



HIT Standards Committee Implementation, Certification and Testing Workgroup Final Transcript February 27, 2015

Presentation

Operator

All lines are bridged with the public.

Michelle Consolazio, MPA – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Implementation, Certification and Testing Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Cris Ross?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Cris. Liz Johnson? Andrey Ostrovsky? Danny Rosenthal? David Kates? John Travis?

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, John. Kyle Meadors?

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Kyle. Rick Moore? Sarah Corley?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Sarah. Steve Waldren? Udayan Mandavia?

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Zabrina Gonzaga?

Zabrina Gonzaga, MSN, RN, cPNP – Senior Nurse Informaticist – Lantana Consulting Group

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And from ONC do we have Brett Andriesen?

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Brett's here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Brett. Alicia Morton?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Alicia. Is Scott on? I didn't hear him.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services

Scott is on.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Scott.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And any other members from ONC on the line?

Mazen Yacoub, MBA – Healthcare Management Consultant

Mazen Yacoub, contract support.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay. Oh hi, Mazen.

Mazen Yacoub, MBA – Healthcare Management Consultant

Hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And with that, I'll turn it over to Cris.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Michelle, thanks very much. So as we all know, our work over the next 90 days is for us to work together in these meetings and offline in order to respond to the interoperability roadmap, that's our focus now, and then to respond to the NPRM, that will begin in March and end in May. So if we've got the...I'm looking at the slides on my screen, I guess I can move kind of the webcast; if we can switch to the first page, please. So this gives us calendar deadlines of what we're looking at for FACA activities, and we're one of several groups looking at responses; if you can go to the next slide, please.

This is the detailed list of activities that we're focusing on. So today we're discussing comments on Interoperability Roadmap Version 1 and our specific assignment, as you all know, is to look at section I-1, testing tools and section I-2, certification programs. And we got some good feedback from people in the workgroup. We assembled both the notes in their sort of raw form, if you will. Liz and I also asked the ONC staff if there was an ability to cluster some of the comments, to group them so that we could see them side-by-side or condensed sort of way, and I think they did some really good work accomplishing that, and that's what we'll be stepping into in just a minute.

So, our next updated activities are a meeting on March 13 and then a meeting of the Standards Committee on March 18. And then you can look ahead to the dates that lead up to the April and May Standards Committee meetings. Can you go to the next slide, please?

This is our process, as you know, and our focus today is on that develop consensus activity. So, there clearly was a lot of common thinking in feedback that we got from all of you and from some others who aren't on the phone. There are also a few differences and there are a lot of times cases when we begin to put comments together like this we discover that maybe even as a group we overlooked something, we under-indexed something, perhaps we see some contradictions that weren't obvious before. So I'm hoping we can have a good robust conversation. And again, all of this is leading to the meeting...our report back of the various workgroups back to the Standards Committee on April 22.

I see that David Kates has joined us, but I think at this point, unless Michelle or Brett, you have any other comments, I think we want to turn this over to Brett, Scott and others to walk us through the workgroup comments.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

All right, sounds good to me. This is Brett Andriesen from ONC, if we can move on to the next slide here, we'll get started. So just a reminder about the ONC guiding principles for the interoperability roadmap work in general, won't read them again as I know that we went pretty in depth into these on our last call. So let's move on to the next slide and we will jump into the comments.

So just a reminder, this is kind of the framework for section I-1, which is on testing tools as well as the charge that workgroup members were charged with answering as well some of the questions that you addressed in your comments and that we can address in our discussion today as we work to build consensus around those comments and bring those recommendations forward and up to the Standards Committee. So let's move on to the next slide and we will jump right into the meat of those.

And again, just a reminder, the full text of all the comments are available as one of the attachments for the meeting if folks are interested in reading specifically what was commented by workgroup members. This is just our kind of rehash and pulling everything together to make it a little bit more digestible. So the charge question, in what ways can semantic interoperability be tested, for example C-CDA content semantics)? Some of the comments that we got from the workgroup were establishing a common definition for interoperability of the ability of a computer system to exchange data with unambiguous shared meaning.

We also saw, focus on parsimonious set of necessary data. Clearly define contextual meanings that are necessary to achieve MU. Defining what patient information should be consumed, displayed and exchanged. The scope of interoperability testing needs to expand beyond just individual patient data exchange between providers at transitions of care or consumer access.

We saw comments around starting with a small prioritized set of content and settings where interoperability is expected, so acute care, ambulatory, long-term, behavioral health, long-term care support services settings and then working to define language and requirements and then testing methods and requirements beyond that, from that core data set and starting there. So there are a couple more slides that deal...that address the same charge question and we'll move on to the next one here.

So comments surrounding removing optionality and constraining how data's represented, packaged and transported. Some suggestions to create a single comprehensive set of tools to ensure consistent testing and implementation; for example, some comments around specific C-CDA files to support testing requirements; ensuring resources are conservative in what they send and liberal in what they accept; evaluating C-CDA to identify missing data elements; providing richer and more standardized templates and tools to validate conformance. And then we'll move on to the next slide here.

Some areas that the workgroup saw as gaps; we started that the C-CDA does not address things such as history, including historical and inactive entries. It doesn't include extra details, include or not, what parts of medication, allergic reactions, etcetera. Additional gaps; the common clinical data sets in C-CDA further needs to be constrained in a manner to make data exchange simplified and more reliable, EHR

certification testing should include validation of codes and vocabulary. And then kind of a final other comment here, narrative text, non-structured data and use of non-structured codified data would all seem to go against semantic interoperability.

So, before we move on and summarize some of the other questions, I think this is probably a good point for workgroup members to jump in and kind of explain some of their points a bit further. I'm sure that we did not do justice to all the work and comments and thoughts that you had put into your comments here. And Cris, if you want to kind of guide the process for formulating these and driving the workgroup discussion.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, I think we want to open up for comments. We may have done some damage by trying to consolidate this, but looking at the raw materials, it was a little hard to get our hands around it. So, I think this is...was a nice, neat summary. But why don't we just open it up for comments and concerns or improvements.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

This is Kyle Meadors and I just want to point out on the gap one, which I think actually ones that came from me. It's not that the C-CDA spec doesn't address these things as much as the one, the spec allows different details and nuances of your medication list or problems to be expressed in different ways. And then two though really more is the point, the test procedures or the guidance, if you will, doesn't necessarily specify some of these details.

So if you want to think of it like we have a, with the C-CDA spec, you have like this powerful machine here with all the options that are available; we don't necessarily have as quite a detailed guide of...currently, like in the test program, of what things can be done or not done or how should be interpreted. So there are a lot of areas there, I think, right now with semantic interoperability that's being broken down, it's not effective right now just because we need to define it and tighten, I guess, some of those requirements there, which I know these are things we actually at the Kaizen we talked about removing the ambiguity and we had talked about that with the ATLS right now about some things like that. So it's...people are aware of this, this isn't a new concept. I just wanted to clarify that when I said C-CDA there, it's really not so much the C-CDA, but for the test procedures dealing with C-CDA, test requirements dealing with the C-CDA and how those should be interpreted.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah Corley. So to that point, we really have to decide what needs to be codified and constrained to a level where you really do have semantic interoperability. So you just heard that there's...you can have fields for these in the C-CDA, but you can put different information in there in different formats and we do know that doctors find more value from prose than they do from computer speak, so we have to identify clearly what the important data elements are that we need to constrain so that they can be consumed by other systems and decision support or other functionality can be run against them.

So I think that that's really what you've heard a lot in a lot of our comments is, we have to find the set that we need that is adequate to meet the needs without impairing the usability of the product. And that probably within the C-CDA right now, there are areas that could be further constrained without impairing usability; so codifying the allergic reactions, which there are code sets for, etcetera. Past medical history is still a bit problematic because patients don't often or always know exact dates, which

the C-CDA would like to have. They don't know the exact medical code or exactly what they had so, the person entering that information may not be able to make it as specific as possible.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

This is John Travis; there are a couple of real good examples I'll just add to that that especially as I think about what CMS is looking to do for the chronic care management benefit and also for the oncology pilot that they're now putting out. Both of those depend on two other areas of data that currently have very poor structure to them, if any at all and one is the care plan and the other is the care team. Whether you want to look at the care term in terms of the roles that...there's not a lot of definition there and from a certification standpoint, the test data doesn't particularly challenge that very much or offer much insight into the regulatory intent of either of those concepts.

So, as we look forward, those are the kinds of things that are going to become very important, certainly know who you need to communicate with, that's the care team presumably identified through that kind of section of a care summary or something, as well as the care plan. And it just right now seems very lacking in definition. And that...I don't know that that's solved by a code set, that's solved by common understanding of structure or something like that. Maybe it is a code set, but it's...

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Yeah, this is Kyle. I think what John said and also Sarah said are important that really we almost need to start with what the providers need and then we kind of work our way back to, you know, then you can define the code set or emphasize these elements are what the prioritized parts. But until we kind of are clear on what we need to communicate, sometimes we've got...in some ways we've gotten the cart before the horse. We've gotten this...

David Kates – Director of Interoperability – The Advisory Board Company

Yeah.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

...detailed C-CDA structure but then providers are like, I don't re...that's not what I need or I'm not sure what I need is where it's supposed to be kind of thing. So, I really want to make sure providers tell us, this is what we need; and then we can kind of go back and codify it and then test it, but we've got to start with what their needs are.

David Kates – Director of Interoperability – The Advisory Board Company

And quick question; this is Dave Kates. Cris, I don't know whether to address it to you or to ONC folks, but, I mean I think we're all on the same page in terms of constraining the C-CDA and making it more both consistent and machine-readable and the like is, to the extent that we are driving in that direction, is that something that we look to the SDO, is that something that we can collectively define a set of implementation guidelines or certification test constraints?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Dave, that's...I think you're right on track, so...this is Cris. Last summer we had some work assigned to the predecessor group under this title around constraining C-CDA. We had some good conversations in the group but we came to a conclusion that it was beyond the capability of this workgroup to be able to actually do the work. So it was taken up by other Kaizen activities and other groups. So I guess I have two questions for this group; number one, for those...this is a process conversation, for those of you who have been involved in some of the C-CDA constraint activities, has it been effective or not? And

number two, what role should we have in either reigniting, reaccelerating or redirecting that work, if you believe that the C-CDA constraint pathway is the right way to go down?

So sorry for the complicated question, but first is the C-CDA constraint activities working? And number two, if yes or now, what should this workgroup focus on?

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Hi, this is Udayan and I have been on that C-CDA constraint workgroup and we have shared some of our thoughts on that group and I would be happy to share the slides which we presented, I'll be sending that by email to the group. One of the examples related to constraining I would like to share here is that the procedures get coded in SNOMED or CPT or ICD-10...and most of the EHRs use only one coding system and they don't have the crosswalks available. So when they receive a file which is not having the coding system they use, then that's where those things like semantic operability starts to play...this is where we need to think about using only one coding system which can be used by everybody. This is one of the...

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Can I ask a...or make a comment along those lines? This is Andrey Ostrovsky. In terms of crosswalks, my understand is the crosswalks, my understanding is the work that was done in Massachusetts with the IMPACT program that they did some pretty extensive cross-walking between the various field definitions for I believe it included procedures, but care plan summaries, transitions of care documents and does anyone know in terms of to what extent that work is contributing to this dis...or could contribute to this discussion in terms of existing crosswalks that could be utilized to push C-CDA and further refining constraints forward?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah; apparently not.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Um hmm.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I will comment on the procedures one is that it is important when you're constraining this to use a code system that is not the kind that you would use for billing where you know exactly what was done because some of these procedures are going to be historical where you don't have the level of detail to know the difference between codes. So you really need more the V-code type things, you know, history of a cholecystectomy and not the mechanism that it was done that would be required for a billing detail.

Zabrina Gonzaga, MSN, RN, cNP – Senior Nurse Informaticist – Lantana Consulting Group

So this is Zabrina Gonzaga from Lantana. I just wanted to just clarify the question regarding...the C-CDA potentially conditioning...transitions of care and the care plan, is the question whether or not there is some guidance that we...that can be used to help with constraining...further constraining those existing documents or sort of the historical background in terms of building those particular documents?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Yeah, I...this is Andrey again, thanks for...that. My...I believe or I thought that that work had already been done or put in motion. I'm not sure where in the process of making it standardized and implemented where it is, but my understanding was that there were crosswalks already done and put in place. Is that the case or is that just work in progress?

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

This is Kyle speaking on the...like there is a companion guide, Meaningful Use companion guide for the C-CDA which is designed kind of the best practice, if you will, about how you should code the C-CDA to support things like with the care plan and procedures. So there is a document in a work that's in place; I know that the balancing act was the kind of how do you call a must versus should and kind of those kind of things.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Um hmm.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

So there is some work, but now the one thing from an ONC certification standpoint is, that's not a required document. That is really out of our scope; it's not in the regulations, it's not addressed in any test procedures so it is something that is not necessarily enforceable at this moment. Now maybe there is something in the future that can be done, but I mean there has been a work that's been in place about how to better define this companion...if you went through the companion guide and maybe some other sources as well, but that's one in particular that comes to my mind. But, from the standpoint of the present ONC certification requirements, there's really not...any constraints as of now; but...

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

That's super helpful and I believe the context in which I'm familiar with that body of work it was proposed for Meaningful Use 3 to the Health IT Policy Committee and so I...it makes sense what you're describing and that it is not part of the current requirements.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, and this is Cris again. I guess the...just from an approach perspective, part of what we're trying to accomplish with this workgroup is when we can do work, to do it. But in several instances, it's been beyond the capability of what we can do in bi-weekly phone call.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Um hmm.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So I just wanted to call up, for those of you have been involved in it, last year we passed this off to another function and activity and I wanted to get viewpoints from this group, since there's so much discussion right out of the gate around constraint of C-CDA being a worthwhile thing. I want to find out, is that working? And as a workgroup, if not, are there things that those of you who are particularly close to the work would recommend?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah. I mean, I can't tell you if it's working because I haven't been involved in the workgroups, but I think that this workgroup could certainly identify areas where we think that there needs to be further constraint that are doable for people to look at and also areas where the current constraints might be causing some issues.

So there are some things that require a complete date, so if a physician doesn't know the complete date, the vendor has to put in some...the rest of the missing elements in order to have a valid C-CDA. And I know there is some indicator I think that the date is approximate, but, those are areas that also

should be identified for consensus to be built around what needs to be done where you really don't have that information and that information is required. So we might not be able to develop the constraints, but we should be able to look at where we think we need further constraints or where the current constraints might be problematic in the C-CDA.

David Kates – Director of Interoperability – The Advisory Board Company

Yeah, so...this is Dave. To just probably reiterate what Sarah just said, put a fine point on it like Cris, it seems like if our workgroup could identify the focus areas and potentially even a set of recommendations and then it seems like it's out of our control, but at least bring back to the Standards Committee and to ONC that these are the areas that we think need to be addressed. And whether that's through certification, through regs or implementation guides, whatever; we could at least provide helpful guidance on the areas of focus.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Okay. So that all makes sense; so I think before we're done, and maybe we can get some help from Brett or Scott as well or people on the workgroup can comment. I think it would be worthwhile for us to have a viewpoint about whether the delegated activities around constraining the C-CDA are working or not and if not, what are our recommendations to either accelerate that work, move it to a different venue, bring other facts to bear, whatever. I don't think we should just hand it off to somebody else and let it disappear, but should speak up on it. So I think David, your formulation is just fine. So let's make sure we put that on the agenda for next time, unless someone wants to try and draw a conclusion today.

David Kates – Director of Interoperability – The Advisory Board Company

Yeah I guess the only friendly amendment is that we can decide next meeting, but that there's probably a sub-workgroup that should just put a straw model together of what those recommendations are, once we take that on.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I hear a volunteer.

David Kates – Director of Interoperability – The Advisory Board Company

I'm happy to help facilitate, Sarah's volunteering though. I just volunteered you Sarah.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Yeah, I figured, as long as you're leading Dave, I will...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

That would be really helpful if you could just convene in whatever way makes sense and come back with a collective viewpoint.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I'm going to volunteer John, too.

David Kates – Director of Interoperability – The Advisory Board Company

I was going to say, at least...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

All right, that's good. So if we...this is a great...this is exactly the conversation we're looking for. So are there any other comments on these slides or the two that preceded or shall we move on to the next topic? Hearing none, Brett, do you want to take us on to the next cluster?

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Sure thing. So moving on to the next slide here, we are looking at in the short term on kind of send, find, receive and use the common clinical data set, ONC, NIST and other health IT stakeholders provide testing tools necessary to support the criteria in ONC's certification program. So you'll see some of the general questions we were asking the workgroup to address. Up at the top of the slide there, and apologize for the font size, trying to cover a lot of material and make it appear on slides here.

So some of the general comments that we saw from the group on this were, vendors need reliable testing tools with which to do their own validation testing prior to certification. Testing tools need to be available with adequate lead time prior to certification. Based on what we...build based on what we currently have, so using the SMART C-CDA scorecard to address coding, for example and providing some additional guidance on these multiple tools to validate various aspects of certification requirements.

Some gaps that the workgroup saw; increasing specificity on the type of data exchanged to achieve contextual and semantic meaning, stability and continuance of availability of the tools, some gaps seen and tools immature and changed over time such that vendors were not tested to identical requirements. Test data not clinically relevant or featured inaccurate or obsolete codes or medications. And requirements developed prior to market readiness.

And then some other comments seen, suggestion to include high level description of what will occur under each of the 3-year milestones. Anticipate interoperability will move beyond EHRs into other digital health spaces and healthcare venues. And suggestion that ONC team with telecommunications and banking industry experts to benefit from best practices and lessons learned.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

All right, comments?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Well...this is Sarah; I would think as far as test tools are concerned, I think that the main purpose of the test tool is to make sure that the product will function in a production environment as expected and as is tested. Currently no matter if we solve the problem of the test tools, which I think we clearly identified a whole lot of issues with the current process for creation of test tools, you know, their quality, their deployment, their stability; we are still left with the issue of the partners in data exchange, if they do not adhere to the same standards that certification is testing the vendors against, there is no guarantee that what you're hoping to accomplish is going to happen in the real world without additional effort.

So...and exchange of a C-CDA between two certified vendors that one would hope that the testing tool then would reflect production success. But, testing an immunization registry or syndromic surveillance interface or a lab interface when the exchange partners are not adhering to the same implementation guide or even the same requirements, it's not going to reflect performance in the real world. So, the

question is, how much effort are we going to invest in the testing tools that are going to be testing those areas where we don't see conformance by partners in the exchange and whether we should focus more of our efforts on making sure that we have good testing tools for where conformance should be assured, which is the exchange of C-CDAs between certified vendor products.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Hi, this is Andrey again. I think that's a great observation and as a technology vendor that is not an EMR and with no direct financial incentive to be Meaningful Use compliant, we are adhering to the standards because there's a business case for us to do so, to exchange information with EMRs. And from my perspective I think a lot of the rest of the digital health ecosystem, if there...if it was more easy to access the test tools and they weren't entirely revolving around, I guess, they weren't all focused on an EMR, but perhaps expanding the use case beyond the EMR to still exchange data in a standardized format, I think there would be more opportunity to get other technologists to actually go through the formal testing process. But I think that's probably out of scope for a lot of what Meaningful Use has been set up to do. But it is, perhaps down the road, an interesting conversation to have. But that's an observation I've had.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

This is John Travis. Aside from a lot of the timeliness of the availability of the tools for vendors to use and having them stable earlier, something had just occurred to me that I hadn't really commented on Sarah either in the Kaizen or preparatory here. I consider how interoperability requirements of other kinds are tested in other healthcare use cases and I'm not sure if any of this is feasible but, the big complaint is, you've seen one C-CDA implementation, even with the conformance testing tools we've had, you've seen one.

Other things that are not unfamiliar to the industry don't rely on proctor observed testing necessarily and I'll just throw it out there. I offer the example of HIPAA EDI certification with EHNAC where there are various levels of conformance that are proven through independent testing, so that's still tool driven, but the level of conformance can be more clearly stated and it's binary. Maybe there is something like that we need to be thinking about with the C-CDA that informs the implementer just what level of capability they have and what remaining level of capability they may need to expect is variable if you're not going to have good companion guides to it to help you through it.

The other is the model we have is the only model we can have. And where I go with that is, what...if they ever get around to health plan certification under HIPAA, they've kind of put that on hold a bit for the moment, but there were going to be two models; one was going to be an independent testing model driven by CAQH CORE. The other was going to be a model that was relying on trading partner testing, to be quite honest, driven by the health plan based on a volume demonstrating compliance with being able to successfully test with trading partners that represented large volumes of activity. I don't even know if there's a metaphor for that in what we're talking about that would be vendor focused, but I offer those as different ways to approach certification than what we've seen so far with ONC and the EHR certification.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Uhh, Udayan and one of the major...that we have raised here is that, and as Sarah states, that reliability and availability of the tools is one of the concerns. And many times we've seen that the versions keep on changing, what we just did, it doesn't work the next day so that's where some of the issues are. And we had a problem on the day of testing that the...tool was not available and we had to like reschedule our

flow of the script and...had to call somebody to get that tool working. So that's the kind of issues we as a vendor face.

And the other issue, which is again very important, is that in taking care of the other end like immunization registries or the laboratories, because we get certified for 2.5.1 standards, but when we go for the immunization registry interfaces, there are so many...and we need to go through for each of the immunization registries, so are there any thoughts going on to take care of the other entities involving the end-to-end transaction?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

So is that a question?

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Yes. So how do we like ensure that the complete transaction is...or interoperability is ensured between all the entities, like EHRs are certified for 2.5.1 version, but when it comes to the immunization interfaces, we face that many times, most of the times, we have to do certain customization; they have got some other optional elements included and different kinds of things. So...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

So, it's a very good point. I think this is...we're going to go through a couple of dimensions that this one is specifically on the testing tools piece of it. So, I think your question that you're raising is a great one, is there something...the general topic is fine, is there anything in particular to testing tools that you might want to call out?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I think, this is Sarah, I think he was just saying the same thing that I said is that the testing tools are not going to reflect real-world performance...

David Kates – Director of Interoperability – The Advisory Board Company

Yeah.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

...when you don't have trading partners that are testing...using the same tools because they're not...because they don't support them.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah. Cris, this is John, I think that's really where I was going with my commentary, that other testing approaches do wind up involving trading partners or do wind up differentiating levels of conformance that...to the comments that were made, help set the expectation of what the implementer has remaining to be done or how much stock they can put in the conformance statements or capability represented by the party that sought the certification. And I'm trying to get out at there's all the stink about how much is left to be done to customize or localize or deal with optionality; I don't know if there is something to be done to address the level of conformance attained by the certification. And that may

be beyond anything we can do, but other kinds of accreditation/certification are not just simply limited to a laboratory testing of one model of conformance necessarily.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah.

David Kates – Director of Interoperability – The Advisory Board Company

Yeah, I mean I think...this is Dave; so, it seems like there are a couple of potential approaches. I mean one is the whole inspection or creating essentially the certification body as an ongoing audit that they are occasionally getting samples of real live C-CDA documents to ensure that what's out in the real world is consistent with what went through testing.

And then the other might just be, it gets back to the earlier conversation about constraining it, that there's a subset of, let's go for the C-CDA that there's known data that you can consistently test for validation...

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Right.

David Kates – Director of Interoperability – The Advisory Board Company

...but...

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah; that...my points were that if we see that we are having all of the problems that were listed and identified with the testing tools, if we could just as a first step focus the primary effort and attention on getting the testing tools correct for the C-CDA exchange and identifying, as Dave said, where the lack of constraints might make for difficulty in exchanging those so that we're spending the most effort where we know that the trading partners are going...that what you're testing is something that all of the trading partners on that data exchange ought to be able to exam...ought to be able to work, if the testing tool is done correctly and the vendors are certified to that that when you take that out into the real world and try and exchange them.

So less focus on trying to use testing tools for the other areas where we know, it's not a case of if you build it, they will come; because we have built these interfaces for the LRI, immunization, syndromic and we can't put those into production because the data exchange partners don't use them. So focus the efforts on where the testing is really going to be meaningful to the people purchasing the products to know that, if I get a certified product, at least the C-CDAs are going to work, even if I'm going to have to sit through waiting for the interface for XYZ registry to be developed because it's not standard.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

So this is great feedback. Brett and Scott, are we capturing these categories? I think these are above and beyond the comments we got...and they sound very good to me.

David Kates – Director of Interoperability – The Advisory Board Company

And this is way outside my policy expertise but I mean even if, I mean, in all these things to the extent that we create more transparency and people are actually using it that will be the forcing function for us to solve some of these things. Like whether its CMS claims attachments or something of that ilk where we're starting to see the volume of these things increase and the uses. Anything that we can do to foster adoption which will then create the deman...create the need for these things to be addressed.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

This is Udayan again. Has anybody used the SMART C-CDA Scorecard? Has anybody got any experience of using that and...

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Well, I'll speak; this is Kyle Meadors. It's one thing that I think I referenced that in my comments; it's not something that's part of the current certification scope so it wasn't something we require. But I will say, we do kind of encourage vendors to look at that with the context that it's a scorecard, it's not an absolute type of thing. But I do think that's kind of getting in a little of what John has mentioned earlier that...I think like with the comments on the transport testing tool, the C-CDA validation; in some ways it's really, I think it's intent was just more kind of a set the floor, so to speak, of basic kind of functionality, not necessarily defining all levels of detail.

There may be something to be said about optional functional...or different levels of conformance, which is really just new criteria possibly, you know, we have a modular certification so the certification may be a basic C-CDA transmit...communication with certain elements. And then there's maybe a level beyond that that deals with certain criteria that deals with certain details and that's when we can get into the scorecard or...aspect of it.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

So there are ways we can approach that. I do want to comment one thing about, the C-CDA is interesting, at least in the context of transition of care, because it really is EHR-to-EHR for the most part and I think we can really do a lot of work there. I think one thing people mentioned about far as the immunization aspects, that's an interesting challenge because while we have requirements within the ONC program, these states aren't necessarily binding to those and so they have their own requirements.

And so you see people sometimes having to implement things for certification that others are not following, frankly. And so, I mean, definitely that is something for us to consider is if we can...if people...if other groups aren't going to follow those, then certainly don't make EH R vendors have to follow them. We kind of see a little bit with the shift we've done with release 2 syndromic surveillance requirement, it's optional ambulatory, but they've basically taken away the standard and basically said, here are some elements that should be part of syndromic, but it would basically free you up if you're working with certain registries and stuff.

So, I mean I think it's one point to make is whenever we're talking, people have to agree on things and if we recognize that some industries aren't ready to regulate or I guess align with certain requirements, then we certainly should not make EHR vendors basically do that until...again until the industry is really ready to say, all right, let's all agree to this common method.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah, I do want to comment about what you just said about the syndromic and making it anything goes. Unfortunately what's happened with that is you're still requiring certification of anything goes which means that in theory, you could have to have a separate certification for hundreds of different public health agencies rather than saying, anything counts as long as you're exchanging, but your vendor doesn't have to certify.

It's requiring certification where there is no criteria so you're spending money and you're getting certified and the question is, do you have to get certified for every single public health agency that has one of these non-compliant registries? So in that case, it sort of made the situation worse from a vendor perspective anyway and introduced the possibility of increasing cost because of the potential for having to certify many, many more interfaces.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Well...speak of...this is John; the frustration level of people thinking they've got an out of the box capability that it turns out they do not have and they feel like they're implementing the capability completely unique to that jurisdiction. I'm just trying to think in terms of the ways you can use this process to reduce the lack of on-page condition between vendors and their provider clients over interoperability and what is certification really giving them is why I made the suggestions I had made earlier. And the test methods might be an avenue for easing that frustration, or at least making it clearer what they really are getting.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

This all makes sense. I don't want to cut this off...this is Cris. We're about halfway...a little bit more than halfway through our time, but I think we haven't gotten quite halfway through our material. So let me just check again, Brett, Scott, are we capturing these comments, which I think are great and can we add them to the next version.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

We definitely are capturing most of these comments and we can do our best to try to capture and incorporate these into some updated slides certainly going forward.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Yeah I think...

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

I will say that we do not need to get through, if we don't want; we can focus in and try to get further on a smaller set of slides today versus trying to get through everything at a higher level. I don't know what makes the most sense to you.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

No, that's fine. So you're listening to this conversation, you know what's ahead and I don't want to cut it off. How many more topics do you think we should try to get through today at a minimum? I'm looking ahead to slide 12, 13, 14, 15 that gets us through this group and there are eight areas to look at; we're just talking about number one. I might make the argument that we should try and get through at

least...that will get us to the end of I-1 and I would think we'd need to at least get to the end of I-1 today.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, I think that would be a smart strategy to try to do.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So unless other workgroup members disagree, I think we should take a few more minutes to finalize up on the testing tool topic, which is key and then see if we can move on to the next seven. Does that work for everybody?

David Kates – Director of Interoperability – The Advisory Board Company

Yup.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Yes.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I'll take that as consent. All right, sorry to cut off the conversation but let's see if we can wrap up the testing comment here in just a few minutes. Any last comments? Maybe that was just the moment, my cue to move us on to number 2; anything left on topic number 1?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I'm done.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Thanks Sarah.

David Kates – Director of Interoperability – The Advisory Board Company

(Indiscernible)

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

All right Brett, move us on.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

All right, so moving on to number 2, health IT developers, SDO and government will explore and accelerate a suite of testing tools that can be used by implementers after implementation to ensure continued interoperability while health IT is in use.

So some general comments in this area...let's see here; use test tools developed outside of the certification program, for example, SMART CDA Scorecard, that focus on niche or specific elements of the interoperability exchange. Create a set of test scenarios based on real world cases of care coordination. Deeming rather than certification for services that are already in place and widely used would increase efficiency, for example, e-Prescribing, lab interfaces, etcetera. Consider using tools provided for certification testing for post-implementation testing rather than having a separate set of

organizations get involved. Use a set of unit tests that look for errors reported from the provider communities and ONC's semantic interoperability error reporting tool.

And then some gaps; include providers. Vendors and SDO resources are too limited, resources to create testing tools for certification requirements that do not reflect work already under way; ONC and NIST to develop inspection tools. And system can pass tests but fail in deployed mode, would recommend an increase in rigor in defining correct implementation, their configurations of certified systems to achieve results as test and vendors must attest that implementation will achieve results upon install. ONC should require random audits of implementation sites to determine effectiveness of implementation. And test tools may not be as cost effective. So I think we'll pass it over to some further comments and discussion for the workgroup now.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

So this is Sarah, I'm going to have to leave at 1, so I just wanted to spend a little bit more time talking about the deeming process. I think that rather than developing...taking the time and resources to develop testing tools where we do have a certification process in place, like e-Prescribing, we should use deeming for that.

And for the other interfaces where we've already...it's quite clear that the data exchange partners are not following the standards that we are required to meet for certification. I think that it would be beneficial to the end users of our products if rather than testing to these non-real world requirements, that we simply list and have validated by the data exchange partners which lab interfaces you have in production that work with your product? Which syndromic surveillance? Which public health agencies are you able currently to exchange data with? Which immunization registries are you able to exchange data with and is it unidirectional or bidirectional?

I think that that would provide more value to the purchasers of these products and not cause a lot of resources to be spent developing testing tools to test something that is not going to reflect success in the production environment, unless and until we have some sort of mechanism to drive compliance of the data exchange partners with the standards that have been selected for certification.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

This is John. I'll echo that Sarah, I think that's a fantastic point when it comes to those criteria and objectives where there is large variability in the production experience. And you don't want to discredit what providers are having to do because they are complying with a state or local requirement for the same type of exchange and certifying to a standard is completely disconnected from that when the standard's not in use. So, that's a powerful idea.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So Sarah, this is Cris. Do you have any particular domains that you would either call out or use as examples? Or is that a...

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I certainly do. I mean, I would use labs. I would use immunization. I would use the syndromic surveillance...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

...because those are all areas that are required for Meaningful Use where we have seen great variability in what we have to build for our interfaces. And I know my company has I think 257 different lab interfaces out there; so if you had a requirement for attestation that vendors would attest to which ones they already have functioning, in production and similar to what happened under CCHIT where CCHIT would verify that you had that product live in production before you could get full certification.

The certifying bodies could randomly verify that yes, you did have Quest interfaces or LabCorp interfaces in production; that there would be some sort of audit so that you could, if necessary, you could confirm that those really were working and in production. That would be a very powerful tool for people purchasing these products to know, in advance, this is the lab I use, this is the state I'm in or the locality I'm in; does the vendor I'm looking at support exchange with the public health agencies, the immunization registry, the labs that I use.

And I think it's great to have standards, but until we have some mechanism to drive the participation by these other parties, and it's not happening quickly, we should be providing value to the physicians and hospitals purchasing our products by being transparent about what we have developed and what they can take advantage of. Because it is disingenuous to say, you are certified for syndromic surveillance reporting and immunization reporting and the LRI, but that doesn't mean you're going to get a functioning interface for where you are.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So that's a great point, Sarah; this is Cris. So just to be clear, with respect to syndromic, labs and immunization you're referring to the public health submission. But I think you're also talking about lab more broadly, including commercial.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Correct. I'm talking about commercial labs, not just reportable labs.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, I think we should call out the three public health as well as the commercial labs. That's a great point.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

And Cris, a friendly amendment; I'd add cancer registry reporting to that.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

...I'm with you John. Yup.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Cancer and the specialty registries...

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

...that would be great. And on that note, I'm going to sign off. Hopefully Dave won't volunteer me for any work while I'm gone, but...

David Kates – Director of Interoperability – The Advisory Board Company

I'll send you the list later, but...

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Bye, bye.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Bye.

David Kates – Director of Interoperability – The Advisory Board Company

And just a comment on the lab side of things; so obviously the industry...the composition of the industry around lab, you've got the commercial labs, but then more than half the lab work's done at a hospital based labs and I don't know to what extent...if we create transparency, which I totally endorse, I think that's a brilliant idea, whether then we add the lab piece...this is a detail, but...to the LIS being used by the hospital or how we would structure that, but...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Um hmm.

David Kates – Director of Interoperability – The Advisory Board Company

...you don't need to answer that, it's just an observation.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Any responses to David; I think it's a good question. In the absence of comment, David do you have a recommendation?

David Kates – Director of Interoperability – The Advisory Board Company

No, I don't. I mean John, maybe...I mean maybe you...I guess...the ven...at least the LIS vendors with whom you've interfaced, that might be a good surrogate, not knowing specifically how...

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Good.

David Kates – Director of Interoperability – The Advisory Board Company

...it's done at X, Y, Z hospital.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

That's a fair point. Are you speaking maybe of commenting on ability not...because LRI is aimed at the reference lab side, but even the interfacing that's available that in the old days would be intra-operability?

David Kates – Director of Interoperability – The Advisory Board Company

Yeah, maybe we can take it offline because maybe I'm...maybe my concern is dated. Maybe there is more standardization.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Well I think that's a fair comment that that despite it may be feeling like intra-operability when it comes to the hospital objective for providing lab results to ambulatory providers, that's going to feel a lot more like the old application-to-application interfacing model...

David Kates – Director of Interoperability – The Advisory Board Company

Yeah, that's what I was referring to.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

...especially when you're talking about local distribution of results; I agree with you, David. It would help to know what your experience is, in a similar way. So maybe it's not the entities you disclose to, it's the vendors you have experience with and what basis of interfacing you enable.

David Kates – Director of Interoperability – The Advisory Board Company

Yeah, so that would be my preliminary recommendation. I mean, I think just pointing out that half a loaf is better than no loaf; let's get transparency around commercial labs and then on the hospital lab, a potential approach would be the LIS systems with which you've interfaced and that we can at least, as a customer, as an EHR customer you can see whether the hospital you do business with is using one of those labs and use that as a surrogate. So that was my answer, Cris.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

That's a pretty good one.

David Kates – Director of Interoperability – The Advisory Board Company

Okay.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I have to tell you, I used to pay close attention to the lab space and I'm not as current as I used to be, but I'm not sure we want to claim in any way that the lab problem's been solved. I think it's still a work in progress in a lot of ways, both intra and interoperability.

David Kates – Director of Interoperability – The Advisory Board Company

Agreed.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

All right, are there any additional comments on this set of issues and recommendations?

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Hi, this is Udayan. The fourth bullet point came from me and my question was, are we thinking of creating a separate tool for post-implementation? And that's where I suggest that we should have the same one, so, I was just trying to understand the gist of this particular bullet point.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Well since you initiated it, this is a great point. What's your recommendation? Do you agree with the way that it's worded here or would you modify the wording?

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

What we suggest is that there should be the same set of tools available for certification of production environment post-implementation so that it remains consistent throughout.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Right. So instead of consider, make it more forceful.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Um hmm. Yup.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I think that makes sense. Any other additional comments on this topic 2? If not, Brett, let's go on to number 3. Brett?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Brett, if you're talking, you're muted.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Sorry about that, I was on mute. Let's move on to the next slide, here. So dealing with SDOs beginning to develop and maintain initial testing tools in support of more stringent testing and standards here.

So comments from the workgroup; more simple testing standards rather than more stringent may actually lead to the aim of reproducibly high quality interoperability. Comments related to a single set of tools for testing would ensure all EHRs conform to the same standards and remain interoperable. Tools may focus on more stringent testing as they moved along various milestones. More stringent tools needed again, kind of an...comment here; two test cases per function is not adequate, we thought.

Mathematical and statistical model could assist in determining the appropriate amount of test cases needed to run through a system to ensure adequate testing of each node in the decision tree. Consider leveraging existing tes...standards tools, like VSAC for file validation on common clinical data sets and consider expanding tools to validate against HL7 value sets. Test tools should originate from organizations beyond NIST, but government should not expect SDOs to bear the financial responsibility to provide these tools required for certification testing. And finally, SDOs are organizations of volunteers without funding or resources for tooling; this would require a change in operation and new sources of funding that's unlikely in the time period...here.

So, now we will again turn it back to the workgroup for further comments and discussion.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah, this is John; I especially made that last comment. I talked to Bob Yencha and some other folks at the certification Kaizen about the potential of this role and it just seemed like a non-starter for SDOs to be involved in tooling development over the funding issue; all other considerations of technical competency to do so aside, they just...that's not what they're really set up to be in the role of doing. And even there, I think, and Dave you know this better than I, but I think in the past when HL7 has gotten into it, they've relied on third parties to do any tooling work they might have done.

David Kates – Director of Interoperability – The Advisory Board Company

Yes...Dave. Agree with your assessment and sort of the overall bullet. I had similar comments, I think, that it might be...it's an unfunded mandate; I mean it would be nice to ask the SDOs to do it, but I just don't think it's feasible and we need t...it needs to be funded, whether that's government funded or industry funded or whatever, but the SDS is...funded.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

This is Kyle Meadors and from the, I mean, and I've been involved with a lot of industries outside of even healthcare and in the area of testing and I think want to just acknowledge is that test tools are important, but they're just...they're not an insignificant undertaking and it's basically like a product that you have to support and maintain...

David Kates – Director of Interoperability – The Advisory Board Company

Yeah.

Kyle Meadors – Director of HER Testing – Drummond Group, Inc.

...it's not something you just build and it's there static, for the most part; it has to be updated and supported. So, I think also when you look for tools, and if we could funding for that to do that at the same time I also think there's a lot to be said about looking at areas that are not just test tool focused, whether it's...I think people made some comments earlier about maybe looking at things that are in current deployment for production to utilize, as far as actual...say, examining a function...a system working with the lab right now and using that...of guidance.

So I mean there has to be a balance, we can't just think we can just rest on a test tool solely, just because it's a lot of work and you've got to find the money to support it and the people to do it, not just one time, but ongoing. Because as specifications evolve or improve, if you want to use that term, the tool has to improve as well, it has to be maintained. So, it's just something to remember, it's not a...there's no silver bullet here that we could just get a test tool and we'll be fine. And I definitely agree, SDOs already are kind of largely volunteer driven to get the work done with what they're doing now, let alone to add on top of making a software product.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

This is John; I think that's a great comment because it kind of ties into what Sarah brought up with deeming; these are all approaches that don't build a dependency on building a new conformance tool that frankly I think a lot of the issues we saw with tools in 2014 certification came from just that. No criticism at all of the NIST folks dealing with compression of time, dealing with available resourcing, but it's a fairly predictable result early on that we saw with the instability we did. So, it might be a hardening of the certification process to make it more tolerant of accepting deeming, accepting production use proof, things of that nature to get additional avenues of potentially more credible proof that the market will find more value in than a fairly academic test case.

David Kates – Director of Interoperability – The Advisory Board Company

This is Dave...oh, go ahead.

M

Go ahead Dave.

David Kates – Director of Interoperability – The Advisory Board Company

So this may be a red state/blue state comment but, I mean, it seems like either if we think certification and the need for conformance, interoperability is something that we want to certify to make it regulatory, then we need to be funded by the certifying body or government. Or the flip side to approach is, if we make it a requirement that industry have some level of interoperability and it behooves industry to create the set of test tools on my own and they self-organize that's fine, too. But it just seems like it's one or the other, I don't think we can just mandate outside that SDOs should do this, because that's just...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, Dave, I'm right there. I guess what I'm trying to do, too, is to see if we can boil up some of these recommendations into things that are powerful kind of overall recommendations to supplement many of the important detailed comments we have. And I think this slide is amenable to that and I'm offering up for the workgroup's consideration that there's maybe three really nice principles in here that we should look at. One of which is the idea in the first bullet, more simple testing rather than more stringent leading to the aim of reproducibly high quality interoperability seems like an idea that we have returned to many times, but we've never been able to really fully crack. And I would suggest that that's a great candidate for a strong recommendation from this group.

The second is the idea of pre-test and post-test being congruent; I guess that's in the previous set of recommendations...sorry, that was number 2. But then the other one is this idea that to recognize that testing tools need to be robust to even move this mission forward, that SDOs are not likely to be that venue. And Dave, to your red state/blue state comment, I guess we could position it either way, but one would be if industry does not develop such a thing, or we don't see clear signs that they're doing so that the government ought to fund that activity. So I'm...

David Kates – Director of Interoperability – The Advisory Board Company

Yeah...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

...candidates for summary from this slide; the simple rather than more stringent and the second around the nature of...the mandatory nature of testing tools and that we need to call out that it's not just going to develop spontaneously. Your point, David, you were going to comment?

David Kates – Director of Interoperability – The Advisory Board Company

Yeah, no, I...this is Dave again; I like all those points; me thinking out loud, I mean, we can ev...I don't know if we want to explicitly say this but you could imagine on that very last point that if industry does not develop those test tools that there's some form of tax or some form of fund-raising associated with getting the product certified that the government would organize that activity not necessarily spontaneously fund it out of no funding resource.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

You live in DC and you actually use the word tax, I'm...

David Kates – Director of Interoperability – The Advisory Board Company

I know, I know. That tells you whether I'm a red state or blue state guy.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Oh, I'm encouraged by...

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Let's use some word other than tax...

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Well, and I do offer again...this is John, the model again, although not implemented yet of what was to be done for health plan certification where honestly they resolved red state/blue state by offering a...so I think it was intended that one would be short term and the other would pick up longer term.

David Kates – Director of Interoperability – The Advisory Board Company

Yeah.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

But one was more or less the attestation driven model proven by trading partner testing activities that kind of mimics your production evidence of capability. And then independent testing done by CAQH CORE or actually I think that a testing body designated to do it on their behalf that would provide the independence maybe as a longer term.

And a lot of that was driven, I think, by timing that not all the conformance testing capabilities were going to be in place early on in that lifecycle, but it did offer an example in federal regulation that's starting out with a self-attestation model based on production, experience or at least use of actual production trading partners to be your point of evidence, and it was auditable evidence moving to an independent testing model. So those things don't necessarily have to be contradictory and there was one instance of where it was not going to be.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

It's a fair point. So actually I'm peeking ahead and I think we've got about I don't know, 5 or 7 minutes before we need to go to public comment and do a few moments on next steps. I'm wondering if we can just peek at number 4 and 5. I think they're strongly related to number 3 and they'll help us, I think, put our arms around this. And if we can get to the end of 5, that would be good. So Brett, could you just walk us through number 4 and number 5 on the next slide really quickly?

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Sure, so again these are related to ONC, NIST and other stakeholders writing updated testing tools as well as maintaining the suite of testing tools kind of by the community at large. So for number 4, if it goes beyond what NIST and ONC may directly provide, other considerations could play in, to deem testing done by other entities like EHNAC or Surescripts where the industry has already accepted their testing role for certain purposes.

A comment here that this is going far into the future and to make sure we leave room for innovation and keep up with the market rather than limit it. Participants and authority for certification testing and inspection shouldn't change over time, just the scope of their activities; should be a single authority for

defining the scope and tooling for testing with contributions from the broader community. And then again, several referred to different remarks from various sections.

And then in number 5, how can we make the suite of testing tools accessible to broader stakeholders so they can understand what they mean for better care and so they can weigh in on clearer use cases of interoperability as well as several no comments and again, reference to previous remarks.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So with all this in mind, I guess I'd like to throw caution to the wind here a little bit and see if we can come up with a fairly strong and well-crafted set of recommendations around 3, 4 and 5. We seem to all be raising the issue about the necessity of testing and the complexity of getting it launched and who should be responsible for it. Maybe we've already beaten this to death, I don't know, but I think it would be helpful if this group, this is a big issue and if we could come back to the Standards Committee with a strong recommendation, we have more chance of actually moving the ball; raising that as a challenge.

David Kates – Director of Interoperability – The Advisory Board Company

I was going to volunteer, but I can only take the one thing.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Cris, this is John. I think this kind of merges in...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Um hmm.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

...Sarah's deeming comment as part of the solution. That goes towards leveraging other programs that may already exist in industry; that's not going to be universal. It brings into point the transparency point around objectives that...or criteria that don't lend themselves to very much value for conformance testing to one standard, all the public health and the lab. And then I think it brings into play the role of self-attestation that's probably the same thing in a way. And then finally from a tooling standpoint, really reserving the investment in tooling to be, I think what Dave was saying was self-funded in a way that...or supported at least in part through user fees, I won't say taxes.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Well done Mr. Kansas.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yes, to go...yeah, exactly. To go seek that kind of testing resource to be developed and available where singular specification and independent conformance testing really is of value.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Right. That sounds like a pretty complete suite. I also really like the first bullet about the idea of more simplified and complete as opposed to stringent.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Yeah.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I don't...I'd love to get a sense of the group whether they all buy in; sounds like you believe that, John.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Well, and the consistency that...honestly there's nothing wrong with these tools being available for whatever purpose they're put to vendor preparation, testing as part of certification or for the implementer to go say, I wonder if this really holds up.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Right.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

And by implementer we might be talking about the vendors consulting people and not necessarily the provider. I think all those things hold up.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yup. Other comments? Well I wouldn't be surprised if John Travis did a great job of summarizing on behalf of the group, that happens often but are there other comments? Or are we just worn out?

David Kates – Director of Interoperability – The Advisory Board Company

The former, John did a great job.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Thank you Dave.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Yeah.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

I hope somebody wrote that down. You have the transcript.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

That seems fair. So I guess what I would want to do, mainly we're just going to talk about next steps here for a minute. We have a couple of other items under I-1 and then we've got to get to I-2 in our next discussion and I think we want to come up with, as much as we can, a clear set of strong recommendations with some detail to follow.

We had one volunteer group which was to provide some feedback on the state and nature of C-CDA conformance and whether when the workgroup assi...delegated that outwards to working groups last summer, is that succeeding or not and if not, what other actions are needed? That's the Kates/Corley/Travis and fellow travelers group. Am I missing anything else in terms of next steps that you all can think of?

David Kates – Director of Interoperability – The Advisory Board Company

Nope.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare

Nope.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Michelle, Brett, Scott, anyone else from ONC, are we hitting the mark? Is there anything you would suggest different before we convene next time?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

This is Michelle, it all sounds good to me.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

Yeah, this is Brett, I agree.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Okay.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services

Yeah this is Scott, I'll echo Brett's comments earlier, we'll get the feedback combined from today and try...and sent back so that we can work from there as a starting point.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

That would be great. I mean, I think you guys did a really good job of summarizing these materials into a set of bullet points out of a lot of really well-written comments. So...and I know that you did it at the last minute at Liz and my request; thank you very much for doing it, I think it improved our conversation. So when do we...

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology

I think so, too and we will aim to have it out a little bit earlier than just hours before this time.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Okay. Perfect. When is our next meeting, Michelle?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I'm looking, but if somebody knows sooner...

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Sorry, didn't mean to call you out here.

Caitlin Chastain – Junior Project Manager – Altarum Institute

March 13.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yeah, March 13; thank you, Caitlin.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

All right, thank you. So we've got two weeks from today before we're back together. So if there is a chance for us to be able to get these materials out, as you said, maybe a couple of days before, then we can steam into the meeting on March 13 with some energy. This is a good conversation, these are exactly what this workgroup is good at, thanks. I think at this point we need to turn it over for public comment.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, Caitlin, can you please open the lines?

Caitlin Chastain – Junior Project Manager – Altarum Institute

If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

While we wait for public comment, so as we talked about, we have a number of next steps that we need to take. So we'll follow up via email to sort of remind everyone of the things that we decided today as far as forming that small group and following up with John Travis, David Kates and Sarah Corley. And we'll work towards being ready for our next meeting. And it looks like we do have a public comment from David Tao. David, just a reminder, you have 3 minutes for public comment. Please state your name and your organization and please go ahead.

David Tao, MS, DSc – Technical Advisor – ICSA Labs

...ICSA Labs. I co-chaired the S&I Transition of Care Workgroup that produced the companion guide to C-CDA that was mentioned earlier in the call and I wanted to just clarify that that was intended as a companion to help in MU 2, not MU 3; but as was correctly observed, it's only informative, not binding and even so, it doesn't fully address all the C-CDA constrained issues that have been raised. So that work is still needed.

I'd like to inform the workgroup there's a new project within the HL7 Structured Documents group called Relevant and Pertinent, which is about C-CDA and is intended to provide guidance to make the C-CDAs more usable by avoiding the unhelpful data dumps, you know, huge C-CDAs that have occurred sometimes in MU 2. However, I'm not aware that there's a project within HL7 Structured Documents to work on further constraints to C-CDA and I think there may be some confusion within the industry as to who is responsible to do this C-CDA constraining work.

And on one separate point, I support Dr. Corley's suggestions for attestation in areas with high variability like lab, immunizations and surveillance. However, that does bring some...its own set of problems since a live interface may have been achieved through customization and localization at additional fee, so it doesn't guarantee that the next customer can get that live interface out of the box. So I suggest there be some transparency to attestation so that just having a long list of live interfaces

doesn't get misinterpreted as implying that everything is plug and play. Thanks for the opportunity to comment.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Thank you, David that was very helpful.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And we have no more public comment at this time.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

All right; well I think we can give everybody back 2-1/2 minutes for good behavior.

John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation

Appreciated.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks Cris and have a wonderful weekend everyone.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Thanks Michelle, don't...

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services

Thanks everybody.