



## HIT Standards Committee Final Transcript June 17, 2014

### Presentation

#### Operator

All lines are bridged with the public.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – 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 the 58<sup>th</sup> meeting of the Health IT Standards Committee. This is a public meeting and at the end of today's meeting, we will have time for public comment. As a reminder, public comment is limited to 3 minutes. Also as a reminder, if you could please state your name before speaking, as this meeting is being transcribed and recorded. And if you are tweeting today, the hashtag for today's meeting is #HITSC. And we'll now just go around the room to take roll. We'll start with Sharon Terry.

#### Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Sharon Terry, Genetic Alliance.

#### Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Cris Ross, Mayo Clinic.

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

Kim Nolen, Pfizer.

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

Stan Huff with Intermountain Healthcare and the University of Utah.

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

Anne LeMaistre, Ascension.

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

Jamie Ferguson, Kaiser Permanente.

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

Floyd Eisenberg, iParsimony.

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

Lisa Gallagher, HIMSS.

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

David McCallie, Cerner.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Dixie Baker, Martin, Blanck and Associates.

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

John Halamka, Beth Israel Deaconess.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Jacob Reider, ONC.

**Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina**

Anne Castro, BlueCross, BlueShield South Carolina.

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

John Derr, long-term post-acute care.

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

Becky Kush, CDISC.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Leslie Kelly Hall, Healthwise and the Foundation for Informed Medical Decision Making.

**Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America**

Jon Perlin, HCA and Vanderbilt University.

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

Steve Posnack, ONC.

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

And is there anyone on the phone?

**M**

Martin –

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

Yes, Lorraine Doo.

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

I heard Lorraine Doo.

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

Liz Johnson, Tenet Healthcare.

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

Hi, Liz.

**Wes Rishel – Independent Consultant**

Wes Rishel, retired healthcare computer nerd.

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

Okay, thank you everyone. And with that, I'll turn it over to Jacob.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Thank you, Michelle. And before we have our opening remarks, I'm going to make some opening remarks and remind folks that this is the 58<sup>th</sup> meeting of the Health IT Standards Committee and we're going to more formally, or perhaps again formally, thank Jonathan Perlin for his 57 meetings of service –

56, no, because you were participating last time, weren't you? So, 57 meetings of service, 56 of them being Chair of this committee.

Last time we gave him the Kinko's version of the plaque so today we have – thanks to those of you who have signed it, and if you haven't, I'm going to give it back to Michelle and we can have you sign it during a break. And for those on the phone, we have a photograph of a typical Standards Committee meeting with nerds talking, and then around the edges, folks from the committee have signed it and it says "Thank you Dr. Perlin." We also have a very handsome plaque thing to put on your desk, Jon that commemorates your service. So, thanks very much.

**Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America**

Thanks to all of you – the last time, just a pleasure to work with all of you and work with the leadership of ONC, worked with John Halamka, just a privilege of a lifetime. And reflecting back on 58 meetings, including today, it's just quite remarkable what has been accomplished. I know that there's a lot more to do, I know that there are things that people would do otherwise, but I marvel everyday about what has been accomplished. Probably recognize that I'm an eternal optimist, I know that that ecosystem of possibility keeps growing and growing, improving patient care, improving the capacity for better health policy, improving the capacity for a learning health system and improving the capacity for the Triple Aim of better health care and value. And for that, again thank you to terrific ONC staff indeed working through the no Christmases, no nights or weekends and to each of you on the committee and really as we see today, large member – gathering of members of the public. This has been a terrific public dialogue that I think has really built that ecosystem, so thanks so much, I'll treasure these mementos. Thank you.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Thank you, Jon. So Unlike Jon, I can't do the opening remarks all from memory and so we have some notes that I've concocted with the help of actually the ONC team, especially Steve Posnack and Michelle Consolazio, partly in order to put context to the meeting that we're having today. And as many of you have seen from the agenda, the focus of our meeting today is the Standards & Interoperability Framework and the activities therein that ONC has been convening, but as you'll hear, ONC isn't necessarily always the source of one of these initiatives. So I wanted to frame that conversation and give you all a sense of what our ask is of you today and in fact, going forward with reference to the activities of ONC in the domain of the Standards & Interoperability Framework.

So the first point that I want to make, and you might hear me make this every time because this will now be my second time making this point at this committee. The Standards Committee for the last few years has been focused, and I think appropriately focused, on the work of ONC in the domain of standards relative to the standards and certification criteria, which have been Velcroed to the Meaningful Use Incentive Program. And as we look forward, we at ONC are seeing the standards and certification criteria as continuing to serve the functional components of the Meaningful Use Incentive Program and beyond. And so we are careful not to think of ourselves as the Office of the National Coordinator for standards that support Meaningful Use, we are the Office of the National Coordinator for Health Information Technology. And health information technology is much broader than Meaningful Use, although Meaningful Use is an important component of the way that we have motivated our nation toward the

adoption and implementation and Meaningful Use of health information technology over the last handful of years.

So this is the Health IT Standards Committee, it is not the Meaningful Use Standards Committee and once in a while I will hear members say, well, we shouldn't talk about that because it's not relevant to Meaningful Use. In fact, you should talk about that, even if it's not relevant to Meaningful Use because there are lots of folks who use health information technology in the United States who are not eligible providers or critical access hospitals or eligible hospitals. That includes the consumers, it includes the behavioral health providers, and it includes the long-term care providers, good thing I winked at John for that. Yeah, I'm learning. So this is important in a way that's much broader than Meaningful Use.

So, as many of you have probably seen in the blog – ONC has changed in recent weeks and we are undergoing an evolution to meet the changing demands of us by the marketplace. And so by the same token, the work that we do may change, and this group is an essential guide, right, so that the Federal Advisory Committees are advisory committees, you give us advice, we sometimes explicitly ask for certain pieces of advice, and then we act on that advice. Much in the way that a teenager will act on the advice of its parents, sometimes we heed it perfectly and sometimes we take it under advisement.

So, we're not asking the committee as we go through the S&I Framework activities that we – our staff will introduce to you today to veto initiatives. This isn't a request to say – for you to say, this is or is not something that ONC should work on, but we'd like to hear your perspective on which may be high priority that we might not have deemed high priority. Maybe there are some things that we have spent a lot of time and effort on that you think might not be of high priority as you think about the needs of the nation in the domain of health information technology. So we're asking for input where possible, on how to make current initiatives better, more focused and to point out where additional depth may be necessary to get something right.

Specific recommendations are needed to review active S&I Initiatives, and you'll hear about three buckets of S&I Initiatives today. One is the active bucket that is an ONC sponsored initiative. Another is an active bucket, perhaps lower case "A" that has been sponsored by somebody else, often somebody else within the federal government, so another agency has said, "Hey ONC, we'd like you to convene a Standards & Interoperability Initiative in this domain." And you might say, well why is ONC doing that and remember the last name that the last word in our name we coordinate. And we think it's much better for these things to be going on and coordinated in the public eye by ONC than for them to be happening within the basement of some other agency where no one can really see it, it's not visible and it's not open for you to participate in, as well as it could be if perhaps ONC was coordinating it. And then the third bucket is, less active or formerly active or inactive initiatives. And you'll hear about some of those.

So how to ensure that initiatives will provide support for interoperability, right, that's a key goal that we have expressed and I think you all have expressed for whatever its purpose, toward ONCs interoperability priorities which you may have seen in our 10-year plan that we released about two weeks ago. So for 3, 6 and 10 years, what – those are the milestones along the path toward the goals that we set out in our 10-year plan. We'd like you to weigh in on the extensibility of the initiatives intended outputs to support delivery reform. So how can we use these to do the things that as Jonathan mentioned, support the Triple Aim. Whether the initiative compliments other activities that are private sector led or do these conflicts with activities that are private sector led. And in fact, before the meeting, I heard from Becky Kush about some great initiatives that have been sort of ongoing and/or

mothballed, but could be re-energized to support the research community that may or may not be in support of or conflict with our structured data capture initiative.

We'd like feedback on how to improve the trajectory of an initiative, how long we should expect pilots to go to consider them successful or not successful. Number of pilots that might be expected or required before something would be included in regulation or guidance. Feasibility of pilots and anything else that would be necessary to show that the initiative is feasible or infeasible, because as our agile friends say, fail early and often. And I think that's okay and we should expect and understand and tolerate and in fact encourage projects that fail. Because then we know what will succeed and if we fail early and if we find ways to close things early, instead of let them fester for months or years, I think we'll learn a lot more and we'll get closer to the same targets.

ONC is interested in bringing future standards and interoperability seeds here, before we start to water, fertilize and feed them. And so we'd like to get your input, before we launch something, we don't want to surprise you, just like the teenagers don't like surprising their parents, we don't want to surprise you, we want to introduce these things to you early and get your perspective on whether we should go ahead with something or not. We'd like to see criteria on whether a new S&I Initiative should be pursued, along the same lines. And the discussion will also help us to guide the plans of our workgroups, in which we hope to soon, and I'm looking at Michelle now, to announce our workgroup Chairs and workgroup assignments. We've been getting emails from folks who have volunteered, so, if you've sent us an email know, we haven't made the selections yet about workgroup membership. And so that's all I'd like to say. We've got a busy day and I have already said too much, so thanks very much, I'll pass the baton to John, who will be our emcee for the day.

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

Ah, emcee for the day, I thought I was just reviewing the agenda. Well, thanks so much. So excellent framing remarks, thanks. And as was said, we're going to look at the S&I Framework with the question of, how as we go forward, given that ONC has reorganized, given that it is no longer the era of ARRA. What can we do to ensure we have the right building blocks and that we can get the work done to the extent that adoption, implementation is our success metric? As you said, ONC recently published its 10-year vision, and for those of you who haven't read that 10-year vision, broken into the 3, 6 and 10-year plan where 3-year achievable goals are things like send, receive, find and use data, for both payers, providers or patients as well. How do you deal with the tricky things like provenance of data and patient matching? How do you make sure there's trust? So Dixie yes, your work will go on forever.

As we look to 6 years, how do you achieve patient stewardship of the record? Leslie Kelly Hall of course is working on such things. How do we ensure there are registries and aggregations of data that can be mined? How do we measure quality? And in the 10-year vision, how do we ensure there's structured data capture from all the various stakeholders in the system? How do you ensure there's good decision support and evidence, support for clinical trials and a learning healthcare system at the point of care? These are all very logical segmentations of the industry and our trajectory as to the things we can achieve now and things that need a bit more environmental ecosystem and cultural time to achieve. So, as we look through that S&I Framework, I think as you've said, let's make sure what we set in motion to work on today and in the future is going to support that vision.

Now with not any prepared remarks, but I also think about Meaningful Use Stage 3, though we are not the committee on Meaningful Use. But if you do in Stage 3 have certain requirements, we probably also want to make sure the S&I Framework and our roadmap provide the necessary standards, vocabularies, clinical content and transmission, to support Stage 3. And it's kind of interesting because as I look at the Stage 3 proposals, and then I look at the 3-year, 6-year and 10-year vision, there are things in the 3-year vision that aren't in the Stage 3 2017 proposals. And so I think as you say, we are an Advisory Committee and it is hopefully our job to take a look at S&I, look at the vision, look at Meaningful Use and make sure that the necessary standards and the foundation are built.

So to that point, we have Dr. Posnack who is now leading the Office of Science and Technology and as folks have seen in my blog, I applaud Steve's appointment to that role because it makes him the single throat to choke. As the guy who is now both a master of regulation writing, but also the guy who ensures that there are good test procedures and scripts and certification processes, all rolled into one, I love it. So I no longer have to complain if there is a disconnect between the regulations that were written and the certification processes that support them. So he will lead us in this discussion of the S&I review where we're going to hear an update, as you said, in the three classes at a high level of S&I Initiatives and then a deep dive into those that are currently active.

And then look forward to that committee discussion as to how we might recommend streamlining, how we might recommend that the foundation is laid appropriately and, I've used things in my blog like, oh, 18 initiatives seems like too many, maybe it should be 10 or 5. The answer is, it just needs to be the right number, based on building blocks that give us, we hope, not so much variation, so that every one of those 18 initiatives is using a different approach or different building blocks. I mean, 18 may be a fine number if the number of building blocks are relatively small and consistent. And so look forward to your comments in that regard.

And then Dixie and Lisa Gallagher are going to present a 2015 NPRM comment update from the Privacy and Security Workgroup, offering their recommendations and wisdom, how the NPRM might be polished in the realm of security. And then, we adjourn, so it is a short day, but as you say, an important day that is going to be setting a foundation for our next several months, if not years, of work. So with that, let us begin with introductions from Steve Posnack, unless there are, I'm looking at Michelle, approval of minutes, presumably is what you want done. Okay. See, this usually is a Jon Perlin task, so –

W

You're covering for him.

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

So covering for Jon Perlin, I am sure you have received the copy of the minutes, the excellent summary of our last meeting and look forward to any revisions or edits that folks recommend. Okay, well none being heard then, Michelle, we will note that the minutes have been approved without amendment and we'll begin the meeting with comments from Steve Posnack.

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

Thanks for the intro John. Just for the record, the only Dr. Posnack in my family is my wife, and she will make sure that we get that straight. But I appreciate the promotion. So I'm Steve Posnack and I am joined here by the magnificent Mera Choi and John Feikema. They are going to be leading, and actually I'm going to turn it over to Mera to really do the full emcee approach for all the deep dive on the Standards & Interoperability Framework initiatives and I was just going to set some context. Oops – we have a slide.

All right, so – we may also have a BH and AH, Before HITECH and After HITECH time period that we might use as a line of demarcation. So before I – many of you may remember, and being involved in HITSP as the kind of pre-cursor to the S&I Framework and all of the work that HITSP was able to produce. And much of that has been used as a foundation in the regulations that I've been responsible for, as well as ongoing work with stakeholders in the community. The S&I Framework kicked off in 2010, really kind of catching the baton from the HITSP work and, as Jacob mentioned, serves as an open, collaborative community made up of stakeholders from the public and private sectors. Really the place that we want to coordinate the acceleration of standards, development and implementation guide specifications.

So each S&I initiative is focused on a critical interoperability challenge and we've through the past four years, been able to figure out the best approach to more definitively structure a process through which all these initiatives follow. And you'll see that in the first graphic that the Mera will show you in terms of a kinds of heads up dashboard of all the three buckets of S&I initiatives. This approach includes the development of clinically oriented user stories or use cases, the focus on harmonization of interoperability specifications and implementation guidance. So this includes aspects where there are multiple standards that may be used for the particular use case in mind or the identification of gaps where there are standards already available.

And then that phases into getting real-world experience and implementation support through pilot initiatives and then getting that feedback mechanism toward the end, as the work products get out of the S&I Framework coordination process and find a home in a standards development organization for formal balloting and the like. And we've had a number of successes through many of these initiatives, some of which are now, as Jacob mentioned, less active or maybe dormant might be a new word that we will say. There are a number of other initiatives that have picked off – picked up where some of the more dormant ones have left off, focusing on more specific aspects and you'll hear more about that today.

So with that being said, ONC uses this – the Standards & Interoperability Framework as a way – as an infrastructure through which the community can get together and focus on these needs. We provide the project management, subject matter experts, coordination tools and other resources to accelerate these timelines. And as has been previously mentioned at the Standards Committee, have had a lot of success in expediting or shrinking the timelines by which a lot of these additional artifacts are produced. So I will turn this over to Mera to navigate you through this and pave the way and clear my seat so that other experts can join her at the table.

**Mera Choi – Acting Standards & Interoperability Coordinator, Office of Science & Technology – Office of the National Coordinator for Health Information Technology**

Thank you, Steve. So as Steve and Jacob mentioned, we have – up here we have the S&I initiative portfolio snapshot. We separated it out into three categories, the first one represents the active

initiatives, and we have about seven listed here. The second category is our community led or other agency led initiatives and these are usually, as Jacob had mentioned before, sponsored by other folks outside of ONC, and usually we don't require a lot of ONC support to lead these efforts and we have about five listed here. The last category is our inactive or closed initiatives. And these are initiatives that have been pretty dormant and they have been picked up by other initiatives so – in leveraging their work and moving on to another area.

So within the active initiatives, the structured data capture work as well as the data access framework and the PDMP initiatives are all in their harmonization phase. They're looking into implementation guide development and balloting right now. The Blue Button initiative has also reached the pilot phase as well as they're looking to transition that work and we're currently in a transition phase for them right now. The clinical quality framework, as well as the data provenance work, are more recent initiatives and they have been pretty much in their use case phase right now. So they just launched and are in the process of developing their user stories.

The community led or other agency led initiatives, particularly public health, LRI, LOI and esMD, as well as LCC, have all pretty much reached their pilot phase. So a lot of them are in their phase of I guess transitioning out and being leveraged more in the community of. The inactive and closed initiatives, as I stated before, data segmentation privacy has been picked up pretty much by the data provenance work. The query health, some of the work there is being leveraged in data access framework and Health eDecisions have been – the work there has been also put under the clinical quality framework .

This next slide is basically a representation of where we thought the – where each of our current active S&I initiatives would fit in the current HITSC workgroups. We felt that structured data capture would fit well with the Content Standards Workgroup, the Architecture, Services and APIs workgroup. Similarly data access framework, we thought the work there could be aligned with the Content Standards Workgroup, the Transport and Security Standards Workgroup as well as the Architecture, Services and APIs Workgroup. The EU and the US eHealth Cooperation initiation would be aligned with the Content Standards Workgroup, the Semantic Standards Workgroup. And then the Blue Button Plus would also be part of the Architecture, as well as the Content Standards Workgroup.

Similarly, the PDMP – we thought that Clinical Quality Framework as well as PDMP would fit under the Content Standards Workgroup as well as Semantic Standards. And finally data provenance would be more aligned with the Transport and Security Standards Workgroup. So this is how we would envision the S&I initiatives to be aligned with the new HITS Workgroups, once launched. So now we're going into the S&I initiative deep dive and I'm going to ask each of our initiative coordinators to come up and present on each of their respective areas.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

And I should also, while Evelyn and Jonathan and company are coming forward, I should also mention that we're going to give an initial overview of each of the initiatives and I'm sure that that will prompt questions and raised cards. But what I'd suggest, especially since we have a number of folks here in the back who have deeper technical support than might be better represented at the table here, that if we could queue all the questions on the initiatives in general until the end, until we've gone through a first pass and then we can go back and dig into any of those in deeper detail. So if that's acceptable, we'll start out and I think the first one goes to Evelyn.

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Good morning everyone, my name is Evelyn Gallego and we appreciate the opportunity to brief you all on this exciting initiative, structured data capture. So I'll briefly – we each have two slides to introduce the initiative and give you a status of where we are, so I'll try to do that short timeframe. So, just to put into context, this initiative was kicked off in January of 2013 in partnership with the National Library of Medicine and AHRQ. During that timeframe we also engaged with our other federal partners, FDA, CMS, CDC, so you'll see there, they'll be referenced within – through these slides.

In terms of the scope of the initiative, our focus has always been to identify the functional and technical specifications to enable EHRs to retrieve, display and fill a structured form or template, and store or submit that form to an external repository. Such examples of structured forms are the electronic case report forms used for clinical research, incident reports used for patient safety and the MedWatch forms used for adverse event reporting, as well as surveillance reports used for public health. When we kicked off this initiative, we recognized that we'd have two separate work streams to enable this work, so we'd have content work streams and then technical work streams.

So the content work streams are listed there, patient safety and adverse events, which we launched in partnership with FDA and AHRQ. And their focus has been to identify what we say semantics, common data elements and the forms those CDEs populate, but very much aligns with piloting of the SDC standards, and we'll explain the status of that in the next slide. The other content work stream, which we have yet to launch but we're in the process of doing so, we'll be looking at in terms of clinical research and particularly PCOR. And a focus on identification of a subset of common data elements and the forms, again to test and validate the SDC specifications. And lastly we have a public health focus. I won't spend too much time detailing this because John – is on the phone and he'll talk more in detail about the Public Health Tiger Team, but it also initiated as an SDC content work stream.

We established technical work streams last year and these have been very much – and now they're complete, except for now our second phase of work, but these have been focused on identifying the four guidance areas. These are the common data element structure, so the representation of a common data element, the form/template structure, the EHR-interaction with the CDEs and forms and the auto-population of these forms with data existing in the patient record. The leadership team is listed on the upper right quadrant, so you'll list us – see us there. And again, we have our federal partners listed, as well as our community leads.

I'll go through the output, so these are deliverables to date. As Jacob mentioned and Steve and Mera that we have – through every initiative, there's a series of outputs or artifacts that are developed. So we've come a long way in over a year, so as listed there, we were successful in developing and – all these – again, these artifacts go through consensus voting by the community, that's the value that the S&I Framework brings. So last year we completed the use case, which really at a high level specifies functional requirements for those guidance areas I listed in the technical work streams. That work then we started based on the SDC solution plan, standard solution plan. We started working with SDOs and in particular initiated with IHE, so, we were successful in presenting and delivering the SDC IT content profile last year.

And that profile now has gone to completion of volume 1, 2 and 3 and it's under public comment now with the intent to have – up for trial implementation in August. So you'll see those dates listed there.

We also, through this work, developed a SOAP/SAML implementation guide. You'll probably ask why do we have two artifacts, we developed the SOAP/SAML implementation guide in advance of the IHE profile. The SOAP/SAML IG very much aligns with the IHE profile. We did not ballot the SOAP/SAML IG, we developed it as a tool that could be made available for organizations to test and pilot in advance of the IHE profile being available for adoption.

Same time we've also done a lot of work in identifying workflows and particularly for our content areas for patient safety and adverse event workgroup. We spent the first part of this year with that community identifying what is the workflow to enable an EHR system to collect data for patient safety and adverse event reporting. We are not being descriptive of what this workflow is, again, this is an artifact to help with piloting of the standards. We are – intend to test or have the SDC IHE profile tested at the IT Connectathon in January of next year and then participate in HIMSS. And we're now working with HL7 on an SDC FHIR profile that will be balloted in January of this year – of next year.

So current status, just to recap, SDC SOAP/SAML IG, we completed that in March of this year. Again to make it available for testing to those content work streams, in particular patient safety and adverse events sub-workgroup and public health that might want to test and validate this with their organizations in advance of the publication of the IHE Profile. The IHE Profile will be available in August for trial implementation. So we have some organizations that have expressed interest in testing that. We engaged with HL7 and our FHIR IG development this year with the intent to ballot in January 2015. There will be a draft for comment published in September of this year. And we have worked with a series of HL7 workgroups, we are sponsored by the Orders and Observations Workgroup within HL7 and we have cosponsors with Vocabulary, Patient Care, Clinical Genomics and a Clinical Interoperability Council.

Patient safety, as noted, we kicked it off in February of this year and we say this is a content work stream, because we really just looked it from – in terms of the content requirements for this work. We're fortunate the AHRQ and FDA had done a lot of work already to identify data elements and forms for patient safety and adverse event reporting. What we've done is take those data elements, so what they've already defined and map it to the SDC common data element attributes. What we've defined, basically what we have in our SOAP/SAML IG and then make that available for those organizations for testing. And like I said, public health, we'll have John detail that much later on.

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

What I worry about is that if we go through all of the slides and have questions at the end that we're going to lose a lot of important threads and thinking. So I've just conferred with Jacob and he has given me permission to open up the floor, before you move on to the data access framework, if there are comments or questions about SDC. Because as I looked at your list of standards, there were some things that leaped out at me, I wasn't quite sure what the SOAP/SAML layer was for, is that just a transport and trust assurance layer or, why is it even in there?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

So we labeled it the SOAP/SAML because we had recognized when we identified our solution plan that there were a series of standards that we could use that were available in the market. So we didn't want to reinvent the wheel and so SOAP – using SOAP/SAMLs transport mechanism was something that

resonated with the community at large, saying that's something that we currently work with and we'd like to adopt or engage and leverage.

But at the same time, FHIR was introduced, so that's why we said we would look at it first from a SOAP/SAML perspective, because those standards were more mature, and then we'd start work on the FHIR piece, new transport mechanism – using REST services, and that's what we're doing right now. So, there will be – the FHIR piece is very much has been focused on the common data element definition, that's – work with HL7. The IHE profile for that does not have a standardization for the – there's no mechanism – no mechanism within the IHE profile to standardize what we mean by a data element definition or data element attribute.

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

And many cards have gone up, so we're going to go in the order that they were put up, but I do want to just ask Becky Kush one question and that is, of course CDISC has worked on a whole variety of standard data capture approaches for many years. And, I mean I was just sort of curious as you think of the CDISC work and your work, has there been an attempt to align th –

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Oh there – yes, we've completely worked, yes.

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

CDISC has been involved in this project. I have to say that I think a lot of it is a repeat what we did with HITSP #158, which was published in early 2010. So I know there was an effort to try to bring this community into this area and we have been definitely engaged in the data capture project. I think we would have taken a different angle if we had just looked at it from supporting quality research and public health, because it's gone down another avenue to try to incorporate a lot of things that are coming in the future. And I guess what I told Jacob earlier, when he asked me is, I would just like to see us do these things. And we had a meeting on May 30 with the Institute of Medicine, where a number of vendors and a number of participants, including FDA and people from IHE, HL7 and CDISC said we have standards that are ready to do this now and I mean I think the statement that everybody was quoting at the end of the day was, no more pilots, no more demos, why aren't we doing this?

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

So Dave McCallie, I think you were first.

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

Um, yeah, I've got a lot of thoughts, I'm not sure how to organize them. First, it concerns me as we actually had a discussion with your group a couple of months ago that the introduction of a forms definition language of any complexity into the EHR world is challenging. And in the era of HTML, we were concerned that maybe it didn't make much sense to define another forms definition language. At

that point you were focused on an ISO standard for – that had seen very limited implementation anywhere outside of – Pharma, that apparently is no longer in use, the ISO standard? And what is the approach to the forms definition work and why isn't it simple HTML?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

We are building off the FHIR questionnaire and questionnaire resources, so we're not again, reinve – we're not going to leverage for our FHIR IG, it will build off the existing FHIR questionnaire.

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

So the proposal that we made to you was that the person who has the questions to ask should be able to push their conversation into the workflow and then ask the question in whatever way made sense to them, with whatever user interface made sense. And then use FHIR to move the data back and forth. That still seems to be to me a much easier approach than what you've come up with. Are there other vendors involved in the group? Why is it so complicated?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

No, that's a good question, David. Our challenge has been that – it's our community as a whole, that this has had that clinical research piece – component to it, which we agree that there is – the difference between the clinical care and clinical research piece. So there is a need to have more granular data and the way that they collect their data now is different that, as you proposed. But we...within the S&I Framework, we're not being prescriptive or saying that that's not viable as – I mean, I had reached out to you saying that I think we would love to have Cerner come in saying what – again, I know, as Becky Kush said it that, we don't want to have any more pilots. But we really do need demonstrations of this to see what works and what doesn't work this is new field. I know that there are many organizations that want to do this, but it's been a challenge. The IOM meeting highlighted that, that there is – although the standards are in place, it's always, if we build it, it doesn't necessarily mean they'll come. Because there is no demand for this right now, so we need to get there. But to get to that demand, we need to make sure what we build is feasible and usable so we definitely need pilots for that.

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

Yeah, just Steve, for your perspective on this, I mean, there may be better ways to solve this problem and if it comes down to a certification test at some point in the future, the challenge will be to certify that you can solve the problem perhaps better than that you have implemented a particular set of standards plucked out of the air and woven together into a potential solution. And this is a problem in general, obviously, with all of these things in this rapidly advancing technology that we live in, these 5 and 7-year timeframes that our cycle is on in this work, just is too slow compared to what's happening in the market and with technology. And I dread getting locked into something that is 10 years out of date when there are better ways to do it. It's a long conversation, we don't have time to finish it here. But, I appreciate the group's willingness to engage with some of us, who haven't been actively participating. That was very gracious of them to do so, Stan and I and Josh Mandell met with them a number of times.

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Thank you.

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

And so I believe we have a virtual card from Wes that has been raised. Wes?

**Wes Rishel – Independent Consultant**

Thanks. So I am responding to the no more demos, no more pilots, just do it comment. And I want to make it clear that there is a lot to be gained from various kinds of options such as demos and pilots and often the actual outcome is overlooked in the publicity associated with the event. So we found, for example, in some recent work we did on the committee that we had done a – that there had been pilots that had been deemed successful for dealing with sending SAMHSA data across the provider – the boundary between SAMHSA providers and general healthcare. And that could have been a rationale for just doing the just do it and saying, okay, let's make that required. But, on closer inspection we asked the question, well, what did they really show? And what they really showed was that there was an acceptable method of sending the data, they didn't show that there is an acceptable method of the dealing with the data with all of the special handling that's required in order for the data to be actually useful.

And so I think it's important to recognize that pilots deserve some sort of meta-analysis just as people do meta-studies of research studies on therapies and things like that to determine whether the information was actually used in the loop – whether there were artifacts that prevented it from being used. I read a paper in draft recently that talked about a pilot where the effectiveness measure of the pilot was that five providers that answered a questionnaire that said, yeah, they thought it might be useful. I think that we need to find a way to deal this general statement, oh, there have been all kinds of pilots and I completely applaud all the work that IHE does in terms of testing. But, anytime it's implemented in an environment where there – it doesn't go to actual use, there's a limitation on what we learn through that effort. So, I think we need some way of systematically approaching pilots to say, wha – have they proven enough for us to go ahead. Thank you.

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

Thank you, Wes. And I think Dixie you were next.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Yeah, I'm kind of responding to your comment, John, as well as Becky's. The – at least 5-7 years ago I was involved in a couple of these demos of the IHE Profile for the retrieved form for data capture. So that profile has existed for a long, long time and has been always RESTful. So – and we did – we used it in our demos, we used it to report TB cases to public health, we used it to report adverse events to FDA, it was shown that it could work and it was very, very simple. RFD is by – since day 1 has been very, very simple. And it seems to me, to add – to be adding a layer of complexity to add this SOAP/SAML layer to something that I personally don't see what – why that would be needed. And maybe you can explain that to me, what are we gaining from this significant layer of complexity that would be added by adding a SOAP/SAML layer to it?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Just to clarify that we are bui – we build off the IHE RFD standard and IHE –

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

I know you did, I know you did. And that's why I brought it up because when you replied to Becky the implication was, well FHIR is a little far off. But aren't these been RESTful since day 1? It's not FHIR, but it's RESTful since day 1. Yeah. So tha – so I'd like to know why – what are we getting from the – to be more articulate, what are we getting from the adding the SOAP/SAML to it?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

So the SOAP and SAML were identified by the community as the transport standards to use. And so this was what was positioned under the IHE Profile. So I think we look at the SDC IHE Profile, as you say it is a combination – a grouping of standards to meet our specific use case requirements, building off existing standards. So it's being able to package them so that any implementer that is seeking to address the interoperability challenges that we're working on can do so. I am not the technical expert to say why we've used SOAP/SAML versus any other – we had identified REST and OAuth as well. But we left that as the second phase when we look at FHIR, so – and we're not saying, I think like we'd love us to have – be able to plug and play these standards eventually, so that you don't have a distinct pick one versus another and we're still working towards that.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

So to find out what we would add, who is your technical expert that would know that?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

So our harmonization team, I can put you in con – we can follow up with you Dixie, thank you.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Thank you.

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

Great. Leslie Kelly Hall?

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Hi, Evelyn.

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Hi, Leslie.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Thanks for all your good work. I did have a couple of questions. One was, I really like your point of being agnostic to some standards and more of a plug and play. To that end, we talked about, in other areas of regulations using the Direct standard for transport and I see we're silent here. In my ideal world we have a toolkit that allows us to take information and have transport as a layer that is added based upon the parties involved and their preference rather than a mandate that so tightly connects content to transport. So like comments about Direct and that.

And then also, one other question, when we're talk about the questionnaire in FHIR or in other areas like in the Consolidated CDA, it's one of the – or PCOR, it is a wonderful opportunity for patient-generated health data. And talked to Chuck Jaffe last week about how do we harmonize the patient as an author across multiple segments, whether it's a longitudinal care team or Consolidated CDA or the structured data capture or now this upcoming provenance group? This idea of a totally new stakeholder coming to the table warrants some harmonization so we don't end up, I guess where we were in defining providers years ago. So, some advice that I think harmonization is worthwhile with regard to the patient and all the associated stakeholders of that patient, their designees and so forth, across these efforts and then specifically transport and Direct.

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Thank you. So, to address the first question, Direct was identified as the transport standard during our solutions or candidate standards list. But as we go through the S&I process and have a list of standards that we have identify, they go through consensus voting. So the community as a whole made the decision that Direct was not as feasible as SOAP/SAML and then REST and OAuth, as the transport mechanism for what we wanted to accomplish with our use case. Saying so, we did have some community members that were interested in Direct, and still are, and we've always stated that they're open to use Direct in their piloting activities, it's just we haven't specified it in our implementation guidance.

To your second question for the FHIR questionnaire, we definitely agree that patient-generated health data plays a role there. And we would love to have those conversations when we kick off our PCOR sub-workgroup, because that's where we'd say, how can we engage with a patient in particular for patient reported outcomes? How does that comes into play, and so I think that's the conversation that we'd love to have with the community as a whole.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Thank you.

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

Jamie?

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

Thank you. I have two questions, one is for Evelyn and one is, I think, for Mera and John. So, the question for Evelyn here on structured data capture is about integration with the frontline workflows. Because in our experience of operating literally hundreds of registries and thousands of research projects for decades is that form data capture, if it's not tailored to the context of the frontline workflow, does not result in appropriate high quality data that's really useful for the intended purposes. And I didn't see anything in the project about integration with frontline workflow or input from actual users of the EHR system in the data capture process. So, I think there may be a danger of imposing something that doesn't really fit, that then, it may work technically fine, in terms of having a form that gets transported to the intended repository, but you're not going to actually get the data capture because it doesn't integrate that well. So what's the mechanism in this project for getting input on integration with the workflow? That's my question for Evelyn.

I'll give the second question now also, though, which really is back on the list of S&I initiatives that was displayed with their progress, the bar chart. I notice that there were several of those that were either in or completed their evaluation phase, but I haven't actually heard of or seen published any analysis or evaluations of the projects as an evaluation report. And so that's my, I guess, follow up question for Mera and John.

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Okay, I'll start. So we – maybe you missed it, I know it's small there at the bottom, but under patient safety and event – adverse event sub-workgroup, we stated we completed our workflow analysis. So that speaks directly to your question. We spent significant time, four weeks with the community saying, if we are going to start collecting – so this has been very focu – content focused.

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

But I guess my question is, does the community include frontline EHR users, clinicians or is the community the –

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

It does.

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

– system developers and vendors and –

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

So, it includes EHR vendors. It includes users, so clinicians, frontline staff, and patient safety risk managers, so, we tried to include the gamut, and then the actual users of the data.

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

Okay.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

So on the second question, to the evaluations at the end. I don't know that there was a formal project overall evaluation. In the majority of the cases, there was an evaluation of the pilot progress, how did that work out. And in all cases, there was something published that said, for query health, here's how the pilots were, here were the successes, and here were the learnings. Same for data segmentation for privacy and so in a number of cases, there were feedback to the community that said, this is what we learned from the projects, and those have all been published, I can point you to that. In a number of other cases, the guidance turned into an understanding that we should launch a follow-on initiative. So for example, query health spawned the data access framework. The data segmentation for privacy helped spawn the data provenance, so that was the other kind of evaluation that tended to flow from it, a realization that there was enough of a gap that we needed to address that in a follow-on initiative.

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

I guess what I would appreciate, perhaps, would be evaluation – analysis and evaluation that would report the overall state of progress against the original objectives at the outset of the project against the original success criteria. And, I agree that certainly there have been iterative progress reports on different phases, such as individual pilots, but I think the overall evaluation would be helpful as well.

**M**

Stan Huff?

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

So, a specific question then a general question, the first question is, in your use of CDEs, common data elements, are you using that in a – are you using that to determine in a general sense or in the specific sense of 11179? And if 11179, are you using 11179 as the model for metadata related to these elements or 11179 has the structure of the repository for these data elements that you're using in the forms?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

We are leveraging 11179 so – but the attributes, the metadata, we – it's not in a clear alignment, so we know that there are – we've received some feedback. We've reviewed and Mark Roche is behind me, he's the subject matter expert, spends a lot of time with the data element attributes. So we're building

off 11179 and looking at it from both ways, the representation of the data element and how it needs to be represented in a repository.

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

And a related follow up question then, how are you establishing the meaning and semantics of those questions? Are you linking to standard terminologies or ontologies and which ones are you using?

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

So, the semantic portion has been – in general, out of – we’ve had – it’s been out of scope for initiative because we really wanted to focus on syntax. However, when we get into the content work streams, we need actual semantics with data elements to use as an example for this representation. So for – what we’ve done is with the patient safety and adverse event, we’ve used the AHRQ common formats and the FDA MedWatch data elements and forms. So that’s been our metadata. When we kick off with clinical research, we’re starting to look at what’s already been defined – identified by other groups, in particular PCORnet, CDRN grantees. We’re also looking at in terms of the Meaningful Use data set as a starter set, but that’s again, just to have some data elements that we could use to act as an example for what we’re trying to do.

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

When I’m talking semantics I’m saying, if this question is asking the question – if what you’re collecting is – I mean, we can do some simple or hard things. It could be collecting a blood pressure, it could be collecting a heart rate, and it could be collecting a question about the patient’s emotional status, socioeconomic status. All of which are things that are modeled not in any of the things that I heard you say, but are modeled basically are defined semantically in LOINC or in SNOMED or other –

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

Yes, um hmm.

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

– I didn’t hear any of those words from you –

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

No – yes.

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

– and it made me nervous.

**Evelyn Gallego-Haag, IMBA, MBA, CPHIMS – S&I Initiative Coordinator – Office of the National Coordinator for Health Information Technology**

No, definitely. And I think of LOINC and SNOMED as the terminology and vocabulary in each – and that’s one of the attributes, I think of it from the terms of the attributes. Is there a value set? Is there a standardized terminology for that particular data element? And sometimes the actual te – LOINC would be the da – there are some instances where it is the question. So, we’re looking at – yes.

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

Okay, thank you. My other question is more general, which is and maybe has some perspective on sort of the whole S&I strategy and that is, from – and of course I am very – I only know about one thing so I talk about that thing. But, from my perspective, there are at least four of the S&I initiatives, the fundamental success of which depends on information modeling and terminology. And that would be structured data capture, clinical data – excuse me, yeah, clinical decision support, data access framework and the quality and eQuality measures and all of that sort of stuff. And what I see kind of going on is sort of as you described, you guys are working at information modeling from the perspective of structured data capture, the other guys are working on it in terms of quality, in terms of defining clinical decision support. And I see an overall need to do that as a discipline as opposed to a sidelight to many different activities, and that’s just a general comment that you’re welcome to respond to. But it seems to me that they’re fundamental infrastructure sort of things around this that should be focused on as a discipline itself as opposed to a part of each...of many, many projects.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Stan, that’s a valid point and it’s worth noting that at this last HL7 meeting, the three initiatives got together, recognized that. The three initiatives being the clinical quality framework, data access framework and structured data capture got together and the technical and team leads from those three initiatives meet weekly now to make sure that we are align all three of them around the same set of principles.

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

I hadn’t had familiarity with ISO 11179. There are many good articles on the web clarifying how metadata standards in an organization be recorded using that framework. I initially typed 1179, which is a plumbing standard, so I guess they are related. I see that...you see where I’m trying to go – Becky did you have another comment?

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

Yeah, first I would like to commend this team that’s been leading the Structured Data Capture Initiative because I think what I’m seeing is, they’re trying to please everybody. And in trying to do that, they keep going up higher levels to make sure that they can accommodate a number of these standards instead of selecting one. And when I referred to the HITSP IS, I think there were three standards that were named, and everybody’s afraid to say, oh, these are the standards and so everybody’s going up to these levels like 11179 saying, oh this can accommodate all these plug and play, which I understand.

But when I heard David McCallie talk, I think there’s still a lack of understanding of some of the things that are going on in the clinical research space and this is – structured data capture has a very distinct

research component here. And what Dixie was talking about is taking a form that is managed by a remote entity and not incorporating this into the EHR, so you're not changing the whole EHR backbone, you're just bringing a form in place and where you can pre-populate it, you do, where you can't you don't, you add data anew.

And that's the whole idea behind this and I think there needs to be an understanding of how the research world works. So while going to HL7, I think that's a huge component of this because you need the standards from the EHRs, but you need to marry that with the standards from the research world and that's where I think there's a lack of expertise on the structured data capture team. Because we keep trying to bring that group in and they haven't been actively involved in these efforts and yet they're out using a lot of these standards.

And the other thing is, I don't mean to downplay pilots, they're important, but sometimes it's not the standards or the technology that's the issue. There is a publication on ASTER, which used RFD that Dixie's talking about, at Harvard and it was wildly successful. And the biggest problem was when we went to send the adverse event reports in, FDA couldn't catch. So, you've got these things that you're

putting together and pushing out and then there's no recipient on the other end so it had nothing to do with the technology, it failed because there was no place to take what we had. They were still receiving fax forms. So, I mean there's this huge going from paper into the electronic world that we still need to address, that has nothing to do with the technology or the standards.

And then I think what Stan said is terribly important that we should all be getting together and bringing these components, we have a whole set of standard data elements, we could call them common data elements, we can call them research concepts, we can call them archetypes, we can call them detailed – models, CIMI has their own. We need to rally around getting a core set of those that we can all be using that map from healthcare to research. So we have a core data set for research that's being required around the world now and we don't have anything to map to on the healthcare side that's stable. It's a moving target. So until we address some of these issues, I don't see how we can take this forward and make everybody do it on the healthcare side. But there are vendors, Cerner, Allscripts, GE, I don't remember who was – it's EPIC, they all sat there on May 30 and said, we have this installed in our EHRs, it's been installed since 2010, why won't anybody use what we've got. So now we're making it more and more complex while the standards get better and better, but why not show that something will work now, and then build upon that and make a glide path for the future. And I'll stop there.

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

Well thank you very much. So we have Dave, Floyd and then last word is from Wes, who has his card up again. And lest John, you think we won't get through the agenda, this is only one of 18, I actually expect that STC and the data access framework will be out points of discussion. This is very important, rich discussion and feedback, and the others won't be so complex. Dave.

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

Yes, David McCallie, just to reiterate Stan's – amplify Stan's point. I think that the goal ought to be to come up with the most powerful spanning set of orthogonal capabilities that solve as many of these problems with the most parsimonious amount of technology development. Instead of taking each of these projects and looking at it as somebody's playpen to go and crib together some interesting

technology. And 7 or 8 or 10 playpens of interesting technology translates to massive amounts of frustrating work for the vendor community, some of which will never get used, so it's doubly frustrating because the provider community says, what was all this about?

So the challenge us, what's the spanning set of capabilities that addresses a lot of these problems? And for the first time we actually have some – technologies that a lot of people have looked and said, they really make sense. One of those is FHIR. It's a thoughtful, very scalable approach to moving data back and forth. Second is FHIR Profiles, which I think Stan would agree, is a limited subset of the full-blown modeling capabilities of something like CIMI, but it's the subset that matters for interchange of data, because it fully specifies the semantics necessary to have data move back and forth. So FHIR in a FHIR Profile is essentially semantics by contract that allows data to move in a very clean fashion.

And then third, I totally agree that the RDF model was the right model in that you're pushing a form in, I would simply say that if you generalize that slightly and allow it to use any web form, any web experience. In other words HTML 5, you can solve all of these broader problems, in addition to the research problem with a very modest change from what you're already doing with RDF. You could –

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

RFD.

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

– RFD, I'm sorry, RDF is the – store, right, RFD, too many Rs. So the challenge for S&I Framework oversight should be, how can we reduce the number of problems that we're actually solving here to these spanning capabilities which enable us to solve really broad problems. So the ability to push an arbitrary conversation into a the physician's workflow using OAuth 2 as modeled by the Blue Button Plus and subsequently improved upon with FHIR to move the data back and forth as necessary. That solves almost all of these problems. And we really ought to think of it that way instead of isolated cottage approaches.

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

So I'm familiar with the RFD standard, which is not RDF. So RFD, an IHE profile that includes among other things, SHTML. It actually uses a series of web centric standards that were articulated from a ballot oh 1998 through 2001, as kind of full – kind of basic in the fact that it's not unique to healthcare, it's more of the web, W3C kind of stuff. Floyd?

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

So, I wanted to reiterate some of the comments that some have made and support them. A lot of this work did happen in HITSP days and IHE, the Quality Research Public Health group with RFD and other mechanisms. I think what's really clear to me is, with all these, to support Stan's comment, a modeling across all of them for data is really what's important. Because they're all reusing data for different purposes rather than redefining it each time. But the most – one of the more important things that concerns me is the recipients, are they there and are they ready?

So it's very clear, I remember the story about ASTER and FDA wasn't ready to receive, they only took faxes. CDC on a very similar requirement for theirs, vaccine adverse event reporting, only takes a fax or mail and – or I think you can – no, I think that's all they take, so they don't work this way either. So we're asking EHRs and clinical folks to do things for one use, but everything else is done a different way, are we pulling together at least the government folks who need this information so they also accept information in the same way using the same data model. Without that, we're asking providers and EHR vendors to develop something that will have very limited use and that really concerns me.

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

So Wes, last word and then we move on to the data access framework.

**Wes Rishel – Independent Consultant**

Thanks, John. I just – early on in this go around after I spoke the last time, one of the speakers made a statement that implied that modularity in standards was the same as optionality in the sense that, if you design your standards so that they're modular at different levels, you can then choose freely which standard to use at which level. And I think we've heard that a lot from some people at ONC in different forms. I just want to make it clear that we're working at two levels, but the ultimate level is that we expect we're going to create by some mechanism interoperability where two systems that are designated as interoperable, perhaps certified as interoperable, actually interoperate. And we have almost never succeeded at that.

We have all kinds of systems that claim to be – support this standard, they've been through this testing program or that testing program or they've been certified. We still don't have Direct fully interoperating because of issues of trust. I think it's important to recognize that modularity in the choice of standards at different levels creates the opportunity to reuse standards, to write less original code when implementing standards to do a whole bunch of things. But it doesn't – it continues to be the case, as Jon Perlin often said, that when you tell the vendor A or B, it means A and B. And if you tell a vendor you can use this standard or that standard for transport, then they have to do both, and this is, I think, where we have to be careful to make the best use of modularity, but not to some wishful thinking around optionality.

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

What a very rich discussion and I think all these lessons learned that we've discussed such as scope, fitness for purpose, integration of the ecosystem, avoiding trying to boil the ocean with a lighter. I mean these are all things that folks have described that could apply to almost any standards effort. But as I read through, again John, just to reassure you, FDC and DAF seem to have the grandest aspirations and therefore possibly the greatest potential for some of the problems that have been articulated. The others look a little more tightly focused so we'll be okay. Jacob, you had a comment? No? Okay. Well, let us move on to the data access framework and we have, we will give you time Dixie, don't worry, there will be at the end of the meeting, you will get to get your agenda item done. Go ahead.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

So with Wes' parting comments in mind, one of the initial goals, in fact in some respects one of the framing goals of data access framework was to create a set – an environment where a modular and substitutable stack of components of a query strategy or a data access strategy could live. So what we wanted – we recognized that query is a – or searching for data or getting access to data is a many-headed beast if you will and the number of use cases and the number of potential user stories was very, very broad.

So one of the things we did right away is, we stepped back during the use case development and looked at three different classes of data search. For example, we focused on two, but local data access being one, meaning how do I enable clinicians within their organizations, knowing that in many cases organizations aren't monolithic, single doorbell locations, they span a variety of EHR systems under one roof or under multiple roofs, but are still organizationally or legally one HIPAA entity. Targeted data access where we knew who the patient was, we had a relationship with them already, they were getting subsequent treatment in a different facility, but I'd already obtained, from a policy standpoint, I'd already obtained permission to access their records. But I didn't necessarily have a technical way to do that, that being the second class of data access problems that we were addressing.

And then an aspirational one that we haven't launched yet, a federated approach, which in general is more attuned to population based kinds of data. Although in an HIE world, obviously there are queries where it is targeted on a single patient, and so we've left that one out of our focus for now and we focused primarily on the local data access and the targeted data access. Within that, again we recognized that there were a variety of different use cases. There were many examples where what we needed were documents about the patients where we would need a Consolidated CDA or we would need something that had already been compiled into a document. But in other cases, we just needed to know what their hemoglobin levels were for a blood test, so a data element based approach.

So again segmenting it into or separating the standards that were appropriate based on that subsequent set of needs and then within – certainly within a practice, the need to do a patient level searches and population level searches. I'd like to take a look at all of my – a class of patients or a cohort that would all be pre-diabetic and how can I do an analysis and run some queries on those so I can look at some health statistics within my practice. We recognized from the outset that a single standard was not likely to address any of those completely and that we would need to identify a family – or a set of standards would need to be investigated. So we broke our standards down into multiple levels of transport, of query type, of language, etcetera, so that we could address those, not assuming that we were going to, as I said, ever get to a single one.

So that's sort of a framing picture of what we wanted to start out with this initiative. We recognize that that will require a lot of different standards and potentially a lot of different use cases. So we didn't try to tackle them all at once, we settled on a couple of very specific ones right out of the gate. But longer term we're looking at pulling together a family of different standards to do this. We – as you can see here on the outputs, we're – we developed some use cases, we've put together with IHE a white paper, and I'll get into a little bit more detail on that in the next slide.

And we're working with not only IHE, but HL7 on some – the mobile health profile and FHIR, which are actually working together across organizations to come up with a harmonized approach using FHIR across both. And we're working with the InM group within HL7 SDO and working actively with PCC and ITI within IHE to look at the same kinds of things. So we're working with both of those mainly because our community is interested in support for both RESTful approaches and SOAP-based approaches.

I realize that an “or” often becomes an “and,” but it may be use case specific. It may not be that every single use case requires or is best suited for both RESTful approaches and SOAP, but we envision that there will be somewhere the vendors want to be able to do both. And we’ve further realized that the query requestor may be a simpler function than the query responder, and perhaps a query responder needs to be able to support more than one approach and a query requestor would only support one. So that’s the other way that we’ve tried to address this interoperability question.

On the next slide here, I’ll probably go from the bottom up on this slide and land with where we are and what’s active in the initiative right now. It was launched about a year ago, come December last year we’d achieved use case on our local data access framework. We followed that up in February with the targeted data access, and at that point we’ve launched a number of technical workgroups taking a look at both document-based access, as I alluded to sort of in my opening comments, as well as the data element based access sub-workgroups. We launched with IHE the development of a white paper, we worked through their process and developed a white paper led by both Nagesh Basham or “Dragon” within the S&I community and Keith Boone within IHE.

And it’s a very interesting white paper because not only did it outline those areas of technology and artifacts and standards that existed off the shelf that could be used for some of these use cases. But in my mind, probably more importantly, they identified the gaps where, for example, IHE Profiles didn’t fully support population based queries or didn’t well – didn’t support well the need for granular data element based queries. And that group has been meeting regularly now and going back through and prioritizing those gaps, those areas where good standards do not exist today and working actively not only within the IHE community but within the HL7 community to take a look at standards that might be leveraged to do just that. And that’s really the phase we are right now, taking a look at that and putting together a set of recommendations that would go through this next cycle, within the SDOs, for creating CPs or profiles that could address those gaps. And I know that there will be a number of questions so rather than continue on with prepared remarks, I’ll go ahead and shift us into Q&A mode.

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

Thank you very much. So Arien Malec, I think, has a virtual comment, then Dave McCallie, is your card up?

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

Yes.

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

Okay.

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

So first of all, thank you so much for the presentation. I think this initiative in particular has a tremendous amount of progre – or promise and also, I think, highlights some of the themes that we’ve been talking about. There is the need for, as David McCallie called it, the orthogonal – the set – the spanning set of orthogonal standards vectors and we’ve got DAF that has a pretty broad and expansive

goal. But instead of finding the parsimonious set of orthogonal standards vectors that span the space, has been, I think, looking for a use case based approach and a standard assembly based approach. I note that the white paper – the IHE, S&I white paper identified 21 IHE standards that span some of the space and then concluded that the appropriate solution is to create a number of others to address some of the concerns for population health. And I wonder whether we just need a different approach here to identify a set of needs, find, as David mentioned, the spanning set of orthogonal vectors – standards vectors that span that set of needs and then work at addressing some of those issues.

I'd also note that in this area we've got a really complex set of interrelated parts and I'm seeing the initiative draft in some ways such a high goal and such a broad set of efforts, without actually identifying some of the core underlying components that are required to pull it all together. So I would look at, for example, privacy and security, looking at some of the work in potentially OAuth 2 and OpenID Connect and leveraging some of the work that DirectTrust has started, in terms of organizational identity assurance. The concern would be that we have a bunch of standards dressed up and ready to go, but we don't have some of the underlying enabling capabilities that enable trust and actual practical interoperability. As I think Wes noted, one of the biggest issues that we've seen in the roll out of Direct isn't actually the technology and the standards, it is making sure that we've got an interoperable trust framework, and that's actually been one of the larger issues that is necessary in order to get broad scale roll out. So, feel free to respond if you want, otherwise we can leave that as a set of puzzles and concerns for the Standards Committee going forward.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Yeah, I agree, thanks very much. There is a – I'll sort of go backwards on your questions. There is a very active community-led Direct-based sub-workgroup within DAF that recognized that there may be some significant opportunities to leverage – for example, asynchronous queries using Direct as a transport platform. And they brought to the initiative a number of folks from the Direct community that hadn't previously participated, including DirectTrust, and are looking very actively at, how do we leverage some of those existing trust frameworks within this kind of a use case. And they also are volunteering to play an active role in bringing that updated set of standards when they're ready or standards suggestions when they're ready, through SDO.

So, we're encouraged by how that might look and how that might play a part in this. We have been looking at those – and looking at leveraging existing privacy and security standards. We're not trying to avoid the privacy and security standards piece, what we're trying to recognize is that we're not trying to set any new policy or change any policy directions here. We're trying to take advantage of what exists and leverage those going forward. And then your last point on the – to David's earlier question, I think you raise a fair point and we'll have to take a look at the – how we approach this from a parsimonious standpoint.

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

Thank you. By the way, just as a small correction, I think looking at transport and Direct, as transport is a wonderful idea. I was actually pointing to the work that DirectTrust has done in creating standards for organizational identity assurance and potentially looking at that as a means for allowing counterparties to exchange, have a level of assurance that their counterparty actually is a healthcare organization in good standing.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Sure, and by their participation, they're bringing that body of work to the larger group as well.

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

Excellent.

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

Thank you. David McCallie?

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

Yes, David McCallie. There are numerous opportunities for parsimony that we're going to have to wrestle with, one on the FACA side or the advisor side, I can think of at least three groups that will touch on this work in addition to the work that you're doing. So trying to keep it all straight and coordinate the recommendations of the various workgroups will be a challenge. In particular, the old power team has got some meetings scheduled to address targeted query. The new API group will undoubtedly, when it's populated take this on. And then there's a JASON Workgroup that just got populated or just got initiated a couple of days ago to go address the recommendations of JASON Report, which are fundamentally for an open API at the discrete data level, which is essentially what you're describing here with your use case. So there are a lot of moving parts on the FACA side.

To me the more interesting question is on the technology side, and again I'll just reiterate the point that I think the emergence of FHIR, which really wasn't on the radar when many of these things were kicked off, has given us an opportunity to consolidate a lot of this work into a well thought out extensible approach. So the combination of FHIR plus FHIR Profiles, plus the appropriate security model, which I think is going to end up being OAuth 2, since that's just what the rest of the Internet's using with OpenID Connect, as Arien suggested for identity, for authentication is a set of spanning vectors that really does address a lot of these cases.

And I would love to see that data access framework shift into focuses on use cases for how to use these new emerging tools, much of what will turn into building of profiles, because it's the profile that matters from an interoperability point of view. And the profiles are where you'd address the semantics that Stan was talking about. But – I mean the good news is I think we have a good, solid emerging foundation from HL7 that can address many of these questions. And we just need to work really hard to make sure we don't create duplicate work.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

So one of the things that's interesting is we – I fielded an e-mail this week or watched an e-mail thread unfold this week from someone who is relatively new to DAF. Who looked at the output, looked at what we were working on and said basically, well, FHIR's looking to do in all of this stuff, why don't we just use FHIR? Why are we even bothering with anything else? And in many respects, I hope that that's what our work leads us to conclude is that there is something that's very viable out there, that can do all this.

And we conclude that even though we've invested in some of these other pieces that the final recommendation at the end of a pilot phase and everything else is that the set of outputs or capabilities from a FHIR-based approach is sufficient to solve all of this and that will be a recommendation going forward.

One of the tenets – however, I want to remind the committee here that one of the tenets of the S&I process is that we don't go into it with a technology dictate saying, this is going to be the solution. We go into it with a set of desired needs and outcomes and we work through the community in a process to say, what's going to get us there? What are the tools that are available? How mature are they? We subject them to the maturity model and we wrestle with, here are some that are well established, that are well deployed but may not be as desirable going forward. Here are some emerging ones and what's our – what's the glide path through them when we want to land this thing? And then we wrestle with and hopefully make a good choice there on where we're going to land.

I think – I'm hopeful that FHIR is moving fast enough that it's glide slope and ours will coincide and that may very well be where we want to land. But we're trying to do this in an open and transparent way with the community and bring them along. I mean we've had a number of discussions with folks around FHIR specifically and one of the pieces of feedback is, here we are chasing the next wonderful looking rabbit. When are we going to stop chasing possibilities and pick something that will work? So, a part of our job is to bring the community along in this process, work with them, listen respectfully to those kind of pieces of feedback and then hopefully pick a path that gets us to a good place.

So, I'm not disagreeing with those recommendations, I'm just trying to set the stage for, we have a community of folks and participants and active and involved members who span a variety of opinions and come with a variety of circumstances. And we're trying to get those to coalesce around a small subset of the possibilities that are in front of us.

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

It's David McCallie again, just to reply to that. I certainly appreciate the challenge of trying to settle of standard in a moving – when the industry is changing so rapidly, particularly when your target date or the date that it would affect those of us in the industries that we represent is three or four years down the road, 2017 and beyond. I think that I would urge you to put your energies into completing the best work rather than fine-tuning the older work. In other words, build communities that are willing to land the good new stuff faster than communities that are merely willing to buff up the standards that they've worked on for the last decade because they've worked on it for the last decade and it could always use a little bit more polishing.

In 2017, 2018, 2019, what technologies are we going to be using, is the question you should be asking. And focus on getting us to that. It's a hard problem, I don't mean to imply that that's just an easy way to do it. I think we – all of us who've worked in Dixie's Power Team have wrestled with, how do you get a mature standard when nobody's using it and you don't use it unless it's mature, it's a chicken and egg problem. But I think we've used FHIR enough in our own work at Cerner, we've done pilots with a number of other vendors, and it's been successful. We've used it in CommonWell successfully. We are very confident that it is the right way to go. Now it's still got a lot of unanswered questions and there will be some mistakes made and some dead-ends I'm sure, but the core of it is really sound and its driven by a really sound team. So, I feel more optimistic about that than any of the standards that I've seen in a long time and I would encourage you to help finish that. That would be welcome input.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

It is a very, very, very, very active part of our work and we are working hard to skate to where the pucks going to be.

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

Thank you.

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

And a related – on Jon Perlin’s comment, as you read the JASON Report, what it suggests is that an API to an EHR with ability to read and write is what we want in the future. And when you look at the data access framework, as you say John, it’s a question of defining scope and approach and what is the role of FHIR. Is the data access framework an API approach or is it an XDS.b approach or what is it exactly, because there are many ways you could cut that particular scope you’ve defined.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

We do hope that there will be APIs that result from this that are usable and leverageable as the JASON Report suggests.

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

Great. Thank you. So Jon Perlin and I see Cris Ross has also put up his card and Nancy Orvis on the phone. Go ahead, Jon.

**Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America**

Thanks, John. Not to add fuel to the FHIR bandwagon, but will do so. I think your comments, David, are right on in terms of FHIR and John, we’re tracking exactly in terms of this concept of an API approach. And when we think about the concept of operating electronic information five years hence, I think perhaps our concept of the relationship of these data access frameworks to electronic health records change and really becomes a relationship of data access to data as opposed to internal machinations within, particularly a large, integrated system.

Toward that end, I mean I think there are a number of applications. One, you mentioned specifically, that whether a person is extracting a single data element or wants a presentation of, you used the example – the use case of a population or cohort of patients with some similarity. The other might be a representation of data from a singular patient for a particular view, say geared to a particular specialty, to a particular clinician type or the like. And toward that end, I mean I think the API approach is particularly important, this is absolutely critical in terms of capacity for innovation.

And thus my comment, Jacob and John, is really then less about the specific standards than really a concept of the use of standards that would make this suggestion, knowing that it's out of our specific purview. That the Policy Committee contemplate this in particular, in terms of the certification framework, in terms of being able to access the data within these systems as a vehicle to really contemplate the use cases that one would want. In the absence of that, one might envision a world in which the standards are available but simply inconsistent with some of the structural limitations of the products that exist today. That would create a glide path both to the evolution of those products and the use cases that were contemplated, as well as an opportunity for innovation on top of those data sets that would allow the sorts of use cases that would involve the representation to occur.

One last comment, envisioning that type of world where there is that innovative sort of capacity. I think a comment that Dixie's group and Dixie will make later is just so well taken is that this concept of remote versus local becomes more fluid because in terms of some of those representation or use cases where there are technologies that make use of the access framework standards, etcetera. They may be actually conducted within the physical plant where care is being provided and so it's really a concept that is in evolution as well. So, thanks.

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

To Jon's comment, I don't know if folks have studied the Apple HealthKit. It's software, it's APIs, well Cris of course would know about it and others who may have collaborated early on. In effect, Jon, what it does is it creates a set of attribute value pairs and doesn't actually have a transport standard. It says, do you have a local app that the patient can say they trust? And a notification would be sent to that app that attribute value pairs are available and then the local app has access to them and can do what it wishes. It can send it to your EHR, it could send it to some unique I don't know, care coordination or care management platform or whatever. And so as Jon you describe, the future as an API approach where we can't be constrained by the architectures of the past, this is a simple set of standards with a trust framework that allows flexibility.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Exactly.

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

Cris Ross.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So I guess in listening to this dialogue carefully, especially the thoughtful comments from John Feikema about what they need to do as a practical step as part of S&I framework. I'm struggling with, how do we as a Standards Committee help accelerate the adoption of this emerging new cadre of standards? When I look to the 2015 edition and the proposed Stage 3, I don't see, obviously these standards as front and center. And it feels to me as though we are therefore relying on non-regulatory efforts like S&I to try to make judgments about where the puck is going, which is good, but it feels to me as though it's potentially suboptimal and inefficient. And I don't think I have a good answer, but it feels to me as

though our work ought to focus on how can we accelerate the maturation, iteration and adoption of these standards.

And I think people outside of our body might question, what are you guys up to and why can't you help move the ball down the field more rapidly? And when I look at the way that our workgroups are going to be organized over the next year and a half, I see either great opportunity or potentially great fractionalization or balkanization of questions in the little corners that we won't be able to get enough critical mass. So I would offer that as hopefully a constructive challenge to figure out how the heck do we get at this problem and not simply observe the challenges that this inflection point between old and new presents us.

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

Jacob has a comment.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

It's a question for Cris, perhaps – and perhaps for the rest of the group because I heard that Genesis of recommendation and – or maybe a wish for a recommendation in what you were talking about, Cris. And I think that you were starting to say, keep it simple smarty-pants.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

That's always good advice.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Well I think – so I think that that's the Genesis of a recommendation for us, to focus on the – rather than make sure all in the corners and maybe even that's something that Becky was saying with her recommendation to get on with it is, maybe we shouldn't solve all of the problems. Maybe we should solve some of the problems in a very explicit way, right, so this is the train tracks metaphor, whichever one you want to pick, all of which are flawed. Because we're talking about complex systems and yet there are some simple components that we – perhaps we can focus on and maybe that would be a place where we'd love to get the group's recommendation in terms of where we should aim our arrows because we don't have a shotgun here.

And if we can focus on things, what should – so as we continue to talk about data access framework, and we've talked about now two, and as John said earlier, these are the broadest conversations perhaps that we'll have in the day. But these may be, and I think I'm hearing you all say, these may be too broad, so how can we focus these initiatives so that they add value near-term and then could iterate towards more detailed sets of guidance? And I also think I heard you say that regulation might be something that we want to do in order to enforce standards. Did you say that, Cris?

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Well, I – perhaps so. I think I would observe that despite any community good effort, the requirement of commercial success for the EHR vendors that they must comply with regulations and in practice that we must meet the attestation standards required. It creates a certain relentlessness that anything we do on top of that is nice, but a lot of organizations are really struggling to hit the recommendation. I guess my observation would be, and I sincerely do not want to derail the conversation or take it in a negative direction but it feels to me as though the game changed and we didn't notice it. Somewhere around the development of Stage 2, these really powerful standards emerged and a lot of really great thinking coalesced around them. And they may not have been quite ready to include in Stage 2 or thinking about probably Stage 3, but I worry a little bit that we will look backwards and say we missed an opportunity to inject this new modern thinking into Stage 3 simply because the timing wasn't right.

And it feels like , I don't want to wait for Stage 4 train or however it is that ONC, which I see as very productive and constructive, to try and create a framework outside Meaningful Use to move these thing along. That sounds great, but I don't know when the next train leaves the station and I think we've got some stuff we want to get on the tracks. Again if I'm taking us in the wrong direction, I apologize to our Co-Chairs, but it feels like to me it's a question in the room that we need to address.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

I pointed at Steve, but I'll just say it. Remember that the MU train and the standards certification train may or may not be forever Velcroed. And I say that because the ONC expression in the 2015 Proposed Rule was that we would have a regular, and we can talk later about what that regular cadence looks like. But ONC would have a regular regulatory cycle that would allow for the expression of new standards to be recognized and implemented so that we don't lock in old things. But I don't think we want to keep that forever tied to a stage of the Meaningful Use Incentive Program. And in fact the things that could fall under that might be beyond things that are appropriate for eligible providers and eligible hospitals. So just want to very quick remind everybody that these things aren't the same.

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

And Steve, did you have a comment? So I would just say Cris, of course we won't get to your answer to that issue today, but I'm hearing in this discussion a lot of thematic commonalities about hmm, FHIR interesting, REST, OAuth, OpenI – umm, it's coalescing there. And as I said in my introductory remarks, I mean we may not be able to solve all 18 S&I framework initiative problems with the toolkits that have been articulated by all of you, but there'll be a whole lot of them that fall into that OAuth, REST, FHIR, JASON kind of approach, I think. So I think we're getting there. Okay, so what we have is Nancy Orvis, Leslie Kelly Hall and then, you know John, we can move on to some really easy things, I mean like there was the Iran-Iraq collaboration you wanted to talk about, next, no problem. Leslie – or Nancy, excuse me, Nancy.

**Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense**

Hi everyone, I – as I'm with DoD, I said, this has been a – you've asked a lot of questions and answered a lot that I had as we went through this, but I do have a couple other ones. I know two things are, again, as a federal provider, we have a real clear use case for having assured, trusted framework that could be a very good plug-and-play by 2017 or 2018. We have a whole Tricare Insurance Plan plus we have our

own hospitals in the DoD. And – but we’re committed to keeping a health record on our patients for 75 to 100 years, because under the federal records laws, a person’s records are kept. DoD and VA have talked about this several times up at like NIST and everything else. We have, in law, that we are keeping this data.

So, all I – one of the – the prime interest is, as federal providers and as federal record keepers, we have to have an assured and trusted framework to allow others to send us data on our patients or for us to send data back, so heavy interest in making sure that you come up with some good simple ones to start with and that we all will still build this data exchange infrastructure that can meet the test of HIPAA Privacy and Security. I had one question though on, when is your first prototype phase ending or beginning?

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

We haven’t determined that yet.

**Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense**

Okay, all right, so that’s an open question on that. As we say, there are great insertion opportunities to mature this, I think. I’m thinking for all the health insurance plans that are out there that we have some good windows in the 2017-18 timeframe. And if there are any other use cases that are – I have a – we have a lot of people in the IHE community and vendors that work with us that are trying to test this out. So, if there are any questions you have to us let us know okay. I think that’s probably – because basically you’ve addressed everything else I had a question for on that one. But it is important to get this done. Thank you.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Thank you.

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

Leslie.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

So building on Cris’s comments and some of Jacob’s comments, I think that we have a cultural divide as much as we have a technology divide that we’ve talked about today. And we’re moving from asynchronous, bilateral, disoriented communication methods that we’re trying to bring together. And so we address those things with how to make asynchronous more synchronous. And we address those by trying to make the end points clearer. But what we really have is this new cultural instance of a collaborative care model. And trying to pigeonhole that asynchronous one-on-one communication methodologies with a future state of collaboration where all parties are involved seemed to be never able to fit. And it’s almost as if we have an S&I framework that needs to address the current state and our understanding of mature standards. But then we have a visionary and collaborative care model that

needs to look at a very robust and very different infrastructure. And the more that we try to make one fit the other, I think, we're going to end up looking back in five years and saying we've not done anything well or we've done the wrong thing well, to Cris's point.

And so I wonder if there in this new day of reorganization and structuring, we should look at a standards and interoperability and innovation framework. And that we deliberately state that this innovation framework is an informing construct that has a natural evolution that we can use the different pieces and parts of today, but not assume that one-size-fits-all. And I am struggling with this conflict because there seems to be a natural tension between the two. In one way I think, gosh, if we could just get Direct right, my goodness, we'd have some wonderful very simple communication methodology. But on the other hand, in the future, I don't want to have asynchronous, bilateral communication with a care team that has to be coordinated with inconsistent provenance and no rules that apply. I'd like to have a collaborative care model as a patient where I and others who co-produce my health can communicate in a meaningful way with my research community, with my home community, with my care providers and professionals. So, I guess I would like to offer some cautionary and perhaps some way to move towards a vision without the imposing of the current mature environment and vice versa, if that makes sense.

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

A very good comment, Jacob and I, before the meeting, had a conversation that although we are all attracted to what is the emerging technology there is installed technology. And we have this interesting challenge of, what can we get going today with what we've got versus what do we want to aspire to in the future and it probably has to be a bit of both. Well David McCallie, was your card still up?

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

Yeah, just a philosophical comment, piggybacking on Cris Ross' high-level comment which is, the de-velcroing of MU and certification, which I really appreciate the clarity that you've given us on that today, I heard that rumor, but that clarity is really appreciated, Jacob. The – if you unhitch the incentive that is pulling for the things that drive the certification, then we need to be sure to focus on enabling market forces that drive us towards the new goals that we want, and then have certification follow those market forces to rough off the rough edges – to smooth off the rough edges.

So, you won't get high levels of interoperability simply because you write regulations around certification of products that require them to be able to interoperate. You'll get high levels of interoperability when the market demands it and then the regulations can help smooth the rough edges, for example, around trust issues or how to use OAuth 2 profiles, because there's a hundred different ways to profile them and we ought to all agree on those kind of nasty things to make the – smooth the road.

So I think if we look at the explosion of interesting capabilities in population health, that didn't come about because of a clever certification requirement, it didn't come about because of the great success in standardizing CDA and C-CDA. It came about because of a change in payment models and everybody realizes they have to move the data in a different way in order to stay in the game, and that's driving phenomenal data interchange that was unimaginable just two years ago. I mean we – in some of our larger population health environments interoperate with a dozen vendors today, and it works. And it's because the clients demanded it because their business demanded it and that's what will push us

forward. So, take a gentle approach to putting cement around regulations of certification until you really understand where the market is going.

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

And this is a fascinating point, you probably, Steve, in your new role, something just to observe. I certified all of Beth Israel Deaconess systems for Meaningful Use Stage 2, inpatient and eligible professional. I work with other vendors who have been certified to a similar extent and there are HISPs in the environment who have sworn that they have implemented faithfully all of the standards that Direct implies. And the challenge of getting those HISP-to-HISP communications and that trust is only overcome because there are market forces demanding that it be overcome. And it has almost nothing to do with the certification processes that got us to the foundation. It's fascinating. Now let's see, I think there was an Arien Malec comment as well.

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

Pretty much what you guys just said, that was the extent of my comment. I've been through this a bunch of times and I would observe that nothing is much harder to get interoperability by defining a standard, then defining the certification requirements, then making everybody implement it than it is to have market forces drive people to solve the need and then – standardize and certify to rough out the edges in solution. So just double down on those two comments.

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

Okay, well see, as Jacob predicted, these two could have been our entire agenda for today. But don't worry, you have 29 minutes to go through the remaining 16, it's going to be fabulous.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

So there's actually just 10 more in this that we want to cover. So that gives us an average of 3 minutes each, assuming we can go one minute over –

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

Go for it.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

– unless we have some that turn out to be quite a bit faster, so we will do what we can to keep our delivery as quick as possible. Getting to the end is going to depend somewhat on feedback.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Logistical issue, for those at home, just put yourself on mute. For those in the room, feel free to go use the restroom if you need to, we're going to keep pushing here.

**Mera Choi – Acting Standards & Interoperability Coordinator, Office of Science & Technology – Office of the National Coordinator for Health Information Technology**

So, I'm going to – this is the EU-US eHealth Cooperation Initiative. I'm going to provide some background, a little bit, on this initiative particularly. It started – it launched in 2013. The impetus for this initiative was due to an MOU signed in December 2010 by the EU and the US. As a result, a roadmap was established, developed and set this initiative in motion. There were two work streams that were created and established. The first one was the interoperability work stream and the second one was the workforce work stream.

The workforce work stream's purpose was to work on semantics, syntactic and interoperability and patient media exchange. And the workforce work stream's goal was to work on workforce issues such as competencies and health IT skill sets in both the EU and US. As you can see on the outputs, you can see that we've worked on the use cases under the interoperability work streams and a standards mapping. We also worked on the workforce role identification as well setting and analysis and selection and then competency and categorization. Our final goal for this piece, we'd like to have a white paper established for the interoperability workgroup by the summer of 2014 and establish a white for – a workforce white paper by early fall 2014.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

And those results are detailed out on this next slide, but I think Mera covered them well in terms of an overall, so, we'll go ahead to the Blue Button Initiative. I think the folks here are pretty well familiar with it, it's been out there quite a while. We've had a number of folks in pilot and most recently, some very active pilot work at the Datapalooza in Washington just I think a week and a half ago. We're currently in a little bit of transition on this initiative, our initiative coordinators have moved on to other things, so we're in between things here and this one will be re – getting into its next phase, we're taking a look at what the next phase should look like and expect to hear more soon on this one.

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

Okay, go ahead. Go ahead.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Yeah, thank you, John. Just one question, I know that Blue Button Plus initially talked about the certification of apps that would be able to access EHRs and that you'd establish a level of trustworthiness of the application itself somehow. Where does that stand?

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

That's a good question. I remember that just at the annual meeting last year or year before last, there was a whole bake-off and we looked at a bunch of them. I'm not really sure where that landed. Do you know? We'll go ahead and get you feedback on that.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Okay, thank you.

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

Thanks everybody. Good morning, I'm Johnathan Coleman, the Initiative Coordinator for the PDMP Health IT Integration Initiative and also the Data Provenance Initiative, so I'll try and combine both initiatives into three minutes or less. To start with, PDMP and Health IT Integration, this is a joint ONC, SAMHSA sponsored initiative. And the goals of the initiative here are to bring in – to bring together the PDMP and the Health IT communities, including the pharmacy community, in an effort to help reduce the number of prescription drug instances and overdoses and misuse within the United States. And I think it's important to recognize that in this initiative we know that there is a complex policy landscape, and we're not trying to create new policy, but really trying to, as Jamie put it, integrate the PDMP data into the frontline workflow of those who need this information, which is the provider community. So, that is the PDMP Health IT Integration Initiative goals.

We are pretty young in terms of where we are in the overall progress. We have a charter and use case that we've achieved consensus on. And we're currently going through and looking at the standards landscape for the various stakeholders that are involved, which include the PDMP community, we've got very strong representation there. We do have some health IT and strong pharmacy vendor community as well. And so again we're currently evaluating the standards in use today and we are developing a solution plan and we have a solution planning workgroup that is looking at how we can integrate those standards together.

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

Comment, so in Massachusetts there is an incredible business interest, to David McCallie's comment about taking say an emergency physician who's in the context of viewing a patient in electronic health records, and without having to respecify context or login or go to a different UI, click and be able to access the Prescription Drug Monitoring Program. It's part of workflow, I mean to Jamie's comment about thinking about workflow. And we have developed a three-page standards specification to do that, which I'm happy to share with you. And it oddly enough uses the sort of things we've all been talking about, it's a RESTful API with an OAuth-like construct. It's amazing and it allows the Prescription Drug Monitoring Program to develop software of its arbitrary choosing and the EHR to develop a UI that's arbitrary for – but to connect the two with workflow integration and so, something to think about.

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

Wonderful, thank you – be in touch momentarily. Thank you. All right, so let's move on and take a look at data provenance. So this project is looking to standardize a way that health data is captured and that the source of origin, the original provenance of the information, can be maintained throughout the

lifecycle and lifespan of that information. And so we're trying to establish some guidance for how to handle data provenance in the context of standards. There's discussion about how deep do you go, how granular to you go, to what level provenance should be captured and maintained.

And we're trying to again not set policy here, but establish guidance on the minimum set of provenance data elements and recognizing the vocabulary bindings that may go along with that so that provenance capabilities can be included within EHR systems. And that other interconnecting components of the health IT landscape will have an understanding of what health IT systems are capable of in terms of tracking, managing and understanding provenance data so that it can be useful in terms of informed decision-making and support a broad range of possible use cases.

On the top right there you see that this is a – Julia Chua, who's in the room, this is an Office of the Chief Privacy Officer sponsored initiative. The state of the project is fairly new, we are in the early stages, we've completed pre-discovery. We have received consensus on the charter and we're now into the use case, recognizing that we are undoubtedly going to need to learn and understand what's currently out there in the standards landscape for provenance. We've also launched the Tiger Team who's working very closely with HL7 to understand, document and articulate current existing provenance capabilities and pull that together in a package that the initiative can use as we continue our work.

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

Okay, so we have David and Jamie.

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

So one question, and I haven't paid enough attention to this workgroup. The Tiger Team – Privacy and Security Tiger Team has recently been wrestling with how to deal with the behavioral health – the interjection of behavioral health data into the data flow with the clinician when those data elements contain additional restrictions that are – go above and beyond what we're currently used to dealing with in vendor products. And we proposed out to the Policy Committee a kind of compromise that said, leave them in sequestered documents for now because we don't have the capabilities of managing discrete elements that have been detached from their structured document, but which still carry redisclosure restrictions. And we've all sort of said, well, we need more information about data provenance to know how to deal with that. So my question is, is this one of your use cases, the management of – or at least the tracking of constraints on the data above and beyond where it came from? Or is it just provenance in the traditional sense of where it came from?

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

So we haven't gotten far enough along in the use case process yet to be able to define which of the use cases the initiative will focus on. But we understand that there are a broad range of applicable use cases that will leverage the work of the provenance initiative and we are very cognizant of that work and want to make sure that whatever we develop can support that particular use case.

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

And then a – that’s good to hear, I think it’s an important use case. I will also register that these changes that may emerge from this work will have profound impact on EHR vendor technology and shouldn’t be taken lightly.

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

Absolutely. And in fact, even within the data provenance Tiger Team that’s just started working with HL7, we’ve found that there’s been significant interest from, at last count 10 different workgroups within HL7, all representing their respective domains, who are interested in supporting and co-sponsoring various aspects of this project. So, the interest is very reassuring and most welcome.

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

So the challenge will be to find the right light touch.

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

Yeah, absolutely.

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

You could make it unmanageable easily and that’s obviously not good for anybody.

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

Right. And so just to, I guess maybe respond to that last point, one of the I think goals of our initiative in terms of execution is to make sure that we scope of our work so that we can come up with reusable building blocks that do support a broad range use cases. And obviously we’ll need to pick one or two to prove the work, but we don’t want to be restricted to those particular workflows.

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

Jamie.

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

Thank you. So Jacob, at the outset of this session, you requested input on relative priorities for the different projects. And while I very much appreciate and support the note of caution that David interjected, my view is, this is probably the highest priority among these projects. When you consider the objectives of the 10-year strategic plan, this is absolutely fundamental. So, this would be my vote for the top priority.

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

Thank you. Leslie.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

I just wanted to remind the group that the patient should be included in this work effort, as you consider provenance, and both as an author or custodian or any other role of data. But then also to consider a tamperproof seal so documents can move without provenance being changed, as the patient does view, download and transmit, they'll be moving data themselves as an exchange of one. And we want to make sure that data is equally trusted and that the provenance is able to stay with that data. Thank you.

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

Thank you.

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

To this point, last evening I gave a webinar and a number of the questions went something like this. Imagine that a patient is the steward of their own data, a patient receives a Beth Israel Deaconess clinical summary, which notes Tylenol #3, has been prescribed for pain. The patient then goes changes Tylenol #3 to OxyContin q. hour and it still has the Beth Israel Deaconess signature on it. And of course then Dixie I explained, hashing and cryptographic signature and check summing and these kinds of things and they understood. But it's this whole notion that we are all talking about, if we're going to be sending packages outside of our institution, to be able to ensure we understand provenance and data integrity is absolutely fundamental.

And so I think I have Dixie and then Becky.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Okay. I think my question might be pretty straightforward, I hope. But at the beginning of this whole session, Mera mentioned that the data segmentation for privacy has now folded into this provenance work and I'd sort of like to know how that all fits together.

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

So the data segmentation project focused on ways to tag data using data – using metadata so that it could be subsequently handled and that spawned the development of a number of pieces of work within HL7 including the healthcare classification scheme, which is security labels, and the development of a data segmentation standard. Within HL7 the data segmentation standard also contains a chapter that introduces provenance. And so that work is included in the landscape survey with this project.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

I see. I see, it's not really that – you guys aren't working on data segmentation for privacy, this is just the next chapter.

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

Correct.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

I see, I see.

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

So I hesitate to bring this up because I may be missing some nuance here but we've been working in the research field for years on data that carries an audit trail. Basically anybody who entered the data, changed the data, why they changed it, when they changed it and it's all built into our operational data model. And I'm just wondering if anybody had looked at that as a resource, because traceability of that data and what I think you are talking about as providence is already being used widely around the world in the research space.

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

Okay. Well, let us now move on to clinical quality, which I know Floyd will have no controversy whatsoever.

**Mera Choi – Acting Standards & Interoperability Coordinator, Office of Science & Technology – Office of the National Coordinator for Health Information Technology**

Marc Hadley on the line?

**Marc Hadley, PhD – Principle Software Systems Engineer – MITRE**

Yes – yeah, so this is Marc Hadley, I'm one of the co-coordinators of the Clinical Quality Framework Initiative. And the scope of this initiative is to harmonize standards used for electronic clinical quality measurement and clinical decision support. And we're focused on three main areas of harmonization. The first is metadata, the second is a common data model and the third is a common expression language. And we're a fairly new initiative, we just started this year, but we're building on work that was already underway in HL7 starting mid-last year. So we're actually further along than you might think in terms of deliverables. Next slide, please. Actually, I'm still looking at the data provenance slide. Ah, thank you.

So far we have published two documents, HQMF, we created the R2.1 package and this modularizes HQMF to allow it to reach out and use the harmonized components that I just discussed. We did the same for the Health eDecisions Knowledge Artifact and R1.2 was approved for publication just recently. We're currently working on a comment only ballot of the – of a logical data model for quality improvement. I think for folks who have been talking about FHIR, you'll be pleased to know that that is

actually based on FHIR. We did an analysis that was balloted in the last HL7 ballot cycle and it showed that FHIR, while it provided a good building block for us, didn't actually capture all of the data we need. So we'll simultaneously be working on a FHIR Profile to add in the extensions we need to capture the extra data.

In parallel with that, we'll also be balloting a for comment ballot of the clinical quality expression language. That is building on top of the work that was done in the Healthy eDecisions Initiative, which was one of the precursors for this initiative. But we're adding to that a human readable expression language on top of the XML expression language. Sorry, was someone trying to ask a question?

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

Although there are questions encouraged, there wasn't a question yet. Any other comments you'd offer?

**Marc Hadley, PhD – Principle Software Systems Engineer – MITRE**

No, I was –

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

Okay. So let's then David McCallie and Floyd.

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

Dave McCallie, a few things you said got – I couldn't hear very clearly, so I may be repeating something you already said. But I think this is an area where great attention should be paid to avoiding reinventing the wheel. I believe I heard you say you were using FHIR or looking at FHIR as a way to profile the data elements that you need and if so, that sounds really good. And then on the expression syntax, our industry is littered with attempts to create custom computer languages for healthcare that have all gone nowhere. So I commend you also on producing a human readable artifact, because that's the one thing that we are guaranteed that people can take advantage of. So if I heard those correctly, I think that sounds really good. Thanks.

**Marc Hadley, PhD – Principle Software Systems Engineer – MITRE**

Yes, you had that correct.

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

This is Floyd, also with more complementary comments here, I think it's high time that we did harmonize across all of these efforts around quality and decision support and reuse of data. My only concern is the piloting as it's being developed is problematic in some ways for the vendors and it would be – I think we need to have some caution in looking at new decision support and quality measure development when the model isn't yet complete. Because there's going to be a lot of rework. So testing is one thing, but there's a whole industry on creating measures in a tool that is still being updated and the model's not done. So, we just need to be a little cautious on the speed.

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

– Jacob Reider, the I2B2 construct, which of course is something that has inspired query health and – other things that you guys have worked on and how that if you could define a data model and ontology, that you could actually have multiple downstream systems capable of parsing questions and returning answers. Rather than pre-computing within an EHR every possible numerator and denominator by hard coding it. Now when you look at the ontology that’s been created, it does not include such things as, well Mr. Smith was your stroke one minute and 59 – one hour and 59 minutes ago or two hours and 1 minute ago, so somebody defining a quality measure of stroke less than 2 hours wouldn’t be possible with such ontology.

And so I think Floyd’s comments are well taken. I love the idea of defining an ontology, which could be mapped to multiple downstream systems and a mechanism of sending questions and constraining our quality measures to the data elements that are available. So, and as Jacob also said, making sure that the CDS and the quality measurement are two sides of the same coin, tell me what I need to do and then measure me on my performance. Do you have a comment?

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

Just a short comment, thank you Marc for the comment and thank you in the room that expressed support in general for this. I would respond to John and just say, that’s spot on. We – ONC and CMS are looking toward how we can empower health information technology to support measurement rather than a set of measures. And so I think that this project is likely to be the one that frames the foundation for quality measurement and quality improvement, two activities going forward rather than a set of measures and a set of decision support interventions that we impose on the community. So ideally, it supports a lot of things rather than a set of things.

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

Thank you. Please go ahead and these we’ve all heard about, so the next six will not be so controversial.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Yeah or the next five actually, we just reviewed the top seven and those top seven are the active ones that are garnering the majority of our investment, not only of time, but resources internally. I’m going to hand it over to John Saindon to go through the Public Health Tiger Team, just to give a quick overview and then I’m going to go back to slide #2 where we show the overall picture. And talk through just for a second or two, the four other ones that are in there, or at least note them and where they are in the process and open it up for questions on any of those specifically. So, John?

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

John, can you hear us? Public Health Tiger Team domain expert? Are you on mute? I don’t think we have him.

James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology for Health Information Technology – Health & Human Services

This is Jim, can you hear me?

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

Yes.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Go ahead.

**James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology – Health & Human Services**

Maybe I can step in for John. I hate for us to skip this, I just need to get – do you want me to walk through these –

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

That would be great. The slide – are you looking at the slide, Jim?

**James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology – Health & Human Services**

No, I need to pull it up. Sorry, just give me just one second and I will do that. So I can start by saying, what we were trying to do with the Public Health Tiger Team is really pull together across many of the S&I initiatives to really look at how they're beneficial to public health. And we've got a few that we're focusing on, the structured data capture obviously, data access framework, especially the query health and finally, the clinical decision support, which is part of the clinical quality framework now, so, those are the three that we're really focusing on. And what we've done is pulled together the old Public Health Reporting Initiative, the PHRI, the community-led effort, we've merged that into our Public Health Tiger Team and so that now we are a consolidated group moving forward, looking at how these three initiatives can really help with public health. And I'm just getting the slide up, so sorry. My apologies.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

No actually Jim, I think you gave a perfectly appropriate overview for where we are, so – and there's additional information in the slide. I think that at least gives people context for where we are. The – and thanks for jumping in.

**James Daniel, MPH – Public Health Coordinator – Office of the National Coordinator for Health Information Technology – Health & Human Services**

Sure.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

The four initiatives that are left, LRI, LOI, ESMD and LCC are really, I don't want to put them in a class that suggests that they aren't important anymore. Instead perhaps I want to graduate them to the next level because they've gotten to a point where they're either in the case of ESMD have a broad set of support from another agency, CMS, who sees continuing to standardize the way they interact with the public as important. And rather than try and do that themselves, they see S&I as a platform, a vehicle for engaging the public in that process. So they're using the platform as part of what we're for, the coordination piece as Jacob said earlier, to bring people together so that the standard that results are interacting with CMS is better than perhaps they could've come up with on their own.

And the other three have matured no to a point where they have very active local communities either inside of SDOs. For example, the LRI and LOI have very, very broad representation within the HL7 community, as does LCC. So all of those have strong followings and are continuing to move ahead, S&I stays involved to provide meeting resources and high-level coordination. But the bulk of the heavy lifting is now done by the community because they've seen the value and the long-term desire to stay involved with those initiatives. So those are the next four. And then the remaining five that were on that earlier slide are ones that have either moved on and are being re-embodied in new initiatives or ones that are well out in the community and self-supporting, like Direct. So that's the – why don't I leave it there and open it up for any final questions that folks might have.

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

With one minute to go, fabulous. Yes, Leslie Kelly Hall.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

– more. I just would like to recognize the work that was done in the Longitudinal Coordination of Care Committee, specifically the Health Story Project that they demonstrated at HIMSS. It was a care plan that started with the patient. The patient generated a care plan what their values, preferences and decisions were in the treatment of cancer. It passed in 11 different settings and 11 different vendors to demonstrate a continuing care plan to be added upon and added upon and added upon when finally coming back full circle to the patient, to show what care plan had been completed and full transparency to the patient. It was just some excellent work and I would just like to recognize that.

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

And to that point, because again Jamie raised the workflow question, which is so important. It turns out REHR – doesn't actually have the kinds of features you described, but there are third-party modules and companies that do. So we've recently demonstrated, Arien will love this, the use of the Direct protocol in taking a patient/doctor set of treatments and care plans and end-of-life orders. Bundling them up in a third-party module and sending them via Direct and then incorporating them into the EHR, so it's then co-mingled with things that may be authored with inside the EHR.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

Yeah, this is done with Direct and 11 different vendors using the Consolidated CDA.

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

Yeah, so – and John Derr.

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

This is John Derr. I just wanted to say that the LCC has been very successful, in fact next Monday/Tuesday is the 10<sup>th</sup> anniversary of the Long-Term Post-Acute Care HIT Collaborative of where the people from S&I are going to be presenting as also is David Hunt. But if anyone wants to go to that, saying there's about 300 people, it's going to be our largest where we only talk about long-term

post-acute care HIT. And just want to really thank the S&I Framework people for really supporting us a lot and especially what Leslie's talking about, longitudinal care, because this is where we're really going into patient-centric longitudinal care that's dynamic and not static.

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

And we have these standards in production in Massachusetts in several facilities. They're being used today.

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

– Terry O'Malley are using that and it's working out very well.

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

Very good. Well, any final closing comments, I mean so much discussion and rich themes. We've heard the need for fewer building blocks, for tighter scope, for getting to implementation and adoption even if it means sacrificing scope. And certainly as we've all talked about, let's move forward to the next generation of standards where possible, recognizing we can't move everything overnight. But, thank you. And now, I mean after a great job by our entire S&I team, Michelle I think we move forward to the Dixie Baker, Lisa Gallagher discussion.

**John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology**

Thanks very much.

**Mera Choi – Acting Standards & Interoperability Coordinator, Office of Science & Technology – Office of the National Coordinator for Health Information Technology**

Thank you.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

I don't think our presentation is going to be all that controversial today. We're going to talk about two things, number one is, we have a couple of updates. At the last meeting, we presented our – the Privacy and Security Workgroup's comments on the NPRM and there was some feedback from this committee. We've incorporated the feedback and we'll will present to you what we are proposing to send on to the ONC. And some of these changes were from comments from the committee members and some were really the result of some clarification that Steve gave us at our last meeting. And the second thing is that following the last meeting, we – when we were doing our applicability statements that we presented at the last meeting and that Lisa read, and during the pr – in that process, we identified a couple of what we perceived as gaps in the existing privacy and security criteria. And I asked Steve whether he would be receptive to our comments and he encouraged us to present those as well so, we are going to present those today.

Okay, the first one, and this is the slide we presented at the last meeting, the NPRM asked questions about authentication, access control and authorization. It specifically asked whether the Policy Committee's recommendations regarding two-factor authentication to be used in two use cases were appropriate and actionable. And also – and what level of assurance would be appropriate. And second it asked whether they should adopt a general two-factor authentication capability requirement for certification. In other words, should all – certify all EHR technology that are certified against the authentication access control and authorization criteria be required to show the ability to support two-factor authentication.

Our response was that we thought that the policy recommendations were actionable from a certification perspective, but that they could only be tested from a – on a functional basis because there aren't sufficient and appropriate standards to support that. But during the discussion with this Committee, it was pointed out that in today's environment remote access sort of has lost its meaning and it might be very difficult to define exactly what remote access is. For example, if a clinician uses a mobile device in a hospital to access the EHR, is that remote access or not? So it's ambiguous what you remote access is in this day in age.

So given this difficulty, the Privacy and Security Workgroup concluded that the level of assurance required should be based upon the risk. And every covered entity is required – and business associate, is required to perform a risk analysis and that risk analysis should tell them not only when they need two-factor authentication, but the level of assurance that should be associated with that two-factor authentication as well. So, next slide.

The NPRM request was regarding the accounting of disclosures. You'll recall that the NPRM is proposing to eliminate the certification of technology as complete EHR technology and to just do EHR modules instead. And it also proposes to eliminate all of the optional tags on certification standards. And so it asks whether – we agreed with eliminating the optional phrase for the accounting of disclosures criterion. And the workgroup agrees with the recommendation to remove the optional designation and with the elimination of this complete EHR concept it really – optional really has no meaning, so it wasn't necessary.

And then the third area that was the NPRM asked a number of questions about had to do with audit reporting – oops, I pushed it here and didn't do it here – thank you. You can't read it anyway, so – I hope you can read it from your printed sheet. And it asks a number of questions all around the ASTM E2147,

which is an auditing for health standard. And the – during the – one of the questions was for the minimum baseline of actions to include in the – as the purpose of an audit. And it specifically asked whether they should add other types of actions to those listed in section 7 of ASTM E2147. We interpreted that to mean, should you require that EHR be required to do – to perform certain actions in order to be audited. And Steve clarified for us that what they really were referring to is a parenthetical remark in section 7.6 of ASTM E2147, which parenthetically lists a list of actions that would be the types of actions that would be included in the audit trail.

And the NPRM asked specifically whether transmission should be added to that list that are in parenthesis. We concluded that those actions that are listed in parentheses are sufficient to already cover transmissions because there's a separate section, section 8 of E2147 that deals with accounting of disclosures, which would be transmissions outside of an institutions. And any transmission within an institution would require a copy, which already is one of the actions in the parenthesis. Does that answer your question, Steve? Leave it like it is, is what we're saying.

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

Sure.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Okay. All right. And then, as I mentioned, the – you'll recall that in our recommendation regarding the certification of EHR modules, we suggested an approach that determines whether each criterion is applicable to that particular product or system that's being certified. And as an exercise for ourselves, to really prove to ourselves that this approach would work, we looked at every certification criteria and tried to write applicability specifications for it. And in doing that, we discovered that there were what we perceive as two gaps in the existing. One is that the aut – one has to do with the authentication requirement – criterion and the other has to do with automatic log-off. The certification – the authentication certification criterion only addresses the authentication of people and the certification of software and servers. And so we recommend that this – the criterion be expanded to include the authentication of the server as well.

For example when you reach out to a server to download something, you want to make sure that you're actually reaching the server that you think you are rather than somebody that is masquerading as a server that you know. So we suggest the wording to be changed to, verify against a unique identifier, username and number, that a person or software application or server seeking access to electronic health information, is the one claimed. This would be especially important in something like Blue Button Plus to authenticate the server that you're reaching out to.

And the other one is in automatic timeouts. The criterion that is there today calls only for automatic logoff. In other words, the termination of the session, you have to login from scratch. And most systems already do an interim kind of a time out, or a screensaver, if you will. And so we suggested that the automatic timeout be added to this so that there would be two time elements set, one for an automatic timeout where the screen would be blank – or any display of PHI would be blanked and you couldn't see the PHI. And then followed by a subsequent time specification for when a user would be automatically logged off the system completely. And we've recommended the words that it be changed

to, automatic timeout and logoff and the words would be automatically block access to PHI until the original user reauthenticates or another authorized user authenticates. And then automatically logoff the user after a longer, sustained, predetermined period of inactivity. That's it.

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

Okay, well Michelle has informed me that we actually need to vote on these recommendations, so that we for the record can record that we think they are appropriate to forward to ONC in their current form. So let me open the floor for comments. David?

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

Dixie, I participated in the discussion where we wrote the last recommendation about automatic timeouts and I don't remember the details of what we discussed, but I want to make sure that we're not requiring the distinction between timeout and logoff in some artificial sense. For example, I can imagine devices where the timeout and the logoff are the same thing. So the notion of logging off sort of implies a particular compute infrastructure and I just don't want to word this such that it creates an artifactual requirement for a logoff. Does that –

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Do you mean like if you have a device that isn't session based?

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

Exactly.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Because any session based would have an automatic logoff.

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

Exactly.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Yeah, I see what you're saying.

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

Those are the concerns if it's not session based, if there's no such thing as a screen ended, but otherwise live session. Maybe that doesn't exist in a particular delivery model.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Yeah, you don't want to dictate the architecture that requires to create a new session, right. So do you think that what we've recommended – well actually, what exists already implies a session-based system,

prevent a user from gaining further access to an electronic session after a predetermined time of inactivity. That's what it currently says.

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

Yeah, so in that context, it's probably okay.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

We aren't changing that at all – or proposing to change that.

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

Steve?

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

At the risk of belaboring the point here, I mean, I think the question that's raised is that the wording suggestions, especially on this one that David just discussed, is how you view certification and whether or not it's smoothing rough edges or looking to check for every particular. And at this point, the current criterion is kind of focused on the last step, so to speak, and not necessarily concern for the purposes of certification, with anything that may precede it. But just an ultimate eventual outcome that after a period of inactivity, everything kind of gets terminated. That's where the philosophical question would come in in terms of, is that the right role for certification, has it smoothed the rough edge enough without being, and I hate to use the word prescriptive, but without being any more prescriptive than need be. And that's where we always kind of run the risk in the balance that we need to, as teenagers deciding whether or not to heed your advice. Looking at balancing the level of detail in what could be a certification criterion that we want to make sure if we were going to approach this from a systems development or implementation perspective, that we have all of those versus what certification needs to assure?

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Um hmm. Yeah, and I think – speaking of rough edges, a termination of a session is a really rough edge, to kick somebody completely off the system after a period of inactivity, so we were trying to kind of soften –

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

And I think the notion of blocking access to the PHI as an interim step might be something to considering certifying.

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

Yeah, it's just – a bigger question for us whether or not that would occur with or without certifications and whether or not certification needs to be there as a maybe forcing function to – for proof.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

You might want to consider, Steve, looking at the existing criterion –

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

Sure.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

– and maybe pulling it back a little bit so that it doesn't just force termination of sessions all over the place and require a hard logon from the beginning. Because really what you really want to do, look at it from a security perspective, you really want to block access to PHI to somebody that's not there anymore, that's what you're trying to do. And so it might be a matter of just revisiting that.

**Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology**

Well yeah, I mean, and so that's where we always look for kind of outcome specified criteria. So it could be that the outcome that we want is blocking access to PHI and that decision leave – that would leave an abundance of flexibility for developers to implement that. There'd be a little bit of a difference in consistency there, which is also the other balance that certification often provides.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

But it would also take into account David's comment about how many systems are not session based these days?

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

Right.

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

Exactly what I was going to suggest because it seems to be worded as if it's a VDI or Citrix or – client session that is sitting on top of an operating system. One hundred percent of the systems that create are stateless, clientless and run on any device. And so what we do is we say, oh, we will, after a certain predetermined time, end what is that sort of stateless connection, but there is no discrimination between the application, the desktop, a login screen or anything of that nature. So exactly as Steve Posnack has suggested, in effect, it is blocking access PHI by whatever means you suggest is – you'd like to implement.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

But, yeah.

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

Right. So perhaps at this point we could change our recommendation here for Steve to reconsider in terms of blocking access to PHI. And reconsider the whole wording.

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

And I think Eric Rose also has a comment.

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

Actually, my comment was already made so I will yield my time.

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

Okay, very good. So other comments on – because in effect Michelle what you want is, as is per usual, these are a set of recommendations forwarded to ONC with the imprimatur of the committee. And so, besides the, I think friendly amendment that we heard, that it's going to block PHI without being overly prescriptive, any other comments or revisions?

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Do we want – what Lisa just – do we need to reword this one or, how do we – what's the proper way of handling this?

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

You can just reword it when you send over the transmittal letter.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Okay. All right.

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

So, assuming that it is the slides as created but with the amendment that this automatic timeout will be worded to block PHI, and Dixie does an excellent job at rewording, so you can trust her. Any objections to moving forward with a recommendation to ONC? Okay, no objections being heard, Michelle, you now have the letter that we will forward to the Secretary or the ONC or whoever it is that you want to forward it to. Thank you so much, Dixie and Lisa.

Well strangely enough, we now are 9 minutes early on the agenda. How did this happen? But we of course have a very important public comment period. I know there are comments in the room and

probably comments on the phone. So Michelle, if there is no other business, shall we move forward to public comment.

### **Public Comment**

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

Sure, so before the operator opens the lines, or as the operator gets ready to, if there's anyone in the room that has a comment, please come up to the table. And as a reminder, public comment is limited to 3 minutes and I'll turn it over to Alan to open up the lines.

#### **Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute**

If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press \*1. Or if you're listening via your telephone, you may press \*1 at this time to be entered into the queue.

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

Dr. Chute?

#### **Christopher Chute, MD, MPH, DrPH, FACMI – Professor – Mayo Clinic College of Medicine**

My name is Chris Chute of Biomedical Informatics, Mayo Clinic. Some members may dimly recall I was once a member of this august Committee, but I choose to make three observations today. But let me begin by commending, particularly S&I Framework for the presentation overview and status of the work. That being said, I think it might be prudent to consider the future nuance and direction of S&I as we move forward. Recall when it was formed, there was a large amount of ARRA money that was allocated for it. And furthermore, in the early days of the HIT Standards Committee, there was a nascent or palpable mistrust of some standards organizations, which I think had to do largely with intellectual property policies that has been largely resolved. We are in a very different state today.

So one modality is through a graceful evolution for S&I Framework to work more closely with the community of standards development organizations to achieve ONC and national goals rather than persist in what rightly or wrongly has to a large extent been a parallel universe kind of behavior. I commend the active communication between the ONC interoperability groups and the other communities. But despite that – particularly successful in consolidated CDA, but despite that there has been nuances.

My second point is that perhaps S&I framework consistent with the JASON Report, consistent with activities we've heard today, might focus on an underlining architecture and model of clinical information that could define many of the derivatives and use cases rather than a use case specific data model that has the risk of fragmentation and dissonance. The use cases can clearly inform the shared model and I agree with Jamie that provenance is going to be a key cornerstone for some of them. But beyond that, partnering with organizations like CIMI and other standard data element organizations to create shared common models from which the use cases can make their derivatives.

The final point, a bit of a detailed issue. As one of the few card-carrying clinical research scientists in the room, I would actually advocate that clinical – sorry, research information standards and for that matter quality standards, should primarily derive from clinical information standards. There was at the end of HITSP a strong push, Becky remembers this well, to ensure the cohesion and alignment of clinical data standards and research data standards. It does not behoove us to have dissonance and differentiation for use case specific purposes. It goes back to the second point of a common model. My time is up, thank you.

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

Thank you very much Chris. And just to add to that, before the meeting, Chris and I were reminiscing how 10 years ago there was out and out warfare in the standards community and now it's peace and harmony. So, thank you. Gary Dickinson.

**Gary Dickinson – Director, Healthcare Standards - CentriHealth**

Yes, thank you, I'm Gary Dickinson, Director of Healthcare Standards at CentriHealth. I'm also lead of the S&I Simplification Workgroup. Just to bring some attention to that workgroup, we've devoted several thousand hours – volunteer hours, over the last three years. You can find us on the left column of the S&I Wiki under cross-initiative S&I simplification. We started off in 2011 as Use Case Simplification and in 2012, we were designated S&I Simplification.

But our intent was to learn some of the lessons, as were mentioned earlier, from HITSP where each initiative was a separate silo. Unfortunately we've seen a lot of that under the S&I initiative as well.

The current analysis of our S&I simplification effort has focused on 19 of the S&I use cases with 41 multistep scenarios. The objectives of our group are to identify a set of core components, probably applicable to and reusable in subsequent specification of use cases. These include requirements, scenarios, events, actions, actors, roles, data objects and elements that we might find in common across

use cases, scenarios and events that we might reuse in a new use case scenario. To establish and maintain a core component registry, to allow each use case initiative to select or reuse core components applicable to their needs, to create anew where they have identified new candidates for core components.

To lay the foundation for consistent infrastructure and build out, to lead to uniformity and requirement specification, standards selections, implementation guidance, software development, testing and certification and implementation. To ensure that requirements have traceability from the point of specification end-to-end to the point of implementation. Since 2011, AHRQ has housed our component

registry in USHIK. Since 2012, NIST has been actively engaged, offering their expertise and guidance to our process. Since 2013, we have engaged with the Federal Health Architecture in the FHIM, Federal Health Information Model team. They've been actively engaged and have analyzed and cataloged the myriad data requirements across the S&I initiatives. With the FHIM, we can now map our data requirements to a number of implementable data standards including HL7 V2, CCD, C-CDA, FHIR, and CPDP X12 to name a few.

In 2014, our simplification methodology was approved as a new work item by ISO TC 215, that's ISO 19969 for those of you that might want to look that up. We started with spreadsheets but now we have two use case authoring tools in development with two volunteer software developers. These are based on the S&I use case requirements template. These are fully integrated with USHIK and the FHIM. We output to the NIST tools implementation guide, authoring management tool and a test case authoring management tool. We hope our simplification efforts will be seriously considered as the refocus of S&I moves forward. Thank you.

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

Beautifully done, right on time, thanks so much. Well, do we have comments from the telephone?

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

It doesn't look like there's anyone on the phone.

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

Okay. Well, Jacob, of course, the last word is yours. We are on time, have covered a rich array of discussions today. And I think as we look to our next meeting, which will be, Michelle, telephonic, in July.

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

It'll be virtual, July 16.

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

Right, we will, I'm sure take up some of the S&I Framework discussions, probably hear about the JASON activities, but, Jacob, closing benediction.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

I'm going to sidestep that for a second. We had one vote from Dr. Ferguson of an initiative that he thought was the highest priority. And so I would actually like to poll the group and get thoughts from each of you, those present and/or those on the phone. You can either say, A) This is the one I think is most important. B) I abstain and will vote later because we're going to talk about these things more. Or C) Anything else you'd like to say as we go around the room. And perhaps we'll start with Sharon. Okay, sorry, we'll start with Jonathan and Jamie told us he thought provenance was most important, we're not going to hold you to this, but I think just to get a feel for what the group thinks is important.

**Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America**

You probably could predict my vote was data access framework.

**Leslie Kelly Hall – Senior Vice President of Policy – Healthwise**

I think that provenance underlines everything we want to do in care coordination, patient-generated health data and interoperability and research. And there's – if we don't know who said it, it hasn't been said.

**W**

I'm actually going to abstain right now.

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

This is John Derr, I just want to echo what Leslie said, care coordination, longitudinal care and the whole team including all of the providers of care, not just the ones that were in the legislation.

**W**

Provenance and care coordination.

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

So once again Jonathan Perlin and I are perfectly aligned, which is that if I look in Massachusetts where we've had to invent standards, it is in the data access framework query response, the idea of a community coordinating care from multiple disparate data sources. Call it an API, call it a DAF, it's that whole set of work.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

Oh man, I agree, Data Access Framework is extremely, extremely important, but so is data provenance. So I guess I would – and so is Blue Button Plus, those are the three I would vote for.

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

Yeah, I think the market forces are addressing the Data Access Framework pretty well so the more fundamental problem that needs long-term addressing, which isn't going to happen just due to simple market forces is probably the data provenance. That's the hardest one that no one would go solve on their own. So that's where we ought to put our joint effort.

**Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates**

It also has international implications, which wasn't mentioned, but huge international implications.

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

Yeah, as far as the ones that are already in progress, I think there are several that I think need to move, but with regard to data provenance, its newest initiative and I think it really needs a lot of priority going forward.

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

So it's difficult to come up with the one highest priority that I think the others have some industry push. I think, a others have said and Jamie started with, provenance, especially dealing with patient data and other data and being reused – being able to reuse data is an extremely high priority and otherwise would not be addressed. So I would agree.

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

So I'm sticking with my vote of provenance, but I would also just note that data access framework and some of the other efforts can result in aggregating data that can't be used reliably without provenance.

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

Can we have the whole list? No, just joking. I think data access framework continues, despite David's comment, to be one of our challenges and we would actually put it number one. Provenance is going to be lurking at its heels, so I actually agree with everyone that's mentioned that one. Probably my number three is medication, that's the one thing I'm asked for that I can't deliver ever and it looks like that's still several years off.

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

I'm going to vote for the clinical quality framework.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Since there seem to be enough votes for provenance and data access framework, I would say provenance makes a lot of sense, but I would hope we would take notes on Becky Kush's comments about the long history and work in the research community around that. And Dr. Chute's comments about the possibility of leveraging SDO work in that space. That seems like a place where there is already momentum and we could complete it. If we worked on data access framework, I'd reinvoke the idea of how can use that as an accelerant for the emerging new standards, that sort of spanning notion that David described earlier, how can we use it to that particular impetus to like together a couple of these initiatives in a really positive way, so I vote C.

**Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance**

So I'm going to second Cris' provenance caveats and add that Leslie's comment that it would be – that we bring the patient to the table in a robust way is important. And I'll also say Blue Button Plus.

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

So on the phone, Arien Malec?

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

I would generally vote data access framework with many of the same concerns that have been raised relative to architecture and room for new standards. I think data access framework with one standard per use case would be a mistake and I think it needs to be coupled with a proper view of architecture and where we're going.

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

Eric Rose?

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

Hello, can you hear me?

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

We can.

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

We can hear you.

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

So I'll throw my weight behind, to the chorus, behind data access framework with an asterisk that the data access framework seems to most directly address the need that I see as most acute from the perspective of a practicing physician. Which is just being able to get the gosh darned data, find out what's happened to my patients recently who have been cared for in other institutions. And apropos of that same urgent and important need is a – I wonder whether there is a need for this committee to be – to focus its attention at all on standards that are already fully fleshed out, in use but not adopted as widely as they should be. And I'm thinking, for instance, Direct, which is not an option to me and most of my colleagues here in Seattle. And it would be good, I think, if we could try to identify – I'm wondering, I'm asking if it's in scope for this committee to try to identify and address the obstacles to more widespread adoption of the standards that we feel are going to help transform healthcare in the ways that we want.

**M**

Wes.

**Wes Rishel – Independent Consultant**

Asynchronous bilateral cutover.

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

Nancy Orvis.

**Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense**

Hi, great discussions. I know for my patients and my insurance issues, I'd say the data access and provenance – data access with a good – a standard way of the privacy security, just it's got to get – we've got to get that infrastructure in place so that anybody can hook into it the right way. But I also would just put a note about the individual mentioned the collaborative environment, data access that collaborates and allows the patient or the visibility across the providers. And I'm just going to caveat with a note that as of my ski injury of four months ago, I have seven patient portals now, each doctor and each result is sending me a new portal. So, there's a problem the patient. And there's a problem – and so if we can look at the data access but make it collaborative so that the doctors can get the stuff between each other and it's not the patient carrying it, but if it has to be, that there's that access works for all of them. Okay? Thanks.

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

Thanks, Nancy. Liz Johnson?

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

So Liz Johnson, are you there?

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

So to Lorraine Doo.

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

Yes and I had submitted this, I would vote for the Blue Button Plus with the interoperability exactly as – was saying that they are connected so that those – we don't have different patient portals that don't speak to each other.

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

Was that Liz In the background? And Wes, did you have an actual vote?

**Wes Rishel – Independent Consultant**

Actually I, maybe I didn't understand the rules but if you want my opinion on what's the most important thing to work on, it's asynchronous bilateral cutover. The fact that no one else mentioned it is an issue.

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

Okay.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

It's a good thing you're keeping to your script, Wes.

**Wes Rishel – Independent Consultant**

Well, someone's got to.

**Jacob Reider, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology**

So that was great and thank you all. I think we heard some unanimity, some very common themes. This is a warning, next time, which I think is virtual, right, Michelle? So the next meeting, you'll be able to hide behind your telephones, but we'll ask you instead of giving you the multiple-choice question, we're going to ask you the short answer questions, which are, what are we missing? As you saw from the presentation, provenance was something that we only recently added and you all thought it was important. What are things that we need to add soon that you all think that are important that we haven't yet added? Are there important things? So you can think about that on your rides home tonight, and then remind yourself before the next meeting what you thought about.

But we'd really like to think about where – and I like the framework that David described, where is the market failing? Where are the things that are not likely to happen? Because this is where government in general should act, right, we should do things that the market won't do and not do the things that the market will do. So that we're not just wasting our time. So I think it's a good principle for us to guide by and in fact, that's what the law tells us to do. And so thank you all for your thoughts and wonderful meeting today, I'm glad we were so efficient and unless there are other thoughts or comments.

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

Well the one thing I will just say, Jacob is, think for a moment when ONC sent out its 10-year vision and said that in the next three years we will work on quote "send, receive, find and use data for patients and providers, provenance, patient matching and trust. Kind of amazing that completely independently all of the people in this room pretty much recapitulated your three-year list. So thanks everybody, we stand adjourned.

<b>Meeting Attendance</b>								
<b>Name</b>	<b>06/17/14</b>	<b>05/21/14</b>	<b>04/24/14</b>	<b>03/26/14</b>	<b>02/18/14</b>	<b>12/18/13</b>	<b>11/13/13</b>	<b>09/18/13</b>
<b>Andrew Wiesenthal</b>		X	X	X	X	X	X	X
<b>Anne Castro</b>	X	X	X	X	X	X		X
<b>Anne LeMaistre</b>	X	X		X			X	X
<b>Arien Malec</b>	X	X	X	X	X	X	X	X
<b>C. Martin Harris</b>	X			X				X
<b>Charles H. Romine</b>				X	X			
<b>Christopher Ross</b>	X		X		X		X	
<b>David McCallie, Jr.</b>	X		X	X	X	X	X	X
<b>Dixie B. Baker</b>	X	X	X	X	X	X	X	X
<b>Elizabeth Johnson</b>	X	X	X	X	X	X	X	X
<b>Eric Rose</b>	X	X	X	X	X	X	X	X
<b>Floyd Eisenberg</b>	X	X	X	X	X	X	X	X
<b>Jacob Reider</b>	X	X						
<b>James Ferguson</b>	X	X	X	X		X	X	X
<b>Jeremy Delinsky</b>			X	X	X		X	
<b>John Halamka</b>	X	X	X	X	X	X	X	X
<b>John F. Derr</b>	X	X	X	X	X	X	X	X
<b>Jonathan B. Perlin</b>	X	X	X	X	X	X	X	X
<b>Keith J. Figlioli</b>		X		X			X	X
<b>Kim Nolen</b>	X	X	X		X	X	X	X

<b>Leslie Kelly Hall</b>	X	X	X	X	X	X	X	X
<b>Lisa Gallagher</b>	X		X	X	X	X	X	X
<b>Lorraine Doo</b>	X		X		X	X	X	
<b>Nancy J. Orvis</b>	X			X				X
<b>Rebecca D. Kush</b>	X	X	X		X	X	X	X
<b>Sharon F. Terry</b>	X	X	X	X	X	X		X
<b>Stanley M. Huff</b>	X	X	X	X	X	X	X	X
<b>Steve Brown</b>		X	X	X	X	X	X	X
<b>Wes Rishel</b>	X	X	X	X	X	X	X	X
<b>Total Attendees</b>	<b>24</b>	<b>21</b>	<b>23</b>	<b>24</b>	<b>23</b>	<b>21</b>	<b>23</b>	<b>24</b>