting process I am alluding to. We also have developed a FHIR app we call the ECR NOW FHIR app that integrates with the EHR using the FHIR ARCOR API, but both of these approaches, as referenced in Arien's and Craig's comments earlier, use a single standard for implementation right now, which is a CDA-based EICR, and I will talk about the versions on that, but the infrastructure accommodates that infrastructure and presents it to the public health agencies for their use and consumption.

We have done all this through the HL7 consensus-based process that Craig alluded to. As he said, the start of this for the EICR and the related standards began in 2015. It really was the start of the electronic case reporting infrastructure that I have alluded to. The EICR was built to accommodate and convey both classical clinical data in the context of what can be typically expected, plus some clinical data that are oriented to public health needs, and actually are not necessarily represented in some of the common clinical constructs like the C-CDA.

So, the EICR was built first using C-CDA templates to try to ensure ease of production of that standard by the clinical care organizations and their EHR companies. It is tracked to the common clinical data set, and it tracks to USCDI wherever possible to minimize the effort in construction of the standard, but it also has certain data that are critical for public health purposes, and the goals of the standard are to provide consistent EHR data to enable conformance testing at multiple steps. We test the EHR companies and their ECR products before they go into prototype, we test them when they are in a pilot situation in a healthcare organization with live data.

The first testing is done with scenario-based data, the second data is done with scenarios and live data, and then we also need to test and monitor their implementations as they roll out to the rest of their customers to ensure that when there is a systems update, the content still abides by the needs for public health case reporting. That is all based on having a standard as the basis for what is tested against, and we use the EICR standard for everyone that is onboarded to this start apology that I have talked about, and to the system and the use of RCKMS to adjudicate the rules, to implement the rules to make sure that everything that is presented to a public health agency is appropriate as per their laws.

So, the standards, the EICR, the reportability response, the electronic reporting and surveillance distribution, play a critical role in this infrastructure as we are moving forward. The EICR is the container for

data that can be reliably presented to RCKMS and also to the public health agencies for their mapping and consumption. The reportability response represents a return transaction. There is one reportability response for every electronic case report that is received that presents information about that EICR, and then, the ERSD, is the set of triggers, trigger codes, and reporting setup that is necessary for either of these approaches, either a native implementer or the FHIR app implementer, to pursue electronic case reporting in an ongoing way. Next slide, please.

So, I have alluded to these standards. There is a description of each of them here. I will not go through them all again. These are the standards that electronic case reporting has been advancing. At the bottom of the screen, you will see a table, which hopefully helpful, Arien, in identifying the standards that we are using, but for those that onboard with this infrastructure, it is unambiguously expressed to them which version of the standard they should be using for these purposes. We have implemented right now Version 1.1 of the EICR that is operationally implemented for all reporters. The version of the reportability response is Version 1.0. Those are both CDA documents.

We have also worked the HL7 process to develop FHIR specifications that are actually in lockstep with those CDA specifications, and if you think about this, we are excited about the eventual progression to FHIR for the nation's healthcare infrastructure. The public health agencies need to be brought along in that regard too, and part of bringing them along is having a suite of standards where the data are the same in both implementations, so when we do operationalize the FHIR standards for electronic case reporting, there will not be data loss, and we will be able to present the standard to the PHA that they can accommodate. So, this is part of our standard strategy, having this full suite of standards, beginning with the CDA versions, but also encompassing FHIR versions that will allow for us to progress and to bring the public health agencies along as they move into the FHIR world as well. Next slide, please.

So, this is my last content slide. From an electronic case reporting, interoperability, and standards need, we really want to identify these specific standards in the ISA. We also would like to advance to having EHR certification for these specific standards. Right now, EHR certification for electronic case reporting is only a functional certification. The particular conveyance vehicle that is used could be anything, so there is a general identification of the data that need to be presented, but there is not the specific identification of the standard needed for conveyance of that data. That would make it very difficult for the public health agencies to receive the data if they are coming in all different kinds of forms and formats.

We are fortunate that the Centers for Medicare and Medicaid Services has advanced two rules for electronic case reporting in the 2022 reporting period. One is for eligible hospitals, the other for eligible providers, and they need to report in 2022. ECR is a requirement in that context. As you well know, those are complex systems. There are caveats to things in terms of implementing, but we have been very pleased by the EHR company response. We are now in the process of unwrapping some 19 electronic health record vendor products now into this infrastructure, but there are a lot more out there. At last count, we saw some 78 products that were certified to the functional certification of electronic case reporting, and unfortunately, we do not know what they are using from a conveyance standpoint, what standard the rest of them are using. We know that they have engaged these nine products with us.

The concern there is that without using the EICR standards, without then being able to take advantage of the decision support engine that is central to this case reporting infrastructure, there will be inappropriate

disclosures to the public health agencies unless complex logic is programmed into those EHRs, and we just do not understand how that can happen in the context of the 132 conditions that the public health agencies author, so there is a basic disconnect here, and we believe getting out of that disconnect starts with identification of the specific electronic case reporting standards that have been worked through the HL7 process and are identified for it, but there will be needs to push and pull with other levers as well.

I mentioned early on in this presentation that coded data is most valuable. It is coded data that the RCKMS system can process and utilize to make the determination of reportability. There are some ambiguities there, but that still is the target. It is coded data that the public health agencies can utilize in the system at an aggregate level, and pushing on some of the levers that are out there, like CLIA, for example, in addition to USCDI, to ensure that the data are both well structured and coded to move this process forward is a critical aspect of advancing this capability nationwide.

So, the final comment here is that a lot of the standards activities view things at a nationwide level, and a lot of federal regulations are very associated with things at a national level. Electronic case reporting actually operates at a state level, and the state laws are what drive the reporting, and there are differences in those state laws. We have tried to mitigate the differences from the standpoint of providers, but it is very important for the federal infrastructure to understand that what is required by state laws is important in the context of electronic case reporting, and not just what is identified at the national level.

Finally, if you could move to the next slide and the slide after that, we have put into the appendix specific recommendations for how the ISA can be updated to support this electronic case reporting endeavor, and I am not going to go through all the specifics of these language changes and recommendations. I had given them to you electronically with these slides. There is a need to focus on these electronic case reporting standards in the identification of electronic case reporting to public health agencies, potentially move out some of the recommendations that really relate to other kinds of public health reporting, and not electronic case reporting, and to then align the standards very specifically with this process that I have alluded to.

So, that is in the packet that is being shared, as well as some slides on the specifics of what data are available in the HL7 electronic initial case report standard as part of a kind of summary record with both mainstream clinical data and some data that are critical to the public health reporting process. So, with that, I will stop. I know that there have been questions that have gone by in the text, but I am happy to answer questions as we proceed.

Steven Lane
Thank you so much, John. Arien, your hand is up.

Arien Malec
Yes, please. Thank you. So, again, we really appreciate this presentation and are incredibly appreciative of the work that you, CDC, and APHL/AIMS have done. I believe this work started triggered by Zika and the recognition that we needed a much more flexible way of responding to emergent crises, and then, some of the work was done just in time for COVID-based case reporting, but it took a little while early on in the pandemic to get EHRs upgraded, and you have been reliant on goodwill, which I think reflected that the larger EHR vendors have had that goodwill and have been partnering to drive ECR into products.

Maybe just in line with the questions I was asking Craig, how does the on-the-ground work that AIMS does in connecting EHRs with states track to the work that HL7 does in the workgroup process to coordinate updates to the implementation guides, and what are the policy recommendations that you have for ONC or that you would contemplate for ONC to make sure that the ISA is a better tool for enabling implementers to get the latest version of what is practically needed to drive interoperability, as well as what has gone through an open, fair, multiparty, etc. balloting process?

John Loonsk
Arien, thank you for that question. I recognize the role of the Council of State and Territorial Epidemiologists in this project as well. ECR is a combined project of the Centers for Disease Control and Prevention, the Association of Public Health Laboratories, and the Council of State and Territorial Epidemiologists. That is a lot of acronyms, but it is important, and all those roles are recognized. The way that we worked this since 2015 is that the ECR team has driven the standards development process through the HL7 public health working group and the other associated working groups in that regard. So, we put the agenda on the table. It is a consensus-based process. They all have wide input from EHR companies, from public health agencies, and from others during that process, but the ECR team has driven the standards development process through that.

From the standpoint of clarity on what standards are used, what versions are implemented, electronic case reporting is not a use case in the HELIOS public health accelerator partly because the standards are mature. They have gone through multiple versions, they are out there for use, and they have been tried and refined as they have gone along, but the identification of them is a critical component of this, that ISA plays a critical role in identifying which standards should be used to the broader audience. No doubt there are communication challenges for all of this, and to make sure, I mentioned the fact that we do not know what those EHR companies are doing that are certified, but not unwrapping to the electronic case reporting infrastructure. We do not know what standard they would use. That is a challenge. It is a challenge for the public health agencies to consume.

I think the specificity of having these standards in EHR certification would also be hugely helpful in terms of moving this along and getting this lined up between the many cats in clinical care that need to be herded and the any cats in the public health agencies that need to be coordinated for this implementation. I think Laura Conn is also on the phone to help with questions and answers. Laura, I do not know if you want to say anything.

Steven Lane
Actually, John, sorry, I do not mean to cut you off, but we did pack two important presentations into today, so as much as I would love to have the rest of our time to dive in here, we really do need to move on. Both Hans and Ike had their hands up. I would really invite you both to put your comments in the chat so we can come back to them at a future meeting, but I really want to thank Craig, John, and Laura for coming and sharing this with us. Really great specificity in the recommendations, and we will take those up as we craft out recommendations to HITAC, but we need to move on.

John Loonsk
Thank you.

Arien Malec
Thank you.

Steven Lane
All right. So, next up, we do have Grace, whom we all know well, who has helped to organize a presentation around standards supporting the HIPAA right to request corrections to the medical record. This is something that has not been a focus within ISA, and Grace has brought it forward and really helped prepare a group presentation for this, so, Grace, why don't you introduce the presenters?

HIPAA Right to Request Corrections (00:51:30)

Grace Cordovano
Great. Thank you, Steven. I want to thank ONC, Steven, Arien, and the workgroup for the opportunity to present on behalf of the HL7 Patient Empowerment Workgroup that is leading the charge on patient requests for medical record corrections, and I have Dave deBronkart and Debi Willis on the line also. They are the leads of this effort and have been tirelessly championing the work, and will be available for questions afterwards. Next slide, please.

I am going to dive in with summarizing the scope of the problem. Next slide. The reality is that the volume of errors that are found in patient and individual medical records is staggering. A number of independent studies summarize some of these key statistics, that up to 95 percent of medication lists have mistakes, 84 percent of progress notes contain at least one documentation error, with an average of just about eight documentation errors per patient. These errors and gaps in patient records can lead to significant negative impacts in patient care, care continuity, and patient safety. We know that medical errors are the third leading cause of death in the United States, and if there is anything that we all can collectively do to reduce, if not eliminate, unnecessary medical errors, it is an opportunity for us to all collaborate. Next slide, please.

As we were working to tailor a presentation that was meaningful and impactful, this quote really resonated. "If we do not have accurate data, we cannot take care of patients appropriately." We are in an era where we are seeing a movement towards participatory medicine, shared decision-making, patient empowerment, and a term which I love, shared accountability. As my mentor and colleague Dave deBronkart would say, let patients help. Patients are recognizing errors in their records, and they want to be able to record and report them and discuss them, and we have a great opportunity here before us. Next slide, please.

There is a plethora and very broad spectrum of different types of errors that patients do report in their records. They can be, as I mentioned, medication errors, both prescription and over-the-counter. There could be different types of documentation about treatment outcomes. For example, it may be noted in the record that a patient's condition, whether it is heart disease, cancer, or a case of strep throat, has resolved, but a patient may very well still be struggling with symptoms and the condition, untreated, unresolved. There could be missing information or incorrect information from pathology results, to lab results, to incorrect diagnoses, as well as incorrect patient demographic and social-determinants-of-health data, and copying-and-pasting errors from previous visits and perceived errors are rampant as well. Next slide, please.

In a recent open-note study from 2020 looking at the frequency and types of patient-recorded errors in EHR ambulatory care notes, we saw that one in five patients surveyed reporting finding a mistake in their note, and I really want to hone in on this point. Forty percent perceived the mistake as serious or very serious.

We talk about not boiling the ocean, and I recognize that this is not going to be a light-switch fix, but what if we, at minimum, offered a way to tackle the serious and very serious errors that can lead to catastrophic consequences? These errors that were reported by patients as perceived to be very serious include this list: Again, missing and incorrect diagnoses, issues with medications, even being the wrong patient or the wrong sidedness, for example a biopsy, a surgical procedure, imaging that is noted as the left side of the body when it needs to be right. I do not have to go on and on to describe the consequences of something as simple as an error like that and what it could lead to with respect to patient care. Next slide, please.

From the open-note study, it was concluded that we should be inviting patients to report any perceived errors that they find in their visit notes, especially the ones that are very serious, because this is going to be associated with improving record accuracy and patient engagement. I want to point this out: Patients requesting copies of their records is patient engagement. Patients requesting corrections to their medical records is patient engagement. So, the call to action from that open-note study was that we really need to focus on developing efficient mechanisms to respond to these types of patient requests. Next slide, please.

When we think about equity by design, it is very clear that errors have a greater impact on our most vulnerable of populations. It is well reported that minorities and those with more complex, poorer health needs are less likely to speak up to report errors, and there are two major barriers here, and I see one of the most common ones in my daily patient advocacy work: Not knowing how to report a mistake. It can be so challenging to figure out how to access one's records and how to request a copy of all the different types of health information.

When you go to look at your healthcare delivery organization, your hospital, your cancer center, many providers and physician practices, I bet you a dollar most do not have a clear-cut path that is described to patients, whether it is a handout or a place on their website, or even a discussion at point of care, discussing how to report an error in their medical record in a standardized and simple fashion. Another barrier is that patients are afraid of being labeled as a troublemaker. They do not want to negatively impact their care, and there is a lot of stigma in many cases that is well reported in simply being a patient, so this can be a challenge in and of itself. Next slide.

In a recent report from ONC, it is noted that patient records often have mistakes or are missing sections of care, so in addition to the negative impact on patient safety, patient care coordination, the impact from a health equity lens, we also now have the potential of unnecessarily repeating tests, which can cause delays in care, which can cause increases in cost, and overburden healthcare facilities in general. Next slide.

Thankfully, we have policies in place to make our health information more readily available and more actionably accessible. However, now, as a consequent, patients, care partners, their advocates, their families are coming across these errors more and more, and I am preaching to the choir here. Chaos will ensue when there is not a standardized process in place. Now, more than ever, we have an urgent need for a standardized process to process patient requests for medical record corrections. Next slide.

Overall, when we summarize and look at what patients are looking for from this said standardized process, patients report wanting clear instructions about how to report a mistake and whom to report the mistake to, and lo and behold, they are looking for ways to report these online, and even asynchronous reporting,

where there may be less anxiety, stigma, and judgment involved, and interestingly, an easy instrument that prefers the use of an objective third-party reviewer sometimes as opposed to one's own doctor. Next slide.

Building on how big the scope of this problem is, now we also have a general data integrity component piece to consider. With the advancement of FHIR, many research organizations, including public health, are increasing their reliance of EHR data. Patients and patient communities recognize from all the reporting and things that they see in social media about how electronic health record information is being used to power innovations such as AI and ML-based predictive analytics and different types of cloud-based tools, but if the research is using poor-quality data, it is going to result in poor-quality research. Patients and their families and patient communities are concerned about trusting these innovations and the conclusions that are found from this research. We have to do better. Next slide.

So, here we are, looking at this not from a functionality standpoint, but from the lens of data integrity, research, and public health. Next slide. And now, more specifically, through the lens of the work that we do here in our Interoperability Standards Workgroup, where, over the last 17 meetings and even last year's meetings, we have talked about many of these spaces, from the success of the information-blocking rules and data that is in USCDI and all EHI come October of this year to the work that is being championed by the Gender Harmony Project, the Gravity Project, Project US@, and even pandemic preparedness and public health. Patient requests for medical record corrections is an underlying feature that is really necessary and critical for the success of all of these different arenas. Next slide, please.

There are plenty of policy levers that we can rely on. Next slide. In its nationwide privacy and security framework for electronic exchange of individually identifiable health information, in 2008, ONC adopted the correction principle, where individuals should have a right to have erroneous information corrected, or to have a dispute documented if their requests are denied. Next slide. We, of course, have the HIPAA privacy rule that provides individuals with the right to correction, which I emphasize as a right. Next slide, please. Both the privacy rule and the correction principle recognize that individuals have a critical stake in the accuracy of their individually identifiable health information. It is now 2022, and it is time for us to really get moving on this piece. Next slide.

In 2011, the Health IT Policy Committee recommended to ONC that they stablish certification criteria to enable the HIPAA request-for-correction amendment process. Next slide. And, of course, the 2015 edition health IT certification criterion also addresses amendments, both amendments that are accepted and denied. Next slide, please.

But, here is the reality where we stand today in 2022, comparing the current ability to access versus the ability to correct. We are able to access electronic health information using standards, using modern technology in interactive and scalable fashions. That is not true for corrections. We do not have standards-based processes. It is labor-intensive, low-tech workflows, it is typically done outside of current EHR workflows, it is not interactive or scalable, and there is a lack of continuity and a frustrating fragmentation that patients and physicians and many at point of care face. So, while we have policies in place that have sharing of data between organizations, we are seeing errors now getting shared and propagated at a concerningly increasing rate. Next slide.

I am happy to introduce the HL7 Patient Empowerment Workgroup, specifically the project on patient requests for corrections, the project leads of which are Debi Willis and Virginia Lorenzi, and this project began the summer of 2020. To date, there have been four very successful connectathons in January, May, and September of 2021, and most recently in January 2022. We have received strong feedback on the draft implementation guide testing, and the implementation guide was balloted in May 2022 and is currently under reconciliation. We have received a plethora of input, but we certainly need more, and we also need more EHR involvement in policy support. And, I want to point out that based on this work, the Netherlands has also mandated patient requests for corrections to be available by FHIR. Next slide, please.

What are our recommendations? Next slide. Our recommendations for ISA are as follows: From a structural standpoint, we request that the change in specialty care and settings menu be changed to use cases, and that the patient requests for corrections be added as an ISA use case for standards development and implementations. More global recommendations include the following: To recognize that the HIPAA right to request corrections to one's medical records use case broadly applies to all information in the designated record set and all EHI. We encourage ONC to establish certification criteria to enable the HIPAA request for correction process by the patient access FHIR API. Next slide, please.

We recommend to ensure that all patients at minimum can make their corrections through the patient access API for all data available through the API, and we encourage ONC to collaborate with the HL7 Patient Empowerment Workgroup to really address any gaps in standards, capabilities, and implementation for this functionality. And, on a granular level, our recommendations to ISA are in the services and exchange and administrative arenas, to add patient requests for corrections to consumer access and exchange of health information, as well as to administrative transactions to support clinical care. Next slide, please. If there are any questions, I will turn the mics over to Debi and Dave.

Steven Lane
Excellent, Grace. Thank you so much for that very clear and concise presentation of all the background, as well as the very specific recommendations that you provided. We have a hand up from David McCallie.

David McCallie
Yeah, thanks, Grace, for the clear presentation, but I am a little confused about whether your recommendations include addressing the myriad workflow questions for how this would work in the real world. Jumping to a FHIR API before figuring out the implications on workflow runs the risk that you have an API that no one ever uses. I may have missed it when you covered it, and if so, I apologize, but would you please clarify that again, if you could?

Debi Willis
Grace, would you like me to get that, or do you want to get it?

Grace Cordovano
Sure, Debi, please.

Debi Willis
Sure. This is Debi. Our implementation guide is not telling the healthcare systems how to make the corrections. Right now, they are getting requests for corrections via fax, via letters, via somebody talking to

the front desk, asking a nurse or a doctor while they are in the exam room, and what happens after that is really outside of our scope. We are really building, basically, the communications channel. We are looking at a standard way to use FHIR to simply communicate the request from a patient over to a healthcare system, and they would use their own workflow that they are using now that will just now have a better way to get that request and respond to that request so everything is documented and easily accessible to the patient, and it is really about the communication, not about how they do the correction.

David McCallie
So, is the FHIR API essentially a back-and-forth conversation with the consumer, or do they edit the note as an amendment and someone has to approve its inclusion? Maybe I was a bit to broad by using "workflow," but I am just not understanding the mechanics.

Debi Willis
We are not saying we want a patient to be able to edit a chart. We do not think that is a good idea; we do not think that any of the providers would think that is a good idea. We are simply using current HL7 resources to communicate a request. We are using the communication resource, which allows a patient to also put in the payload their text if they just want to specify, "Hey, you have my medications wrong," and then, down the line, if we want to get more sophisticated to actually include resources so that health systems can see exactly what the patient is talking about, but right now, it is the communication resource. We are not inventing anything new; we are just using what is already there to make a request. We are not saying the patient has the right to actually change the chart, but the patient does have the right to make the request, and we would like to use FHIR to do that.

Dave deBronkart
This is Dave deBronkart. If I could add briefly to that, as rabidly as I am known for advocating for just listening to the patient, there are limits to that. I will never forget the South Dakota nurses talking about how some of their patients in the ICU denied they have COVID right up to the moment they died of it, and we do not want any random person editing. I think the point that Grace made in her slides was superb, which is right now, whatever universe of requests would be out there are all just disorderly, as if all the spam junk mail in the world got dumped in your yard, and what we are proposing to do is get it organized. Every request should arrive tied to the specific fact that was wrong. In the interests of Gravity, I will say I expect a new ecosystem to spring up of apps and EHR extensions to process efficiently all of these requests.

Debi Willis
Yes, and even to add to what Dave said, in this implementation guide, when a communication is sent from a patient to a health system and actually back and forth, it has a specific type. It identifies that particular communication as a request for corrections. So, if a health organization wants to filter and sort the different communications coming in, it would be easy to say, "Okay, everything coming in with this type goes over to this department, if they would like that."

Steven Lane
Arien?

Arien Malec

Thank you. So, first of all, I just comment that in my experience with secure messaging that goes back more years than I wish to admit, the use of unstructured secure messaging to request corrections to records was fairly common, and as noted, it leads to an ad hoc or disorganized process that often does not honor the right to correction. So, I think the minimum request that we have for the ISA is to track HIPAA right to correction as a use case, and then to track the standards that are going through the patient empowerment accelerator as implementation guidance to be tracked under that use case.

Sort of following on David's comments and being mindful of the experience, perhaps, that the Netherlands has had in real-world testing, is there an approach that the Patient Empowerment Workgroup has for real-world testing with EHRs, either through Argonaut or through other mechanisms to drive these workflows into actual production use prior to potential standardization?

Debi Willis
We would love that to happen. It really means that one of the vendors needs to step up and work with us to do that. That is one of the problems that we have, is we need that part.

Arien Malec
Perfect, thank you.

Steven Lane
Any other questions from members of the workgroup?

Grace Cordovano
I do just have one more slide at the end, and it is just contact information if anyone wants to follow up. It is included in the deck.

Arien Malec
Thank you, Grace. So, Grace, you have done a great job pulling together these very specific recommendations, and of course, you have full access to our spreadsheet to instantiate those there as draft language for our detailed review and consideration, so I would really encourage you to do that. I think I have my name on the ECR item, and I will try to do the same with he ECR recommendations that came from that team and accounting for the comments that have been going, questions and answers in the chat itself. Christina, your hand is up.

Christina Caraballo
Sorry, I have a little bit of a cold. I was just trying to follow along with the recommendation on the structural change. Where it says "change specialty care setting menu to use cases," can you explain that more? I am not quite following that recommendation.

Grace Cordovano
That is a great question. So, as I was noodling through the USCDI and ISA website, which I am just pulling up so I can actually verbally walk you through, when you go to ISA, you get four tabs across the screen, and it is only when you click down that you get a different view, and I was speaking with Mark Savage on this. There is a different view of ISA you can come up with that has a menu along the left-hand side of the screen, and at the bottom, there is specialty care, and I was recommending as a group that we change that

to use cases so that there are different use cases for ISA as opposed to just specialty care. Mark, I do not know if you wanted to also chime in on that.

Arien Malec
This is Arien. I will just note that I have a recommendation in the spreadsheet that tracks this item so that for our next meeting, we can go through and look at the more formal recommendation that we are proposing. But, basically, we need a view of the ISA that is tracked not through… Right now, you go through transport services content terminology, and then you track down through use cases to specific implementation guides. We would like a view where we root on use case, and then look at all the standards and implementation guidance that associates with that use case, and right now, there are four areas where ONC has already done that. This would be an area where we would be recommending that ONC include that view more by default in the ISA.

Christina Caraballo
Okay, thank you. I will look at our recommendation. Thanks, Arien.

Steven Lane
Yeah, and again, for workgroup members, you are welcome to tweak the text of the recommendations that are there with attribution. You can either do it in suggestion mode to make that easy, or you can enter your name and do it as an edit. All right, we are a little ahead of schedule. We do have public comment planned for five minutes before the hour. I put a note in the chat that members of the public are welcome to raise their hand at any time to get in queue, so I would encourage any members of the public who have a comment to let us know by raising their hand, and perhaps we could do that early.

This does give us some time to also go back and open up for further discussion related to the ECR topic as well, if people want to do that. I know there has been quite a bit of chat. Some questions were raised, and some answered, but I know that Hans, you had some questions about the ECR topic and had some dialogue with Laura Conn. I was hoping that perhaps we would all be able to reread that in the future based on our minutes, but why don't we take some time now, since we have a few minutes, if you want to put voice to your questions, Hans?

Hans Buitendijk
Sure, and I think of the two questions, one has already been mostly addressed. The questions are around the fact that there are two standards, a CDA-based and a FHIR-based. What are some of the considerations to shift from one, to add one or the other? What are some of the challenges there? So, that was one question, to not only recognize there are two, but since HITAC also has interest in recommendations beyond the ISA, how should we consider that? Where are some of the challenges from a public health perspective to accept FHIR-based? I think Laura already started to answer that question.

The other question that I had is a little bit more in as we want to move in that direction, what are some of the barriers to public health? It seems that there are potential opportunities, perhaps, to move that forward as well, where FHIR payloads of the EICR could be used. So, Laura might have some further ideas on that. That is a little bit of a deeper dive into taking advantage of existing networks to help with the transition as well while they are still trying to get fully on FHIR.

Arien Malec
Hans, if I might add to that, my understanding is that the limit right now for ECR for the FHIR-based workflow is that most of the major EMR vendors, including Epic and Cerner, have gone forward with the CDA version of ECR, and that the AIMS platform supports both, but it is really a provider-side, supply-side standards issue to enable the transition more than it is an AIMS platform or public health-side view to accept. Maybe Laura or John can correct me if I have that wrong.

Hans Buitendijk
Arien, it is on the public health side that I was trying to understand better from that perspective what some of the challenges may or may not be to accept that because we all know that while a standard may be there on both sides of the equations, there might be reasons that is not yet ready to move forward, so I was trying to get that perspective.

Arien Malec
I was understanding from the presentation that the way most public health consumes this data is through the AIMS platform, and that on the public health side of this, it is mostly bespoke and custom through integration engines more than it is standards-based so that functionally, the way this has been working is that the EHRs publish through the CDA implementation guide that gets to the AIMS platform, and then the last mile from AIMS into public health is anything goes. And so, like usual in public health, it is the last-mile public health systems that are the grodiest bit in terms of standards evolution. But, again, I guess they dropped, but I would welcome any of our public health commenters, maybe Ike, who can provide some context here.

Steven Lane
My understanding, Hans, is that the FHIR app really only is a means to allow the EHRs to assemble the EICR document, and then get it sent out the door to the APHL AIMS platform, that it is not a full, end-to-end FHIR transmission or FHIR consumption at the public health level, that they are working on that, but that was not the point of the discussion today. There are just two options. Either the EHRs can develop their own native functionality for manifesting the trigger codes and producing the CDA document, or they can use the FHIR app for that.

Hans Buitendijk
The reason why I brought up the other part is that you are correct, that is the current approach, but as part of the ISA update discussion, there is also the notion of a FHIR-based standard that would be end-to-end that FHIR was interested in that perspective. So, that was a wrapping-up question.

Steven Eichner
It is correct that right now, the FHIR app interface is between either the ECR NOW back end if you are using the app or, if you are using built-in technology into the EHR, that side, but on the exchange between or connection between the AIMS platform and public health, it is not standardized as a FHIR interface. If you are trying to lift all public health to require implementation of that side, there would probably be some fairly substantial investments necessary.

Steven Lane

Thank you, Ike. Okay, we are on time now for public comment. Again, members of the public, please feel free to raise your hand within the Zoom app, and then, when we see your hand up, we can unmute you. Sorry, ONC, I did not mean to steal your fire there.

Arien Malec
A fire/FHIR joke. While we are waiting for public comment, I just want to express a profound appreciation for the two presenters today.

Public Comment (01:23:34)

Michelle Murray
Let me just finish what Steven was saying about how to access the public comment feature. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are connected by phone only, press *9 to raise your hand. Once called upon, press *6 to mute or unmute your line. Do you see any public comment?

Steven Lane
I do not see any hands. Do we have any on the phone? All right. Well, it is always nice to have that opportunity for the public to engage, and we wish they did more so. All right, that gives us just a couple of closing minutes to entertain any further comments or questions from the group. There were some other items that had come up in the chat. Did anybody want to ask those questions or comment verbally?

Arien Malec
Maybe as people are thinking about that, just another plea to the workgroup to use the spreadsheet mechanism that we have established, and as a help to format the comments in the recommendation column, I find it very useful to start drafting "We recommend that ONC…" because it is all too easy to write down the desired state of the world that you wish to see, and it turns out it is considerably harder to make recommendations that ONC use the policy levers that it has at its disposal.

So, as an exercise for the workgroup members, if you can go through, look at the recommendations that you have made, and recast them in terms of "We recommend that ONC…", then we will be in really good shape for the reviews that we are doing the next couple of weeks, leading forward to the full HITAC meeting, and then, again, just as a reminder, to the extent that your recommendations are of the form "We recommend that ONC, in the ISA, track Use Case Y or Standard Implementation X associated with Use Case Y," those are going to be really easy for us to write recommendations around, and to the extent that there are other actors that are required to get into the act, a helpful formulation is "We recommend that ONC coordinate with other federal agencies…in order to lead to end result."

Again, the more that we can write recommendations that are easy for ONC to pick up and do something with or evaluate, the better off we are all going to be, so, just an encouragement as we get down to crunch time to write our formal recommendations letter, this is the time to start thinking about how we take our intent for what the real world should look like and turn that into recommendations to ONC.

Steven Lane
Thank you. And, speaking of crunch time, we are at the end of our time this morning, and next week, we are going to dive back into our spreadsheet. A number of you have drafted recommendations. We have

really only finalized one so far, so that is what we are going to be doing for the next few weeks, is working through the recommendations that have been provided. I know a number of you have done some work on care plans. Once we have some draft recommendations there, we can tackle that, but we will continue to rely on the prioritizations that you have offered to kind of guide us through where we spend our time because we know that we will probably run out of time to have a deep discussion about every single recommendation, so we will do the ones that you have all designated as the highest priority first. And, with that, we are at the top of the hour. Thank you very much, and we hope to see many and more of you next week. Bye-bye.

Arien Malec
Thank you all. Bye-bye.

Adjourn (01:27:58)