



HIT Standards Committee

Final Transcript

January 27, 2015

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. 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 will now take roll. Jon White?

P. Jonathan White, MD – Acting Deputy National Coordinator – 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, Jon. John Halamka?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Here.

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

Hi, John. Andy Wiesenthal? Anne Castro? Anne LeMaistre?

Anne LeMaistre, MD – Senior Director Clinical Information Systems & Chief Medical Information Officer - Ascension Health

Present.

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

Hi, Anne. Arien Malec?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

I'm here.

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

Hi, Arien. Marty Harris?

C. Martin Harris, MD, MBA – Chief Information Officer - Cleveland Clinic Foundation

Here.

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

Hi, Marty. Charles Romine, Kevin Brady for Charles Romine?

Kevin Brady, MS – Group Leader, ITL Interoperability Group - National Institute of Standards and Technology

Yes, here.

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

Cris Ross?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

I'm here.

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

Hi, Cris? David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Here.

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

Hi, David. Dixie Baker?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm here.

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

Hi, Dixie. Liz Johnson?

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

I'm here.

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

Hi, Liz. Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Here.

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

Hi, Eric. Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Here.

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

Hi, Floyd. Jamie Ferguson?

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

Here.

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

Hi, Jamie. Jeremy Delinsky?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.

Here.

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

Hi, Jeremy. John Derr?

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

Here.

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

Hi, John. Jon Perlin? Keith Figlioli?

Lauren Choi, MA, JD – Senior Director, Federal & International Affairs - Premier, Inc.

Hi, this is Lauren Choi calling in for Keith.

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

Okay. Kim Nolen?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Hi, Michelle, I'm here.

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

Hi, Kim. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi.

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

Hi, Leslie. Lisa Gallagher?

Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy & Security – Healthcare Information & Management Systems Society

I'm here.

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

Hi, Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Hi.

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

Lorraine Doo?

Lorraine Doo, MSWA, MPH – Senior Policy Advisor - Centers for Medicare & Medicaid Services – Health and Human Services

Yes, I'm here.

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

Hi, Lorraine. Nancy Orvis? Becky Kush? Sharon Terry? Stan Huff?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Here.

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

Hi, Stan. Steve Brown? And Wes Rishel?

Wes Rishel – Independent Consultant

Here.

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

Hi, Wes. With that I will turn it over to you Jon White.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you, very much, Michelle. On behalf of Karen DeSalvo, Lisa Lewis, Jodi Daniel, Steve Posnack and the rest of the ONC and federal family, a very happy 2015 to you. Thank you so much for your time, energy, effort, commitment, all the wonderful things that are happening and especially in light of a short meeting today and the weather conditions that persist, at least for some of us, really appreciate both your time and the power in your house that is allowing you to continue to participate in this; so, thank you for being with us today and for bearing with us as we abbreviate the schedule to be able to accommodate some of the changes that are happening in our different environments.

So, I will just...given that it's a brief meeting I'm just going to offer a few brief comments. To me the importance and relevance of the work that you have done here and that you will be doing over the coming year is only growing. You all are well aware of some of the large moving objects in our field which include the Federal Health IT Strategic Plan which you've seen, the forthcoming draft Interoperability Roadmap and other large significant products that will be coming forward for review that shall remain nameless at this point. But there is a lot happening in our area right now and our renewed attention and focus to both advancing the standards and policies around standards for the purpose of interoperability and the pursuit of better health is really becoming more obvious everywhere we go and in everything that we do.

Yesterday the Secretary announced significant initiatives related to delivery system reform related to moving a significant amount of Medicare and Medicaid payments into value-based purchasing programs and good information is just absolutely key to making that happen. So the relevance of what we do goes well beyond just the health IT space and is getting into all of healthcare. So, with that I'll stop, I'll thank you again for your contributions and your efforts and I look forward to the discussion today.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, hey, I think that's my cue Michelle. So, it is a compressed meeting and we have two major items on our agenda today. We will get to the approval of minutes, don't worry, Michelle. Our two major items, we'll hear from Arien and Stan Huff about their S&I Framework Task Force and really the purpose of this Task Force is to ask what is it given the challenges that Jon White has just told us about, the 10-year Interoperability Roadmap, the Federal HIT Strategic Plan, changes in Medicare reimbursement that we need, from a standards making perspective, to support those efforts. Is it the S&I Framework, it is something else? How do we build on what we've learned and then create a path forward to the future? So, we'll hear more about the "how" and the "what" than an answer to that today but they'll outline a very important process.

We'll also hear from Lisa Gallagher on data provenance and reviewing, well what is the classification scheme we want for data provenance? What use cases should we use? How do we focus and scope that work? And we will have some recommendations from Lisa and I understand there will be, as we often do, a vote, a show of support that that direction, that set of recommendations seems very reasonable and then of course we will have public comment.

So, as Jon White said it's going to be an exciting year. I mean, this is a kind of almost hiatus period in a federal advisory committee perspective because we are catching up on work from 2014 while we are awaiting the very imminent release of the 10-year Interoperability Strategic Plan and the Meaningful

Use NPRM and the finalization of the HIT Strategic Plan. So, all of those remember are going to happen over the next couple of months in 2015. So we will have an immense amount to react to.

So as Jon said, certainly thank you for your enthusiasm and your support. And if for some reason Michelle, I have to urgently leave the call, that would simply be because I am staring at about 5000 trees all bending at a 20° angle and I can only hope that the power and the house stays intact during this call. So Michelle, let us ask if there any amendments or revisions to the minutes? Okay, well none being heard, those are approved by consensus so Michelle, I will turn it back to you and then we will get started.

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

Okay, thank you, John and hopefully you will be safe for the next half hour...hour and a half, I'm sorry. So, let's turn it over to Stan and Arien to give a brief update on the new task force for the S&I Framework.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Okay, this is Stan. I'm going to do the first couple of slides and then let Arien do the heavy lifting and Jon stole all my thunder. So, anyway, next slide. So the charge to the committee to the task force was to consider the question, do we still need the S&I framework? Are there things that should be done or that are appropriate roles for that S&I framework and...or as the time passes, they're...things have changed and we don't need it anymore.

And so that's the first question, really, should it continue to exist and...but then, if whichever way that question goes, if there isn't a reason, then figure out what we would do to close out the current work. But if there is a purpose for the committee to continue or the S&I Framework activities to continue, then how could we make it better? Should it be done differently, even though those same requirements and goals exist and an opportunity to provide value, could it be organized or done in a better way? And so that's the charge of the committee and next slide.

In considering that then, we...Arien and I are Co-Chairs of the committee and then we have the folks that you can see listed. We tried to keep the group small enough that we could have good discussions and also we tried to make it kind of an equal blend of vendors, providers, representation from HL7 and from IHE; people who that are really good at technical things and some people who are maybe more working at the requirements and goals level. And so we tried to make it as balanced as we could and I think we've got an excellent team and certainly from the first conference call, we had had great insights and discussions. So, I'll stop there and let Arien describe what we discussed and where we're at. Arien.

Arien Malec- Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you. So we divided our work into two parts; the first part was exploring what are the key jobs that SDOs and other organizations don't have in their mission or operating plans, but that may well be important for national needs and make some recommendations on what key jobs national facilitation might address. And we weren't implying or presuming that there were any key jobs, but this was a really important first step to establishing whether something like the S&I Framework should indeed exist.

And then the second stage is presuming that we conclude that there are appropriate jobs to be done, we will then evaluate the "how." So, evaluate the current S&I Framework against some criteria for completion and make recommendations for how the S&I or equivalent organization should conduct its

mission or whether there needs to be a reorganization of function. So again, just splitting the “what” versus the “how;” the “what” is evaluating key jobs to be done that help fill in gaps that SDOs currently may be occupying.

Our conclusions...tentative conclusions out of the first meeting, so it was a very productive meeting, were that there were...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Do we want to advance the slides, Arien?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

...oh yes, sorry, thank you; if you could advance the slide? So our tentative conclusion was that there are some key jobs to be done, and we’ve listed them here. This was based on a pretty good amount of discussion, as I said, in our first meeting.

The first job to be done is to support and identified national priorities, I’m going to put an asterisk on identified national priorities because that will come into our work plan; support identified national priorities by reducing optionality, coordinating across SDOs and supporting SDOs and facilitating consolidated artifacts; so examples of consolidated artifacts may well be a consolidated implementation guide that’s associated with aspects or areas that are relative to national priorities.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

We should be on slide 5 I think, folks.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you, I’m having trouble with the web conference so I’m reading off the slides; thanks Stan for keeping us honest. Let me just wait a second to see...are we synced back up?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

Yeah, yes, I’m seeing slides now.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Perfect. Okay, good. Excellent. So, as I said, first job is support identified national priorities by reducing optionality, coordinating across SDOs and supporting SDOs and facilitating consolidated artifacts.

The second major job to be done is supporting production use by facilitating pilots and effective production implementation, feeding learnings back to SDOs; for example, reducing optionality, clarifying ambiguity, all the things that happened when you take a putative standard implementation guide and try to implement it and then evaluating success of standards and implementation guidance in achieving national priorities.

A third major goal is to facilitate effective participation in SDOs. I’m going to put an asterisk there and just do a little comment at the end. And then the fourth is recommending needs for infrastructure and non-traditional SDO artifacts. So some examples that came out of discussion are the need for value sets and value set curation; the need for provider directory data sources and potentially even working infrastructure. So an example of this is the CMS NPPES Modernization that is currently going on that has one of its aims to supply data for provider directories. And then a recent example that I think was somewhat poorly coordinated was the need for organizational identity assurance to support Direct and

support other kinds of health information exchange in the large where DirectTrust kind of filled in the breach, but we had an awkward transition from the Direct Project to production use and some more organized work might well have sped the glide path between standard implementation guidance and production use.

I put an asterisk around national priorities. We had some discussion about that one of key functions is to identify national priorities. We had some perspective that although federal partners willing to spend money is an indication that there may well be a national priority, it's not a presumption that there is a national priority. And I think there has been comment in the past that priorities doesn't mean anything anybody wants, it probably should be small and targeted. So that's going to be our next area of the work plan. If you go on to the next slide, slide 6, is to look at the framework for looking at national priorities. And then to further discuss aspects of the "how." So I'm going to pause there Stan, if you have anything else you want to add to that overview.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

No I...no, that's good. Thanks, Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Then we turn it back to the committee.

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

Thanks Arien, we actually have a question in the queue from David McCallie.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

What a surprise.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I didn't want to disappoint you. I think you may have answer...at the end of what you were saying, Arien, you came closer to what my question was addressing; I had raised my hand at the beginning of your explanation of that slide. But, I'll just make the comment anyway that I think the...to me, the key think when you kick off one of these groups, which is going to cause a...if they continue, they cause a lot of part...I mean, they lead to a lot of participation, a lot of effort by lots of stakeholders, so they are non-trivial exercises. Once one gets kicked off, it matters and it consumes a lot of people's time and energy.

So it's really important to know that you are, in fact, solving a problem that needs to be solved. And I think that one of the suggestions that I would have is that, when it's contemplated that an S&I project be kicked off that there be better clarity, at least compared to the past, about what problem we're trying to solve and why it is a priority. So, you talked about national priorities, I think that's the higher level goal, but then what problem are you really trying to solve; if you don't understand that, then the group will end up going off in directions that are driven more by the interest of the people who chose to show up than by an actual commitment to solve a particular important problem.

And I suspect, this is a second comment, that in a future where we have better access to standard APIs, like we are pushing for in other parts of our work here, that the notion of quickly assembling things that you can do on top of an API would require coordination at the S&I level, but maybe with less deep dive, because you have the APIs available to you to leverage. So, I can see a shifting focus in the future where it's, how do we use these APIs to achieve a very particular task, let's all get together, figure out that we

want to achieve that task then figure out how to do it and that that might be a lighter weight approach to what we've done in the past; so two somewhat unrelated comments. Thanks.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Great feedback. One of the other comments that came out in the out in the discussion relating to prioritization was the point that Keith Boone had made to me a number of times which is that the most non...resource in this area are the talent and time of key stakeholders and that proliferation of lots of functions ends up both diluting effort and inadvertently diluting talent pools out of the SDOs. So, you only have so many folks who can go around who can actually devote time, energy and effort in these areas and the more activities you spin up, the more you're diluting effort.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, and that was my lead thought there is you don't do these things lightly because there is a precious set of resources that we have to be very thoughtful about how to use, otherwise we get diluted and don't achieve things.

One third comment if I can take back...or continue the microphone here, and Arien, I'm sure you've thought about this, but I wonder if your group would surface other industries approaches to dealing with this, and I'm thinking of the Internet and the RFC process and the way the Internet evolved and sort of solved its problems in real-time as they arose with an informal but highly prototype-driven, pilot-driven process. I wonder if that's worth calling out in one of your future sessions.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

It's a good call, we do have time for a listening session and it might be appropriate for us to have a listening session that is extra to healthcare.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Stan, I don't know what you think about that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Stan must be on mute or...

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

No, oh, no I wasn't sure that was directed to me. No, I think that's a great idea. I was pondering the depth of the comment. I think that's excellent and part of the discussion we had as well and...was, I think that flows actually from part of what we listed which was, support for prototypes and implementations, a much more agile process. Because I think the other thing, even if we're doing something that's important, if we have a long...if we do a typical waterfall strategy where we gather requirements and then we design for a long time and then we build, a year later something gets done.

And in fact, as my mentor, Al Pryor used to say, you'll learn more in one hour of live use than you will in two years of sort of dry lab design. And so I'm very much in the...of the same mindset that we need to do things where we get good enough requirements, we try something early which helps us clarify the requirements and make version 2 and...because, I can tell you, I've never made version 1 that was right yet. So, I think that's an excellent suggestion.

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

This is Michelle, there are a few more folks in the queue and I just want to make sure that we stay as close to our agenda today as possible, because we have a short one. So, we have John Derr, Wes Rishel and Leslie Kelly Hall all in the queue.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Gold Living, LLC

This is John Derr; just a couple of comments. One, the S&I Framework was extremely helpful to us in the LCC or Longitudinal Care Committee that's now in the community and we're still working on it. And also I'm on the S&I Framework group for the TEFT Grant. And Evelyn Gallego is doing an excellent job and it's very, very meaningful and so I just want to put my two cents in that we should continue with the S&I Framework.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you.

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

Next up is Wes.

Wes Rishel – Independent Consultant

Thank you. I want to also comment that specific efforts within the S&I Framework have done a great deal to clarify and pound out some details that had been really aborting implementations that I think there would be...it would be good in your evaluation to look at those that made it into production to date and think about why they made it into production. Was it because of an external factor like a Meaningful Use criterion? Was it because of a short incremental change that allowed fast implementation and so forth? One of the ones that come to mind is lab reporting.

The question that I have kind of has two points of entry into the process; it's a question about the degree to which final...which testing of interfaces is in or outside of the purview of S&I? It comes up at two spots; one is prototypes or early projects or whatever you want to call that relates to Stan's version 1. Prototypes take on a...or conceptual whatever the euphemism is for an ineffective prototype; they take on...

M

(Indiscernible)

Wes Rishel – Independent Consultant

...yeah. They take on a life of their own once they become a project and they will succeed, but changes the definition of success. And so we not...I don't really mean to pick on SAMHSA because they have an extremely difficult problem and were dealt an extremely difficult hand by legislation, but we started hearing about a successful prototype of sending SAMHSA information to an EHR and it was only in digging in during questioning we found out that it had been successfully sent, it hadn't been successfully received by an EHR. And it was, in fact, an accomplishment to have gotten something out of the SAMHSA system, but it didn't have the implied readiness that one might have thought they heard of from the prototype. I think that there needs to be any one of a series of prototypes or trial implementations or pre-standard implementation, whatever you want to call it, but we need to be evaluating the goals as built in the proj...in those projects, I suppose, to the goals at the start.

The second has to do with a process that's similar to what would be called certification but would come in a different place organizationally, but we know that certification has limits based on the burden on the developer to be certified. We know that some of the most widely known and widely participated in efforts, like IHE, tend to emphasize the happy path just for the same reason, economy of resources, as opposed to sort of the kind of testing program that a developer would use for a product. And somewhere in the process of going from a glimmer in an S&I Framework subcommittee to the steps that are necessary in order to get the job done, a more complete level of testing and certification needs to occur. Thanks.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Can you go back one slide to the jobs to be done?

Wes Rishel – Independent Consultant

You want 5 or 6?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, right here at 5.

Wes Rishel – Independent Consultant

Okay.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

So I think Wes what you're talking about was captured in the phrase "effective production implementation," feeding learnings back to SDOs and evaluating success. We had a specific discussion about how prototypes and pilots aren't enough and that production implementation isn't enough, we really want to evaluate towards effective production implementation.

Wes Rishel – Independent Consultant

Right. I see that as you...and it's good to be able to see that the words are intended in the way I described; look forward to the results.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thanks.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie and I have two comments; one is the S&I Framework also did a good job starting to represent people that were in stakeholders like consumers and patients that weren't always on the table. And so I hope that you're review puts that in mind. To John's point, the long-term post-acute care group is not often represented and consumers are also not often represented and I think it's an area where the beginnings of that took place. That's one comment.

And then the other is, I noticed in your review you talked about an organizational level or assurance and identity and we will continually see the need for the patient and the consumer and I believe the White House has an intern there that the HIMSS has helped to work with on discussing identity matching and I wondered if that was also included in your review; sort of an orphan piece of work that needs to be done.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thanks for the comments. I mean I think the first comment is much more about a “how” and the second comment is an example of the kind of supporting infrastructure that isn’t traditionally captured by an SDO. We’re really looking at the process as opposed to the actual deliverables and outputs. I think those questions would be subordinate to a determination on national prioritization.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Arien, where do you see then, in your review of standards organizations, talking about the “who?” And that’s really the people who are not generally represented.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, so I think the...just to be explicit, I think the question about representation definitely is a question that we want to take up in the “how.” And there was absolutely healthy discussion about the level of participation that the S&I Framework received relative to perception of participation in SDOs. So that’s absolutely...we just punted that question because it was secondary to the question of what function the S&I Framework should achieve. Stan, I don’t know if you have additional comment there.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare

No, I don’t have anything...any wisdom. I guess, I mean, what comes to mind and being very candid is, in a situation where you have limited resources, you have to prioritize and I participated in a lot of conference calls with John Derr and he represents the long term care organizations extremely well and it...but I guess coming back to what you said is, somebody has to say what the national priority is and if its supporting long term care organizations, that’s great. I think in some sense we’re looking...it’s more of a policy decision than it is a standards decision.

I think in a sense the standards could probably work in any of those environments equally well and they could be used for direct patient access and for patient identity as well as they could be used for communications between laboratories and EHRs. So, it’s...I guess what I’m saying is that I really have great empathy for wanting to include and be inclusive of all groups and it would be helpful to have some policy sorts of decisions around that and discussions of where that...where things fall. How do we take...how do we have the greatest value for the largest number of people, whether...whatever their situation and whether they’re in long term care or whether it’s direct consumer or all of those things. It just...I’m stumbling through this because I just see it as a difficult problem in a resource-restricted environment.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Stan.

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

Okay, well thank you both to Stan and Arien for the update and I’m sure we’ll hear more, maybe at the March meeting. And so now we’re going to turn it over to Lisa to provide the data provenance recommendations. I just want to thank Lisa for her dedicated support. We...this was a very rapid work effort and she has given us a great deal of her time, so thank you so much, Lisa and we’ll turn it over to you now.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you, Michelle. Could we go to the next slide, please? Okay, so I'm going to talk today about the Data Provenance Task Force. Our task force...I'll introduce the members in a moment; we were given a specific charge in the form of a specific question and supporting questions from ONC. So when we go through our recommendations today, we'll go through in that format; we'll introduce the specific question and the supporting question and provide our recommendations related to those. And then we'll follow with a committee discussion. Next slide, please.

So I'd just like to spend a few minutes talking about the task force and its approach. As Michelle mentioned, the task force started and completed its work in the month of January. So, we introduced our task, we had three meetings. We analyzed the documents and the input that we got in between meetings. We spent the third meeting coming up with recommendations and prepared ourselves to be here today.

So, I'd really like to commend and profoundly thank all the members of the task force and the ONC support team. That compressed schedule was very daunting, but that didn't preclude a lot of work in between the meetings and dedication by the task force members to completing our task. So here's the list of task force members and I just wanted to say thank you to everyone.

So the...I also want to say a few words about our approach before we go to the specific charge that we had. Our work included a review of the S&I Framework's Data Provenance Initiative, so that was the scope of our focus. We reviewed their use case, their executive summary documents related to that use case and, as mentioned, the set of questions by ONC. ONC also provided a format and sample recommendations for us to give us some guidance. We had some informational briefings from Johnathan Coleman, who's the project lead for the S&I Data Provenance Initiative and he's on the phone with us today, in case we have any questions for him.

We spent the second meeting getting some additional input. We decided to have an extended public comment period with some invited panelists, so we also heard from Reed Gelzer of the HL7 Records Management Evidentiary Support Workgroup, Gary Dickenson from CentriHealth and Adrian Gropper from Patient Privacy Rights. And we had an informational briefing from the S&I Framework's eSMD Initiative or the Electronic Submission of Medical Documentation for Medicare Fee-for-service initiative. So we got quite a bit of public input, because we thought that would be critical to the formulation of our recommendations. So, on to the specific question from ONC.

Okay, yeah, the specific question; given the work that's already been done in this community developed S&I Data Provenance Use Case, what is the first step in the area of data provenance standardization that would be most broadly applicable and immediately useful to the industry? So then even in consideration of the more specific...the more detailed questions, our charge is to identify a focus that could be broadly applicable and immediately useful. And we believe that we kept our focus on that. Next slide, please.

So these are the supporting questions and as you see, as we go through the slides, you'll see that we map our recommendations to these questions. I want to review them quickly. There are three scenarios in the current use case and in looking at the scope and those three scenarios, are there any areas of data provenance that are missing? The second question is, the use case is very broad and it spans a lot of challenges. Where should the initiative start in terms of evaluation of standards for...to meet the use case requirement? And also, are there any architectural or technology specific issues for the community

or that initiative to consider? So those are the three questions and with that, I'll move on to our set of recommendations. Next slide.

Okay. So, the format that I'm going to follow is that for each of these questions we have a high level recommendation and then some more detailed recommendations. So for question one, we do have a high level recommendation or a way to frame our recommended focus for the Data Provenance Initiative. So in looking at the use case, the three scenarios and its identified scope, the task force felt that the use case may be over-specified. And in using the term over-specified, the task force means that when considering provenance data, we may not need to know exactly where the data has been, but rather what is the origin and the source of the data and if it's been changed.

So we'll address each of these topics as we go through the briefing to follow. But we also covered the area of can I trust the data? And we'll have some comments on that as well. But in keeping the scope fairly straightforward, this is the sort of overarching framework that we were working with. Next slide, please.

So related to the first question, our detailed recommendation includes a recognition that we should probably focus on the provenance data from the perspective of an EHR. So begin with the focus from that perspective and include provenance for information that is created in the EHR and when it's exchanged between other parties. Provenance of the intermediaries is only important if the source data has changed. So, this italicized comment here, the notion of who viewed it, conveyed it without modification along the way may not necessarily be important for the provenance data, as long as the information or the data itself wasn't changed.

I also want to note here that as I did here and I will again in subsequent slides, there's a lot of terminology throughout, starting at the EHR or EHR-to-EHR exchange, but I want to point out that the task force believes the goal is to define requirements and is a simple use case to start with, but that these can also apply to content that's received by a source system where that source system is patient controlled. So the provenance data would contain information to identify that source. So we're not limiting to the EHR, this is just a starting point and we have considered and feel that the issue of source system that is patient controlled has been considered throughout. Next slide, please.

So this is a pretty detailed slide meant to convey a lot of information but at the highest level, the task force recommends that the initiative should differentiate between communications or information exchange requirements and then system requirements. With respect to the communication requirements, the task force emphasized that data may be traversed through multiple transport protocols and that transport or conversion should be lossless that is, the content should be unchanged and that's the notion of data integrity. But also the integrity of the provenance data should be maintained.

With respect to the system requirements for provenance, the task force advises the initiative to begin its initial focus on the provenance data from the perspective of the EHR, as stated on the previous slide, at the time of import, creation, maintenance and export. That they should...the initiative should evaluate the existing work of the FDA that defines a set of basic provenance requirements and the definition for the term "source of the data." And again, the task force stresses that provenance data should be agnostic of transport technology and should be maintained regardless of the transport protocols which it traverses. Next slide, please.

And so here are our recommendations three, four and five as they relate to question number 1. This third recommendation relates to the implications of any change to the original data. So the task force recommends that the definition of “change” should be evaluated and specified. The task force also recommends that any change to the data, for example amend, update, append or other changes, should be considered a provenance event and finally that the information relating to the change to the data should be stored and maintained as part of provenance data.

The task force did consider that there must be mechanisms for traceability back to the actual original source data itself sepa...but, that perhaps we should consider that this should be done through linkages to prior data and may not be maintained as part of the provenance data. And that leads us to the next bullet, recommendation number 4; that audit and other security functions can play a separate but nonetheless important role in the overall set of information about the data. This is an area recommended for focus for the Data Provenance Initiative. So how does the security data relate and how does it enhance the trust decision down the road?

And finally, we did note that it’s possible that the initiative could encounter policy questions and if that happens, they should identify those and communicate them to ONC and to the Policy Committee. And one example of that here, in consideration of the decision downstream to trust data, there might be a need to discuss levels of trust and types of data, whether its provenance or security data that might facilitate that decision. So defining levels of trust might be an example of a policy issue, so we just ask that the initiative be mindful of that possibility and consider seeking the advice of ONC and the Policy Committee, if there is such a challenge. Okay, next slide, please.

So this is the second of the specific questions that were provided by ONC. The use case is broad and spans a lot of challenges; where should the initiative start in terms of evaluating standards to meet these case requirements? The optional response that we were given had four items and we were to order them in terms of priority. So we did provide the order here, a through d; again, we wanted to emphasize though that the initiative should, out of its work from the use case and...to perform some more foundational work, clearly differentiate a set of basic or core requirements for provenance. As we said earlier, the task force believes the goal is to define a core set of requirements and a simple use case and that can also apply to contents received by other source systems including patient controlled sources. So we did do this order, but again our focus and our reminder is on a basic set of core requirements for provenance. Next slide, please.

Some more specific detailed recommendations on items that came up during our discussion; the task force does recognize that the term “origination of patient care event record” or “point of origin” has been discussed by the initiative previously as to whether to include or exclude this from the use case. For example, for quality measures, clinical decision support or researchers it might matter where the data was manually entered into the EHR or if it came from a device.

So we think that the initiative should continue to look at this topic. We think that we will be informed by understanding the core requirements for EHR reliability and source record authenticity...authorship, amendments and audit ability. There are some other related considerations here on this slide, and again, we refer the initiative to work done by the FDA in this area, particularly the e-Source Exchange Guidance Document. Next slide, please.

A second recommendation for question number 2 is that the initiative evaluates the CDISC Operational Data Model maintained by CDISC. It is a specification for the acquisition, archive and exchange of

metadata and data as it relates to clinical research studies, but they have addressed many of the challenges that the initiative is seeing and we view that as a recommended source document or standard for evaluation by the initiative.

The third recommendation reflects that the task force was mindful that there may be some value in reviewing related regulatory requirements or program specific requirements or other sources of requirements that may have an impact or applicability to the provenance question. We've listed a few examples here, but in general, just to a requirements review and see if there's anything that might impact the basic core set of provenance requirements. Next slide, please.

So question number 3, are there any architecture or technology specific issues for the community to consider? So here we feel that these are good questions, but that at the basic level these questions will be informed by the development of a basic set of requirements for provenance data. We had recommended in item "a" that when thinking about whether to refine the provenance capabilities for C-CDA while supporting FHIR and other questions that they consider related work on HL7 projects, and those are listed here.

There's also source data capture work review of 21 CFR 11, which is an FDA regulation on electronic signatures and other security standards that may be relevant. So here we think that with the core set of requirements defined, this will inform the question of whether we need to refine specific provenance capabilities for specific systems. And then for item "b," the task force reiterates from previous slide that for information exchange the provenance of content should be lossless. And I believe that concludes my slides...let's see, next slide.

Yes, so I think Michelle, I turn it back to you for committee discussion or any comments or input. I also would note that I have on the line Johnathan Coleman and members of the task force who please are welcome to participate in the discussion. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And Michelle, given that we are going to vote on this one and make sure that we can forward the recommendations through the usual ONC process, I'm happy to lead the committee discussion.

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

Okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so, are there comments in queue?

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

There are a number of them. Do you have a comment first, John?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, and so in general, I think what we've heard is that we're refining the scope, we're limiting the use case, we're thinking about how do we understand where the source of data was and how is there integrity. So, I mean, as I react to seeing these slides, the devil will be in the details of operationalizing it and figuring out how, within the context of existent workflows this will happen; but certainly the notion of scaling back the use case and directing it to just these couple of points seems very reasonable. But, let us open it up to your reactions. So who is first in queue?

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

David McCallie.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

David.

David McCallie Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, I'll echo what John said. I...hats off to the task force for doing an admirable job of showing us how this feedback process to some of these S&I projects can be useful. I think the...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thanks David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...S&I team...yeah, great work. The S&I team cast a broad net, surfaced a lot of possibilities and then an external group of experts helped focus narrower and prioritized those and I happen to...I think I agree with your priorities to the best I understand them. The only concern or complaint that I might have is that we...you've already finished your work and nobody else had a chance to review it until now, which is a timing issue, not a...not something you chose to do on purpose.

But, I like this process, I think this is exactly what we need is feedback and focus on problems that need to be solved. You know, this is one of those cases where a little bit of effort can achieve a lot, a whole lot more effort won't achieve a whole lot more. So we need to find that inflection point in the curve where we get the maximum benefit for the most reasonable effort and I think you guys have nailed it pretty well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you, David.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, others in queue.

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

Wes Rishel.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Wes.

Wes Rishel – Independent Consultant

Thanks. I also would like to applaud the common sense involved in this set of recommendations. I have a couple of questions or comments, some of which you may have addressed on the more detailed slides, but, you talk about emphasizing EHR interchange and yet the source of a lot of data is systems that certainly might or might not be thought of as a module of an EHR but are not a complete EHR, such as a lab system, a radiology information system, a dictation system and so forth. Because those are the source of the data, wouldn't that be important to include them in the recommendations from the start?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes, so to clarify; we recommend that the initiative focus on the provenance requirements of an EHR and we specifically note that there is a way to capture and specify source for the data that is received to an EHR. That could be a patient controlled system, a device and other types of systems. So, the scope of the definition of the core set of requirements would be that provenance data needed by an EHR and that does include source data. Hopefully that's clarifying.

Wes Rishel – Independent Consultant

Okay, well then, the question is, are you distinguishing between those systems used by clinicians to create source data and personal care devices, but...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

Wes Rishel – Independent Consultant

Okay, thanks.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So what we've asked them to do is look at the work the FDA has done on defining source and how it offers a standard for specifying source to include those options.

Wes Rishel – Independent Consultant

Okay, but in prioritizing the...never mind, I think you probably have got it.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Wes I think...this is Becky Kush and I'm on the task force...

Wes Rishel – Independent Consultant

Yes.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

...and I think we wanted to make sure that we go back and look at the requirements and that they would support all of those exchanges.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

Wes Rishel – Independent Consultant

Well, there's no question in the long run this presentation was about prioritization, EHR came first and I'm only raising this issue because the EHR is not the source of a great deal of the data, particularly the data that might go through several intermediate steps and be trusted by a clinician downstream.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Absolutely right and this was a lot of discussion that we had on this task force. So, I think if you look at what's been done in the FDA document that there is a common set of requirements across all of those exchanges and that's what we were trying to shoot for.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah...

Wes Rishel – Independent Consultant

Okay, I...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I think I failed to clarify that, Wes that when we asked them to focus on a core set of requirements starting with the EHR, the assumption was that that core set of requirements would apply to all of those types of exchanges and that this was just the specific use case that we would start with.

Wes Rishel – Independent Consultant

Okay, well, I mean, I think there are problems of economics, problems of policy levers around...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Wes Rishel – Independent Consultant

...putting ODM into an App that reads blood pressure on my arm and I would...just trying to understand whether this is one swell foop or whether you expect to get...to make some incremental steps along the way in terms of the impacted products that would have to change in order to support provenance. But I think you understand my general concern, rather than take a lot of time, I'd like to move on.

The notion of protection of data from change has several subtopics and I'm just trying to determine which you're addressing. There's the overt change made by a clinician looking at a record and saying, that's wrong, I'm going to change it or that we have...that clearly needs to be a provenance event. There are possible changes of unknown impact that happen when codes are translated from one character set to another and I'm wondering is that level of change in the semantic accuracy of an event considered...do you think that should be considered a provenance event or not?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So Wes, in our...oh.

Wes Rishel – Independent Consultant

Go ahead.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I was going to say, in our recommendations; I think we recognized that the use case in that it didn't have a specified set of core requirements, didn't seem to have considered the definition of change and the implications of types of changes and how those could be incorporated into provenance data. So, our recommendation was higher level, consider this topic and in fact, have it part of the core requirements definition.

Wes Rishel – Independent Consultant

Okay. If you found that for a change, you certainly must have found that for the requirements for trusting.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Wes Rishel – Independent Consultant

So I don't need to belabor that point. It's not clear to me where you come out with regards to the issue of data shredding. So a report that has a certain provenance comes to an EHR; there are coded clinical data in there that can be split out into discrete items in the database of the EHR and then a composite is created later. Is your position that in the composite the source of the discrete data items must be tracked or that the composite is a new, effectively a new document with new provenance that would...that doesn't need to be tracked back to the source; so we don't really know if so and so reports lab values, we don't really know what lab they came from and so forth.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right, that topic was discussed pretty thoroughly and it is pretty vexing of a challenge. We did view that we should consider...the initiative should consider that the provenance data should persist and that the information about the original source of the data may not be retained, but could be determined through linkage, whether it's through audit data or otherwise. But this is something that we are asking the initiative to specifically consider. I don't know if anyone else wants to chime in; there were several folks who helped us work through that. Johnathan, did you have any additional depth on that for me?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Thanks Lisa and I think these are all really good questions and they're things that we've discussed a little bit in the initiative, but we definitely look forward to taking these recommendations to the next level and really drilling down into the weeds as we move forward. So, I don't have any specific comments on the recommendations at this point other than they...we've got a lot of work to do and they seem like excellent guidance on how to proceed.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, so Wes, I guess I would sum it up in saying we did talk about that and we think it's a really hard question that they need to specifically address. There are lots of implications there and there's some source work to go through and some decisions to be made and that is definitely an area of focus.

Wes Rishel – Independent Consultant

Yeah, thanks. So I'm done, but John, I would like to ask you before we vote to have them put the specific things that we're recommending...that we're concurring to back up on the screen.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Who else do we have in queue?

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

Arien Malec.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Howdy. So I'm...so I'll admit it, first of all, I really like the work I think it was...it represents a huge state of advance over the more broad use case that was originally considered. I'm a little confused though about the recommendation. I get the notion of understanding source; I'm confused by the notion of losslessness and change. And the reason I'm confused is that I'm not sure if the scope, the original scope that you're considering is to only consider information exchange from point A to point B without changes that is that it hashes exactly the same or if you are also including in scope data that goes from point A to point B without semantic change, but may require some content reshuffling. Just as an understanding of the scope.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I'm not sure what you mean by content shuffling.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, so most of the HIE work that I do does not involve sending something from point A to point B where it is presumed that point B understands what's submitted by point A; would that it were so. So

most information exchange requires that it has a situation where point B literally would not understand what point A is saying and where the goal is to get it from point A to point B in a form that point B understands without changing the semantics of the data. So as an example, lab data transfer from an originating system, an LIS, to an EHR has clear provenance considerations and our goal is to be CLIA and CAP compliant, to make sure that the information is received in semantically the same shape that it was sent. But if I sent the information from the LIS to the EHR in the same format that the LIS mitted in ways where it would hash the same, the EHR would not understand it, would reject the transaction.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay. So I would say that in terms of priority, we are recommending that they start with the simple use case...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...most typically described by EHR to EHR, on the priority list is exchange with an HIE or other types of systems.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

So I'm...okay, maybe I'm not understanding; is your scope confined to transport considerations like Direct where it is presumed that the body of the content is hashed the same from sender to receiver? Is that your definition of losslessness?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, I mean yes and I think it is...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Okay. Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...it's only in terms of the starting priority use case.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, that's perfectly fine; I just wanted to make sure I understood it.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you Arien.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Michelle, who's next?

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

Eric Rose.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Eric.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Hi, this...my thoughts are primarily about recommendation 3 about the definition of change to data, which I think is...may be one of the most challenging things to get right; and by the way, I think the recommendations over all are great and there's a lot of wisdom in there. Number 3 reminds me of, there's an old metaphysics thought exercise about the ship of Odysseus, the idea is that on Odysseus' trip, bits of the ship were replaced until eventually there...none of the original bits of the ship were still there so was it still Odysseus' ship and if so...and if not, when did it stop being Odysseus' ship or the same ship?

And I think this is...this can really drive you crazy if you think about it too much and I think it's extremely important to whatever approach is recommended as the industry standard be simple to understand and feasible to implement given the varied data models from one system to another. And so I'm curious if your group thought about sort of an in what cases a change should simply be considered not a...or a user action in a system that results in...that involves data entry, so to speak, should be considered not a change but a creation of a new data object and the provenance chain should be broken?

And in particular, one of the things that people talk about a lot is problem list reconciliation; so you receive an inbound summary of care document and you, as presumably a qualified user, move a problem in an inbound document onto the patient's problem list in your system, thereby presumably making some responsible assertion that that really is a problem that the patient has. I'm curious if the chain of provenance was meant to be maintained in that use case, if that was anything that your team discussed.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I don...I could give you what I think my answer to that would be, but I think it's important to note here that our consideration on the topic of change was that in the use case as specified, we didn't really see it addressed. So we asked that they address it and then we...they address it in terms of the core set of requirements for provenance data, starting with what is simple and reasonable, etcetera. Those specific types of questions that you have will not necessarily be considered by the initiative. We couldn't solve those in the 3 weeks we had. But this was something that we felt had needed much more attention.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Lisa, this is Floyd Eisenberg, may I add to that as a member of the task force?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes please.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

So one of the things we discussed was related to exactly that is, at what point have you basically changed it enough that it is new information and the original source is no longer related to it. And that is why we did end up saying we really need those requirements specified and identified and that's something that...and that's really what we...our response is, we need the requirements carefully defined.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Thank you.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

This is Arien; I just want to double down on my previous question in this area of change would request that you first consider, and this may be a funny term, but that kind of semantically lossless change that I described where the intent is to simply fit a square peg into a round hole with as little change as possible because that is a very important provenance use case and I think more...much simpler than the case of send it from point A to point B, point B does a lot of editing and sends it to point C; is it still the same thing that as was sent from point A; so, just an editorial.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, I mean, Arien if you have a recommendation of a change of the wording for item number 3...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

I will be happy to send a copy of that to you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...we'd certainly consider that. I mean, I think our recommendation is high level, consider a definition of change, specify it and make sure that it is addressed in the requirements that we've recommended be developed.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yup.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

I think that that's why...this is Becky, it's important to also define the source data because that helps you define when a change is made to that data or if it's new data.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Exactly. Thank you, Becky. Michelle, other questions in the queue?

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

Dixie Baker.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Dixie, go ahead.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Hi, Dixie.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

Hi, Lisa.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Hi.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

This is great work it is a really important topic and you did a really good job and I agree with your overall recommendations and I just had a couple of comments. You mentioned manual input versus device input but did you also discuss natural language processing of textual data fields, which is, of course, an important consideration with respect to trustworthiness of the data.

And the second comment was that on one of the later slides you called digital signature a related requirement but it seems to me that digital signature should be a core...is a core technology for data provenance as well as other integrity mechanisms that we've discussed here. So I was kind of wondering why that was considered a related requirement rather than kind of core to data provenance.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, so related to the first question, and Dixie, remind me of that one?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

Oh, I'm sorry, I went through too fast. You mentioned manual input versus device input...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

...and I was wondering about whether you discussed natural language processing of text.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So what we discussed was that there is a need to define source and to look at available work on standards of specification of source, and of course natural language processing would be another example of that. This use case needs to spend a little bit more time understanding how source data can be specified in terms of provenance and then how it could impact provenance data going forward, as just discussed with the change example and others. So we didn't list that as an example but I would imagine there is a way to make sure that we specify any type of source and we need the initiative to go look at that.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

Yeah, I think...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

With regard to the second question...I'm sorry.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

...that is often brought up by clinicians so I do think it needs to be considered.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Okay, definitely. And then with regard to the second question, what I really meant to say was that we were...it's not that electronic signature would not be part of the core requirements, that's something the initiative has to determine. Really what I meant to say is there are a whole bunch of other potential requirement sources including the work on digital signature, including the work...the other works that I mentioned including regulatory and program requirements as well. So we need to understand where all the sources are for particular concerns that would help inform the creation of the core set of provenance requirements, does that make sense? So, digital signature is definitely on that list along with requirements for medical record retention, what are the data receipt requirements and digital signature is on the list as well.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates

Yeah, I see what you're saying, yeah, yeah, yeah. Okay, thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

All right. Thank you, Dixie.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Others on the list?

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

Anne LeMaistre.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Anne.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Thank you. Let me just commend the work again, I'm amazed at how much you all have gotten done in 3 weeks. Back on slide 11, Lisa, Becky, Floyd, I...let me say overall I agree with all the recommendations, I'm still struggling, however, a little bit with the sequencing on the first two items of putting the point of origin after the exchange of data and I just was wondering if you all had some more insight as on why you went that direction? Part of my concern is, many times when I get into issues in this area I usually trace them back to the point of origin, data creation and just logically it seems like that's a good place to start. So I'd appreciate your thoughts on that?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yeah, I mean, I think with regards to the order of A and B, I think we would have said A and B at the same time...it's part of the same definition of the core set of requirements. So, looking at the core set of requirements with regard to provenance for an EHR and then defining source, looking at origination, those are the core of our recommendation. So I'm not really sure that we had a way to say that we were given this list in a different order, we put it in this order, but A and B, I think, are part of the same starting place. Floyd, Becky, anyone want to add to that?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Well, this is Floyd. I think we had a challenge with this because we felt that if we could identify the requirements, we did not really feel that ordering in this way was the best way to go. But we were given a task to put them in order, so that's why they're the way they are.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Well thank you, it's good to know that you experts are struggling with it as well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

So, that's why we added a bullet at the bottom to focus on the basic or core set of requirements, because we don't that in use case as specified. It can be derived from that, but we don't have it developed. So...

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

We basically felt that if the...this is Floyd, if the core requirements were identified that they would all flow.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So Michelle, given that we have about 8 minutes left, how are we doing on the queue overall?

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

We have one person left, so I think we're perfect. Leslie Kelly Hall.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, I will echo my compliments of the work and I think by identifying that it's what data that's been accepted into the EMR and then move on from there is a great way to start. And I just wanted to make sure that the source was also considered for the patient because we have huge amount of data like demographic data, insurance information, and advance directives, increasingly more prevalent that will be accepted into the EHR and then moved beyond that. So, am I right in assuming that source also includes the patient?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

I tried to say that throughout the briefing, it's not on the slides, but the belief is that with the definition of a core set of requirements, we should be able to develop consent...provenance in source data that would include patient controlled data and patient generated data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, Lisa.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So Michelle, is the queue empty at this point?

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

It is.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, well let me summarize what we've discussed during this presentation, again Lisa, thanks so much. The recommendations that we would like to forward in a sense look like use case scope will be

narrowed to look at where the data came from, the source provenance, if it has been changed and if the data can be trusted, with a prioritization recognizing that some of these are in parallel, it's hard to order them. Exchange of data between EHRs at a point of origin in an EHR or HIE with the transfer of data from patient generated data, PHR to an EHR and point of data creation in a patient controlled device.

The technology related concerns; ensuring we are aligned with the existent C-CDA work that is going on and we look forward to the FHIR provenance work, and make sure that we don't have multiple silos of effort here, we try to align with those. And that we also recognize that there is this concept, whether it's a push or pull transaction, that the provenance of the content should be lossless, there should be this sense of integrity. So as Gary Dickinson has often told us in Standards Committee meetings, our ideal system would identify provenance from the source of the data to its ultimate use ensuring the integrity along that path.

So in effect Lisa, what you have done in more detailed form is incorporate that idea. And so I think there were a few friendly amendments. Did I hear Lisa that maybe Arien was going to try to take a stab as to what it meant to be lossless?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Yes.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

I've got that in flight.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And per Wes' comment, Wes, were there other things that you noted that might be a friendly amendment?

Wes Rishel – Independent Consultant

John, that's why I was going to ask you to put it back up on the screen, I don't have access to the hand out right now, so...

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So that's in effect what it is, it's the scope, the priorities and the technology with the recognition, and I think kind of we heard two things, that there's going to be a better definition of losslessness and there's an understanding that although the list of priorities went one, two, three, four, they're all kind of equivalent. They're nearly parallel, how about that? I think that's...

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Or it could be adequately addressed with a core set of requirements defined.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Right. So Michelle or Jon White, were there other issues or recommendation or changes you heard before we ask if folks are willing to endorse these?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Michelle.

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

This is Michelle, I didn't hear anything.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

And the only thing I'll add is I love you guys, too, just like everybody else did. I really, really appreciate the short turnaround work, its excellent work, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well then, with the friendly amendments recognizing that there will be some language that's clarifying on 3, the technology integrity and losslessness, are there any objections to moving forward with this set of recommendations as we will craft a letter to ONC? Well, none being heard then, we will begin our drafting process once we get our new language and again, wonderful work on a short time frame. This is an exemplar of how our, I don't know what we want to call them, ad hoc tiger teams, power teams, task forces, should work. And so Michelle, I think we have now our public comment period.

Public Comment

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

Yup. Operator, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time. Thank you.

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

While we wait for public comment, just a reminder to folks that public comment is limited to 3 minutes. Also to the Standards Committee, just a reminder that our next meeting is on February 10 and it will be in person. We will be starting a little bit later than normal, but...so it will go, I believe at this moment we're thinking from 11 to about 5 PM, but we haven't quite finalized the agenda yet. Just keep that in mind for travel plans. And it looks like we have no public comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well Michelle, by February 10 we might all be dug out; so, well wonderful. Well, with no public comments in the queue I certainly thank everybody for attending today. I hope you're warm and well and look forward to seeing you on February 10; Jon, any closing benediction?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Nothing in addition to what you said. Thank you everybody...thank you very much everybody for your focused, productive discussion and keeping us on time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

We are adjourned.

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

Thank you.

Public Comment Received During the Meeting

1. Glad to see interest in continuing S&I Framework. Suggest greater focus on re-use of successful elements of prior Initiatives, supported by S&I repository and tooling for new Use Case development.
2. Excellent recommendations from the Data Provenance Task Force. Agree completely. It would help to include details in Lisa's narrative.
3. Will the other agenda items on DAF and Feikama be done at a later date

Meeting Attendance						
Name	01/27/15	12/10/14	11/18/14	10/15/14	09/10/14	08/20/14
Andrew Wiesenthal	X	X				X
Anne Castro	X	X	X		X	
Anne LeMaistre	X	X	X			X
Arien Malec	X	X	X		X	X
C. Martin Harris	X	X	X		X	
Charles H. Romine	X					
Christopher Ross	X				X	X
David McCallie, Jr.	X	X	X		X	X
Dixie B. Baker	X	X	X		X	X
Elizabeth Johnson	X	X	X		X	X
Eric Rose	X	X	X		X	X
Floyd Eisenberg	X	X	X			
James Ferguson	X	X			X	X
Jeremy Delinsky	X		X			
John Halamka	X	X	X		X	X
John F. Derr	X	X	X		X	X
Jon White	X	X				
Jonathan B. Perlin						X
Keith J. Figlioli		X			X	
Kim Nolen	X	X	X		X	X
Leslie Kelly Hall	X	X	X		X	X
Lisa Gallagher	X	X	X		X	X
Lorraine Doo	X	X	X		X	X
Nancy J. Orvis	X				X	
Rebecca D. Kush	X		X		X	X
Sharon F. Terry					X	X
Stanley M. Huff	X	X	X		X	X
Steve Brown		X			X	
Wes Rishel	X	X	X			X
Total Attendees	25	22	20	1	22	21