Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) PUBLIC HEALTH DATA SYSTEMS TASK FORCE 2022 MEETING

August 31, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Gillian Haney	**Council of State and Territorial Epidemiologists (CSTE)**	**Co-Chair**
Arien Malec	**Change Healthcare**	**Co-Chair**
Rachelle Boulton	Utah Department of Health and Human Services	Member
Hans Buitendijk	Oracle Cerner	Member
Heather Cooks-Sinclair	Austin Public Health	Member
Charles Cross	Indian Health Service	Member
Steven Eichner	Texas Department of State Health Services	Member
Joe Gibson	CDC Foundation	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Erin Holt Coyne	Tennessee Department of Health, Office of Informatics and Analytics	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Steven Lane	Sutter Health	Member
Jennifer Layden	Centers for Disease Control and Prevention (CDC)	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Mark Marostica	Conduent Government Health Solutions	Member
Aaron Miri	Baptist Health	Member
Alex Mugge	Centers for Medicare & Medicaid Service	Member
Stephen Murphy	Network for Public Health Law	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Jamie Pina	Association of State and Territorial Health Officials (ASTHO)	Member

Name	Organization	Role
Abby Sears	OCHIN	Member
Vivian Singletary	Task Force for Global Health	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Carelon Digital Platforms (an Elevance Health company)	Member
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director of the Office of Technology
Dan Jernigan	Centers for Disease Control and Prevention	Deputy Director for Public Health Science and Surveillance
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Aaron Bieringer	MN Department of Health	Presenter
Mary Beth Kurilo	AIRA	Presenter

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

Mike Berry
Good morning, everyone. I am Mike Berry with ONC. I would like to thank you for joining the public health data systems task force. All task force meetings are open to the public and your feedback is always welcome, either in the Zoom chat or during the public comment period that is scheduled about 11:50 Eastern time this morning. On behalf of ONC, I would like to express our deep appreciation to the task force members who have volunteered their time and expertise. Today we also have a couple of guest presenters with us. I would like to thank them for participating.

I am going to begin roll call of our task force members. So, when I call your name, please indicate that you are here. I will start with our co-chairs. Gillian Haney?

Gillian Haney
Present.

Mike Berry
Arien Malec?

Arien Malec
Good morning.

Mike Berry
Rachelle Boulton?

Rachelle Boulton
Present.

Mike Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Mike Berry
Heather Cooks-Sinclair?

Heather Cooks-Sinclair
Here.

Mike Berry
Erin Hold Coyne?

Erin Hold Coyne
Good morning.

Mike Berry
Charles Cross?

Charles Cross

Here.

Mike Berry
Steven Eichner?

Steven Eichner
Good morning.

Mike Berry
Joe Gibson?

Joe Gibson
Good morning.

Mike Berry
Raj Godavarthi?

Raj Godavarthi
Good morning.

Mike Berry
Jim Jirjis?

John Kansky?

John Kansky
Good morning

Mike Berry
Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Mike Berry
Steven Lane?

Steven Lane
Good morning

Mike Berry
Jennifer Layden?

Jennifer Layden
Hi. Good morning. No conflicts

Mike Berry
Leslie Lenert?

Leslie Lenert
Good morning.

Mike Berry
Hung Luu is not able to be with us today, but she will be back with us next week.

Mark Marostica?

Mark Marostica
Good morning.

Mike Berry
Aaron Miri?

Alex Mugge?

Alex Mugge
Good morning.

Mike Berry
Stephen Murphy?

Stephen Murphy
Good morning.

Mike Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Mike Berry
Jamie Pina?

Jamie Pina
Present. Good morning.

Mike Berry
Abby Sears?

Abby Sears

Good morning.

Mike Berry
Vivian Singletary?

Vivian Singletary
Good morning.

Mike Berry
Fill Southerland?

Fillipe Southerland
Good morning.

Mike Berry
And Sheryl Turney?

All right, thank you so much everyone. Now please join me in welcoming Arien and Gillian for their opening remarks.

Gillian Haney
Thank you, and welcome to the second meeting today. I am really pleased that we are going to be beginning the review of the F criteria with immunizations. Today we will be hearing from subject matter expertise from both state and local territories, as well as from one of the healthcare providers. That is going to be followed by a review of the work that ARAS has been doing in recent years to encourage voluntary engagement with their measurement and improvement initiative that seeks to an alignment with functional standards and data quality for immunization and information systems. I think that these presentations will provide us with a good foundation for discussions about potential ideas around certification as well as be able to frame some of the work that has already been done and look to lessons learned. I will turn it over to you, Arien if you would like to give some opening remarks and we will get into the presentations.

Arien Malec
No, let us get into it. Very exciting, as you said, to look at an area that we made a lot of progress in and look at whether we accelerate that going forward. Shall we go to the panel session?

So, the order here, we will change on the fly. We will start with Hans, then go to Aaron and then go to Marybeth. Hans and Aaron represent, if you will, the pitchers and the catchers in this immunization data flow. The AIRA work represents the public/private coordination work to both improve standards as well as improve operational guidance and otherwise improve data flows for immunization. Clearly we have had a lot of practice at getting immunization right over the past few years, so a good opportunity to do a look back and assess what has been working and where there is opportunity for improvement.

So, with no further ado, we are going to turn it over to Hans to represent the sender side. Although, for immunization we have both the transmission as well as the queries. So, each of the actors has both a send and a transmit function. Hans, over to you.

F1: Transmit Immunizations and Immunizations Query (00:05:33)

Hans Buitendijk
Thank you, I will try to run back and forth between pitcher and catcher. I think it is 11 feet. Thank you for this opportunity. In preparation of the question reaching out to give an update, I reached out to fellow members at EHRA to give a sense of what are some of the key challenges, opportunities for where have we gotten to.

I want to first, on the next slide, acknowledge that we have made substantial progress. That does not mean that we are where we want to be or need to be, but if we look at the number of aspects of it, registry participation, connections, coverage that are in place, substantial progress has been made. Data completeness is improving and enhancing, as well as data quality. A lot of work that imparts by the pandemic has been accelerated. It has attained more focus to move forward in that direction, and the achievements made, as well as the foundation that had been laid before that that we could build on. That has been a team sport with everybody involved. Mary Beth Kurilo can surely give quite a few of the statistics of where we are at, the work that has been done with IRP. Lots of thanks for the work that has been done there. We also see increased bidirectional exchange. One of the areas that we have seen an uptake in use is in the queries to get information back but has also identified some challenges that we will get to. A lot that we can look at that has moved forward and made good progress.

On the next slide, and that is where I am going to spend most of the remaining time, is on some of the challenges and opportunities that we have in and around questions. When we look at some of the challenges, variations exist among registries on the day-to-day need, and some of the variations on how we would like to have that. And with COVID something we have seen with electronically reporting, lab reporting, as well is that here there are additional data that is required, that is of interest. That is not always necessarily directly related to the vaccine at hand, and the reporting of that, but provides for the context. That is something everybody has to react to. Not everybody asks for the same information in the same way.

Data quality is still an area to work on to ensure that, as best as possible, the data collected and gathered is complete, accurate, and can be used, etc. There is still work to be done, but what we have seen, and we have met with stakeholders throughout the last couple of years, we have seen improvements, but we also believe more can be done in that space.

Vaccine updates have been at a high pace, high flurry. We are constantly getting updates on what is about to come. That is actually interesting is that we have learned with EHRA and the CDC and ARA on the calls and others is that getting frequent and constant updates helps us be prepared, aware, and otherwise. But it has created challenges to keep up with it, and how can we settle that into a new cadence? There has been a need that arose for bulk queries. Some of the workflows for different providers, different contexts. Instead of doing one patient at a time that works for many situations there some areas were for some of the members, it was clear that getting data query in bulk has advantages and that is what is identified, as well and created some challenges along the way. And all throughout, no matter where we are talking through operability, patient matching. Particularly whatever kind of query it is. If we are trying to get information back on patients, whether it goes in or out, how we make sure that the data that we provide and that registries have can be matched up? When we get information back from the registries, that we can do that as well because the patient may have been different places. That continues to be a challenge.

Some of the opportunities that we are looking at and have been discussing is around certification alignment, certification is typically on one side of the exchange. But we believe that with aligning certification further, better on both sides, that it has the opportunity to further synchronize and make the errors consistent where they can be and flow through that. We can also look at, in some areas maybe it does not stand out as much as the lab reporting, but data that is not directly related to the immunizations. Other opportunities that if the data already flows other ways, that can be taken advantage of. That might not be an immediately interoperability challenge only, but how can the variety of public health data point, how can they further take advantage of the data that they already receive through different channels.

Opportunity is a work in progress with **[inaudible] [00:11:29]** around bulk queries to address those needs in that area. And then how do we have the opportunity that ties back to potentially certification, as well, that we put effort around to getting data out. When we get it back in, ensuring that it is fully ingested and reconciled with all the other information. Which then gets us back to some of the challenges of how do we need to make sure that we match it to the right patents, etc. So, there are areas in here that we can enhance, improve upon. Certification is certainly one of the components that can contribute to that. And surely, we are going to talk further about that on how to take advantage of it and keep it manageable. It comes with overhead in many ways. So, we need to be cautious and careful on applying it to the areas that truly need it and do not overburden where it is not necessary based on the experience today.

So, I am going to stop there. I think **[inaudible – crosstalk] [00:12:39]**.

Arien Malec
If you count to six as five, that was fantastic, so much information. Aaron, we will turn it over to you to give the catchers side, although in immunization, as I said, all catchers are senders as well.

Aaron Bieringer
Great, thank you. Can you hear me okay?

Arien Malec
We got you.

Aaron Bieringer
Awesome. Thank you, I am Aaron Bieringer. I work with the Minnesota Department of Health. You can skip ahead two slides. I probably do not need a slide to tell you about what we are going to talk about. I only have five minutes. Really three slides, sorry, go back one more.

Today, I want to try and tell you a little bit of a story about where we are at in Minnesota with immunization messaging. The guide that came out in late 2014, the newest version of HL-7, we adopted pretty early on. We were fairly early adopters. We had it in place by the end of 2016. With that work, that was being pushed really hard from the promoting interoperability, or at the time it was called meaningful use side of things where providers were getting money to use 2015 certified EHR technology, and that was part of their requirements was to use this format. So, we had pressure to have this in place and ready and they had pressure to use it. So, when we started up it was, unfortunately, one businessperson and one developer who had to go through 110-page document and figure out how our state laws and policies applied to that document and try to implement it.

We thought we did a pretty good job. It turns out we were off standard in some places unintentionally and that did not know it. What we learned as we started to connect with groups was that the 2105 CERT, it certified the system, but not the use of the system. So, we were getting really variable messages coming out of providers, even though they were all certified. They were not on standard. So, we were having a lot of conversations with people and finding a lot of one-off problems, and then they would fix their messages and we would make slight changes on our system. It was a lot of one-off fixes. The lion's share of the work was being done on the provider's side to fix their systems to meet our needs.

Better tooling comes along. This is the stuff that Mary Beth is going to talk about next M&I project, the arch tool, and the ability to do some really good testing of IAS. So, better tooling came along, and we started to use that to look at our system. And we found out we are actually off standard in quite a few areas that nobody had recognized. So, we were like, "Okay, this is something we need to fix." We started to attempt to make really big changes to our interface. The problem with is we started communicating that out to our providers and our partners and saying, "Hey, we're going to make all these changes to our interface because we want to be on standard to make this easier for everyone," and we got a lot of pushback saying, "Woah, woah, woah. We did a bunch of work to go off standard to meet your needs. Now, if you go on standard, it is going to break our interface and we are going to have to spend a bunch of time and energy to get back on standard."

So, we had to step back, reevaluate. We decided what we are going to do is build a second endpoint. So, we are going to leave the existing one alone, let people use it, do not interrupt that, build a second one that is on standard. And then onboard people to that new providers. And as there is interest from existing providers, move over to the new one. It is on standard. It is going to be easier to work with. We started building that and then COVID happen. Basically, all resources went into pandemic response. We stopped working on the new interface. They started coming back, monkeypox is happening. So, they have been pulled away again, a little bit. We have also been in pandemic response so long that we have a bunch of structural, infrastructure, security type work that we have to do. So, we do not currently have plans to pick up the new endpoint work and finish it. It is really unfortunate. We know we really need to do it. We do not have the resources.

So, that is kind of where we stand right now. If you go to the next slide, we can talk about what that means for us in Minnesota. So, I have talked about how we are off standard. But I want to stress that being off standard does not mean it is not functional. We have a very well-functioning endpoint right now. In the last six months, it has successfully processed 16 million messages. It is responsible for over 96% of the immunizations added to our system. We have over 124 interfaces providing messages for over 6,000 physical locations using this off-standard endpoint. So, just to make that point again, off-standard does not mean it is not working. But we agree we are off standard. We know we need to fix it. Some of the problems with being off-standard is we have no interjurisdictional exchange using HL-7. All the jurisdictions are off a little bit on their own and nobody has the resources to get on standard. So, we are struggling to connect with each other. We know that is on us, we need to fix it. We are just trying to figure out how to do that.

Same thing with federal agencies. So, the Veteran's Affairs, Department of Defense, they are new partners in the game. They expect to use the standards and use it properly. We are not ready for that. We cannot connect with them. We need to make changes. One other problem that being off standard now causes for us is everyone we have onboarded and everyone we continue to onboard, we know we will have to onboard again. So, it is like we are creating duplicative work. We know that the work we are doing right now, we will

have to redo once we get the new endpoint up. We do not love it, but it is kind of where we are at. It is kind of what we have to do.

So, if we go to the next slide, talk about some recommendations. So, how does this all apply to you guys? Why do you care about this story of what we have done, what has been going on in Minnesota? I would really suggest that you do not certify software, but you certify use of systems. In this day and age, there are so many microservices and interface engines and data intermediaries and things that are between the actual systems in use that I think it is kind of a miss to say does your system have the capability to do this or not and move forward from there. I can have a system with a capability and three things in between that ruin the message, or vice versa, I could have a system with no capability but have an interesting little interface engine that makes it work properly to everyone who interacts with it. So, just really being careful not to certify software. I think that is something we learned from meaningful use.

Leverage existing testing programs. I thought Mary Beth was going to go first and you were going to have some of this background, but she is up next. There is a very strong immunization testing program in place. I really think you guys should look at how do we use this to do our certification. You are going to have better buy in from people. We have a huge amount of participation in it already. I am not going to spoil Mary Beth's presentation. I really think focus on leveraging that. There needs to be some kind of funding to make these changes. So, again, we know the problems we have. We want to make the changes. We have no resources to get on standards. We would fail certification today if you certified us in Minnesota, even though we have a very effective end point.

And there are ripple effects. So, as we make changes in our systems, expect slow but steady improvement because we have to work with our partners to make sure the changes we make do not break the things already in place. So, we are interested in doing the work, we want to do the work, we see the value, but there is repercussions to doing the work. So, make sure that we kind of set our expectations there.

Arien Malec
Fantastic. That is great. Thank you, Aaron. Now, we will transition over to Mary Beth to talk about the work that has been done to better align immunization standards. So, Mary Beth, over to you.

Mary Beth Kurilo
Thank you very much. Can you hear me OK?

Arien Malec
We got you.

Mary Beth Kurilo
Great. So ,thank you so much for the opportunity to share some information with you today. For those of you who are not familiar with AIRA, we are an association that supports IIS and promotes the use of immunization information when and where it is needed. I am going to start with sharing a little bit about the current state IIS and then move to some thoughts about public health measurement, generally. So, on the next slide, I will just talk a little bit about our measurement process. So, in collaboration with CDC, AIRA began measuring IIS way back in 2015. The goals of this process were really twofold, to test IIS alignment with standards and then provided IIS with information and assistance that they can use to make improvements and needed enhancements. So, we really used two methods to do our testing. We connect

with and send test messages to pre-production IIS systems. Then we also extract de-identified data and analyze that for data quality purposes.

We work really closely with NIIS on developing our tooling. We have an advisory body that oversees our work, made up of NIIS, CDC, IIS, and Immunization Program staff, technology partners who really influence and inform this work. And then we also send everything we do out for community review. So, on the next slide, I will talk about the engagement that Aaron mentioned. We have great participation across the country, particularly considering this whole effort is voluntary. So, the map shows in green all of the jurisdictions that have been tested in at least one content area in the last 12 months. So, 60 out of 61 IIS have been tested in the last year. When we build the M&I program, we knew we needed to measure at the implantation level. So, we are measuring IIS programs and their ability to meet the CDC functional standards. The technology system that supports that is really just one component of all that.

I just want to say a little bit about the landscape of IIS. We currently have multiple platforms and vendors that support IIS across the country. But there really are just two commercial off-the-shelf systems that are in use in about half the IIS across the country. About 32 jurisdictions use these commercial off-the-shelf products. The rest of the jurisdictions either use locally developed systems or they use a public domain system that was developed way back in the late 90s by the state of Wisconsin. That is customized by each state.

On the next slide, I just want to give a quick glimpse of the AART tool that Aaron mentioned. This is the aggregate analysis reporting tool. This is how we make all of our test results and test cases and expected and actual outcomes visible to all of our participants. So, next slide I am going to show an at-a-glace diagram of how each content area moves through our measurement stages. On the lefthand column, you will see all the content areas we measure. The ones that map most closely with the F1 criteria are submission acknowledgement and query response. And then as you move across the diagram from left to right, the stages of measurement get increasingly more formalized. It really culminates with what we call validation, which is in some ways a parallel with the concept of certification. This is where we publish the results for not just the community to see, but also all of our IIS partners and vendors to know that our systems are meeting expected standards.

On the next slide I will give a glimpse of the progress that we have seen. This graph shows improvements in Quarter 2 of 2017 through Quarter 2 of 2022. That green bar displays the IIS that are measured, and the multiple-colored lines show distinct concepts that we measure and likely ability for an IIS to accept well-formatted BXU or updated message. That blue line at the bottom that is just a little lower than the rest shows, I think, an important gap in where we have room to improve. That is where is IIS returned fully standardized acknowledgement messages to their EHR partners. This we know is really critical for data quality purposes.

I just want to take a second to call out a couple important points here. One is that we know there are some areas where IIS diverge from standards because of policy and law in their jurisdictions and they have to perform a certain way to meet their own policy and law. The other piece I want to call out is a bit of a shoutout for IIS partners. A lot of this improvement that you see over the last two years really took place while programs were responding to the COVID-19 pandemic, which I think shows the IIS community's commitment to continuing standardization, even in the midst of an emergency response.

Next slide shows a similar view, but this one is around query and response. Again, that green bar displays the number of IIS measured and then the colored lines show distinct query measures. Again, that gray line that is at the bottom is where we see another gap. That is IIS sending back the fully standardized response message. So, again, we see improvements year over year from a trend line that we know we have room to improve in getting that response message compliance back up where it needs to be.

Next slide I just go back to that overall at-a-glance graphic. I just want to mention that we did meet with our advisory work group just last month to really look at where do we go next now that a lot of these are already in validation. We did some prioritization with the topics that are down in that bottom left corner. So, what is next in the queue is measuring provider participation, patient matching, patient saturation, vaccine matching, and onboard. So, we are working on getting those ramped up over the next year or so in collaboration with the community.

Next slide, I will just take a moment to mention one other program that AIRA leads that is likely familiar to many of you, that is the immunization integration program or IIP. It is a CDC funded collaboration with HIMSS, Drummond, and a few other partners that offers and alternative option for ONC F1 testing for EHRs. This one tests more key immunization focused capabilities. IIP also coordinates a collaborative forum to develop recommendations around solutions to improve EHR IIS interoperability.

So, on the next slide, it provides just a quick graphic of our overall vision with this. That is through testing both EHRs and IIS. Or, as Arian mentioned at the start, the pitchers and catchers of immunization data, if you will, we can much more quickly pinpoint challenges for interoperability. We can use this pipeline approach to then funnel some of the solutions that the IIP group comes up with into testing both for EHRs and for IIS. We feel like this level of detailed testing is especially important because given the maturity of immunization interoperability, we have really already harvested the low-hanging fruit.

Between certifications of EHRs and validations of IIS systems, we have seen great improvements, which is why literally millions of submission and query messages are flowing every day. That is not to say that there is not still room for improvement, by any means. But the improvements are going to take detailed testing and in some cases, as Aaron mentioned, really close coordination between interface partners to make sure that in promoting standards, we are not actually breaking existing interfaces, especially now when we are still in the midst of the COVID response, we have got monkeypox right behind it. We are heading into a new level of polio response. There is lots of reasons to make sure we are not interrupting interfaces that are working right now.

To just hit some summary points, our recommendations would be to consider testing implemented systems, rather than vender products, as Aaron mentioned, just to make sure we are getting at the use piece of all this. Build on the test cases and processes already in place. Involve and engage the public health community in this whole process. Really consider the role of state law and policy and how it influences interoperability. And then, lastly, just allowing adequate time and providing funding for making these changes and really seeing progress because we know this is not an overnight fix. With that, I will stop, and happy to take any questions.

Discussion (00:29:53)

Arien Malec

Fantastic. I think we are going to go to a panel Q&A. Gillian, I am going to turn it over to you. Really amazing presentations, really appreciate everything. Gillian, as we turn it over to you, I am going to actually insert my hand.

Gillian Haney
By all means, go ahead.

Arien Malec
I have 10,000 questions. So, I apologize in advance. Hans, maybe a follow-up on vaccine terminology. My understanding is the F criteria primarily validate the immunization HL-7 message. We do not have criteria for getting a CVX update. Is that right?

Hans Buitendijk
If you mean that with CVX in an automated fashion or the criteria is focusing on the actual transaction, the VXU transactions.

Arien Malec
Got it, perfect.

Hans Buitendijk
With the right terminology included –

Arien Malec
With the right terminology, that is right. So, the test method actually tests with the precondition that you have actually got the right terminology and I would imagine there is some variation in the field as to whether you go the right terminology. You are mentioning if I update the IIS and EHR to use the latest terminology off cycle, I could be in the position where the immunization registry does not recognize the vaccine message that I am sending up because it fails basic terminology check, right?

Hans Buitendijk
That potential is there. But off cycle, at this point in time, really means continuous because as we have seen, particularly with **[audio drops out] [00:31:40]** right now, codes are coming in at times fast and furious, that everybody is getting their respective systems up to date with. Is that a potential? Yes. I would at look at Mary Beth to see whether it is actually rising to the top of major issues. We have not heard that this is currently, at this point in time, a major issue that they are out of synch with being on the latest and most current.

Arien Malec
And Hans, as you mentioned, it is because everyone is updating all the time, right?

Hans Buitendijk
Yes. A different cadence than what that environment was used to because of codes becoming available before the vaccines are actually already available. That is part in order to make sure that when they become available, that everybody is up and running and can immediately start to utilize them. There is a shift that has occurred.

Mary Beth Kurilo
Just to jump into that, we are launching a project right now to look at code set implementation and to try to streamline that a little bit and really make sure we are collaborating across not just EHRs and IIS, but HIEs, as well, to make sure everyone has the correct code sets in place as quickly as possible.

Arien Malec
Where I am going now is whether there is a missing certification element of querying a terminology server and getting an update. Or at least validating as part of the test method, that you can demonstrate that you have updated your terminology set.

Gillian Haney
I am going to quickly jump in, if you do not mind. To follow up on some of the comment, I am wondering about the use of some of the NIIS tools for certification or validation for both data quality and syntax. Perhaps you could comment on what you have learned there.

Hans Buitendijk
Is the question directed to me or Mary Beth or either one of us?

Gillian Haney
Either one of you.

Hans Buitendijk
NIIS tools are focusing on adherence of the EHR site to the message that it is coming across with the minimally required data. We are purposefully using that because it does not test for everything that can come across, necessarily, and with a certain set data. So, that is what it tests against there. If there are optional fields that are used by particular IIS registries by not by another, NIIS may not pick them up, depending on how they defined in the standard to be required, or must support, or required event, etc. when valued. So, there are a variety of different things they would not pick up that in a certification, although it would come up because of the variations that start to exist between what is certified and what is actually used.

Mary Beth Kurilo
I would support what Hans said. I think it really does not get into the vocabulary question that was raised about code sets.

Arien Malec
Gillian, I really do have a long list of questions. I am happy to yield and then reinsert myself back at the back of the list.

Gillian Haney
Okay. Bryant?

Bryant Thomas Karras
Mine may dive into the weeks a little bit on that point, Arien. My question was around the – Aaron, you mentioned you were off standard. I am curious if you can disclose or confess, when you say that you are

not compliant with the HL-7 standard, is that you have implemented within the standard, it is just not constrained to the implementation guide itself? I think we need to be very careful that we are properly designating that things can be standard but still not be exactly the same. It is because of variations in interpretations of implementation guides or optional components within implementation guides that you may have executed that others did not. If you could talk a little bit about that. And then I put a comment in the chat about I totally agree, vocabulary standards, especially as vaccines are coming out fast and furious, need to be updated in a timely manner. This may be a recommendation that we need to make not to ONC but to CDC that it needs resources to keep those reference vocabulary tables up to date. Mary Beth, I know is working with them on that.

Aaron Bieringer
I will jump in on the first question you had about my comments about being off standard. I think because we were early adopters and because the implementation guide had some maybe not as concrete language as it could, there were places where the guide itself was just not razor's edge clear of this is exactly how this should work in every scenario. So, we made some assumptions that then the rest of the community decided were not the right assumptions. So, we were off standard on how the rest of the community is using the guide in some places. But in other places, there were just parts where we got it wrong. We send the wrong code in some certain scenarios, and we need to fix that. It is kind of a mixed bag of use of the standard will drive better definition of the standard, will drive a lot of people needing to change their system to meet the new standard. But also, it is a really complicated document. It is a 410 page, very technical document. We just got it wrong in a couple spots, again, mostly because we did not have great tools for figuring out if we had it right.

Now that we do, everything that we build going forward, we can run against the NIIS tool or, preferably, AIRA's testing tool. We can figure out are we on standard, are we off standard. Okay, let us fix that before we even roll it out. Testing validation-based development rather than going back and fixing things that already exist.

Gillian Haney
Arien?

Arien Malec
First of all, just definitely, the NIIS tool checks HL-7 syntax. I think we have heard it does not check data semantics. We have recommended transport standards. Do we have a certification guide that packages transport and associated test methods that package both transport and content.

Hans Buitendijk
Not specifically, but Mary Beth, you may want to address the work that has happened to **[inaudible] [00:39:10]** on transport. Although, I am not sure that everybody is totally aligned yet.

Mary Beth Kurilo
We actually test transport. That was our very first content area. It is not specified, necessarily, in certification criteria or F1. But the IIS community, in collaboration with CDC actually selected Silk Web Services and use of the CDC WSDL as our preferred standard. So, we do test for that. We have seen a lot of improvement

in alignment. There are a couple of places where HIE stand in the middle and mandate a different kind of transport. But for the most part, I believe the community is in pretty well alignment with that.

Arien Malec
I was part of the CDC task force that made that recommendation, which was back in, I believe 2011. So, we are 11 years on, and we still do not have a consolidated set of certification criteria that include content and transport. I just want to dive into the question of needed variation that is jurisdictional. Maybe I can ask what an example of jurisdictional variation in data is. I am really just sort of probing for this notion of can we certify to a floor such that ceiling implementations are compliant with the standard and implementation guide. Also, Hans, just interested in your question about are there other places where we can put that jurisdictional variation and maybe expand this notion of using ECR. Or improving the standard itself, if there is necessary contextual information associated with a vaccine that is not being carried in the vaccine message itself.

Gillian Haney
I am going to address your first question and ask some of my public health partners to chime in. But I think in terms of variation, I know for example, Washington State has a recently enacted law that mandates a very, very sensitive level of granularity in terms of collecting race and ethnicity and how is that going to be captured within immunization systems and within the transport method. There are other laws in place in other jurisdictions that are around opt in and opt out. I do not know if Bryant or Steve would want to speak to additional legal requirements that are jurisdictionally based.

Bryant Thomas Karras
I will just caveat that our state Board of Health has enacted a law that goes into effect the first of the year, 2023, that requires race and ethnicity at a very granular level, a level that exceeds current federal requirements. We recognized early on in the pandemic that we were not able to identify disparities because of the lack of granularity in the current reporting systems that EHR systems were able to collect. So, we are enacting that. The challenge is going to be Washington is a little out ahead of the curve. We got hit by the pandemic first. We pivoted and adjusted first. If we are held to the national floor, we are not going to be able to make that adjustment. I am hopeful that optional components like sending along data sets that are different, perhaps, than the rest of the country is asking for is still an allowable variance for those providers who reside within our state.

Arien Malec
That is actually an interesting area where you can establish a floor and allow for a ceiling at the same time because the existing **[inaudible – crosstalk] [00:43:20]** is the OMB set. But the code set is the CDC set. And the code set, as long as you are selecting your additional granularity for race, ethnicity coding, you should be able to fit the implementation guide. Hans, you have been exposed to multiple systems in multiple jurisdictions. I am interested in this question of is there a way that we can certify to a floor that allows for jurisdictional ceilings to be raised?

Hans Buitendijk
Generally, that should be possible. But the question is how it is done and how do the standards support that in a working way. So, some of the examples that Gillian and Bryant mentioned, whether it is extended demographic data, whether it is health screening results that one may have a particular ones they are

looking for, others do not, therapeutic interventions. We have some funding sources using OBX that may not be acceptable by some, or they reject it and not accept it. I think it is a mix of not only what are those difference, but how does the standards support that. In all of those areas, is it clear that vocabular are extensible. In some of them, they are not necessarily clearly defined. The OMB categories are fairly clear, they are certified. But then you have the evasive ethnicity where you have lists that are much more detailed. To what extent can you extend them, is the standard clear enough around that, and how do you then accommodate that?

So, I think we would then have to look at eh combination of things so that can work appropriately. Then you have the other part, as you said, if something is optional in the standard that might be extended upon and used as additional attributes, how do you make sure that there is clarity, that there is high probability, or that these five out of 50 or whatever it is actually using it, so that it behooves you to start to implement those and do so consistently. Once a field is optional in the standard, the way that Washington goes about it versus Texas versus New York, for the field, there is no agreed to standard specifically because it is optional, and everybody can have a reasonable standards compliance way to then approach that. So, how can we then coordinate so that field that is chosen by one is not going to be chose by somebody else for a slightly different purpose? So, that is the kind of work we have to go through.

Arien Malec
The ideal state here would be one where the certified system can send a message that the IAS can understand, even if it does not contain all of the jurisdictionally specific data while the actors work on adding information. I am also interested in this question of some of the stuff that is jurisdictionally variation, is there a need to update the standard to make sure it can handle that data in a more standard way. Hans, it sounded like maybe some safety information is being carried in vaccine messages. We have a theme of more granular race, ethnicity. We have a theme of being able to handle state-based consent rules or redisclosure rules, to update IASs. Where are the themes of variation? That might be an interesting homework assignment, to make sure that we can call out where those themes of variation and implementation practice exist.

Hans Buitendijk
That was where the comment with the ECR example comes in mind. We have different data streams. But some of the data streams, particularly right now, are starting to include some of that context that is not necessarily specific to that individual vaccine but could be shared or is being shared through other channels. At the same point and time, how are they connected? How can we take advantage of it, etc.? That might also ease some of those challenges. It needs us to rethink in certain areas of what is the balance of data flows to make that happen. Are we ready for that? Or is it still the easiest path of adding to the vaccine administration messages. That is part of the challenge because then you can create much wider variations more quickly.

Arien Malec
Mary Beth, it sounds like we are making improvements in query retrieve. Would it be safe to say the bulk of messages are update only? What is the percentage?

Mary Beth Kurilo

No. I think the last data we have available, which is 2020, showed that out of the, I think it is 125,000 active interfaces, HL-7 interfaces that are in place, about 65% were bidirectional, meaning they were able to query and submit data. We know that is going to be higher now. We have seen huge improvements during the COVID response. We are anxious to get more recent data. We know it is well over half at this point.

Aaron Bieringer
In Minnesota, 80% of our real-time messages are query messages.

Arien Malec
That, again, is truly fantastic. This is one of those never waste a crisis moments where nothing gets us to improve the systems that theoretically we should be improving like a crisis.

Gillian Haney
Arien, I wanted to go back to something I think I picked up on, which was about the work that CDC may have played in developing some of those standards. I was wondering if you were a part of that role, you mentioned, back in 2011 when some of this work was initiated.

Arien Malec
That is right. The CDC established an ad hoc task force that was a two-day seminar where we had members of STLTS and members of IIS system vendors, as well as some technology experts to look at where we should establish standards on the transport side. That task force made a recommendation. We evaluated use of direct, use of http host, use of a restful transaction and use of SOAP. At the time, we made a recommendation that we should align on a single SOAP transport standard, which from a technology perspective is a little old fashion. But it is also very standard. Out of that recommendation, CDC put together an implementation guide with an associated WSDL to carry the HL-7 content via a fairly simple SOAP message. Mary Beth, I would just be interested in the prevalence of immunization and of IIS nationwide that are compliant to that implementation guide.

Mary Beth Kurilo
Nearly all of them at this point. As I mentioned, there are a couple where an HIE stands in the middle of those messages and mandates their own form of transport. But I think at this point, we just have a handful of sites that have not yet implemented the SOAP and CDC WSDL for transport.

Arien Malec
Perfect, awesome. Having a certification criteria would just be enshrining usual practice and might help in some of the intermediary actors that are not currently compliant.

Mary Beth Kurilo
Yes.

Arien Malec
Perfect. Gillian, I think I have drained my questions.

Gillian Haney

Okay. In the few minutes we have left, I wanted to raise what I am seeing in the chat, as well as what was made during the presentations about certifying the use of systems, not the systems themselves, and if anybody would like to comment on that.

Hans Buitendijk
This is Hans. That is a very interesting approach. I think that in principle, because of the variations, that would make a lot of sense. At the same point in time, the less we can certify and the greatest amount of consistency we can get from that, therefore impacting the least amount of provider's organizations and other systems or organizations that use them, the better the design related to the word use. So, what can we do? Some of that, I think with the programs that you see have started to get that consistency, no matter how many parties are sitting in the middle. The more we can get there, the better it is because the few amount of parts need to be examined that are critical. Because of the variations that we have, the more that need to do that, it is just harder to scale. It is harder to do. So, it is extra effort. I am not saying that might not be necessary, but where possible, we should try to focus on the least amount of critical points to test and certify rather than everything because there is many more looking at the variety of IIS registries as well as the providers that are connecting with it and the pharmacies, etc. So, how can we streamline that?

So, it is more a concern of volume. And it is a concern with principle.

Aaron Bieringer
This is Aaron from Minnesota. I want to hop in and say what you are saying certification means will vary greatly on what you are measuring. So, again, we found this with meaningful use where a lot of providers had 2015 certified EHR technology that said our system can do this. We are certified. But in use, in practice, they could not generate a standard message that met the IG. If the goal of certification is to say this system has the capability, whether or not it is used, I don't know, yes, that is easy to do. If the goal is to say the community is using their systems to meet this standard, it is just a very different thing. It kind of depends on what you want certification to mean, where you measure and what you measure.

Hans Buitendijk
Currently, SME system rolled out real world testing, has an opportunity to address that concern further. It is one thing, completely agreed, what is tested. And then you have what is used based on the variety of **[inaudible] [00:54:41]** the intent behind that is to close that loop further so that there is that consistency there that you would expect. But balancing that, it should be looked at. Going to the next step and certifying every use of it, which could very quickly translate in every connection between a provider and an IIS is that what the certification then means? Is it an onboarding validation? Is it a certification? Otherwise, what is involved in that because now we are talking a much higher volume of connections to be validated. How can we make that as efficient and proactive as possible.

Gillian Haney
Mary Beth, I am going to give you the final word before I switch it over to Arien to walk us through –

Mary Beth Kurilo
Thank you, Gillian. I am just going to provide a really simple phrase that we started saying early on when we started measuring. That was really looking at the difference between can you do it, do you do it, do you do it well. We are really pushing for do you do it well, getting at the quality end content of that interface. I

really think if we are going to make this meaningful, that that is where it needs to be. I think we are also lucky to have a finite number of public health jurisdictions that we are measuring. So, that helps too. We have a defined denominator. But I really think that that is where we are going to get the most bang for our buck in improving interoperability in data exchange.

Arien Malec
If I could summarize this dialogue between Hans and Mary Beth, it is we want certification to cleanly associate with can do it well in practice. Right now, those two things are decoupled. Perfect, thank you. Mary Beth, fantastic document on the variation. Super quick perusal, what I am seeing is a fair amount of variation of opt in, opt out or privacy handling, a fair amount of variation in additional stock and inventory data that may be required. It feels like that could be an update to systems. Not in that document, but something to mention is making sure the implementation guide addresses the ability to add more codes than the OMB-5, as long as they conform to the CDC set. Perfect, thank you. This is fantastic.

Gillian Haney
I want to thank all of our panelists. Those were really excellent presentations and stimulating discussions. So, thank you very much. I am going to turn it over to Arien now who is going to walk us through worksheet tools that we will be using to move this work further ahead. Arien?

Topics Worksheet (00:57:40)

Arien Malec
So, anybody who was part of the last workgroup that Steven Lane and I facilitated, this actually aligns with the last public health data systems task force and how we collected input. I refer to this lovingly as the stone soup method for recommendations writing, is a practice of continuously collecting the feedback out of these panels and out of our deliberation in written feedback memorialized in a shared document that we then joint edit and get to crisp reconditions letter. So, we have created a default form. We can stick to this or in the past, we have added additional information over time but within those same basic fields. Again, that same notion of having a minimum standard and then some variation on top of it. So, Brenda, I think you have the rubric that we are going to be collecting data into.

Brenda
Yes, let me get that screen up now.

Arien Malec
Thank you. I was sharing with Gillian that in the old days, I actually refer to this as the Micky method because Micky Tripathi led a work group on the JASON report that called for APIs in healthcare. He co-led this with David McCally. We heard a ton of testimony, a lot of deliberation. Then we literally handcrafted the recommendations text. So, I used to go off and when I cochaired things, do the same thing, listen to all the testimony, and then spend a day writing the recommendations and then reviewing it. The stone soup method is far superior to that method, at least for my typing. So, what we want is as you hear content that you think we should start to memorialize in recommendations, if you could go into this worksheet, which we will share with all of you. It is a Google Docs worksheet. First tag yourself, just so we know who to go back to to get clarification. What we are really looking to do is grab some topics. I think we have established against the F criteria. If there are things that are off that criteria, maybe we should add an other category or separate category.

Mostly what we are looking for is adding your textual observations. To the extent that you are able to, formalizing that as a recommendations text. But it is a recommendations text that we will do joint editing for. If you ever do want to write recommendations, to get you into the right frame for writing recommendations, the practice that is helpful is to start every sentence with, "We recommend that ONC," and then blah. It is very easy to write recommendations from the perspective of an ideal state of the world. It would be nice if all systems could blah-blah-blah. Our recommendations are to the national coordinator. They are not recommendations to CDC or CMS, even though we are lucky enough to have representatives from CDC and CMS on this task force. So, in areas where there is coordination that is required between ONC and CDC or ONC and STLTS or ONC and CMS, the right way to write that is "We recommend that ONC coordinate with the respective other organizations in order to da-da-da-da." So, just keep that it in mind that it is most helpful if we are recommending that ONC do something specific, recommend that ONC is the actor.

That also gets you in the right frame of thinking if you were the national coordinator, how could you affect the change that you were looking for. Again, it is easy to think about the right state of the world and surprisingly hard to think about the policy levers that drive the right state of the word. In most cases, you should be first filling out your observations or fuzzy recommendations. Feel free to put those into the observation section. And if you can, with extra credit, go ahead and see if you can frame up formalized recommendations. As we go over this process, we will be not changing the work in the observations column, but we will be jointly editing and refining the work in the recommendations. And there if there is white papers or supplemental material, such as Mary Beth just dropped in in terms of variation and IIS, that goes into Column D.

First of all, any questions on how we are proceeding in terms of collecting feedback and use of this tool? Jamie?

Jamie Pina
Good morning, everyone. Thank you for the introduction to the tool, Arien. This makes a lot of sense to me. I had just a recommendations procedurally about the spreadsheet here. My guess is as we move forward, many of us are going to have similar ideas. Often when there are group where there are opportunities like this to share ideas or develop them, there will be an opportunity for participants to comment on or advocate for one of the ideas or recommendations, in this case, that others have put there. So, I am wondering if we could add a column or two that might allow others to say, "Yes, I endorse this idea or this one sounds good to me." Or maybe even to say, "Yes, I endorse it with a modifier." That might reduce your effort to have to aggregate them later if they sound similar.

Arien Malec
Thank you for that. What I would recommend there, first of all, is before you add a row, make sure you review the rows that are already in the spreadsheet. And then if you want to endorse or modify or add additional context, just go ahead and edit, add to the observations cell for that row so that we consolidate observations or additional context to extent possible in the same row. Jamie, thank you for that. Clearly, if it is a brand-new topic, in informatics, we have the great separation between the lumpers and the splitters. Your context of being the same or different may be different from mine. But to the extent that it is a truly different one, feel free to add an additional row. We may end up going over time and pulling out some of

the observations and carrying them into their own rows, so they get memorialized as different recommendations. Jamie, thank you for that.

Gillian Haney
Were you also thinking about adding an additional column for endorsement as well, Jamie? Or was that specific to adding rows?

Jamie Pina
My thought is that the number of panelists that endorse or feel that a recommendation is very strong or optimal might be data to suggest that it is worth promoting more strongly or calling it to light with other parties. Yes, that is what I was thinking. So, in addition to modifying it or adding context, there might just be an opportunity to note that one or more panelists endorses the recommendations somebody else dreamed up.

Arien Malec
In practice, that has not been an issue. So, when we got into discussions sessions, it has been pretty clear that we have general panel endorsement. As I said, I recommend just using the observations cell to add your plus one or your endorsement as a way to facilitate that. Let us try that and see if that gets us where we are going. If we need to add an endorsements column, we can if we feel that is going to be critical. As I said, in the history that we have done this and followed this practice, it has not been an issue in practice because it has generally been pretty obvious which topics have general endorsement and move forward. The chairs tend to help facilitate some of that. Ike, you have a question. Ike, you are on mute.

Steven Eichner
Sorry about that. Just to add on to the concept of using that single column, it really is helpful when we are going to assemble because often an endorsement is an endorsement plus a little extra comment. Putting it into two comments kind of makes it difficult to follow. Looking at supporting a comment above, it is helpful, however, to know whose perspective you are supporting just to keep track of it. So, if it is I agree with Ike or I agree with Arien, or whatever, as you are making comments further down, so just in case something got inserted in a line between, that there is a good internal reference within that cell. I agree with Arien that using a single column is probably best for now.

Arien Malec
Yes. And it is know to just tag all those comments with your name so we can accommodate multiple commentors in the same field. We made pretty quick work through all of that. Any other questions on the worksheet as a whole? With that, I would like to assign homework for the task force members: To familiarize yourself with the worksheet and take your observations and notes and memorialize them as observations that could be turned into recommendations for the IIS and vaccine F criteria. Any questions on that? I am already seeing some wonderful observation text in the chat itself. So, feel free to copy and paste your own incredible comments. I know that for the stuff that is tracked to everybody, we keep those as part of the public record, as well, so they become part of the annotations for this work group. Those also serve as a fantastic frame. And once we have the transcripts out of these meetings, that can also be a helpful frame to go search through and mine for good observations.

Bryant, go ahead.

Bryant Thomas Karras
Just a quick technology process. It is probably because I am on an agency issued laptop. It is not allowing me to copy content from the chat. Is anybody else able to?

Arien Malec
This may well be data loss prevention. So, we definitely have issues using this format of you may have data loss prevention or other kinds of controls that limit your access to Google Docs. You may need to work with your local IT organization or **[inaudible – crosstalk] [01:10:58]**

Bryant Thomas Karras
Not in the Google Docs. I have a work around for that. I am talking in the Zoom, you said there are some great ideas in the chat. Hopefully, somebody with authorization can capture those because I am not able to.

Arien Malec
Thank you for that. I am not sure what controls we have under the chat that prevent people from copying and pasting the chat comments. But the ones that go to everybody do become part of the public record. So, we can take that chat content and make it available. Maybe I will ask the ONC team the method that we can pull that content out, or the Excel team, how we can pull that content out.

Mike Berry
We can copy the chat for the task force members and send it along to anyone who cannot copy it.

Arien Malec
Perfect. Thank you. I think all of us are having the same issue of being able to select the text, but not being able to copy it. Any other questions? Or comments? Having gone through a really efficient panel session, having gotten some homework, I wonder whether it is time to go to public comment and give ourselves back a little bit of time. Gillian any other feedback or comments that you have?

Gillian Haney
No, that is good.

Mike Berry
Before we go to public comment, I just wanted to suggest to the co-chairs, we have a couple of members that were not able to make it during our first meeting but are here today, Bryant and Eliel, who have not had a chance to introduce themselves to the rest of the task force members. If you want to give them 20 seconds to introduce themselves more formally.

Arien Malec
Please. First Bryant and then Eliel.

Bryant Thomas Karras
Thank you. I think I know many of the folks on this call from a previous instantiation of the task force. I am Dr. Bryant Thomas Karras. I am the chief medical informatics officer for Washington State Department of Health. I have been in state service for over 22 years. I am both a physician, biomedical engineer, and a

NIH, NLM trained medical informatician. Looking forward to working with you all on this fast and furious endeavor.

Arien Malec
All right. Eliel?

Eliel Oliveira
Hello everyone, good morning. My name is Eliel Oliveira. I am the director of research and innovation at the Dell Medical School in Austin. I also serve on HITAC. I have been in the field for a little over 20 years. I was previously the chief information officer for the Louisiana Public Health Institute. I do support our health information exchange in Central Texas as I did in Louisiana. Also, it was a pleasure to part of this group. Thank you.

Public Comment (01:14:47)

Mike Berry
Thank you both. We are going to open up our meeting for any public comments. If you are Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand. Once called upon, press *6 to mute and unmute your line. So, let us pause to see if anyone raises their hand. In the meantime, I just want to remind everyone that our next task force meeting is next Friday, not Wednesday, but Friday. That is the ninth. We had to pick an alternate date because we have another HITAC subcommittee meeting next Wednesday, and we cannot do two meetings at the same time. Anyway, I just want to remind people about that. Also, that the materials for today's meeting can always be found on healthit.gov on the HITAC calendar. I am not seeing any hands raised, so I will turn it back to Arien and Gillian.

Next Steps (01:15:41)

Arien Malec
Just a reminder to do your homework. We will send you an email reminder to do your homework, as well. I want to thank the presenters for some truly amazing and helpful feedback and comment. It is pretty apparent that we have learned a ton. It is a credit to all the work that went into the current state of immunization information systems and EHR certification that we were able to track vaccine administration. I think that it is fair to say that during the process, it was not characterized by no special effort. There was a fair amount of special effort that went into making it happen. But it was at least possible, which, as I said, is a credit to how far we came in the last 10 years. As we go forward in certification, let us make sure that our recommendation texts makes sure the next EHR that gets implemented in the next still jurisdiction is switched on by default to send vaccine administration data and to query for immunization records by default with no special effort. Gillian?

Gillian Haney
I think will add to that to thank everybody again for their engagement and participation. I am personally looking forward to having a chance to digest all of the comments in the chat and perhaps listen to the meeting again. There was a lot of really interesting content and issues raised. I think for me, one of the things that still continues to stand out is the need to develop specific tools to address data quality. It seems

there are a lot of lessons that have been learned with the work that AIRA has done. I really look forward to continuing this conversation. I clearly have a lot of homework to do, too.

Arien Malec
Thanks everybody. Shall we adjourn early? With no objections, let us give ourselves a little bit of time. Thanks for the reminder of the upcoming meetings. As a reminder, yes, on Friday, we are meeting again. Thanks everybody.

Adjourn (01:18:11)