



## HIT Standards Committee

### **Draft Transcript**

March 18, 2015

#### **Presentation**

##### **Operator**

All lines are bridged with the public.

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

All right. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is a public meeting and there will be time for public comment before lunch and at the end of today's meeting. As a reminder to those commenting, your comments are limited to 3 minutes. If you are tweeting today, the hashtag for today's meeting is #HITSC. And with that, we'll go around the room to take attendance and we'll start with Jamie Ferguson.

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

Hi, Jamie Ferguson, Kaiser Permanente.

##### **Wes Rishel – Independent Consultant**

Wes Rishel.

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

Arien Malec.

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

Kim Nolen.

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

Stan Huff with Intermountain Healthcare and the University of Utah.

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

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

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

Jeremy Delinsky, athenahealth.

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

Lisa Gallagher, HIMSS.

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

Jon White, ONC.

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

Dixie Baker, Martin, Blanck & Associates.

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

John Derr, long-term care.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Liz Johnson, Tenet Healthcare.

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

Floyd Eisenberg, iParsimony.

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

Anne LeMaistre, Ascension.

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

David McCallie with Cerner.

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

Eric Rose, IMO.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Andy Wiesenthal, Deloitte Consulting.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – 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 Cris Ross is here, he just stepped out for a moment. John Halamka is on his way, he was on a 13 hour flight I think it was. So folks on the phone, I see Anne Castro. Anne are you here? Marty Harris?

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

I'm here.

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

Hi, Marty.

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

Hi.

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

Keith Figlioli?

**W**

Yes, Keith will be stepping in momentarily.

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

Okay, thank you. And is there anyone else on the line?

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

Yes, Kevin Brady for Dr. Charles Romine.

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

Hi Kevin, thank you. Okay with that I'll turn it over to you, Jon White.

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

Thank you very much Michelle. Thank you everybody for coming here today, it's been another quiet week in Lake Wobegon, my hometown out on the prairie so looking forward to wonderful set of discussion today for us to be going through. So the one brief...two brief comments I want to make; the first is that I look very much forward to being your moderator for today, at least until the Dr. Halamka gets here. John did his best imitation of around the world in 80 hours over the past couple of days, but he did strap himself on a jet fuel filled metal tube 17 hours ago and I think at this moment is on his way in from Dulles, so he will get here as soon as he can.

In addition to many of the other things that are kind of floating around, the one thing that we don't have on the agenda but I do kind of want to just briefly bring up for your consideration and thought. There has been a lot of activity recently on Capitol Hill around the issues of interoperability and health IT. There was a hearing yesterday at the Health Committee and in particular discussion has begun to bubble up from some of the workgroups for the Standards Committee about some of the legislation, it's implications for the federal advisory committees and things like that. And I fully get that this is of interest to everybody, to say the least.

I think though, I think it is probably worth mentioning that as the administration, we don't lobby for legislation, that's not kind of our job or our role, it's not really appropriate for us to do. And therefore, to the extent that this legislation is out there and although I get it people are interested, it's probably not appropriate for workgroups to advise us on that legislation because really we're not going to be able to do anything about it. So...in that sense, through the workgroups. So...so we...so my gentle request for the workgroups and the folks here around the table is if you want to sit about and talk it over coffee that's one thing. But in our formal discussions, we can't really comment on proposed or active legislation.

So, I would also add that whatever is out there now does not impact on the current work occurring in both the Health IT Standards Committee and the Policy Committee's workgroups. So that moves apace, do not worry about that being disrupted. So please carry on with that. And I know it's been on everybody's mind, so I appreciate that it's been on everybody's mind, it may or may not have been on our minds as well, just in terms of the discussions for the workgroups and then bubbling up to the actual Standards Committee, I just want to kind of lay that out there, so.

Want to briefly bring up review and approval of the minutes from the January 27 Health IT Standards Committee and the joint Health IT Policy Committee and Standards Committee on February 10. Are there any questions or comments related to those summaries? Okay. Do I have a motion to approve?

**W**

So moved.

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

Anybody second? All right, second. All in favor of approval of the minutes raise your hand. Anybody on the phone object? So approved. All right, thank you very much.

Let me briefly go through the agenda here, a lot of...like I said, a lot of rich stuff for discussion. First Ron Ross from National Institute for Standards and Technology will be talking to us about security risk management with discussion. Dawn Heisey-Grove from ONC will be providing us a data update. Then Evelyn Gallego-Haag from the S&I Framework will come talk to us about electronic long-term support services and progress there. And then Stan Huff and Arien Malec will be talking to us about the Standards & Interoperability Initiative Task Force recommendations.

After lunch we will move to progress updates on the interoperability roadmap from a cast of characters. Back to the Arien show, this time with David looking at a framework review for the Architecture, Services and API's aspect of the interoperability roadmap. And then we will close out the day...the presentations with Julia Skapik from ONC talking about the quality improvement standards evolution and then finally public comment.

I do want to take a moment and I will do this again later, but I really do want to thank Arien in particular. I know that you all know this, but he really has been working furiously hard and devoting a lot of time to both what we're going to hear about today as well as a lot of other things though. On behalf of all of us and everybody else, we really appreciate the effort and not just the effort but really the excellence that you are bring into it, so, thanks.

All right, any questions about the agenda? All right. Mr. Ross you're on.

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division - National Institute of Standards and Technology**

Thank you very much. Can you all hear me okay? Good? Well I want to thank first Lisa and Dixie for inviting me here today. I've actually known those folks I think it was 25 years now we first crossed paths back in 1990, when we first started bringing cybersecurity into the forefront and it's been a long time. We've had a lot of things that have transpired. And this morning I'd like to take a little time to go over this concept of security risk management because the perception of what cybersecurity is and how we

manage risk and the realities are sometimes at odds today. They're kind of working down different paths. And, let me see if I can get the first slide here.

I think the most important thing that I've observed is that we have a continued growing dependence on this wonderful information technology that many of you are dealing with every day. And that technology, we are totally dependent on the technology for our mission success and our business success today in every sector, whether it's the energy sector, finance, healthcare, the war fighters, the or federal government; we're all basically using the same information technology.

In the healthcare sector, obviously this has a very impactful message because we're looking at security from a very holistic point of view. It starts with the sanctity of the patient's record, the confidentiality of patient's private information. And again, I think that we're seeing a series of these cyber-attacks that are happening over and over and over again; in fact my slide this morning is when I get to three or four in here, it's already outdated because we had another breach this morning from I think it's Premera Blue Cross in Alaska and Washington.

The good news is, it wasn't 80 million, it was only 11 million and so I guess we're making some progress there. But the privacy of patients' information is critical, that's the confidentiality aspect. But security also goes to other...two other dimensions which a lot of people don't worry about or care about as much sometimes, that's integrity and availability. Integrity of mission-critical data; this could be data that a researcher in a medical university is carrying out. That data needs to be protected, it can't be compromised, it might be part of a study that is ongoing. It could be the integrity of the information of the medical device that is controlling critical patient applications in a hospital.

And then of course there is the availability of services; when the IT is compromised, it can...you can lose the capability, and that could be in a hospital or it could be in a records part of a large information system in a hospital or a small doctor's office. So the extent of this problem is very large, it's broad-based and I think our key challenge today is how do we manage risk in a world where we depend upon this wonderful technology to make us more productive, more efficient and do things that we never imagined we could do. And at the same time maintain the trust of our customer base; that is really critical.

If you think back when credit cards first came out, there was...the Congress didn't have this law that protected consumers. So if your credit card was stolen you could be liable, back in the old days for all of the fraudulent charges until they passed legislation which protected the consumer up to I think it's \$50. That really...the explosion of credit cards started from that point time. And now we're moving into the world where the electronic patient records and my hospital is up at John Hopkins in Baltimore and we have a new online record system. You can login anytime and you can see your information from all your visits and it's shared by all the doctors. And so we are clearly moving into a new world order here that we have to maintain the trust of our customer base. And I guess my key message today is that we're going to have to do some things differently if we want to maintain that trust.

Why are we vulnerable today? Well, the threat sources that you have to deal with a very broad. They can start with cyber-attacks and that includes insider threat, and that's a huge problem today within the federal government. You've been reading about a lot of those stories in the news. We have the ongoing natural disasters like Hurricane Katrina, Hurricane Sandy and we have just good old-fashioned structural failures, the hard drive gives way and it just goes south and you have to buy new equipment. And then there's the ongoing misuse of the technology, whether it's an insider or someone coming in from the outside. And there are also just good old-fashioned errors, when software developers are

building a new app for a hospital or a doctor's office, they make mistakes. And sometimes the software is not developed with secure coding techniques and best practices which help eliminate those vulnerabilities.

So we have a wide range of vulnerabilities we have to deal with today and so in some sense our problem is not just compliance, because a lot of people think we do security because it's a compliance activity. It really is much more than that; it goes to the heart of the healthcare industry at its core. Its business operations, everything that is involved in bringing the healthcare to the citizens and to the consumers.

This is the slide that is a little outdated, I have to change that Anthem and put Premera in there; I guess I'll do that when I get home. The advanced persistent threat, you might have heard a lot about this. This is a level of threat that we haven't seen in the past. What's happening out there is that the adversary is getting better quickly. They are empowered with something as simple as a laptop computer, they can go out to the Internet today and they can buy very sophisticated cyber-attack technology. It does not cost a lot.

It used to be back when I first started working with Dixie and Lisa that the hackers had to be very talented; it was about tradecraft. And today, with the Internet and everything that you can get, we really empowered the globe to do damage to our systems and our applications. So the advanced persistent threat, they use a combination of cyber, physical and deception to try to get a foothold within your organization or your systems.

And the persistent part is that they want to be there for the long term either to bring that down your capability; that is a big concern was some of our federal agencies like the Federal Aviation Administration Air Traffic Control. But the bigger problem, I think, is in something called exfiltration where they...the malware is implanted within the system and they can steal stuff over time. Sometimes these attacks are so good that they're not detected for a long time and there can lots of exfiltration going on during the time when that attack is not on the radar of the organizations.

I think the Director of NSA estimated, about a year or so ago, he made a speech about the loss of this intellectual property and the exfiltration problem. And the estimate that he gave was about a trillion dollars a year in lost intellectual property and information that has real value. That's about a third, I think, of our GDP, maybe a fourth. And of course the healthcare sector, depending on what figures you are looking at is maybe one-sixth or one-seventh of the national economy now. So this is a big, big deal for lots and lots of people.

What I want to point out with this slide is that the Defense Science Board almost two years ago did a study and the military is using the same technology that everybody else is and they wanted to know could the United States military survive an advanced cyber-attack and still be able to defend the country? That's kind of the ultimate question that they were looking at. And in the course of the study they talked about three different tiers of vulnerabilities, and you'll probably recognize some of these, but not all of them.

The first tier is your known vulnerability. That's when you're operating in your organization and Microsoft or Oracle or one of the big companies announces a vulnerability and a patch is delivered to you which you have to install to close down that vulnerability. That's a known vulnerability. The second class is what we call the zero day class of vulnerability. That's where you don't know you have the vulnerability but the adversary does know and they exploit and then it goes to the known class. The

third category is once they've breached your perimeter and they've established a presence within your system or your organization, now they can create new vulnerabilities that they can come back later and exploit.

Now these are not just things that we are projecting or surmising, we have lots and lots of threat data that we've collected over the years; some of its classified, some of its open-source. So we know where the attacks are coming from, we know who's being targeted; we know the success rate and these are very, very good adversaries. They can be nation state level resources; they can be terrorist groups, hackers, all the way down to disgruntled employees.

So today we're doing a lot of things, we have a lot of cyber hygiene going on. We're doing inventories, we're counting our boxes, the hardware, the software, we're doing all the patching and we're configuring our products the best we can to try to do everything we can to close down these different avenues of approach where the adversary may breach our systems. And one of the big areas that we will continue to have to work on is just good old-fashioned education, training and awareness because most of the cyber-attacks that are launched against any organization, whether it's healthcare, finance or energy sector, 90% come in from web and email. And there's a lot that we can do to close those down just at the start.

So we're doing a lot, but some of these problems are beyond our control at the organization level. So when you buy a new system or a new application, you're working to...you're working under the contract to build a system or buy a new application and the quality that goes into those applications, or the quality of the engineering that goes into that system when its build and delivered to you, makes a big, big difference today. And in some sense, as consumers we have been very quiet when it comes to our demands of industry in bringing better quality things to us.

And I use the example of the automobile and the seatbelts. When I first bought my first car had seatbelts, but airbags were optional. I was a Second Lieutenant, just graduated and I went to buy the new car and they said, you can either have a...back in the day it was 8-track, I know some of you don't remember 8-tracks, but that's how we used to listen to music, or you can have the airbag. The airbag \$500 and I said, I'll pass on the airbag because second lieutenants are bulletproof and we didn't need to worry about airbags. So, I bought the 8-track.

Now you fast forward 20 years or so and now, when you go to buy a car, you don't have an option of an airbag; it's installed in the vehicle along with the seatbelts, along with the steel reinforced doors. And all of this technology takes the worry out of consumers. And what we need to be able to do is work with industry as consumers and demand that they bring greater protections to our products and our systems that we are using in very, very critical applications today. If we were as tolerant as the kinds of weaknesses and deficiencies that we have in our software in our systems as we are in our refrigerators and our automobiles, my goodness gracious, people would be out of business by now.

So we just have to understand that a lot of these vulnerabilities that you are going to inherit are things that are out of your control and the only way we can get better is to demand through contracts and through pressure on the industry is to up their game on using secure coding techniques for example. Carl...where one of our founding fathers in cyber security has something he's talking about is secure building codes for software. How do we make sure that we do everything we can to make sure that software is as good as it can be, not perfect, but make sure that we do things just like an automobile manufacturer, to make sure that the consumer is as protected as they need to be in a very risk-based environment.

So one of the things we're doing at NIST is to try to put a greater focus on software assurance, system security engineering, which has over 30 years or almost 40 years now, of best practices. And of course supply chain risk management. We're dealing with a supply chain that goes international now, our companies that are multinational and so we have to be concerned about the products, the systems, the components where they're coming from; what kind of assurances we can bring to the development process based upon all those different sources.

So how do we get the attention of the C-Suite? Well, this has been a problem. We have a message that we have to get, but we have to be able to convey it in the terms that the C-Suite really will pay attention. And of course they're not really concerned about security, they hear about it, they know it's important, but by the time it gets from the C-Suite down to the actual operators on the front line, there is a lot of distance sometimes between that. And so how do we do that?

There are five areas that I think really characterize the modern cyber security problems and how we can deal with it with the C-Suite. And I came up with the acronym because it...actually the acronym I kind of backed into it, I came up with the five areas first; it's called TACIT. And it stands for Threat Assets Complexity Integration and Trustworthiness and if you look in the dictionary, tacit, the dictionary definition is something that's expressed or understood without being directly stated.

And I'm saying this would be really great if we could look at security as not something special but something that is integrated into our day-to-day operations, it becomes institutionalized. It's part of the way we do business. It's a cost, it's an investment in our mission success, whether its healthcare or finance or wherever we choose to do business where we have to depend on this information technology for our mission and our businesses success.

So let me go reach one of these very briefly. It's critical today that everybody understands the modern threats base, what is the adversary capable of doing to you from 10,000 miles away with that laptop computer and with some downloaded attack tools from the Internet that they bought? And some of these groups are extremely well-funded; they have millions of dollars to spend on cyber-attacks and cyber-attack technology. And so getting threat data from as many sources as possible, open-source we have the semantic report, Verizon, there's a whole bunch of open-source threat data that's available to organizations. You can also go to the US Cert, and they also have threat data. If you're within the federal government, you might be able to get access to even classified threat data through some of the sources that they have access to.

This is a big area because we have so much information technology data that understanding what's important and being able to categorize our assets within a healthcare organization that includes data assets as well as physical assets because we can't protect everything to the highest degree. We have to make decisions about what's important and I use the analogy of a safe deposit box. I have one, I can't get all my stuff into that little box, but I have to make some decisions on what's going to go into that safe deposit box. And it's a pain; I have to go to the bank, I have to sign in. I have to open the...they have to open the vault, I have to get my key, two keys actually, just like the captains in NORAD. And I put my stuff in there.

But, I understand that the lock on my front door, although I have a double lock, it's not sophisticated or strong enough to stop all attackers or all thieves. So I have to put some of the things most critical into that safe deposit box. We have a very similar analogy; when we look at our data and our information,

it's not the same. When you look at your systems within a hospital or a doctor's office, they're doing different things. Some of those are what we call high-impact where the loss of that system or that data would have severe or catastrophic effect on the mission, or the patient in this case.

The other categories, it might be a serious effect, it might be a moderate level asset or it could be a low-impact asset where, hey, it doesn't make that much difference if we lose it, we can recover. There's no real immediate effect on the mission. So being able to categorize assets is one of the primary steps to understanding how to protect those assets because we're going to...stronger protections, stronger safeguards and countermeasures to those assets that are the most critical.

I think complexity is the number one threat today to every organization in all of the sectors. If you look at how we're building our systems today, just look at the typical operating system. It's about 50 million lines of code. I remember back in the day when Dixie and I we used to be talk about building trusted systems and there was the security kernel, this is a very small piece of trusted code. These systems are getting so complicated now; we don't even understand how to protect them in some cases. Now, some of that's our fault and some of that is the fault of industry. But we all share a shared responsibility here.

I went to a movie over the holidays and I'm sitting there watching the coming attractions and on the screen comes the announcer and he said, here's an App that you can download to your smart phone and this App will tell you, for this movie when the optimal time to go to the restroom. Now I use this is a metaphor because we are going to have to make some very difficult decisions, some of those will be part of this committee's discussions. We cannot continue to go down the road where we continue to pile endless levels of complexity on these devices and have a prayer of protecting the critical data that's going to be riding on some of those same networks and systems. It's not possible.

In fact, a first-year computer scientist will tell you the complexity theory, that's one of the things we study in computer sciences, we've already blown past that because our demand for the technology and our thirst for new applications is far exceeding...that's driving the discussion right now. And at some point there's going to have to be a rebalancing of our load here to say look, I can buy my teenager a car that goes 100 miles an hour but maybe that's not a good idea because it's high risk.

And we're going to have to make some very difficult decisions that some of these systems, and we know how to build systems that are highly assured, highly trusted; they just can't do everything. But what they do do is they something very specialized with high assurance; that could be a medical device. Is that going to be driven by a 50 million line operating system where you don't have any idea what's going on within that 50 million lines of code? Or are we going to be able to neck that back and build very targeted, highly assured software? These are the questions that we're going to have to ask and complexity is something that every enterprise has to deal with.

We have a lot of tools that are at your disposal today that deal with enterprise architecture where just the fundamental tenets of enterprise architecture forces an organization to consolidate, optimize and standardize the IT infrastructure. And that's important because we are in control of that part of our problem. And so having duplicative functions going on or two systems where you could have one; this is part of engineering an architecture that is critical to every organization.

Cloud computing offers a terrific opportunity to manage and reduce complexity. Not only does cloud provide on-demand services which really expands our research capabilities, our ability to provide efficient healthcare services to our customers, but it also allows us to offload some of these things to

the public cloud or build a private cloud that internally can be secured because you have less complexity once you offload some of those applications to the public cloud.

And the cloud providers are doing their share; under the FedRAMP Program they have very rigid security specifications they have to comply with and they are assessed by an independent third party organization. So there's lots of good news in the cloud world and the message here is that this complexity is totally under our control. It's a leadership and a vision type of thing for every organization that they can deal with internally.

Integration is still a problem. We still consider cyber security as kind of like on the outside, it's a cost, it's a drag on the system; I know I hear this every day. I work at NIST and we have a lot of commonality with some of the researchers out there in the medical community. They're scientists, they're engineers, they don't want to be bothered with security. But what they don't understand is that their critical research that they're working on can be compromised in a nanosecond by a cyber-attack. And if you think about the healthcare research that's going on and things that are part of studies where the integrity of that data is mission-critical for that researcher, we have to be able to talk about these things in terms that get to the sweet spot of the audience we're talking to. And everybody has that sweet spot; you just have to find where that message resonates with that individual.

But as far as integration goes, if your security office is in a little room down the hall and that team is just all by themselves talking to each other, that's not a good idea today. These security folks, and make no mistake about it, these professionals are highly skilled, there are not a lot of them, they're in high demand, they need to be integrated into the mainstream parts of the organization. And there are four areas I list on this slide where I observe that these security folks are not being integrated.

And the primary one is enterprise architecture. An enterprise architect really can't figure out where the security safeguards ought to be deployed unless they have the expertise. So having the system security folks sit right beside the enterprise architect and that team forces that integration. So when the enterprise architecture is built out, you have that cyber security, all of those considerations have been integrated as part of that architectural design.

The system development lifecycle; again the cyber security folks need to be involved early. We try to push security up from the bottom instead of having the stakeholders involved around the table at the start. So when you have the brand-new healthcare system or that application that you want to build, you bring in the security folks early in the process, when you're first figuring out, what is this healthcare application going to do? What kind of data are we going to be processing, storing and transmitting? What environment of operation will we be operating in?

And given that threat space that I talked about earlier, what can the adversary do to us and what can a protection should I build into this system? And I know how much it's going to cost upfront and I'm balancing that as a risk management decision. That's very different than somebody coming in from the cyber security office saying, hey, you've got to do all these controls because HIPAA says you got to do it. Well obviously that's important, because HIPAA makes a difference, but protecting your assets because the adversary, and the adversary doesn't care about HIPAA to be honest with you. We care about it because it's the law, but the adversary wants to get your stuff and they will stop at very little to do that. So integrating into the acquisition process is the other area.

The engineering process, if you have some system engineers that are building your system, have them have a conversation with the security folks. They don't speak the same language all the time. I know the architects speak different languages than the cyber folks and the acquisition folks surely do. But the leadership of the organization is critical; making sure these people get in the same room, have a conversation and start to get to know each other, that's where you start to build a team, an integrated project solution.

Well, this is really the big ticket item today. There are a lot of technologies out there at the hardware, the operating system level, middleware, protocols that can help you to bring greater trustworthiness to your systems and your applications. You have to ask for it though and sometimes it's not the greatest idea to go out there and buy the newest bell or whistle just because it looks slick and you could do it on your smart phone but it can't be protected. We have to be able to take a very sober look at what we're building, how we're building it and go out to the people who are producing these great technologies. Trust technology, when you try to harden your networks and your systems, what that does is it makes it harder for the adversary to get in, more difficult, penetration resistance.

But looking at all this threat data, some of it classified, some of it open source, I can tell you that we cannot stop every cyber-attack today. We can probably stop 90% with best practices that come out of them NIST Security Control and Privacy Control Catalog. If you're using ISO 27001, following HIPAA; if you do a good job you can stop maybe 90% of those attacks with our current technology. But we have to be able to answer the question, what happens when that 10% is successful? That's why the categorization I mentioned earlier of your critical assets is so critical.

I use the analogy, I spent 20 years in the military, and when I was in the Army we didn't have the GPS. We used to get around the battlefield with a map and a compass. Today the military and all of our sectors are totally with an emphasis on the "totally" dependent on the technology for our mission success. What if the GPS goes down today? What if one of your hospital systems goes down? What if a medical device has malware on it and stops working?

We have to be able to answer those kind of...that's the 10% question that doesn't make a difference for your kid's iPhone, if that gets infected and they can't use their iPhone for a couple of days or an hour; it may be a crisis around your house. But what happens when that patient's medical device stops working because we weren't paying attention to the quality of the software that went in and is driving that device. That's the question that we have to be able to answer today. And that's driven a lot by culture and by leadership, because we have technologies to do what we need to do.

So that's just a summary of the TACIT; it's kind of the elevator speech, unfortunately for cyber security it takes a tall building with a long elevator to get all these points across. But nonetheless, it's worth having that that discussion.

These are the five publications within the federal government that we have standardized on now. This is...these publications were developed by NIST, but under our partnership with the Defense Department and the intelligence community, so they're very broad-based and they're risk management based. And I wanted just to cover very, very briefly so you just have just the numbers in your head. And you can go to the website and you can download these free of charge. I have my contact information on the last slide, you can call me anytime, I'll give you my cell phone number, if you have any questions.

But the first one is enterprise-wide risk management, that's the 800-39. That talks about how do you take a look at the enterprise at large and start to develop a strategy for how you're going to protect all

this stuff, because it's a daunting exercise when you look across some of these very large hospitals or very big doctor's offices, the practices that we see today. And having a strategy on how you're going to organize for the cyber battle is really important. How to get that message to the C-Suite is really a critical starting point.

Doing a risk assessment is really the first order of business; that's characterized in our 800-30 publication. The 800-37 is what we call our risk management framework. The HIPAA Security Rule really...and the risk management framework are very similar and the fact that the HIPAA rule is very risk-based. In fact I've got a slide coming up later that overlays our risk management framework with some of the key things coming out of the HIPAA rule.

Of course our security controls publication; you might have heard about that one is 800-53. About two years ago we added an entire appendix for privacy controls. This is going to be critical if you want to really focus on the protection of the patient's data, the confidentiality aspect of patient privacy information. And then of course 53A document has all of the procedures. How do you know the controls that you decided to select for your systems or your applications, how do you know they're effective? Are they doing what they're supposed to do? Or do I still have residual vulnerabilities which translates to residual risk and how much risk of my willing to accept? What's my level of risk tolerance? In some areas it may be very narrow; on that medical device you might have very little tolerance for risk in a medical device versus some other type of medical application where it's not quite as critical and life-threatening.

This graphic comes out of the 800-39 publication. I just put it up to show you that typically in an organization you have very defined layers. The C-Suite is up at that top layer; we call that the governance layer and that's where all of the organization's missions and business activities...functions are defined and usually they're prioritized as well.

And then when you get to the second layer, this is where all of those missions and business operations start to take life. They're mission and business processes that are created to actually carry out those business and mission functions. And that's also where the enterprise architecture kicks in because those mission and business processes are feeding into your enterprise architecture.

And then down at the third tier, this is where you actually see the healthcare systems emerging and some of the medical devices that are actually on the ground doing the operational work. Our problem, even today, is that the communication between the first to tiers and that third tier is really broken in many cases. You've got people at the third tier trying to protect systems without sufficient budget or sufficient people and it's not tied back to the mission space very well. And so the message here is that when you look at the threats base today, the C-Suite, the CIO, the CFO, the CTO, the head of the agency, the CEO; they have to understand what that threat looks like. They have to be able to feel it; it has to be tied back to mission.

And so you can't start talking about two-factor authentication and encryption because their eyes are going to roll back in their head. They don't care much or understand all of that, but you...we can translate that into mission; the medical device stops working and the patient dies, that's something that everybody understands and we can really do a lot to make that threat space real by looking at the threats in the context of our specific vulnerabilities. Because after all, that's what risk assessments do, they look at the threats, they look at your vulnerabilities and what's the likelihood that those threats are going to actually exploit your vulnerabilities to cause mission impact, healthcare mission impact. And

that's something we...that's where we have our risk assessment process to figure that out. How susceptible are we today to some of these types of threats?

Well, without getting into the details, this is our risk management framework and I overlaid some of the HIPAA security requirements coming out of the rule. And you can see that they actually align, it's hard to see the chart here; these slides will be available to anyone who would like it. If you want a copy of the PowerPoint, I'll send you a copy if they're available through the working group.

But the RMF is a very logical process. That first step up there which is called categorize is what I talked about when you categorize your information; is it high, moderate or low impact? In other words, does it have mission critical impact if that data is compromised or if it's not that important? The data then...all the data types get categorized and then the system takes on a category as well. Is it a high impact system, a moderate or low impact system? That is going to drive your second step, which is the security control selection process.

This is why this is risk based. We have over...almost 860 controls in our catalog, just on the security side of the house and we probably have another hundred or so privacy controls. You don't select all those controls because you don't need them all, but you have to figure out which ones you do need based upon the specific healthcare mission application environment of operation.

Those controls are then implemented. Some of the controls are buried in the commercial products that you're going to buy. Other ones, because controls can be either management, operational or technical, they can be under your control within the enterprise; the management and operational control are largely in that category. And then, of course, you assess the controls to see if they're effective. And then we have step called the authorization step, in the federal government. This is a senior leader, could be a CEO taking responsibility for putting that system into operation, understanding all the risks and then saying, hey, we're good to go; we've considered everything and that's the extent.

And the last step is about monitoring. Today everything is changing, the threat space, the facilities where you're operating from, the environment of operation; the technology changes, the people. And so all this change, whatever security you've deployed, we have to be vigilant and understand how that is affected, based upon the changes that you're bringing routinely into the healthcare facility or organization.

This...just wrapping up here, a few more slides on protection strategies; up to this point, our strategy has been to keep the bad guys out, protect the boundary. But we know that doesn't work 100% of the time anymore because, gosh, we have cloud computing, we have mobile devices, we have technology that's exploding. And now we are willing to understand that look, about 10% of the attacks are going to get through, so now we're focusing on how can we build a more resilient system. In other words, does the malware come in, 10% of its going to get through. Does it spread throughout your entire network, affecting every device in the hospital or have you engineered through good architecture and engineering techniques so that malware is cordoned off and it can't move throughout the entire network? Those are architectural and engineering decisions that don't happen by magic, they are driven by senior leadership understanding of the problem and that's where...really where we are today, agile defense.

Coming out this year, another publication from NIST that's going to get to the heart of what I've been talking about today. This is going to be a guideline and it's going to address how you can integrate security into the lifecycle of how we build systems and applications. We took an IEEE and an ISO

standard that goes by the number 15288 and every one of the steps you can see; these are all the technical processes. We've integrated cyber security activities, key activities into every one of these lifecycle steps.

And so you can see the very first one is the stakeholders; we're going to get around the table with them very early in the process so they are buying in, they have to own the problem. And today, in security, the problem is outsourced to other people; they don't own the problem. And as long as they don't own the problem, we're not going to have fundamental change to make a difference.

Well I think that...just a couple of final thoughts. Security and we define that again very broadly, confidentiality, integrity and availability. Confidentiality, privacy of the patient's the records, the information, integrity of mission critical data; the medical device, the researches information and availability of critical services. So when we're looking at this, we look at, it's a privacy issue and it's a safety issue for our consumers out there, the consumers of health care commodities or healthcare services. And the bottom line is this is never going to get better unless security is built in as part of our design, our development and integrated into our mainstream organizational processes today.

Proactive, not reactive; patching, chasing a never-ending set of vulnerabilities is a nonstarter in the 21st century. They are building malware faster than you can ever build antivirus signatures; in fact, your antivirus products only catch about half the malware because they're producing that fast. This is all about a team solution. It's not government; it's government, academia and of course the industry. The industry that builds these systems and the healthcare industry again, you guys have a lot of throw weight out there. If healthcare folks get behind these practices that we're talking about today, it will absolutely move industry and give us better solutions. It's all about balance at the end of the day; mission, healthcare, all of the things that we know we have to provide to consumers and achieving that balance is really what we're after.

This is our contact information. Again, my email address is up on the slide there and I will also give you my cell phone because I know sometimes you want to ask questions at odd hours and we work literally 24/7 because we believe in this mission and it's important. So my cell phone is 301-651-5083. And I'll say that one more time, 301-651-5083. And whether you're in the public sector or the private sector, you're all our customers at NIST, so feel free to call and engage anytime. And I want to thank the committee for your time today and I'll take any questions that you might have. Thank you.

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

All right, a fantastic presentation; thank you so much for bringing your experience and depth of knowledge on this. And I will apologize to you for calling you Mr. Ross, Dr. Ross, so...

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division – National Institute of Standards and Technology**

That's probably better, actually.

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

So we have 7 minutes for discussion of a fairly rich topic, so we're probably not going to get as much in. In addition to being a paragon of diligence and expertise, Arien is modeling very nice manners for you all

by tipping up his nameplate. So if you want to talk, tip up your nameplate; I've got Arien first and then David. The floor is yours.

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

Thank you very much. That was a very nice presentation. I feel like the attempt here is to get everybody from a B to A, and I believe that in healthcare our challenges people getting from an F or a D up to a C. I'd like to address the role of NIST 800-53 and related publications and the federal role particularly in healthcare. We're working with our partners in DoD to achieve a DISA level 4 certification and the federal response in general to the cloud has been to create federal enclaves, to create walled off areas both...in all of the major cloud providers.

The federal response in healthcare has been by and large to secure the healthcare...the federal healthcare enterprise. And I'd like to provide maybe a different framework for federal participation with respect to healthcare, which is to ensure that major cloud providers are FedRAMP certified at the highest levels, whether that's the DoD SRG framework and DISA level 4, and are done so by default. If you actually talk to the cloud providers, they apply the same security controls to their commercial environment as to their federal environment and yet the federal response to engaging actually does not drive those same security controls to a level where we need to.

Most VA...most veterans engage both in the commercial sector and in the VA sector; most service members, family members and retirees receive care in the commercial sector as well as the civilian sector. So in many ways the federal response is counterproductive to NIST's mission. And I'd like to propose or counter-propose a framework for having a healthcare cloud that is FedRAMP certified by default and making sure that the federal participation in that cloud doesn't have the counterproductive intent of enclaving off, but rather making sure that we're secure by default.

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division – National Institute of Standards and Technology**

That's a great point and I think a lot of people have observed that same...your same observation. I think the feds...FedRAMPs been around a while now, it's still a fairly new program though and the repository has not been populated as much as we would like to see. I think a lot of federal agencies are risk-averse in this case. I talked about our categorization standard, FIPS 199.

The reason that's important is when you categorize low, moderate or high; you can then start to move the low impact applications to the public cloud first. I've even suggested to the feds they do a second level categorization because if you look at the demographics of our systems at the federal level, about 70% are what we call moderate impact systems; 20% are down at the low end and about 10% are high impact systems. That's kind of what OMB tracks.

If you could categorize all of your moderate systems again, so you'd have a low moderate, a moderate moderate and a high moderate, you then would have a better spread to figure out how do I start moving those things out to the public cloud even if I am a little risk-averse? It's kind of like getting it into the water and test the waters and I think that once we do that, we'll find that you'll have two effects; there will be less things that you have to worry about within your perimeter, the cloud providers are doing a really good job of managing those FedRAMP applications and services because they have the FedRAMP controls that are defined by the federal government. Independent third parties have looked at those and done an assessment and what's left in your boundary then becomes less complicated as well.

So, we have to work on strategies and how to push that to kind of jumpstart the process. But I know what you're saying is correct, because I see it every day.

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

Thank you very much. David McCallie, you're next.

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

That was...Arien's question was my first question although he used far more acronyms than I would have been able to use, so I'll have to have him interpret the answer. But my second question is, doesn't require too many acronyms, which is if you do a risk assessment across the suite of healthcare operations as you describe in your slides, I'm sure that to your mind there's some low hanging fruit that's just obviously begging to be addressed and then there's stuff that's more sophisticated and complicated and then there's stuff we probably don't...haven't even figured out yet. I'm curious; can you list off some of the low hanging fruit that we could, as an industry do to just get the no-brainers out of the way? Where we making the biggest mistakes?

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division – National Institute of Standards and Technology**

I think if you look at...you can kind of categorize things in a couple of different camps. There are certainly some architectural things we could do, segregating our critical assets into their own domains and then providing greater protection for those domains. Greater education and training for our users, our customer, the user community. Providing some of the basic hygiene things that we take for granted, just understanding the different components on the network.

We do vulnerability scans all the time in the federal government and we find usually always we find boxes we didn't know we had. Sometimes we find whole networks we didn't know we had. And so doing just good configuration management and control of what hardware, software, firmware, things that you own and that you're managing, because if you don't control those things, they're not being managed, those are ripe for cyber-attacks.

I think strong identity management is critical. I know, and the federal government, people live in glass houses shouldn't throw stones. So I say this with some trepidation, we've been trying to become two-factor authentication capable now for the past eight years; we're still not fully there yet. I know at NIST we do two-factor; it really cuts down a whole class of cyber-attacks because you don't have to worry about the password problem. That was one of...that's still one of our vexing challenges today because the more technology we deploy, the more applications out there and if they're password-based, we're asking people to remember 10, 20 passwords.

And then we're asking them to change those things every 60-90 days. It's enough to make your head explode. And it's very easily subverted by an adversary because they're brute force attacks now with the technology and the power of the computers that they're going through this thing like a hot knife through butter. Two-factors is an affordable technology, it's a relatively easy technology to use and it does really get some of that low hanging fruit off the table, so to speak; so good education, training and awareness, stronger authentication, identity management and a better control of your inventory of assets.

And the last thing I would say is there's a term called white listing. If you have your system locked down and it can only execute those programs, services or protocols that you consider safe and mission essential that will go a long, long way toward reducing the number of successful cyber-attacks. Now people are not going to like some of these things. It's hard to tell an employee on their lunch hour that they can't surf the web at their desk. Because even in the federal government, we get a half an hour for lunch and they're out there going to Home Depot or Lowes.com, whatever they're doing.

And they don't understand that those sites...many of those sites have been pre-infected by malware; they call them watering holes. And then when you go there and you hit that site, faster than you can blink your eyes, that malware is sitting on that desktop and if that desktop is connected back to your critical network system and components, that malware has a clear path all the way through your system. So that's an education, training and awareness issue that you can deal with, but it also has to be backed up by, policies are one thing, but having it locked down by technology is something else.

And those are decisions you have to make as an organization. Again it's not for everybody, but you've got to figure out, in the places where it really makes a difference, can you afford to have that malware bring down parts of the organization or different applications at any critical time? So those are just some ideas.

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

Thank you.

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

So, I have two of you in the queue, I have Eric and then Dixie just put her plate up. We're over time, are you all able to keep your comments or questions concise? Okay, then I give you permission to go.

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

Thank you for your presentation. One of the responsibilities of this committee is to recommend standards for can be applied across all of healthcare in the United States, which of course includes a lot of small physician offices, small hospitals, critical access hospitals where the IT team may be no more than one full-time person. In the case of physician offices, the IT team may be the same as the office manager, the janitor, the security; so, can you talk a little bit about how we ought to be approaching the task of identifying appropriate standards for security that can be implemented in such environments?

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division – National Institute of Standards and Technology**

Well I think, look, there are tons of standards out there. I mean the ones that we deal with routinely obviously are the NIST standards and guidelines; we have the security control catalog I mentioned on all those guidance documents I had in the slide. There are also ISO standards, which a lot of our private companies are implementing; ISO 27,000 has a whole suite of things.

But the basic idea, no matter what framework you pick or what set of controls you choose to implement, the problem is the same, large organizations, midsize and small organizations. And what you have to be able to do is figure out at the enterprise level, if you've got a large organization you have to be able to figure out what controls are essential for that organization to protect itself in the large context of being a large enterprise. There are different problems that they have than a small doctor's office, for example.

But our control catalog, our risk management framework is flexible and tailorable. So even if you're talking about a small doctor's office, I use the example of a contingency plan. In the federal government we have to have a contingency plan, it's one of our controls. That plan may be 500 pages for DHS, but if it's a small doctor's office, the concept of a contingency plan is still applicable but it's scaled-down to the...to kind of the context of the small doctor's office.

What does that doctor's office do if there's a malware infection and their patient record system goes down or their billing system goes down? What kinds of best practices can we apply in that environment where you don't have the skilled workforce necessarily? Can we apply some of the commercial technologies to that office in a very cost-effective way? You have to start to make some decisions on what you can actually do down at that level and how much protection as appropriate based upon what the small enterprise is doing and how it affects potentially other people who they're communicating with.

There are ways to do that and I think a lot of this is going to have to be...I think one of the things we could do is to define scenarios or different types of scenarios where I have a large healthcare organization scenario, this is a typical package of things that we would recommend deploying for that large organization. Maybe you have a scenario for a small doctor's office; here are the types of things that we recommend for a small doctor's office, things that are very targeted, a lot of fewer controls but the ones that really can make a difference for that office and that environment with a lot less expertise and resources.

If you don't give those scenarios out, I think if you leave it up to the individual practice, these are folks that don't have the expertise so they're likely not going to make those good risk-based decisions without some help. That's why I think it's incumbent upon industry to build a lot of these safeguards into the basic products and the systems that we're buying so we don't have to. It's the seatbelt and the airbag scenario again, but even with seatbelts and airbags, I still get the owner's manual, I still have certain responsibilities on my part as a car owner. I've got to check the tires to make sure the air pressure is okay. And so all those things, they have to be scaled and targeted at the audience that you're trying to achieve.

And I don't think it's just two scenarios, it's going to be a large...you might have a dozen different types of scenarios that you can think of that would maybe get 90% of the healthcare customers and providers out there, consumers and providers. And I don't know if we have that today, but that's something I think would be very worthwhile for all of your customer base.

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

So, Dawn's got 8 minutes left for her presentation, so you've got 30 seconds and then you've got 30 seconds.

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

Oh, well then, thank you...presentation. I'll send you an email. We do have significant challenges around certification of EHR technology because currently the certification of EHR technology does not include security. So, we do have a Meaningful Use incentive payment criteria do include requirements for healthcare enterprises to conduct risk assessment once they have adopted certified EHR technology, but I was wondering what advice you would give to a healthcare enterprise in assessing vulnerabilities that

are inherent in certified products and the integration of those products given such low visibility into the internal workings of those in certified products.

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division – National Institute of Standards and Technology**

Well this is the common criteria story that you're very familiar with and Lisa is very familiar with. There was a vision 20 or 30 years ago that we would be able to influence industry by having good, defined security requirements and there is an ISO standard, it's 15408, the common criteria. There are functional security requirements and there are assurance requirements; they're two different volumes. As consumers, industry is going to follow what we ask for; if we're not savvy consumers and asking for these kind of security features to be built into the products and to be tested and evaluated, that is not going to happen, necessarily.

And so I think it goes back to when you buy a product today, you don't have any visibility. You have to trust that the vendor used best practices in that software development process to make sure that they do things that attack surface reduction; they make the attack surface smaller so the adversary doesn't have as many places they can bore in on you. And without having that consumer-based push from this side, industry may or may not address those kinds of things. Once that product comes to you or the system shows up on the loading dock, the game is pretty much over from your perspective. There's not a lot you can do at that point.

So we're talking about working on two different planes here; what can influence in the industry so they build better products and systems that come to you? And then once you get those products and systems, what can you do as the enterprise to make the sure that the architectural constructs that you're using to build the enterprise architecture with those systems and products and the policies and procedures that you develop to run the enterprise and to address security as an institutional process; those are things that are under your control.

And so you have to kind of work in two different lanes. The first one is very frustrating because there's not a lot that you can do about that. But we do have the voice of the consumers and the healthcare consumers are very, very numerous and have a lot of the GDP at stake here. So I think they speak with a loud voice.

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

All right, Ron, on behalf of the Standards Committee and ONC, thank you both for your expertise and your federal collegiality and we look forward to more discussion in the future.

**Ron Ross, MS, PhD – Fellow, Information Technology Laboratory Computer Security Division – National Institute of Standards and Technology**

Thanks very much for having me; thank you very much.

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

Absolutely. All right, next up we have Dawn Heisey-Grove with the data updates. Dawn, if you don't mind, I'm going to try to ask you to keep it to 10 minutes and then we'll steal 5 minutes from Evelyn as well, when she comes after you. So, thank you very much.

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Okay. I will try to do my best to keep this brief and I'll...maybe it'll help if I skip all of the summary slides since you can read those at your leisure. So today I'm going to be talking about the characteristics associated with performance in meaningful use measures mostly on Stage 2 measures among eligible hospitals. And the measures that I'm going to be looking at, the categories of the measures I'm going to be looking at are listed right there.

This is a figure that I think many of you may have already seen before, but it bears highlighting just because the hospitals that we're talking about when we talk about Stage 2 measures are just those that started their meaningful use progress or pathway in 2011 and 2012, so that's those first two lines there. Everybody else, when we talk about the Stage 2 data, will not be included because they were not scheduled to start Stage 2 until either 2015 or 2016.

This graph shows two bars; among the hospitals that were scheduled to attest to Stage 2 in 2014, the top bar are those that actually attested to Stage 2 and the bottom bar are those that used the Flex Rule to actually attest to Stage 1. So what we see here is the distribution of the different types of hospitals that attested to Stage 2 versus Stage 1.

The blue are the critical access hospitals, green are small rural, which is less than 100 beds. The green are the small urban hospitals, again less than 100 beds. Medium are between 100 and 399 hospitals...no, 399 beds. And the blue are 400 or more beds. And what you see here is that the distribution is pretty similar between those two bars. So that means...that tells us that there isn't any more of one type of hospital attesting to Stage 2 versus using the Flex Rule to attest to Stage 1 for 2014.

So the first measure that I'm going to be talking about is the care transitions measure. This shows you the measure that was new for Stage 2 in 2014 and that is that hospitals had to transmit at least 10% of their summary of care documents electronically. And what we see here is that the mean for all hospitals was 36% and that for the most part, the bars are fairly well clustered around that overall mean. The critical access hospitals are performing highest, at 44%; the large hospitals have the lowest percentage at 32%. And I will skip this slide in the interest of time, but this just summarizes the data that you just saw.

The next set is the patient engagement measure. Again, for Stage 2 there was a new measure that required that hospitals have at least 5% of their patients view, download or transmit their electronic health information at least once. And what we see here is that 15% of patients at these Stage 2 hospitals viewed, downloaded or transmitted their electronic health information at least once over the course of their reporting period. Again, the average bar based on the characteristics are fairly well clustered around that means, so most of the hospitals are performing pretty much the same. The hospitals who have been in the program the longest, who first attested in 2011, have the highest average and also small urban hospitals have the highest average. But everybody is really tightly clustered around that mean.

This is another way of looking at that same data. What we have here along the "X" axis are...is the month that the hospital actually attested to Meaningful Use. So we see that in April and May, when we had a few hospitals attest very, very early in the attestation period, their scores were fairly low; they were right near the threshold of 5%. But as time went on and when...the month where we had the most hospitals attest, in November, we see that that mean when up to 17%. So as time went on, the hospitals

that attested later were able to report more of their patients viewing, downloading or transmitting electronic health information. This is again a summary of the information I just presented, so I will skip that for time.

The next two measures that I'm going to be talking about are patient safety measures that are again unique for Stage 2. The first one is the tracking of all doses of medication orders through an electronic medication administration record, eMAR, and these are inpatient medication orders. What we see here is the threshold for this measure, this was a core measure for State 2, brand new, the threshold was 10%. The average for the hospitals that are reporting on this measure was 70%. So, 70% of their medication orders had all dosage tracked through their eMAR. So they're doing well above that minimum threshold that they had to meet. And again, the means and bars for each of the hospital types is fairly well clustered; we see that medium hospitals, those that have 100 to 399 beds are performing the best, as well as those that have been in the program the longest.

The second safety measure that I'm going to mention is actually a menu measure; that means that hospitals opted to report on this, but that they did not have to. So that's why the numbers that you see on the bottom of this graph are different from the numbers we've seen previously. These are the hospitals that specifically decided to do ePrescribing for their discharge medications. So the minimum threshold here is 10% and we see that on average, of the hospitals that chose to report on this menu measure, 56% of their discharge medications were transmitted through ePrescribing. And again, very tightly clustered medium-size hospitals are reporting the lowest proportion of discharge medications reported through or transmitted through ePrescribing, with critical access and small urban having the highest rates. Again, summary slide; you can read that at your leisure.

The last one that I'm going to be talking about is public health reporting. And this is one set of measures that actually includes Stage 1 as well as Stage 2 performance. For Stage 1, the hospitals had an option, and all of the public health measures were menu measures, and they had to report on at least one of three different menu measures, immunization reporting, syndromic surveillance reporting or electronic laboratory results reporting. And so they did not have to report on all three.

This graph shows you the percent of hospitals who reported on all three measures for Stage 1 versus Stage 2. Stage 2 the hospitals...those three menu measures became core, that means they're required. And so the map on the right shows you the proportion of hospitals for Stage 2 that are actually reporting on all three measures. There are exclusions for each of these measures, and so what you see here is why it's not 100% is that there is some small rates of exclusion among some states if the state can't accept the transmission and the hospital can take an exclusion; they don't offer the appropriate vaccinations or they don't offer vaccinations for the population of interest, they could also take an exclusion for example.

This tells us that most hospitals have the capability to do public health reporting on most, if not all, of the measures and that the public health...local public health agencies that are set to receive those can...most of them can receive the message as well. There is a lot more information on this particular aspect of public health reporting on a data brief and the link is down below at the bottom of this slide. That is a summary of what I just said, and hopefully I have made it in record time.

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

Data analysis presentation ninja, well done; thank you very much. Any clarifying questions? We'll start with Jeremy and anybody else if you have them, put them up.

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

Thank you, very interesting data. So you have any theory that explains why critical access hospitals might be outperforming larger hospitals on two of those measures?

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

I have two theories, and they are my own personal theories; but the first one is that they have been forced for a while to do these measures, they may have stronger relationships with their patients and therefore it may be easier for the patient engagement measure, for example. The other possibility is they have a lower denominator and so it may be easier. So it's something that we're going to be looking at is controlling for some of those characteristics and seeing if that still...the performance is still high.

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

It stands out as being so different that it would be important understand.

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Agreed; very, very good question.

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

Made it a lot of fun to go present to the National Rural Health Association the other day, so. All right...oh, Floyd.

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

Thank you. Just two quick questions, this is actually very helpful. On summary of care record, I've heard reports that sometimes the record that's sent is very voluminous, and...is there any information about how useful that was to those who used it? The first question, and the second is, eMAR is something that many hospitals were starting before meaningful use so is there any previous percentage to compare the current to?

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Okay. So those are good questions; the first one, the usefulness of the summary of care record. I think that's the \$5 million question when it comes to summary of care documents. The data in the meaningful...the meaningful use data, we don't have any information about how useful it is. I think it's something that ONC as a whole is trying to explore because it is such a very important question. In terms of eMAR, that is also not something I have access to. I think, yeah, I don't know if we have any data or if it's something that we're working towards.

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

And last quick question, Cries.

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

Really encouraging data, thank you. Will you be doing similar research for ambulatory outpatient care in addition to hospitals?

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Yes, so we hope to report on the eligible professional data when it is available. Because their deadline was extended through March, it means that we probably won't report on that for a couple more months...

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

Right.

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

...but definitely.

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

Thank you.

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

...so much and thank you so much for your presentation. Oh, right, yes.

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

Thank you very much, a really encouraging report. On the other patient engagement scores that went from menu to actually required now, like patient specific education materials, do have the most current data? Last month we heard some that were pretty...very, very positive, wanted to find out if you've seen that trend continuing.

**Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology**

Yeah, I don't know the numbers off the top of my head, but that is...the patient engagement numbers that I remember were good, but I don't remember them off the top of my head. If you want to reach out to me through Michelle, we can probably provide that.

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

Okay, and again, thank you, as my former boss used to say, a brief brilliant presentation. So Evelyn, come on up, you've still got 10 minutes, don't worry.

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

While we switch to Evelyn, if you're going to get lunch, I'm going to come around and get your menu.

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

Yeah, most importantly. Evelyn will be presenting to us on the S&I Framework's electronic long-term support services progress, so, thank you so much for being here and look forward to your discussion.

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

Thank you. Can you hear me? Good. All right, well I'd like to start by thanking that HIT Standards Committee for the opportunity to provide you a progress update on the electronic long-term services and supports initiative, which I will refer to as the ELTSS initiative. We originally introduced this initiative in November, soon after it launched as a new S&I Initiative under the S&I Framework. So for today I'm going to be really quick, just give you a recap update of what the initiative is and then end with a series of targeted questions for the HITSC Standards Committee that will help frame next steps for the initiative.

So as a recap, the ELTSS initiative was launched in November in partnership with the Centers for Medicare and Medicaid Services. It is driven by the requirements of the CMS testing experience and functional tools and Medicaid community-based long-term services and supports demonstration grant. Lots of words, I'll call it the test program. This work was initially introduced under the ACA as a requirement for HHS to identify and publish of voluntary set of adult quality measures for adults eligible for Medicaid. CMS adopted this requirement as a call to action to standardize how data is collected and shared for LTSS within home and community-based settings.

As a result, CMS announced this opportunity...grant opportunity, and awarded Medicaid grants to nine states in March of last year. Six of those states are required to participate in the initiative and have been doing so. I do want to clarify that even though the initiative is driven by the CMS task demonstration grant requirements, it's managed under the S&I Framework as an open, collaborative and public facing initiative.

For the first two months of this initiative, the community has refined and finalized the scope of this work to what you see on a slide today. So I'll summarize by saying that the scope is to identify, evaluate and harmonize standards for key domains and associated data elements for person centered planning and the creation of an assessable and interoperable person centered plan that can be exchanged electronically across and between providers, beneficiaries or individuals, accountable entities and payers. Ultimately the initiative will identify the required standards to support the creation of a person centered electronic plan. And by person centered, we mean one that supports the patient, makes him or her central to the process and then experts on their goals and needs.

In addition to supporting person centered planning as directed by existing rules and guidance published by CMS and the HHS Administration of Community Living, the standards identified through this process will support interoperable exchange with various information systems, as noted on the slide. The last group is important here because this has specifically been called out by the community and you usually don't see it in other initiatives, the opportunity to exchange information with legal, justice, education systems.

So in November we walked through this projected roadmap and timeline for the initiative. We explained the initiative would align with the timeline directed by the test demonstration program which runs until end of 2017. The majority of this work is still projected to complete within the first year...this first year, with the remaining two years focused on piloting, testing and evaluation of the identified standards. In other words by the end of this year, we expect to have completed a first iteration of an implementation guide which will then be tested through in 2016, refined based on feedback from the pilot projects and then retested in 2017. The second version of this implementation guide is what will be presented to a standard development organization for balloting and publication.

As noted here, we have successfully completed phase 1 of this work and achieved delivery of our first deliverable, a consensus approved project charter. We kicked off of phase 2 in January and are currently working through the development of the use case.

I want to clarify that the artifacts and deliverables of this work to date have been developed and refined by the ELTSS community. And when I speak of the community and participant organizations, I'm not only speaking of the six test grantees that are required to participate as part of their test requirements. I'm speaking about a community that is much broader than that. This slide is meant to illustrate all the diversity of participant organizations to date.

I must acknowledge the significant work of the CMS test leadership team and the test grantees themselves in having...in helping bring these broad stakeholder groups to the ELTSS weekly meetings. Saying so we recognize that we need to do more work to educate and engage with other stakeholder groups to include consumer advocacy groups and mobile solution providers. For metrics sake, we currently have over 400 individual participants and 74 of these are registered, committed members. On average we have 60 to 70 individuals join our weekly meetings.

Recognizing we have such a large and diverse stakeholder group, we recently shifted our approach for use case development by starting the process asking these four larger stakeholder groups why the ELTSS plan was valuable to them. Our intent was to get to the key business or motivational drivers for why each of these stakeholder groups would want to access an ELTSS plan. The following three slides summarize key findings from this exercises, of course I won't spend time going through all of them. What's important here is that this work is currently helping both CMS and ONC better facilitate development of the...of a value driven use case.

So, I'll jump to slide 11. So in terms for next steps; we're working...as I mentioned, we're working through development of the use case. Right now we're working through identification of user scenarios that are defined by the three stakeholder groups which we label beneficiary, provider and payer or accountable entity. Once this exercise is complete, we'll move on to use case data set requirements identification. And there's a series of inputs we've included here on the slide already. Our target is May of this year.

Here is a slightly updated version of the "2B" scenario we originally presented back in November. It is clear from recent discussions from the eLTSS community that the beneficiary and his or her caregiver are central to the exchange process. We recognize we're still too early in this work to determine how information will flow across the four touch points. What we do know is that the goal of this work is to identify a standard that will enable the eLTSS plan, wherever may live, to be accessible to the various systems used by the actors presented here.

We know that the eLTSS plan will be generated by a system, managed by the service team functioning within a community-based setting, so what you see on the top right hand corner. We also know the eLTSS plan will not live within a clinical IT system or be embedded within an individual's electronic health record. And we know pieces or parts of this plan need to be shared across the various systems in an interoperable way.

So this brings me to our last slide, and I hope I'm good on time. We are at a good place right now to gather your feedback and guidance from where we should go next. So I'll read these questions out loud and look forward to your responses. So one is what candidate standards exist that lend to this type of

work? What standard development organization should we consider engaging with? Do you have guidance for engaging with digital and mobile health innovators that of course play a critical role for the scenario I just presented? And lastly, what are we missing here? Thank you.

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

Once again, my thanks to you for a concise, elegant presentation; well done. So let's take our time and take a look at these answers or these questions and if you have answers to them or comments to them. I would also like to welcome to the table Dr. Halamka.

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

Thank you.

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

Thank you so much...

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

Commuting in the Middle East was easy, commuting in Washington was hard.

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

I've heard that before. So let's go around the room, start with Wes.

**Wes Rishel – Independent Consultant**

Can you go back one slide, please? Sort of vaguely up there on the left there's a thing about accountable systems, is that supposed to be accounting or some other...

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

Accountable systems; so these are, at the state level there are systems that authorize, approve and pay. So they're different...they're labeled differently. So it's the community came up with this word saying that there's accountable entities that are responsible for the services that are delivered and paying for those services and they use their respective systems.

**Wes Rishel – Independent Consultant**

Sort of hard to believe that the other systems don't need to be accountable, but, all right. Thanks.

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

Very good. Leslie.

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

Thanks, I really appreciate this work and the emphasis placed on the patient as a participant and an active participant involved in their care planning; so thank you for that work. I did have a question about semantics and taxonomy because I think that might be a gap that's not listed here. How can we work on synonyms and on general vocabulary and taxonomy for high degree of interoperability for the patients

involved in care planning, specifically around goals of care, value-based care and informed medical decision-making? So, would like to see some work in that area.

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

Yup. Absolutely. We are getting into...of the data requirements looking at what definitions exist out there for data elements that need to be collected. So, that will be an opportunity to focus on the harmonization of those semantics.

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

Sorry, John Derr.

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

Mine's just a comment. I just want to give a shout out to Evelyn and all the hard work she does. I'm on that committee and she really herds cats and does an excellent job about that. Thanks, Evelyn.

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

Thank you.

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

I agree. David McCallie.

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

Thank you. I don't like to confess how little I understand of the work that you're doing, although it looks very impressive and very important. But it also looks like it's at the stage when the questions you're asking raises the opportunity for us to test some of this against a framework that Arien and I will present later this afternoon about sort of different way to think about building interoperability standards. It may be that where we are and where you are don't line up in terms of time, we may be not quite mature enough to take on something that has your particular deliverable timetable, but I would certainly like to at least volunteer the thought that we could explore matching some of your needs to this framework that we'll talk about this afternoon.

Arien, I don't know if that makes sense to you, but for example, I think there are a number of things here where moving access to a shared application, an App, a plug-in App might be much less complex than moving really complex data structures around. So bring the data to the individual that needs to see it in the form of an App rather than sending them a complex CDA derivative structure that nobody knows how to parse and would be questionably useful anyway. So, just register the thought that we should think about this.

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

That would be great.

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

Evelyn, your bobber just twitched, you got a nibble. Ooohhh, reel em in. Andy Wiesenthal.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Okay. Thank you again; others have said good work; a couple of comments and maybe the beginning of an answer to some of your questions. Please don't invent new standards, take a look at the existing standards work and find ways to extend them, okay, this is not Judy Garland and Mickey Rooney let's have a show.

Second, you made a comment that I really disagree with that this kind of plan cannot live within an EHR. I would suggest while that may not necessarily be the only repository for it, or even sometimes the primary one, it actually must live within an EHR because people who work within an EHR as their daily way of doing their work have to interact with the plan. So I don't under...maybe I just didn't understand what you meant.

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

I can clarify, Andrew. So an EHR contains clinical data and what this initiative is looking beyond clinical data to services...

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

I understand that, completely but I resist is a doctor the notion that I'm not interested in anything but clinical data, okay. I interacted with social workers, people at schools and so on and that's the final point; this is not just about old folks.

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

Absolutely.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Okay? Actually, everybody needs a plan and so to create a framework so that all of us can have a care plan and whether we don't need much care or not is actually the right thing to do. And the people who are working on this and thinking about this, in sort of the more farseeing managed care or accountable care organizations are in fact looking at it that way.

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

Okay.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

So if you look at...I'm a pediatrician, if you look at what I had to do with children with disabilities, it's very much the same thing. And the planning around what services they require required interaction with

all kinds of community providers that aren't classically healthcare providers. So it does have to live within an EHR and it has to be accessible to clinical providers and they do think about it.

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

Okay.

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

All right. Eric Rose who just attacked by a spider from the ceiling, I think.

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

Is it? Okay...

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

I don't know, I saw something down...coming o

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

Well, our bodies are ecosystems as I tell my patients all the time. So thank you very much for that, this is really important work. It's going to benefit hopefully some of the most vulnerable members of our communities. One of the things that the British NHS did a couple of years ago, at least they developed the prototype, I'm not sure if they ever brought it into production use. And...but I wonder if it might fit into the scope of what you are doing; has to do with the informal networks of caregivers that many of these individuals have that include family members, neighbors, friends and often do some of the same work as the professionals who are getting paid to do it and often there needs to be coordination.

You know, the Meals on Wheels might provide these meals during the week, but the neighbor might provide it these other...and so the NHS decided to develop an App that would allow coordination of these informal caregiver networks for an individual to coordinate their...everything from meals to logistics of transport back and forth to appointments to just checking on someone, that sort of thing. And I wonder if that needs to or should be part of what you're trying to build here. And it creates a whole host of interesting problems in terms of who owns and gets to create the data, privacy and confidentiality and so forth; but it might jibe with the reality of what's actually happening in the trenches for these folks.

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

Excellent, thank you; you've hit the nail on the head. We've heard that exactly the scenario about the care...we see the caregiver taking on that role as well and how do we bring them into the fold and enable access that they need. So, absolutely; that's a great...we'll look that up.

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

Thank you. Last comment goes to Jeremy.

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

I'll qualify with David's which is, I'm also ignorant, I think, of the bulk of the work that your team has done and it sounds fantastic. But just listening to David's and Eric's and Andy's comments, I wonder whether this isn't really a standards conversation at all, that in fact we're at a pre-standards level for understanding how to best to deliver these kinds of services. And an application which is kind of what emerged as an idea to me isn't a standard and I would encourage this committee, but also kind of all the conversations around where health IT needs to go to not jump too quickly to standards when we don't even have really any semblance of a solution yet. And I wan...and specifically asked about how to engage innovators and digital health companies and mobile companies, standards will scare them away; invitations to help solve problems will attract them.

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

Yeah, that's a go...yeah, absolutely. Thank you.

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

All right Evelyn, thank you so much...

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

Thank you very much.

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

...for your work that led up to this as well as your engagement, so...and with that to Dr. Halamka.

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

Well great. Good morning everybody, apologize for the delay. So my 17 hour flight I did have the opportunity to read all of Arien's fine work in detail and so...and it is, of course today we'll hear from Arien and Stan and then later in the afternoon we'll hear from Arien and David. But I just...I think you already called out; there was a lot of Arien in this, so thank you.

So I think it was on February 27 I wrote a blog piece on the role of ONC and just looking at its multiple years of effort and where has it really been strong in such areas as convening, and incentivizing, and catalyzing; in figuring out how to be a front door for many disparate federal agencies. So when we ask what is the S&I Framework? I harken back to the HITSP days when the HITSP group was a harmonizer and it was trying to be a layer on top of SDOs. And then, of course, we had S&I that tried to do something similar. So in this broader context of, well what should ONC do and where has it succeeded? Where should we take the lessons from HITSP and S&I and go forward? We will hear from Arien and Stan, and this is really, I think, a remarkable, very important framework for our future. So Arien, thank you.

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

Thank you. I'm going to go first. So the charge of the committee evolved a little bit from actually ask the first question, do we need S&I at all? And if so, then what could we do to improve or enhance...1:36:19-1:36:47(lost audio)

**W**

Hello?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

Yes. Just stand by, we're just trying to get the audio back up in the room.

**W**

Thanks.

No audio: 1:36:55-1:38:20

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

We didn't want to basically always use S&I framework as the name of the thing that might be...1:38:28-1:39:48 (No audio)

**M**

...and spell your first and last name and then press the pound key to continue.

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

Thank...

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

Another way of saying that is that SDOs as an open consensus process sort of work by their own schedule and it's hard then sometimes to take advantage of what's done as part of a regulatory or other kind of standard-setting process. And so there's an opportunity there to better try and correlate SDO activities the national priorities and to the work schedule.

And then ensuring that such standards and implementation guidance are informed by working reference implementations and production use, and again, it's just a recommendation or a recognition that oftentimes, in spite of what Dixie's tried to teach us and other things, we jump...we create a standard and we want to move, we're excited and...to try and make progress. And in fact, we would be much better off to have implemented and seen some of these things working at scale before we impose them or inflict them on the country as a standard. So, those are just observations.

And then, when we look at the recommendations then, we do say ONC should support a convening function that focuses on the following key enabling activities and associated recommendations. So that first thing is essentially a recommendation that we think there are valid things that a convening function should do. And then the second item with a lot of sub-bullets talks about work with SDOs, coordinate across SDOs and perform additional activities to support identified national priorities. And so this list is structured in a way basically to point out what the convening function does and to emphasize some things that the convening function supports the SDOs to do and that's an important distinction in this list.

And so, the convening function defines critical needs, desired outcomes and evaluation criteria for projects and it shows that they have traceability to national priorities. And the convening function also

develops, identifies and refines use cases. They include front end clinical and other requirements into the use case development.

But then things that they support SDOs to do, so these are things that the convening function itself doesn't do, but supports SDOs to do and that's identify gaps in existing standards and implementation guides, work to reduce optionality for existing standards and implementation guides and create easy to consume consolidated artifacts.

And so, the point being of that last one, that the function of the S&I isn't to be an SDO, S&I...at least the feeling of the committee was that S&I shouldn't produce things that people start thinking of as standards. The standards should be produced in the SDOs and S&I should work with the standards to produce those. And then finally, when new implementation guidance is needed, use a defined process for selecting which SDOs to work with. So that's essentially a triage function, knowing if we've got a new project, do you take it to HL7, to NCPDP, to X12, to...you know, one of the groups.

The next area of the convening function, support production use of the above by facilitating, including funding of pilots and again a focus on implementation and getting experience with the standards then taking the knowledge that was gained from that, feeding it back in an iterative way to improve the standard. Evaluating the success; and some of this comes from probably a lot of our association with research where a good research project always has to include some way of evaluating whether you've done what you set out to do. And we think there could be an increased emphasis on evaluation.

And then, facilitating and supporting the development of widely available reference implementations. And this is both a way of making sure that the standards will work as well as the priming the pump to give people publically available software that triggers implementation and facilitates implementation. And then creation of tools...excuse me, testing tools in parallel with development of pilots and other projects.

So four...fourth recommendation; facilitate effective federal participation in SDOs by working with ONC to coordinate involvement of relevant federal agencies. That would include identifying representatives from each relevant agency; ensure the federal role in SDOs and similar organizations as aligned with national priorities. And ensure active federal participation in pilot technology development, early production and national adoption of standards and implementation guidance; so all of those things are things that we would encourage, basically coordinating and facilitating the involvement of federal agencies in SDO activities.

And then fifth, identifying needs for infrastructure and artifacts that may be developed outside of or across SDOs. So the observation there again is that often times if we're driven by use cases, you develop a solution for each particular thing. But there are things like value sets and provider directories and other things that in fact help all implementations of these kinds of standards. And there needs to be focus on that infrastructure as a thing, not just as a part of many different projects but actually focused on as a very important foundational and infrastructural piece of what we're doing. So with that I'll stop and let the real boss take over here.

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

Thanks, can I borrow you're slides because it's slowly dawning on me that my wife kept telling me, you're eyesight's going go and I keep looking at the menu and the menu was just fine. She said, no, no,

no, it's going to happen and turns out I have no problem with things that are up close, it's those slides over there that are hard to read.

So our next...so the first section really dealt with what should a convening function do? A lot of the questions on what a convening function should do were secondary to what an identified national priority is? And we looked at this question about identified national priority; we recognized that since we're a workgroup of the Standards Committee, it's not really our job to say what a national priority is. It is, however, our job to talk about what needs to be true of identified national priorities as a set in order for a convening function to be successful with them.

This was secondary to our finding that the S&I Framework often took on such a large set of priorities or projects that it was difficult identify how to get involved, also secondary to a finding that if you have a large set of products at a single time, you tend to dilute the resources, particularly the smart folks who know stuff, who participate both in convening functions as well as in SDOs. So what we decided to approach this on is what needs to be true of a prioritized list of an identified national priority for the convening function to be successful?

And we came up with a set of recommendations; this is an identified national...or an accepted project into the convening function must meet all of the following criteria; so this isn't a meets any, this is meets all. The first one is that it has objectively high priority according to a rank order prioritization determined by stakeholders with balanced representation, with beneficiaries and developers as well as other stakeholders. And we particularly examined the topic of a single federal agency that wants to get something done and has some dollars to spend.

And our conclusion is that it would be...because of the issues of dilution, it would be inappropriate for a single federal agency that wants to address a need to spawn a convening function project independent of rank order prioritization. It doesn't mean that a federal agency can't sponsor a project; it just means that just because a federal agency sponsors a project doesn't mean its ipso facto high on the priority list.

The second, again remember, this is an all of the above test, the second is that the project needs to lead to measurable and meaningful real-world outcomes that will advance the given national priority. And you'll see that the outcome focus further on, in terms of our recommendations for how. So first test is, high-priority, second test is, it's actually going to do something. And the third test is that it's likely to be effective, the project itself is likely to be effective and have a high likelihood of success. So again, think about this as is rank order of high-priority; if it works it's going to make a meaningful difference and it's likely to work.

And likely to work has a number of facets. We suggested a number of "for examples," so there's a reasonable path to scale the effective production implementation. It takes in consideration the full Lifecycle, not just the SDO and standards development activities, but the developers actually implementing technology and providers standing up working systems, also inclusive of workflow and adoption.

So one of the examples as given is if you're looking for two or three different things that affect clinical workflow in care planning, for example, you may be taxing the system more than the system can change in terms of clinical workflow. Or likewise, if you're asking for, and this is another example, if you're asking for physicians to take on some set of activities that they heretofore haven't taken on, you're not likely to be successful in that endeavor.

Number two is there are key enablers. Again providers, vendors, developers who seek to implement the outcome it's a bad sign. If you've got something that wants to get done but no provider organizations say, well, we actually want to solve this problem and no developer organization say, we're willing to write the code that gets that job done.

And then again, takes into consideration the parallel efforts that are going on at the same time and is considered and aligned with SDO process and timeline. So for example, if you have an initiative or a project that you're taking on and you haven't lined up...and it requires HL7 to do something, but you haven't actually sought HL7's support and lined up the calendars, you're not likely to be successful. Again, this is a for example.

The key three points are; needs to be high rank order prioritized. Number 2, has to make a meaningful difference. Number 3, has to have a reasonable likelihood of success. So that's our test for identified national priorities. The next sections deal with some of the how criteria, if we go on...I go on to the next slide. That's what that's for.

So we talked...one of the things we realized in the course of our progress in the task force was that we were focusing on the convening function but we needed to see the convening function in the context of the full lifecycle where that lifecycle is inclusive of SDOs, implementers, adopters and providers. And so we need to be thinking about the lifecycle in which this activity occurs.

We heard some testimony from a wide variety of actors. One of the key points in that testimony is that outside of healthcare, standards implementation guides are developed in close concert with implementation and production use and that there's often a tight feedback, sometimes very rapid, sometimes over long period. So as two examples, the OAuth 2 specification in IETF went through 31 drafts before it was formalized as a candidate standard or a provisional standard by IETF.

Many of those 31 drafts were actually stood up as implementations by large consumer Internet companies so that the changes...suggested changes to the OAuth 2 draft were done in context of solving real-world problems and also were done in context of real-world production use. Another example was the HTTP 2 specification which was informed by production use of the SPDY protocol by Google. And within two weeks of the final draft of the HTTP 2 specification being endorsed by IETF, there were working implementations of HTTP 2 in production, in the browsers as well as in some Web servers.

So again, examples outside of healthcare that you can have a tight feedback loop between standards development and implementation and testing. And a whole bunch of stuff. So, it was outside of our scope, but we encourage SDOs to work with...in the healthcare domain to start to consider some of those lessons. So for example, could HL7, as an example, have a something in between a draft...a draft standard for trial use and that gets formally balloted, but more of an intermediate process.

And you'll see that HL7 FHIR actually follows such a process where a lot of the drafting gets done in close concert with implementers. But it's sort of kind of inside HL7 and then there are some sync up loops relative to DSTUs, relative to final standards. IETF has a quazi-more formalized way of doing that.

Number 2, and two recommendations for the role of ONC and certification with respect to standards adoption; so the finding here is that that iterative approach to standards development works best when economic and mission drives interoperability. That is, in the Internet domain somebody wants to solve a

business problem and they work with implementers and technologists and standards developers to solve a business problems and standardize on the basis of having solved that business problem.

In healthcare over the last few years, we've adopted coordinated adoption of standards through national regulatory timetables that are aligned with the key national programs. Meaningful Use is the obvious example, but alternative payment methodologies as certification may or may not be aligned with additional programmatic.

And so the key issue here is that if you're going to align with market and mission, you need to have some level of flexibility for that market and mission to drive standards development. If you're going to align with national timetable, you need to make sure that you build into those national timetables the pilot implementation testing that's required.

Now we finally found that SDOs perform critical roles with respect to balance of interest, IP rights management and other activities that are aligned with OMB Circular A-119 on the use of voluntary consensus standards. And so it was a strong perspective that the convening function should carefully align its role with respect to the role of SDOs. So that again, with respect to this lifecycle of pilot, test, refine that you don't have implementation guidance that's stranded with respect to standards development organizations. So those are the findings.

Recommendation number 1...or recognition number 7, I think we had some numbering issues here but hopefully this all lines up, is that we have a coordinated lifecycle for standards development, where ONC actively encourages and seeks to discourage policies that...seeks to avoid policies that discourage market and mission based work.

We gave an example of a policy that seeks...that inadvertently discourages loading a certification time cycle to the level that developers and implementers do mostly nothing but Meaningful Use development and adoption; reduces flexibility of developers to do market and mission-based adoption. Other examples would be certification criteria and attestation criteria that are so tightly defined that there's really no way to do anything innovative.

The second two relate to the cycles of implementation and standards adoption. So when working with SDOs that have processes that are accommodative of cycled implementation and standards development that the convening function should work within those functions. In areas where the SDO doesn't have a formal process that's accommodative of those cycles, the convening function should encourage those cycles of feedback and implementation and seek to align those with the SDOs formal balloting process. Again, some of the work that DAF and Argonauts are doing with HL7 are interesting models of lining up with DSTU cycles, but driving feedback and implementation during the cycles. ONC should not create certification criteria for standards implementation guidance that lack adequate real-world piloting and production use. I think we've sometimes underestimated the amount to which we learn in implementation guidance, I certainly did. And this is...actually in line with our previous recommendations relative to the standards lifecycle that the...what was then the new empower team proposed for standards maturity. And then the last recommendation is the ONC should ensure that the certification criteria point to work that's aligned with OMB Circular A-119.

So these are, again, just to situate us. First set of recommendations dealt with what the convening function should do; second set of recommendations that with what an identified national priority should look like and third set of recommendations deal with how the coordinating function should work within

a coordinated lifecycle for standards development that's inclusive of implementation, development, adoption and use. And the last set of recommendations deal with work practices that are relevant for the convening function itself; so again, I need to click the clicker.

We found that in general, the S&I processes have been sound and well-founded. There were several work practices that are especially necessary, for example, clear chartering, business requirements. We had a number of discussions with respect to the role of facilitators and the extent to which facilitators may be driving outcomes as opposed to facilitating. And so on the basis of that and other recommendations, we came up with a set of critical work practice recommendations.

I want to make it clear that there were work practice recommendations below these recommendations that may also be important. We didn't evaluate all of the work practices of the convening function and there were...there was feedback, public feedback, given around for example use case cataloging and those sorts of things that fell below the level of the scope at which we were seeking to drive recommendations.

So critical recommendation number 1 is clear chartering driving toward real-world outcomes and there are two parts. Number one is driving each project with a charter. Number two is making sure that charter is inclusive of the full lifecycle and production delivery and outcomes, not just process measures, although process measures are important.

Number 2 that you've got to look at both the process and the outcome measures when you evaluate the success or not of the project. And the project has to have a clear plan for how the outcome could be evaluated. So again, it's not just enough to say we have a standard, the standard is good, job is done, but to the extent that, as the example here in terms of long-term care and care planning, we need to drive that all the way through to what an outcome would look like in terms of clinical benefit, in terms of economic and operational benefit.

Recommendation for clear roles for facilitators; and so again here just trying to keep clear the role of facilitators that are funded through ONC or through other federal agencies. It gets a little squishy because the ONC may fund subject matter experts who have a material role to play. The negative success pattern here is where a facilitator who is hired by ONC or another federal agency inadvertently is driving the project instead of the material stakeholders of the project or has, in effect, an outsized vote. A subject matter expert who's hired who's hired through ONC may be perceived as having a potentially outsized vote and need to make sure that there's no disproportionate influence on the project outcomes.

And last but not least, recommendations relative to clear project management processes. And we heard a lot of feedback of both S&I fatigue as well as time scales and time horizons for S&I projects that did not allow business or clinical stakeholders to adequately participate. So with respect to the convening function, we recommend narrowing scope of projects to target specific achievable outcomes. Number 2, setting time limits, project plans and processes to expedite the narrowly defined results; so processes should be appropriate to allow the project to move forward expeditiously. The recommendations that we time box phases and then recommendations that there are clear expectations for roles and responsibilities; you often have a pattern where the technologist will take over in one phase. If you don't carefully manage that, the net effect is to drive our out business stakeholders or clinical stakeholders because kind of the geeks have taken over.

So it's useful to make sure that there are appropriate mechanisms for business holders and clinical stakeholders to participate even while folks are geeking out. And to think about the time horizons in which...and the time box is one of the reasons why time boxes are also very critical, to think about the time horizons when they can come back and more critically participate in the project.

And then the last recommendation is to have an oversight project. One of the examples of a project that I think many of us supported was Blue Button Plus. But at some point, the developers didn't show up and the implementers didn't show up, so as brilliant as Blue Button Plus was, it would have been good to call it. Nobody's showing up, so it's better to say, hey, we don't have a time cycle and a horizon for people to show up and implement this in a world. Until we get this, it's better to shut this project down; so well-defined checkpoints to evaluate project success.

There's a natural tendency that every project has to continue. There's a lot of decisional biases that we all have and you need some kind of outside forcing function to say, it's great, you've done great work but the implementers haven't shown up. Or it's great, you've done great work, but physicians aren't ever going to implement that workflow, so let's think about additional processes we might take on.

I know that's a lot of recommendations and text. Again, to Stan's point, I want to thank all the members of the Workgroup. There was a lot of drafting, but there was also a huge amount of editing, iterative refinement, feedback that we got and I think the final work product reflects all of that. So hopefully all of you do as well and I think now we open it up for questions.

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

Stan and Arien, thank you so much. And this work is such high quality that I actually have sent it on to my teams that are trying to manage a portfolio of projects within my IT department and of course the complaints that we have heard from our customers are such things as, "there are too many projects on the plate simultaneously," "you may not have the right resources engaged simultaneously in trying to do those projects." "Governance could be markedly improved, because often niche departmental projects get elevated by a single actor into a priority." "Communication could be improved and sometimes there's unrealistic business owner expectations." So wait, if I'm saying this for running my organization, you've just elevated this to national scale. It is so beautifully done.

Now I have been watching the cards going up. We had a Dave McCallie first followed by Wes, followed by Dixie and others. So let us start with David.

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

David has the first comment, how unusual.

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

Really, preemptive card raising. So Arien, it's great work and admit I haven't had a chance to read it in deep detail so I suspect my question is answered in the text and I just need to hear it may be drawn out. And it basically boils down to you define pretty clear roles for the convening function and some pretty clear roles for the SDOs, but if you add up all the people that participate in the convening function and in the SDOs, you're up to maybe 1 or 2% of the people who actually create things in the market.

And so what's the role of the people that aren't part of that in actually creating the solutions to these particular problems, driven by I'll say business in the broadest sense of what business is. And if you look

at all those standards that are now in our future, every one of them started with a private initiative, right? OAuth came out of Twitter, HTTP 2 came out of Google, HTML and HTTP came out of individual private research labs, SMART project came out of a government grant, but basically given by individuals with an insight.

I would argue that the Blue Button Plus devolved because SMART picked it up and ran much better with it, more efficiently as an outside entity. Even FHIR was invented and crafted, all the hard parts, by an individual before he donated it to HL7. Where's the role for that in your model? How did I miss that?

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

It's a great question. A couple of points; number 1 is, we expressed a preference in our recommendations for processes that are driven by mission and market, not processes that are driven by regulatory timelines. Number 2 is that we clearly indicate that projects before they're accepted have to have likelihood of success and that one of the clear tests for likelihood of success is there are developers who are willing to develop and providers who are willing to use and that an initiative or project that wants to happen that can't... that doesn't have a base of support in terms of a vendor or developer who wants to write some code and a provider who wants to change clinical practice ipso facto doesn't have a high likelihood of success.

Our recommendations were particular to the convening function and so one of the things we tried to do was highlight what the convening function should and shouldn't do and situate that convening function within the context of the full lifecycle. I think it is a clear preference expressed in the requirements that we don't have the convening function driving the timetable.

There is a role, though, and I think about the early work when I was working with ONC on Stage 2; there is a clear role to say there's something that wants to happen and the implementation and standards development timetable isn't lined up towards that thing that wants to happen. And I think that's the place where a convening function has a role to play, a role to play that we articulated. Again just to underline, that role is not to drive the standards development process independent of developers and providers who want to get that job done. Stan, I don't know if you have additional thoughts there?

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

Well I think the only thing I would add is, I think we're thinking the same as you Dave that there's a lot of work that goes on before, and we focused sort of on not the skunk works beginning part where things are creative and innovative and people are doing a lot of work, but sort of when it starts emerging as something that we might enforce a standard. That's the part that we kind of focused on is that part later and our assumption is it would work exactly as you said, that there would be all kinds of innovative and creative things that are going on that people should be encouraged to do. But probably it's not prioritized yet, it's not a national priority yet, necessarily and so that's sort of assumed to be happening and then when things reach a point where we think there is value and it is a national priority, then kind of the things we said are how things should move forward.

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

Yeah it seems to me that, and I really like that mission and a market-driven phrase, I caught that in the slides and I think that's a great one to call out. It seems to me that if you have to bring a committee together to figure out how to solve a problem, you either have a problem that isn't important enough for people to have already started working on or you're going to just create something that people ignore because it just doesn't fit some demand, some drive. And that the convening function and the

SDOs are there to step in when you need a referee because there's a skirmish going on where there's an attempt to solve a problem that's going to get in its own way and you need a referee. But they don't play the game, right? Other people play the game.

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

That's right.

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

So, anyway.

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

Great, and in fact, I sh...before we move on to Wes as our next commenter, Michelle, I believe you actually are seeking the recommendation of the committee as we are going to forward a letter to ONC based on this work. So just keep that in mind. So Wes.

**Wes Rishel – Independent Consultant**

Thank you. If there's one take away...I guess first I should supplement your wife's comments by saying it's easier to the screen if there are fewer words and bigger fonts, okay? The...I've worked on a lot of committees here that use this format because in effect, you've written your recommendation letter on the slides. But I had a lot better job understanding it today with you adding ad hoc comments along the way than I did trying to get anything but generalities out of the slides.

If there's one thing that, among the many things that are suggested here, if there's one thing that rises to the top and gets to drive this process, it needs to be the part about there are implementations along the way. Many of the things that go on in these processes otherwise many different things would be solved simply by saying, if we haven't implemented it, we don't know if we're right yet.

I think about the standard for sending lab data from a lab to an EHR and HL7 went through a standard and then an implementation guide, there was, I think, a HITSP process, H-I-S-P-C process and we still had a spec that was trying to jam together two kinds of lab reporting into one spec. And the disagreements were solved by ambiguity, which is typically how a committee solv...reconciles to get a job done on time. It was only through the S&I Framework that they got together and wrote a divergent pair of specifications and I actually don't know how well that's been adopted. It would be interesting to get some data on that.

The real world as we see it, if we call what we do here the real world; initiatives are driven by two things; one is legislative mandates and the second is election cycles. And there's a need to show progress that goes into the internal planning by...at certain election times that tends to be the thing that drives priorities. It's going to be very hard to establish national priorities, get them through the process of many trial implementations to be good and then get them into standards in the timeframe of those underlying or overlying pressure on deadlines. I think part of the problem we've had going back through the history of government adopted standards is they have...and I'm not just talking about the United States, they have to be done in a timeframe whether they're right or not.

So it's going to be a hard job to get that idea that things have to have been implemented before they're taken as standards into the process; but if you achieve that, you could do a lot. I would like to suggest that the fundamental idea of starting with a policy-based prioritization avo...doesn't pay attention to the

opportunistic nature of development of things to interoperate about. So in an engineering facility, in a product development place or a self-development place, there's always a balance between what do we need and what could we do? What is a realistic next step in terms of engineering cycles?

And the way this was presented today, it almost sounds like that's not a factor in the prioritization. In other words, it's not...it's what do we need nationally that sets the priorities and then find a way to do it which is sort of perfect top-down logic. But the reality is that that opportunism needs to be raised up to the level of...and I know that you have criteria in selecting projects that involves practicality and things like that, but I just kind of feel like there needs to be a separate path for market and mission-based private development to be recognized having not been on the priority list and then raised into the priority list with a high credibility based on the fact that this work got done on the outside.

And some of the things you cited, the projects he cited, would fall into that category. So again, S&I Framework has done...had some very good accomplishments. It's always good to take a step back and think about it; you've done a very thorough and thoughtful job of doing that. And I certainly hope that the single most overriding factor is this notion of incremental development of the standard through implementation. If that doesn't fall down against other recommendations, if it becomes a primary thing, then I think this will be a spectacular success. Thank you.

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

Thanks, Wes. I just want to comment on one thing. I was very conscious and I'm sure Stan was as well through this process of recognizing that the tension that you just articulated is actually written into legislation in terms of the separation of the Policy Committee and the Standards Committee. And that in practice, we've had a set of policy Desiderata that are unconstrained by implementation time cycles.

The way that we tried to address that in the context of these recommendations was to have this strict test. I would hope that in practice the strict test would say "no" more often than it would say "yes." It is absolutely...it's a flaw, I think, in the setup of a Policy Committee and a Standards Committee as two independent bodies that the policy outcomes aren't constrained by what's achievable in the real world. So I'm living within the framework that's created; I also agree with you that I think it's a flaw.

**Wes Rishel – Independent Consultant**

Well I understand that and I think it's even broader than just the way the two committees are architected, it's more fundamental to the way goals get created in legislation and so forth. But again, if the...any plan that doesn't include that cyclical implementation where the implementation actually requires the functional users, such as the physicians, to do what they need to do for the standard to work, any test that doe...any plan that doesn't include that just isn't the plan, I mean, it's a pipe dream. And if that can be the predominant insight that comes out of this, then a lot of that other stuff will fall by the road because you won't be able to get a plan implemented. Thanks.

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

Great; and this is really an excellent point because as I commuted from Dulles to here today, I thought we really need flying cars, that's what we need. But alas, the incremental step forward would be a completed Silver Line. So we know what the problem is, we know we can do the short term, we know we need the long-term. There we go. Okay, Dixie?

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

Thank you. Well first, this is...this really is brilliant work and congratulations and thank you very much for it. I noticed on Slide 8 and elsewhere that implementation guidance is mentioned and it's usually associated with SDOs. Implementation guidance is usually use case specific and it's usually...and typically SDOs don't develop implementation guidance. So in fact implementation guidance often incorporates multiple standards. So I was wondering who you foresee developing the implementation guidance and what the role of the convening function would be?

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

So, there are probably two kinds of implementation guides because...I mean, HL7 does a bunch of implementation guides. So that...and it's probably an ambiguous term because you know what, HL7 for instance, you have the...going back to the base standards, you know, we had Version 2.X for laboratory data and then the implementation guides went on to basically further constrain the standard to make it much closer to interoperable. So I think that kind of activity we would see continuing to happen within the SDOs. And I think the other activities I would see happening actually still within the SDOs as well, rather than as a convening function.

It probably would require some encouragement of, if you're going to do things where the implementation requires multiple standards, a combination of security standards and clinical data exchange standards or standards for API and FHIR services and that sort of thing, and then I think people need to get together. But I guess I would go back to some of the things that we've already said, too; that there's a lot of that work that I would see going on just within SMART or within HSPC or other activities that are not either a convening function or an SDO, but are people who are just trying to get work done and are happy and glad to share their work and try and move the progress along. But I don't know that's...maybe Arien's got a better idea than I have about that.

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

I've got two thoughts there; one is that the term standards implementation guidance in certification criteria is a term of art that's used in the HITECH Act and so I've sought to use that...those terms in the context of these recommendations. It is a bit of a hmmm; in some cases, as Stan mentions, the LRI spec, the US Realm spec for lab results was formally adopted as a DSTU through HL7. IETF has a process for creating applicability statements that fulfill the guide or fulfill the role of implementation guidance. In the real world though, implementation guides are often created ad hoc and refer back to existing standards.

And I think it's a great point, it's just a hmm, with respect to OMB circular A-119 and the role of ONC to point to implementation guides and implementation guidance that may well be created and maintained in an ad hoc way. I don't have a great answer for you; again, it's one of those areas that it's enshrined in legislation, it's enshrined in the regulatory framework that ONC has to use and yet you really do want, as you're pointing out, an implementation guide to be a slightly different artifact from the underlying standard that it's based on.

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

But the use of the term in this presentation and in the letter is really referring to what Stan is talking about, the more specific implemen...constrained standards implementation guide.

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

Yeah to the extent that it exists here, it's really a reflection of the legislative language in the HITECH Act.

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

Hmm, interesting, thank you.

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

So I have tried to dutifully scribe all the cards in order they have gone up, so Eric Rose?

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

So thanks, this was a very clear presentation despite having probably the largest word to slide ratio of anything that's ever been put on PowerPoint outside of Microsoft, I used to work at Microsoft; they love to jam things on slides.

So the question in my mind is not to do with any of the rationale you presented, which all makes perfect sense to me, but why S&I...the S&I Framework needs to be completely replaced, which seems to be the implication and you did have some information of course that you presented about what's not going right with S&I. But if you could flesh that out a little bit because it doesn't quite...it's not crystal clear why those aren't fixable problems with just some recalibration of how the S&I Framework works. Why do we need something completely new with a different name?

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

So, I...the new name was just to talk about it because if you...we weren't trying to constrain the way that this might be done; so in fact, it might be done exactly the way you said. It could be an evolution of S&I. If you continue to call it S&I, then you have the potential that people assume that then it's what it always was. And so if it remains and it's just an evolution of S&I, somehow you've got to be very definitive in saying how it's different than it used to be. And there's no assumption that you have to rebuild this from scratch, that...I don't think we said that anywhere and if that was implied, then I don't think that's what we meant.

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

Well can you...

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

We're just trying to make it different word to say that this entity, whether it's an evolution of S&I or it's something else, make a name for the new thing that distinguished it from the old thing.

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

All right. So, can you expand though on what is it about the way things have worked up until now with the S&I Framework that has not fulfilled all the potential to unblock interoperability that it was meant to do?

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

Well, I think there...I mean it's all 10 things; everything that we put there was prompted by experience. I can point out a few examples, I mean, people said very definitely, look, you start up and I don't know that I want to...but, no, I'll use one as an example. The structured data capture activity. There are a number of people that people would say, if you're going to do that kind of activity, here are the people that need to be involved.

And then what happened is that that was started as an initiative, I was given the timeline and people said okay, if you're interested in this, we're going to have meetings Tuesday at 10:00 or whatever it is. Turns out the experts in that can't meet at Tuesday at 10:00, but the process as it was run didn't change, didn't accommodate, didn't say, oh, you know there are experts that we need to have here that can't attend and so you don't end up with.

And that's what we're try...in all of the words we say, in the end what it's saying is, you've got to organize in a way that the people who really care and really have the knowledge and are the experts in the field can participate and their time goes to their day job and then it probably goes to their involvement in SDOs. And if you hold S&I Framework activities that are in conflict with those things, then you're not going to end up having something that's representative out of that.

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

Right.

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

And we had some of the other things behind this. I mean, we have things, and again, I'm not trying to talk out of school, but you have important government agencies that say we need this, they'll provide money to ONC to do it and that becomes a project. And...but it hasn't looked at, okay, even though that's needed and even though there's money and it's important, unless you've thought through who's going to implement it? What it does to the clinical workflow? Whether it's technically possible? If those things haven't been considered, it's still not something S&I should do, even though there's money and a need, if you will.

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

Um hmm.

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

And so I think every one of these recommendations came from things that we saw as opportunities to improve the current process.

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

Thanks. Lorraine Doo?

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

Good morning and thank you for that presentation. It was almost as if you have been reading a paper I was writing to apply an innovation grant on studying standards. And Dixie, you've become my new hero recently because of the work it you did in 2012 in the NwHIN evaluation for standards, which I had found. So thank you for all of that. I agree completely with the...all of the comments you had made about the development of the standards, the timing of them, the evaluation of them, the adoption of them and the implementation and I've just been trying to set up a meeting with my colleague Steve, from ONC. I'm on the administrative side of standards in the HIPAA realm and the Affordable Care Act. So the convergence of administrative and clinical is obviously becoming very important; people have been talking about that.

So it's partly a confirmation that everything that you've said is spot on. The issue of the timing and the length of time it takes for standards to be developed and then testing them before we adopt them, because we don't currently do that. So we adopt something, we also are under the umbrella of OMB 119, which says we've got to use standards that already exist, but we don't have a mechanism by which we evaluate them before we do that. And the other piece of OMB is the Administrative Procedures Act.

So we have to adopt them through regulation; we don't have a lot of other options and so that timeframe then of using the Administrative Procedures Act is a limiting factor also. And so it's really is trying to work within what you've described and finding some other recommendations for what we can do to have standards that work both from the SDO perspective and industry's perspective that will then further progress along.

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

Thank you for that. I'd also add that it's been my experience that if CMS or another agency sets a clear set of expectations vendors, implementers, providers will have a strong incentive to make sure that that outcome be achieved in the way that makes sense. As the example that we've been discussing, requiring utilization reviews before imaging tests is a classic example where if the policy statements very clear, and it's expressed not as adopting a standard that already exists, but adopting it as a challenge to implementers to go solve this problem in an elegant way, I th...my belief is that providers of care and developers would rather have that thing adopted in a way that works and doesn't lead to nightmares and headaches. But that policy statement needs to proceed with an appropriate amount of time to go through the time cycle of, is there a good standard? No, there isn't. So we've got go do some early implementation work and figure this out; so having a policy framework that's inclusive of that timeline with clarity of outcome at the end of it, helps that process along.

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

Now this is a bit, see Arien, it's my vision thing here. I think I'm looking at two cards, I believe it was Jeremy then Liz and then Nancy.

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

Thank you, I thought the report was excellent; I thought it was very specific and I recommend that we adopt your recommendations. There are two that stood out to me as resonating strongly with me; number 5 around the need for someone to identify infrastructure outside of standards or outside of standard setting organizations I think is absolutely critical. And I think that actually gets to that point about national priorities, as well with number 6. But there are...so I guess what I'd first say is that I think EHR vendors, developers are looking for clear direction from ONC about prioritization. And I think in the absence of national priorities, I don't really know that we need ONC to be a convener because I don't think...there are other forums to convene and cooperate and set standards.

But I think maybe what you're saying here subtly is that there are things that we need to advance the cause of interoperability that aren't being championed or chartered by ONC or by a convener. And specifically I'm...you have listed here the need for provider directory, I'd add the need for a record locator service, so I applaud that and I hope that ONC takes that role of really pushing key components of infrastructure forward that are gaps in the market today. I think that, to me, typifies what ONC can do is fill the gap where the market isn't responding where they need to. Thank you.

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

I want to give Jamie some credit for spawning that recommendation. Thanks.

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

I mean, to this point, would we have a global entry system to make travel easier unless there was a convener who brought together...just wasn't just a market force solution. And so I say, record locator service, provider directory are that kind of government as conveners to facilitate.

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

Thank you. I would also ask questions about how you see consumer technology working in this, or stakeholders who today do not have a strong voice in standards development organizations within health information technology? So I would see ONC's role or this convening body's role as an important representative for those who don't currently have a voice. How do you see that working in your proposal is one question?

And a specific question that might help clarify that is, in your example on the imaging and appropriate care for imaging; today the work that's going on is largely focused around the appropriateness of the care clinically. But shared decision-making with a patient participating to determine whether that imaging should be done is very informative and highly effective at determined appropriate care and reduces the amount of radiation a patient is exposed to and many other benefits. So what is your feeling about this convening recommendation with regard to consumer or others without a voice that would need representation in this kind of work?

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

So, to me it's a hard question and the reason I say that is obviously agree with you that there needs to be a consumer voice, there needs to be a consumer or a person's voice or peoples' voices. And the...my tendency would be to say have them contribute to the SDOs because I'm troubled if you do it a different way. If we said part of the convening function was to recruit consumers to place a requirement, then you've got requirements being gathered in one venue and ultimately, at least if we're talking about things that we're trying to standardize, that has to be transmitted to the SDO and then how do you resolve the conflict then? It's a...so...

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

But there are other consumer technology companies and consumer technology standards that yet we haven't had to play with because they've been outside that realm; so I think it's worth some deliberation and discussion because we can't go forward with recommendations where the government as the representative of the individual and the taxpayer, has...doesn't have a way to have that consumer participate. I mean, look at advance directives; we don't even have advance directives, it's very specific detailed information that can be incorporated into the record and completely empowering patient and providing lower cost and higher quality of care in most cases. Where are with that voice be? How would we integrate just those specific examples are important to remember who we serve? And how do we make sure that voice is heard?

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

So I completely agree with you. The task force did specifically deliberate on that particular question. The intent of, and I'm...I have a hard time off the top of my head remembering the number of the recommendation, but there was a key criterion that before a project is effectively chartered that all of

the stakeholders need to...you need to make sure that you've got participation from all of the key stakeholders. We thought about including specifically the consumer, I think it was the intent of the task force that sometimes it's absolutely critical the consumer be at that table; sometimes it's more of an administrative issue. So that was the intent of all of the key stakeholders participating.

The other thing that we talked about was the...this didn't get into the findings because we didn't quite know what to do with it but sort of an immutable law of these activities that you can convene all you want and you can include all the stakeholders you want, but the people who show up meeting after meeting to get something done are the ones who drive that, for good or for ill. So we actually did consider the role of the convening function with respect to making sure key participants were included.

The recommendation that we have that nods towards that is the recommendation of considering the time cycle and the key responsibilities for individuals within that time cycle to make sure that there are appropriate roles for business stakeholders, we should put in consumer stakeholders. So I'm happy to amend in that section particularly the notion of a consumer as somebody who may not be the folks who are funded to show up day in, day out, attend every meeting and comment on every activity. But just like clinicians and business stakeholders, need to have a place to show up and provide their input.

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

So I agree with that and support that recommendation but would also just like to include that there are opportunities for the convening body to act where there is no voice and they have aligned interest in supporting that voice.

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

It looks like it's Nancy.

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

Speaking as part of...as a provider organization and an agency trying to work among competing priorities I do also commend the thoughtfulness and the rigor of this. One of the key takeaways I'm getting out of this, and it would work for whether someone was a developer, vendor or for a provider organization, is the four areas that you say are part of standards and interoperability; the development of the standard, the implementation and technology development side, the adoption of it and then the clinical and operational workflow.

And it's really critical, I think, I can take this back in my organization and say we have traditionally put people and efforts into this part of it, but we're at the phase now where we, for instance, there's a lot more implementation and technology development and I have to go back and ask for different kinds of dollars because those are analysis of alternative dollars or early requ...or working with the clinicians or other administrative people to get what's your problem with workflow? What would you like to see as an ideal application? Because they don't care about the standard; they care about I can't do this and I want to do this function.

And I think if...a comment on that is that I think these recommendations...an S&I Framework could be called or could just...I don't know if there's a legal reason or not, it could keep the same name but it could say we are now a convening function. I think that would communicate pretty clearly across...the nation or wherever we are going on this, that we're going to focus on this and we're going to focus on

these kind of problems and we're going to focus on having these key stakeholders in order to solve any of these problems. And if we don't have any of the key stakeholders for this type of adoption, implementation issue, we'll put that off on a priority.

So all I'm saying is I think jelling that a little more clearly that you want this convening function to deal with some other aspects in more detail now is important. And that secondarily that you have, whether you change...I don't know that we ca...the committee cares or not whether we keep the name or just publish a thing, I don't think it would be a problem to just say the focus of S&I Framework is going to now do this in the future. So that's my comment.

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

And of course the only reason to rename S&I is that ampersands are very challenging in webpages; but beyond that...so we have Cris Ross and then we have Andy Wiesenthal.

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

So thanks for this great work, people are really tough on you on too many words; I don't agree with that at all. By analogy I've got a daughter who now is in college in Paris. She meets with her Art History class at the Louvre twice a week and she was complaining about how hard it was to find her class in a particular gallery and I said, honey, it's the Louvre, it's probably worth the effort to find it. So I think this is worth the effort to read carefully.

I would speak in favor of the idea of a convening function overall. I take Jeremy's point, but I think that what you have outlined is really critical. You did...spoke a lot about prioritization of what things should we attend to first; this is going to sound critical, but again, it's brilliant work, so consider it an intent to be additive. Did you...how would you think about handling issues related to standards maturity and the latency between the time at which the need arises and the time in which a mature standard might be developed?

So it might be possible to identify, here's a high-priority item, but of that high-priority list, some things might be near at hand and some things may take a number of years to develop. Did you have thoughts about in this convenient function would it also have a sense around that kind of timeline for development and so on? You can probably frame what the right question is in that neighborhood.

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

There's a three-part test that's proposed for identified national priorities; the first one is the rank order prioritization, the second one is the obvious one that if you succeed at this, it's going to make a dent in the universe, to quote Steve Jobs. The third one really gets at your question which is that it has a high likelihood of success and that highly likelihood of success is gated on a variety of factors. We gave some for examples, but clearly the ability to go through implementation testing, standards development, adoption and use in the timeframe that's indicated is a clear aspect of that test. So it's the third part of that three-part test that gets at the standards maturity angle.

The classic example of this is, I want a standard for, and we can pick on care planning. I want a standard for an interoperable care plan, but we don't actually have the clinical experience of care planning that informs what the standard should do and how the workflow should work. Our first example...our first activity should be to gain clinical experience in shared collaborative decision-making rather than develop a standard. And that's just an example, but you need to consider the intent of that third part of the

three part test is to consider the full lifecycle and activities required to get to adoption and use and make sure that that...you have high likelihood of success prior to starting the project.

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

So let me...that's helpful; let me ask one quick follow-up which is, convening function has a certain amount of sort of deus ex machina to it, that it's going to arrive at the right time, at the right place. Do you have a notion that this convening function would create and maintain some kind of roadmap so that we would understand kind of a midter...near-term, midterm, long-term viewpoint that this convening function might have around where we're going and why? What ground is solid, what ground is still swampy and needs to be developed? I just didn't get a strong sense of that.

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

And that was deliberate, and I go back to my earlier comments on this is actually written in legislation, the separation between the Policy Committee and the Standards Committee, the separation of the role of policy and the role of standards. As far as we looked at this, it was the critical role that the convening function has to only accept projects that have a likelihood of success. And as I said, you'll know the convening function's successful if it says no in ways that disappoint policymakers a lot. You'll know that it's a failure if policymakers...

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

Yeah, absolutely.

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

...you'll know if it's a failure if policymakers are really happy because that means we're taking on a bunch of stuff that we have no business taking on.

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

We will ask for consensus on this with Andy, oh, and I didn't see an arm, is this a supplement to something that Cris...

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

Yeah, it's just a follow up on the comment again, it always assumes that there's some...that all policies coming forward that just represents the provider and provider workflow when there's a gap and a need that's coming from consumers and patients themselves. How does it get filled in that same...we do have gaps. And so...gaps that can be filled with standards or they can be filled...and I just don't want to end up because of our bias towards trying to keep the things you've stated that the very provider centric, how do we then represent the patient and the consumer?

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

Andy?

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Thanks; and I'll join the chorus of people congratulating you on really hard and good work. It was extremely helpful to read the document and to listen to you today. I have a couple of comments related

to the concerns you raised around the timing and latency of standards development, and it relates particularly to the organization I know best, because it's an international organization that the US doesn't actually control.

So, I'm wondering whether you think there's room for two things; one, a national body like the National Library of Medicine that coordinates and does some of the latency management for all of the standards in healthcare and also a prototyping sort of safe prototyping zone where implementers can take things and test them in real operation, but not in any damaging way. Because I don't think we have that. And just let me add that I support the notion of the federal government and ONC as a convener; I think that's the most powerful thing we can do actually, but my questions are the former.

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

I'm looking to Stan as our expert on the panel for international standards organizations that...work in the US realm and work with US federal government.

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

I'm not...yeah, I'm sort of stumped. The...

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

To be honest, for everybody else's benefit the IHTSDO wants to do what the US wants, but it also wants to do what the other 30 some member nations want and there's a little bit of tail wagging the dog but there are large...other large member nations that have different needs.

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

Yeah, but I was focusing, I guess, more on the idea of whether we needed, as part of the convening function or as part of other...a federal agency that sort of had the particular responsibility to try and work with the latency and work with the coordination...

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Yeah, I think it's that.

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

I think I don't know that we covered that. It seems like actually a very reasonable sort of ask that somehow that be coordinated because it...because, I mean, that's...when it is sort of a US realm, if you will, sort of issue, you need something bigger than the individual SDOs and you need something that has the responsibility and the authority at the level of the country...of the whole country in that. And so I don't know that we addressed that, but I'm not sure exactly how we'd want to say it either because I...

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

You know, so it seems to me if HL7 has release cycle and the IHTSDO has a release cycle and the AMA puts out CPT modifications and updates, somehow in order to not drive the vendor community completely around the bend and worse, the consumer or other community comple...we have to find a way of getting it all to cycle together at least as it's released into the mainstream. And I think that's a role for a federal body and the convening function can get all those players to the table that say how would you participate in such a United States cycling for its own purposes.

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

Yeah, I'll double down on Stan's comment; it's a great comment. It's not something that we explicitly considered so maybe it's appropriate for follow-on activity, not that I want to take on more follow-on activity.

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

...that we're doing resource leveling, understanding what is the marketplace? What is the need? And who is available to work on it? I mean this...yeah. I certainly think today you've outlined a framework for some of the next steps forward and this does seem like a very valid point to work on over time.

Well we have, I think our lunch coming next but Michelle, we do want to ask, given all those comments; sounded like they were most all of them friendly and maybe polish, but nothing that seemed to be in any way contradictory to conclusions that Arien and Stan have presented. Do we have any objections with forwarding their delightful PowerPoint and all the recommendations forward to ONC?

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

It's a letter...

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

Okay. Yes, Wes?

**Wes Rishel – Independent Consultant**

I'm just wondering if in that...in doing so we are effectively cutting off any effective action on this last point that Andy brought up, I mean, how...what would be the steps by which that idea got incorporated into this action? I mean, I just don't see...I'm afraid we'll lose it.

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

The transmittal doesn't preclude that role. I guess I look to Steve and Michelle for what the role of the supplemental transmittal might or could be if accept this as a transmittal and then re-supplement?

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

It sounds like...I'm on. This is Steve Posnack; I mean, it sounds like the committee as a whole, as these recommendations have been brought forward, want to make an amendment before it gets forwarded. If that's....

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

But what I would wonder is that if what we have here is a set of principles and that ultimately S&I or whatever we call it, is going to be re-chartered, it's going to be streamlined. I mean, so it doesn't seem to me in that re-chartering that there is any...by forwarding this set of frameworks there's any problem. But yes Jamie, please.

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

Yeah, so on Andy's point that we need to essentially coordinate schedules to better operationalize the release dates of standards and things of that nature. This is an existing problem; there's nothing new or different in the recommendations that would change the existing situation that everybody operates in today. And the other thing I would say about that is that as you'll see...you'll here in our comments on the interoperability roadmap this afternoon, after lunch, some of the workgroup have in fact mentioned that as something that ONC should try to do something about, but not in this context of this recommendation, but as a comment on the interoperability roadmap.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Michelle and I have had a quick sidebar here. I think one suggestion that we could offer up is that as part of the cover memo to this, that it could be highlighted that the committee, during its discussion of the recommendations, also called out this point as an important thing keep track of.

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

And so whether or not the notion of air traffic control was done as Jamie said within context of a re-chartered S&I or as part of another activity, it's clearly a point that we all want addressed. But, yes, Stan.

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

Well, I guess the other thought that came to mind is that it's an important function and it probably falls to ONC, but is it necessarily an S&I activity? Is it necessarily a convening function or is that some other part of the overriding mission of ONC to do that kind of coordination. Actually that seems better and better to me that we give that charge to ONC general, rather than think of it as part of or necessarily box it in S&I.

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

What I'm hearing is we're going to request, as part of this transmittal, that here's our recommendations, we also request ONC to consider the role of a convening function or ONC or otherwise to coordinate calendars across multiple SDOs internationally. And that seems to like a reasonable way of kicking off the appropriate work.

**Wes Rishel – Independent Consultant**

Andy, is that the limit of what you were suggesting, for the coordinating calendars, because I thought you were suggesting a national presence or national consensus approach towards dealing with those organizations.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Yes, because I thought that was implicit in some of the comments in the documents.

**Wes Rishel – Independent Consultant**

Yeah.

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

Yeah.

**Wes Rishel – Independent Consultant**

So I mean I'd be happy with the friendly amendment to Arien's friendly amendment...

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

Yup.

**Wes Rishel – Independent Consultant**

...which gave this just a little broader context, the ability to establish US consensus positions in dealing with international...

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

I move that Wes and Andy help draft that language.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

Very good.

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

Well with that, I think we have heard no objections, just a friendly amendment and a consensus on who will put that language together. So, Michelle, I believe we are breaking until 1:00 o'clock?

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

But we have public comment.

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

Oh, of course. Yes, well let us ask for public comment and then we will break.

**Public Comment**

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

While we wait for the operator, if there's anyone in the room who would like to make a public comment, please come up to the table. As a reminder, public comment is limited to 3 minutes and I'll turn it to you, Alan.

**Alan Merritt – Specialist - 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.

**M**

...Dr. Mostashari and I'd like to make a public comment.

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

We have no public comment.

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

Very good.

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

So, we'll come back after lunch at 1:00.

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

And then we will have an entire afternoon of interoperability roadmap and quality. Very good, thank you everybody.

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

We're going to get started, if you could take your seats, please. Are we ready?

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

Okay, well so you are going to take this next ...

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

Jon White?

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

All right. Welcome back; hope that you had a delightful lunch. I did, with my laptop. All right, next up we have the interoperability roadmap progress update. And under this there are a lot of different sub-headings. First up we have the Implementation, Certification and Testing, led by Liz Johnson and Cris Ross. So, are you all staying where you are or are you...

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

From where we are.

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

Okay, very good. Proceed apace.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So the good news for the committee and for those on the phone is that we...this will be 5 minutes or so we think. Of course as John Halamka would tell you, famous last words, right? So the first thing I want to

do is move to the next slide, please...thank...I don't have a clicker, so if I am supposed to do it, I can't do it. Oh, it's because it's on the big people's table and I didn't go up there.

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

Thanks, Michelle.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Thanks, Michelle.

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

As always.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So the first thing we want to do, as always with all the groups, is recognize our membership. We have a relatively new set of memberships this time and they are doing a tremendous job. Every meeting is packed with people and we never stay within our timeframe because there's so much input; so that's a really great opportunity.

Cris is going to bring you sort of the interim results, but we want to point out to you something we're really looking forward to and hoping to integrate into our recommendations at the next meeting and that is, we believe the Certification Rules are going to be out very soon and we think the overlap of what we're doing around testing is very evident. So, although we know you're in a period of silence, we are really looking forward to that and so as we come forward with results, you'll see us sort of holding back a little bit looking for that.

There's also tremendous detail in the appendix of all of the individual comments and so on that came back to us going forward. And of course we couldn't miss the opportunity, Jon to ask, we're just asking with tongue in cheek, we think Meaningful Use 3 is coming, too, so...

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

Why I do have...on that.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Oh, good. Go ahead. We're anxious.

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

...but thank you for asking.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Anyway, with that I'll turn it over to Cris to talk just a little bit about some actual recommendations.

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

Thanks, Liz. On this sheet also for some reason David Kates was not listed and I mention him because he carried a lot of weight in the last couple of weeks. If you can go to the next slide; we were asked to comment on two components of the interoperability roadmap; I1 on testing tools and then on the next page, I2 on certification program. And we're going to report today on...reports on section I1 and we're going to complete our work on I2.

So within testing tools we had basically four simple recommendations or feedback. The first was an observation that C-CDA simplification has improved between release 1 and release 2. You'll also see attached to the printed materials a deck that was produced by a small working group of David Kates, Sarah Corley and John Travis that looked at gaps in C-CDA and so goals for simplification.

Our workgroup was assigned to take that on late last spring, early last summer. We tried our best to do that in the context of the workgroup, did not make a lot of progress. We turfed it over to an HL7 volunteer group that did a lot of good work. What this small workgroup did was essentially to validate some of that work. So you may want to look at the appendix slide related to C-CDA simplification. I was surprised by at the amount of progress between release 1 and release 2.

The second is a recommendation about practical effective industry run tools for post-certification testing in support of the reasons that you describe. We often invoke the spirit of Wes Rishel around asynchronous bilateral...do I have it right? How do you move from one standard to another where not every vendor and every system has to do the stroke of midnight kind of synchronous changeover is one particular issue, but the other one relates to things like vocabularies, technologies and processes.

The third is, we wanted to get further definition of what is meant by "regular use" of testing tools and what is the purpose for them as they span across certification and ongoing management. And then finally, explore an idea that has been floating through ONC and the Policy and Standards Committees for some time which is the potential for deeming rather than certification. So, an example given was ePrescribing where if someone is certified via Surescripts, for example, does that constitute deeming for purposes of certification under Meaningful Use.

And then we simply have a placeholder for I2, that's on our agenda for the next workgroup meeting and then as Liz says, we want to wrap up our work on the interoperability comments so that we can move forward with certification, when those rules arrive.

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

That's where we are.

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

Partner, anything else?

**Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I think that does it. Jon, back to all of you.

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

Excellent. Questions on the update? All right, I should have observed at the beginning, but thank you for your brilliant...I should have observed at the beginning that we have until 1:45 and we've got a number of these folks to go through, so that was perfect, although of course if there are questions or discussion, please want to hear them and bring them up. So thank you very much. Okay, shifting to a different side of the table, Rich Elmore and Andy Wiesenthal will give us an update on Content Standards. Gentlemen.

**Richard Elmore – President, Strategic Initiatives – Allscripts**

Okay, if we could just get the...okay, thank you. So Andy and I have been leading a group, a terrific group of experts in the content standards area. This is some broader strategic themes that came out of the workgroup; we will have more specific comments as part of the input over the next couple of months. In general the questions were focused on section J. This is the team, we want to shout out a thanks to everybody that's here; we've got really a lot of the experts in the country and beyond who have been a part of this and we really appreciate all of their terrific work.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

And there are really two additional comments I would make; first of all, actually a subgroup of them split off and did double duty because they're very concerned about the content as it applies specifically to research use cases; so they've been meeting extra. And the second is that nobody on this group is in any way reticent, which is to say they're all talking as much as Clem. So, it's a pretty full meaning when we have it.

**Richard Elmore – President, Strategic Initiatives – Allscripts**

Okay, so we wanted to start out with just an acknowledgment that we think there's some terrific work that's in the interoperability roadmap and some real positives in terms of framing where we're going as a country over the next 10 years. And so we wanted to call that out. We do have some recommendations as well for improvement, but the need for consistency in data formats and semantics and using SDOs to be able to develop, curate and maintain those standards, a lot of what we heard in some of the earlier conversation with Stan and with Arien.

Improving the consistency of the implementation of consolidated CDA through further guidance or constraints, we think is really important and would concur with the earlier team's assessment that the move from R1 to R2 will accomplish a lot of that. Extension of standards to promote exchange across the care continuum including new sources of patient generated data; there's a need for real focus there and I think that the roadmap calls that out. Agreement on a core standardized, common clinical data set that is extensible and consistently shared during care transitions and agreement on use cases that each vocabulary supports.

So we're very supportive of the exchange of information, more granular discrete forms such as FHIR and there were many specific initiatives listed for the convening group, let's call it, which...and others which include FHIR and CIMI, Data Access Framework and so on that the workgroup thought were positive to include as part of the roadmap path.

In terms of recommendations, broad stroke recommendations, we felt that it was important first of all to really get clear about what is the specificity of a learning health system. There are comments in the roadmap on that, but we need to consider it in terms of the constraints on policy and privacy in

particular. And there are lots of great reference points for this from IOM where a lot of this originated. And it originated, if you will, in trying to compress the time between research to bedside in terms of use. Learning Community, ESTEL, ONC's Query Health Initiative, others; and we think that if we can get better understanding of the targeting of that, we'll do a better job of being able to do content standards and other parts of the standards that are affected in roadmap.

We are encouraging ONC, and I think this will become easier once Stage 3 is released, that we get greater specificity, particularly in the early standards that were very specific in how the standards are going to support prioritized use cases for each wave of interoperability. And we try and refine those standards over time, but limit structural change so that we get targets that the country is able...and all of the stakeholders are able to coalesce around and really make progress towards. There is a bright shiny object tendency for all of us and I think we have to balance that with making sure that we complete the work of standards that we elect to try and get out there into the marketplace.

And then the last thing is that we think that it's really important as part of that is to have a laser focus on how we achieve national scale. So not enough to get the standards to pilot through pilot, not enough to get them through early implementation where we have the feedback into the implementation guides and those refinements, but really making sure that at the end of the day there's a national group of stakeholders that are able to take advantage of these. All of these levers that are available to us through the country should be able to support that and we think that ONC should be looking as much as possible to be able to address that.

Part of this is also just a consideration of the timing; there's the advisory document which is separate...Standards Advisory Document which is separate from this which contemplates a year's cycle of updates to the standards. We applaud certainly the publication of the Advisory; we want to make sure that as we think about how that's being applied, that we're sensitive to the fact that achieving national scale, achieving real meaningful adoption of standards that work is a multi-year cycle that we don't want to iterate to quickly and lose that particular focus.

Here is kind of a broad point; there's a standards categorization document, right above section J that calls out a number of different hierarchies from vocabulary down to security and services. We think that there may be some need for refinement here or improvement both in terms of how some of the concepts are logically separated and perhaps also some of how the examples are...could be made perhaps more meaningful or applicable. So we just encourage ONC as they think about the roadmap to see if there are some improvements because this framework we thought was very helpful but there were some conflation of terms that we thought could be better organized.

Then lastly, this is the point that Andy was making and really if you think about back to where IOM started with learning health system, and if that's ultimately the goal of this roadmap then the ability to get from research to clinical use and to be able to have feedback from clinical use to research is an incredibly important part of a learning health system. What we came across as we worked with the workgroup was that there are some different standards that are being applied in each area and that if there's a way to be able to bridge those standards in a way that's open, that's authoritative, that's maintainable, that we can go a long ways in terms of being able to bridge information that's important for research, bridge information that's important for healthcare and bridge to information that's important for consumers.

This is both in terms of SNOMED CT and MedDRA, MedDRA being used in research. It's in terms of how drug nomenclature was used earlier in its lifecycle and there may be others as well that the subgroup is working through. So we think if we can overcome these differences in how information is captured and represented, we think that would really facilitate the exchange of information to a broad group of stakeholders and really promote the fundamental objective of the interoperability roadmap.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

So a couple of areas of color commentary; one of the things we discussed and that Rich pointed out a few moments ago is that the notion that we should try to find ways of extending these standards so that they apply to use cases that aren't purely clinical. So it has to do with the point that was being made in the earlier presentation related to incorporating nonclinical or non-pure clinical data into a longitudinal care plan for patients.

And then here, the research community has a different set of problems to solve because many large research projects are now multinational in scope and need ways of collating data and presenting data that span nations. So that some of the SDOs are multinational or international and some are not and they're trying to bridge that gap as well. So it's an issue that's peculiar to them. And we can stop and entertain questions or comments.

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

So thank you again for the outstanding work as well as the excellent presentation. I'll just briefly comment that both in my capacity as the Director of Health IT at the Agency for Healthcare Research and Quality, which is my day job while I'm moonlighting here, but also since the President announced the Precision Medicine Initiative in which ONC is involved, the need for this kind of work gets a finer and finer point put on it for me. So, I appreciate your extensive thought about it; it's something we've been thinking about a lot, too. So with that, questions? Wes.

**Wes Rishel – Independent Consultant**

Thanks. So you have a recommendation to, and I forget the exact words, but it's limit the changes in the evolution of standards or something like that. And I've heard those words used in a way that changes the balance point between innovation and standardization, particularly concerned about how that principle might work against the adoption of FHIR. So in your sense, is there a conflict there, is there a distinction that would help to understand? I just think that this is an area that's going to come for debate and like to hear your position on it.

**Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)**

We have obviously hadn't had a chance to talk about that specific question that you're asking but it seems to me that we're not interested in stifling innovation, we're interested in stifling scattershot random stuff. And to the extent that something like FHIR is a focused area of national import, this should not represent a problem at all. To the extent that, as I think was pointed out a couple of hours ago, different federal agencies might have specific needs that they want to fulfill and are busy sort of pushing that into the standards development community; that we need to control a little bit better because it creates a situation in which some standard is being modified in some way, the other standards which may be related to it haven't caught up, the vendors can't incorporate it, the release cycles are all out of kilter and even though you're fond of asynchronous things, that's a bad asynchrony.

**Wes Rishel – Independent Consultant**

I'd certainly like to see it work sometime before I'm dead.

**Richard Elmore – President, Strategic Initiatives – Allscripts**

I think the thought is, Wes, to pick some and then create focus on those and refine...

**Wes Rishel – Independent Consultant**

Uh huh.

**Richard Elmore – President, Strategic Initiatives – Allscripts**

...but don't iterate on structural change that is disruptive to getting to national scale.

**Wes Rishel – Independent Consultant**

My concern is more that this principle not be misinterpreted than any sense that your position was against FHIR. So, I just wanted to get a chance for you to go on record that way.

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

Other questions, or comments? All right, thanks guys, you're off the hook. Next up Becky Kush, who is not here, right, and Jamie. So Jamie, with Semantic Standards the floor is yours.

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

Thank you. So first, thanks for the opportunity to report out here today. I'm sorry my Co-Chair Becky Kush couldn't be here today, so I'm also going to try to represent her. And let's see...so you can see here listed the members of our workgroup on Semantics Standards. We had, I think, excellent participation on a number of different calls. I want to give special thanks to Tricia Grimes sitting in the back there, who has been holding the pen on our drafts on our calls and who has really done an outstanding job for us.

So similar to the other workgroups, we were assigned a section, we were assigned Table J, I think also known as Table 10. So we had similar or the same questions as other workgroups for our section. The process that we used was first to review the roadmap and review our section. Then we solicited comments by email from all of the workgroup members and so Tricia very kindly took in those comments and collated them and made them ready for the group discussion. Then in going through those, we were able to identify both common themes where we had support...general support in the workgroup for particular perspectives or some areas where we had divergent views or multiple views. And then as we were able to go through, we could very quickly sort of knockoff, well these are the areas where, from the comments received by the individual members, everybody generally agrees, and then we had generally limited discussion on those items. And then we had much more discussion to work through the items where we had divergent or multiple views.

But we ended up with agreement on all of the common themes and in many cases the areas where originally we thought we had divergent or opposing views, it was just it question of putting in an "and" that we need "A and B" as opposed to "A or B." And then finally we do have an additional meeting or two coming up to finalize our draft and to consider some additional comments.

So I am going to read a couple of slides here of some of the common themes and then I'll just sort of broadly characterize some of the others. So first, we said that there needs to be a shared understanding of the importance of information models and terminology bindings for semantics standards and that we need to have agreement on highly granular information models bound to terminologies, particularly for information exchange. And I would say the key word here is agreement, so it's not just that we need highly granular models, because it doesn't do any good if everybody has their own highly granular information models.

We said that data standards, particularly for information extracted from the electronic health record, should reflect the semantics that are actually implemented in the EHR systems. And we actually had a discussion about how the eQMs that are intended to be produced from the EHR actually cannot be produced without manual intervention. We said that there needs to be greater attention paid to challenges of data aggregation when data's assembled from multiple sources, and talked about some reconciliation issues with semantics standards. We said that it's critically important for data provenance to be both workable and practical. And we recognize that this is true in many different areas but it's particularly true for semantics and semantic interoperability. And then finally on this page, we agreed that NIEM we thought was not useful for healthcare interoperability because it has little or no healthcare coverage in NIEM.

Moving on then, we found some areas that we thought were missing. In particular, some of the common data elements, both in Meaningful Use and in the interoperability roadmap are missing things the clinicians most frequently request in information exchange in terms of clinical studies. EKG was one example that was used, time series data; things that were frequently the reason why new HL7 version 2 interfaces are implemented even when people are connected to the same health information exchange.

We said that the roadmap should support semantic web standards including OWL and RDF and we had some discussion about the Yosemite Project using RDF for common representation of semantics. We would like to recommend minimizing mapping between different standards because mapping is always imprecise. And so it's better if you can actually implement the standard and so along those lines, we wish to support or we wish that the roadmap frankly would support the use of interface terminologies that allow accurate and precise use of the target standards as opposed to using local semantics and then mapping to a standard later.

And then finally here, we saw a need for explicit support of semantic interoperability by multiple mechanisms and methods. So there's a great deal of focus in the roadmap on data exchange meaning extracting data from one system, shipping it to another system via transactions using content standards. But we saw that there's a need equally for the use of APIs, particularly for access to data at its source where there's shared access to original data sources. And so then we talked about I think three or four different ways that this could work. And so there are multiple models for shared access and we also said that in many cases combinations of both transactionally moving data as well as accessing data at its source would be needed in reality.

Then we saw...this page I'm not going to read, but I'll just say that we did find a number of areas with some specific references to areas where we thought more clarification was needed, that the roadmap was just too vague or general. And then we also wanted to call for more coordination of ONC with the standards development organizations and in particular in two areas; one is to reduce overlap and improve coordination and the other, going back to a part of Andy's comment earlier is to improve

operations by things like aligning the release schedules for release of standards in the US. And so I'll stop there and take any questions or comments.

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

All right, nothing controversial in there. David and then David and then Dixie.

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

Jamie I'm sure this is a question that's too...the answer for which is too detailed for probably for much discussion here, but I'm just curious. I understand for sure the need for information models that tie together the broad thing that we are dissecting and communicating so that people know the context of a snippet of a message, because it references back to an information model. And I know how hard Stan's been working on that for a long time and how hard that is to do. Nonetheless, I think it's important, but I'm not so clear on what you see the role for OWL and RDF and why that got a mention?

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

Well...

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

My experience with them has just been that they are just alternate ways of slicing existing knowledge.

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

Well that's right, but RDF is a way that currently, for example, the Department of Defense and others we heard from are mapping semantics to a common representation using RDF and it seems to work. And so we thought that that was something that should be referenced.

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

And my concern, again, probably too much for this discussion but, the semantic granularity problem of the same term means different things to different people in different contexts makes RDF really hard to use unless everything is named so incredibly precisely that it can only mean one thing at which point you've really kind of defeated the purpose of RDF. But we can take it up some other time.

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

Well we should, perhaps, because I think our experience with RDF is different.

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

I sense a beer summit coming on. Dixie.

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

Yeah, thank you Jamie. On slide 6, I guess it is, number 11, you mention the need for support for semantic interoperability for data exchange and the access to data at its source. It seems to me, that for a learning health system, it's also important to have semantic interoperability to support clinical decision support.

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

Um, hmm.

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

Did you discuss that at all?

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

Well we did and in fact, so some of the key use cases that...where we talked about the different models and methods, particularly for access to data at its source, had to do that specifically with having clinical decision support applications that could use a common API and a common data model to access the data. And I don't know, Stan may want to talk more about that, that's sort of his bailiwick, but...so, clinical decision support was very specifically one of the areas where we had talked about.

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

I see, I see, yeah, I see what you're saying, yeah.

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

Stan, did you want to comment?

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

(Indiscernible)

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

Okay.

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

So...agree that that's the scope...I mean, that's...in many ways, that's the primary use case we're trying to support is algorithmic processing of that data to improve patient care.

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

Okay. Leslie Kelly Hall and then Nancy.

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

So Jamie, I bet you know what I'm going to ask you. So would the patient-generated health data emphasis so much in the interoperability roadmap, how does that impact your recommendations and work going forward?

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

I'm sorry, could you repeat that?

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

On the patient-generated health data, the need for consumer taxonomy, how does that impact the work going forward?

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

Yeah, I thought you were going to talk about sort of the consumer terminologies and consumer facing and we incorporated that discussion into a recommendation for interface terminologies saying that we need interface terminologies including consumer facing terminologies that accurately and precisely allow the use of the standards. So we don't see that it's useful to have a consumer terminology that's in a different hierarchy that doesn't map precisely to the standards, but it can be very useful to have consumer facing or consumer...patient friendly synonyms for the standard terms that we would want to support fully.

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

Okay.

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

Okay, Nancy?

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

Jamie that just follows right on my question which was on item 10, support the use of interface terminologies. What...and I apologize if I missed it in the original roadmap or was there a lot of discussion of interface terminology?

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

No, there wasn't and that's why we wanted to add it.

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

Okay, that's why I'm asking that question then, because I think ple...knowing how difficult it is to talk about semantic versus content standards to even a group of engineers, you would need to really...or anybody, I'm going to really say to anybody, that can clarify what are some examples of interface terminologies that you are talking about.

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

I think what we're really talking about here are synonyms like those that the NLM publishes for the US extension to SNOMED. So NLM publishes the synonyms for interface terminologies. Of course there are also commercially...

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

And again I'm going to ask do developers or everybody else know how to get to those and what they are?

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

I don't know the answer to that.

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

Just, I think that's a really good point to keep in but it's a tough thing to talk about. And it's call...how do you sema...how do you label the stuff that goes between applications or systems or consumers or providers? And I have a hard time when I tell my constituents there is...I want to label certain things a way when the data's moving out to somebody else, but I don't needed to be called that when it's in my internal system.

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

Right, right and so the...so we had, I think, what I would call violent agreement in the workgroup that the fully specified descriptions of standards, whether SNOMED or ICD are not what clinicians want to use for the original documentation, which is why you have the need for interface terminologies. We wanted to avoid the...a reference of one-to-one mapping, but that's essentially when you're talking about a synonym, it really is a...one, an interface term that does have a one-to-one match with a reference term in the underlying terminology standards.

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

And just...does that include what some kinds of that was called a data capture terminology?

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

That would be a different term for it, yes.

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

Okay.

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

That would be a synonym.

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

It's a synonym, and I think that's important, like what a physician needs to write down when they are documenting; what a patient needs to write down when they're documenting and giving something.

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

Right.

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

So that's what you're calling interface terminology?

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

Yes.

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

So I'm just going to throw that word phrase out there, you may want to reference that...

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

So you should explain what we mean by what's an interface terminology.

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

Yeah, versus data capture. You might want to put it back in.

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

Or a...so also called, clinician friendly terms.

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

Yup, so time check; there's one more presentation after this; got Wes, then I got David and then capiche.

**Wes Rishel – Independent Consultant**

So, this follows directly on Nancy's comment. But, the notion...and it's interesting that you really are focusing on the word synonym because it's a little hard to think of synonyms in, for example a consumer technology, what's the synonym for a bellyache and so forth and does whatever term the physician use actually imply a little more than what the consumer is ready to express? And even among physicians in different specialties or primary care physicians and specialized physicians, there seems to be a level...a lack of communication person-to-person based on different mental hierarchies and much less through the computer system.

So I'm reminded of the situation we found where we began to send data from one EHR to another and discovered in implementation that that accepting the data or accepting selected data out of it was a user function that was incumbent on the physician, it wasn't just a thing that was going to happen in the background, like I certainly imagined and I think a lot of other people did as well. And I am concerned that we consider this the focus on exact synonyms very carefully in terms of what would be the impact on the workflow of the physician or what would be the impact on the consumer-physician relationship because of different implicit levels of the specificity between them. Thanks.

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

Thank you.

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

All right, David.

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

Just an additional commentary on Nancy's point and the Wes' comments, just that a synonym is a synonym until you refine the granularity of the core that it's mapped to at which point it's no longer a synonym to that one, but it's something else.

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

Something else, absolutely.

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

So it's really important to preserve what the physician actually captured...

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

Yes.

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

...even if you also transmit what it's mapped to, and especially if that's patient generated, because they may be using the word in a completely different way and you think they meant acid indigestion but when they said bellyache, what they were really talking about was they were mad at their parents or something, I mean, who knows. So you have to preserve causality.

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

In the immortal words of Mandy Patinkin as Inigo Montoya, do not ignore me...think it means. Okay, thank you for an excellent discussion on that. Turning to my two pillars of support here, Dixie Baker and Lisa Gallagher.

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

This is the report from the Transport and Security Workgroup. Next slide, and I apologize to all of our members that we haven't included all of your names here, but I assure you that we really sincerely appreciate all of the efforts and we'll correct the next time. We were assigned three sections in the roadmap, sections E, F and G. Section E has to do with secure network infrastructure, F has to do with identity and authentication and G has to do with consent. So far we've gotten through section E and section E has two topics included; in one, they call cybersecurity and the other, which is actually a subset, I guess, of cybersecurity which is encryption.

We are asked two questions about cybersecurity, what should the federal government specifically focus on first to move towards a uniform approach to enforcing cybersecurity in health care? And the second question was are there frameworks and methodologies, incentive programs, etcetera, that the

healthcare industry has not but should consider? And then the question about encryption was, are there other gaps aside from the lack of policies and guidance for implementing encryption in technology and standards for encryption? So we're going to present our draft responses for the section E questions today. Okay, this is our first...this is our work plan and we're...as you can see, we still need to...we've begun our discussions of section F and then we'll finish with the section G.

Okay, I'm sure you can't read that either. The first question was what should the federal government specifically focus on first to move toward a uniform approach to cybersecurity? Our draft response is that we recommend that first of all ONC work with NIST, the Office of Civil Rights and other federal agencies to come up with the uniform approach to enforcing cybersecurity in healthcare. And I think what we heard from Ron Ross this morning just only reinforces this recommendation.

The second is that we wanted to emphasize that ONC should work to advance a consistent trust framework across all of the healthcare IT ecosystem. Second, ONC should endorse a set of appropriate baseline security controls that are uniformly applied to all health IT technologies that enter the ecosystem. You'll hear that this is sort of a recurring theme that we heard from our members is that they really want more specifics on what is expected of them. They understand that HIPAA is risk-based...based on a risk assessment type framework, but they want to really know what are the things that we need to do?

The third is that ONC should work with industry to accommodate a diversity of emerging health IT technologies across the infrastructure. I think we all know that on a daily basis we see new technologies coming into the infrastructure and these technologies really shouldn't break the security if you choose to use them. But rather the infrastructures themselves and the trust framework needs to be...need to be sufficiently flexible that they can accommodate changes in technology. And then forth, ONC should provide guidance on proper governance in cybersecurity, which is essential for building trust.

Next slide is, are there frameworks, methodologies, incentive programs that should be considered? We wanted to reiterate that this trust is essential to building secure health IT ecosystem. We suggested that possible framework are the NIST Trustmark framework, the PCI framework, which is what's used in the financial industry and ISO should be considered as potential frameworks for establishing trust. Cybersecu...we wanted to stress that cybersecurity needs to be considered both for within enterprises as well as for the interconnections among enterprises.

Again this is that recurring theme that the healthcare industry needs a minimum set of standards and metrics for measuring the strength of security protections. We had a really useful discussion around this that there exist a number of these minimum standard sets already exist, like when OCR goes out to do HIPAA audit, what is that list of things that they're looking for as a minimum set of standards? There's also the CAB-forum which is a certification that's already in browsers which CAB stands for, but they have specified set of baseline requirements. And even when they bring in the cybersecurity insurance companies, when you go to these insurance companies to get cybersecurity insurance, there's a baseline set of questions that they ask. Financial auditors, there's a baseline set of questions that they ask and our members really felt that these need to be brought to the forefront rather than leaving it...so much leeway to HIPAA, but what are the minimum things we have to do in today's world? Finally, there's an existing security control frameworks including NISTs cybersecurity framework that should be considered.

The final question has to do with encryption; are there other gaps, aside from lack of policies and guidance for implementing encryption, in technology and standards for encryption? I think that's kind of an oddly worded question because the biggest gap is the lack of policies and guidance in implementing encryption. So that said, actually what exists in our standards, the only really encryption standard there is the FIPS 140-2 Annex A, which is a minimum...which has to do with encryption algorithms and integrity algorithms.

Our draft response is that ONC should work with OCR and federal partners to address these three issues, all of which really have to do with encryption infrastructure. Specifically the first is that the ONC should provide guidance on encryption key lifecycle management. Encryption...the strength and effectiveness of encryption is based on several factors. One is the strength of the algorithm, which FIPS 140-2 addresses. Second is how it's integrated and third is the strength of the key and how that key is protected. And all three of these really address key, the protection of the encryption keys and how they are protected and how they're distributed.

So we felt there was a need for guidance on encryption key lifecycle management, there's a need for guidance on the method for encryption key escrow recovery. And finally, should published guidance on key oversight and authorization.

And then the last recommendation is that ONC should consider providing guidance on again, a minimum set of encryption requirements. And this has not have to do with key...the protection of encryption keys but rather, when encryption is necessary and they want more guidance on that. We already have some guidance with respect to protection from breach notification, but they really wanted more specifics on when encryption should be used...in conclusion.

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

Okay, and did you have any comments?

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

No.

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

Okay. All right, I was hoping I didn't...

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

Well, no...lined up.

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

Dr. McCallie?

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

Dixie on your first a slide you use the phrase consistent trust framework across the health IT ecosystem and I was wondering what you might mean by that? Do you think that there's one trust framework that

can meet all the needs of health IT? And if so, isn't that by default the federal trust framework because it's 50% of health IT? Or what did you mean by it, I guess is really the question.

**Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associate**

Well I think when I hear trust framework it's really not a baseline set of policies that's enforced across the ecosystem. But secondly, there needs to be mechanisms for sharing the details about how that trust framework is implemented between the nodes in the ecosystem. They don't all need to be in identical; we don't all need to be FISMA, right? But we do need a way to let each other know how we are enforcing a consistent baseline policy.

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

And there are emerging frameworks or ecosystems like NSTIC that could be evaluated for that role.

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

I mean, my concern is obvious that in the world of deployed systems we have different kinds of trust frameworks managed under different governance models that are appropriate to the scale and scope and risk factors of each implemented, what we called in the JASON Task Force data sharing network. And it's hard to see moving away from that to something where everybody implements the same model because some of the models are so complex and expensive...

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

I don't think...

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

...with the high risk.

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

Yeah, we won't.

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

I mean, for one thing, security and privacy policy is at the state level, for the most part, in the United States, so you'll never...you're not going to achieve a uniform policy across the ecosystem to begin with.

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

Right. Yup.

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

But you do need to have ways of sharing with each other how your...how their data will be secured if they choose to exchange it.

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

Right, and that's what the Trustmark Program is looking to address, whether it's right for us or not. But there are folks looking at that and that's something that we think is something that we should look at in the sector as well.

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

And that's what she's talking about when she mentioned NSTIC...

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

Trustmarks.

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

...is the Trustmark part of NSTIC.

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

I know and NSTICs been working on this ever since we first started having these meetings and they still don't have much to show for it. So it's a big hard problem that I don't think a top-down solution is going to work, I guess is my...

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

I think they have a pilot on Trustmarks, which is separate from the other work they're doing that we need to look at.

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

And they're working with NIST on that, it's not just identity, it's broader than that.

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

So, this will get back to the previous set of draft responses, like David's, actually, response. So, as I was listening to Ron this morning and as I was listening to you now, it strikes me that what we're talking about is the ultra-large-scale systems kind of principles, right? And I just didn't know if you all had felt like that was...principles for the dynamics of those kind of systems are addressed in here. That's good enough, I'll just leave it like that. Does that sound applicable to you all?

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

Of course; yeah.

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

Okay. All right, it just...as I read through these and my brain turns them over, I may go back and try to compare text to text and see if this is reflected back and forth. All right, any other comments? All right, oh Wes, I'm sorry; a blind spot, I just went right past you.

**Wes Rishel – Independent Consultant**

It's always the same hands. So it's amazing how a bunch of ideas that come at you can sound good until you have to think of them together. And I'm thinking now about the sort of tentative state that we heard about...just in this presentation about creating a trust framework and the presentation that Arien and others made this morning, Arien and Stan, about creating an environment where we can test applications or test applications of standards before the standards actually become standards.

And it's just possible that the legal requirements on federal agencies are so different than the HIPAA framework that it will be almost impossible to get any project operating quickly between a federal agency and a private healthcare organization. And I think as we approach these two problems, we need to find some way to accelerate trust agreements for the purpose of these prototype actual production applications. And it may be that that approach is much more specific and limiting than we would want a general trust framework to be. Thanks.

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

Any response or just...

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

Well, I think getting together trust agreements, yes he's right. It will be...yeah, it's very difficult and it's an essential part of the whole trust framework. But if we had a common way to communicate with each other so that we could quickly identify differences in the policy and the technology that's implemented, I think that would help make those agreements go little more quickly. But yeah, that's a...he's right, that's a big challenge.

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

Okay, great. Any others that I've missed? No. Okay, all right. Thank you so much to all the individuals, both here and elsewhere have worked on this. I really appreciate that it's a tremendous amount of work, thank you so much and just on behalf of the folks at ONC that are working on this, we really do appreciate that input, thank you. So, all right, with that, doctor.

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

Well, as you head off to a call to do good things for us, we will now turn to Arien and David and just as you heard from the presentation from Stan and Arien this morning, a very important framework. This body of work, I think you will find amazingly impressive. We've all worked together on these issues for 20, 40, 50 years and we...Wes, you know we ask such questions as, well what's optionality versus specificity? What are the asynchronous upgrade issues?

What you have today is a presentation that tries to actually drill down on the continuum of all these issues and recommend some paths forward as we have to ex...we recognize that APIs and the use of FHIR and these sorts of things have potential for the future, but there is an existent body of work that we have today and how do the two co-exist and how do we deal with the multitude of use cases and how do we think of the continuum of the next five years in making progress while continuing day-to-day production? All of that in 16 slides or less. Go for it!

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

No problem.

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

All right, here we go. So first off I want to acknowledge our co-contributors here. This is the intrepid group that stuck with us through the slog of deep technology and high-level architectural arguments and showed up for literally, I believe, every one of our meetings and all contributed deeply to what you'll see

presented here today; so a good breadth of representation of vendors in the industry and thanks to the team.

The next slide here is the timetable that we're on. I put it up only to say that we started out before the roadmap was dropped and we basically picked up our initial charge, which I'll put up here on the slides, as the follow-on to the recommendations that came out of the JASON Task Force. So as you recall, the JTF called for a public...this notion of a public API, data sharing networks that would find ways to combine the components of the public API to solve useful problems, useful use cases around interoperability and other things.

So we started our work with that question in mind and began to flesh out a framework to explain how that might be made real in the next decade or so. Then the framework came out and had specific questions. So rather than go back to each of those questions, which were fairly granular and answer them one by one, we just basically said, take it or leave, we're going to flesh out this framework and try to reference the answers to those specific questions in the context of the framework. So we're architecturally thinking here, you can't answer low-level questions about your house plan until you look back and zoom out at the high-level architecture.

So this first charge that we have, define architectural patterns sufficient for an ecosystem of nationwide scale information sharing and modular applications serving patients, providers, provider organizations and researchers. That's what you're going to hear from us today is a first cut at addressing that question. We'll do our duty and complete specific answers to the specific questions that were asked us, but most of them are going to say, referencing the framework, you'd answer it this way.

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

All right, so I'm going to present the general framework, David's going to go through a bunch of thinking on how to apply that framework in practice. And then we'll end with some specific draft recommendations for the roadmap period. We generally went back to the Internet hourglass as our framing and this ended up being, and you'll see the way that we applied this, this ended up being quite explanatory and helpful. The Internet hourglass, the classic Internet hourglass starts with IP in the middle, so homogeneity, parsimony, I'm not sure if anybody's heard the word parsimony in this committee before. Above that homogeneity layer and then heterogeneity competition, innovation and duplication; the point here is that good architectural thinking about the components at the narrow waist lead to high levels of innovation above the line.

So, the reason you tend to get homogeneity is actually a straightforward application of network dynamics. And I looked at an example of REST over HTTP as an example for where we're able to see these trends. The world that used to be called distributed objects or service oriented architectures originally started with HTTP in the original formulation of REST by fielding, but also had SOAP, XML-RPC, before that CORBA and whatever the Microsoft equivalent to CORBA was and what's happened over the last decade or so is that everybody has to implement at least HTTP the way that HTTP was designed. And in point of fact, if you want to get distributed objects or service oriented architecture or APIs to work on a wide range of devices, you can't use SOAP, you can't use XML-RPC, you certainly can't use CORBA, you basically are using REST over HTTP because it's the toolkit that's built into every mobile phone. It's built into every web browser. It's built into every programming language that you use. And because it is ubiquitous, you can build a whole lot of stuff on top of it. If you choose to build on something else, if you're just a true believer and you went back to build a CORBA stack, you'd be living in a world where you can implement only on one technology, only on one ecosystem and only one stack.

So if you're looking for the highest degree of heterogeneous innovative use cases, you need to standardize on heterogen...homogeneity and parsimony.

You see the same trends in play in XML...the way that we applied this to the healthcare stack is as follows. On the bottom of the narrow waist, if you will, of the healthcare ecosystem stack are Internet standards, primarily HTTP, HTTPS. And then we discovered through looking at HL7 version 2, HL7 version 3 and the IHE stack and FHIR, we discovered a notion of what we called core composables and orchestration patterns. And David's going to go into a lot more detail about what the core composables and orchestration patterns are.

But one thing that was, I thought, very explanatory for the longevity of the HL7 version 2 has had is that core composables in a version 2 world are the core segments and fields in a version 2 message. The orchestration patterns were use of version 2 for messaging and the quasi-higher-level guides for what an ADT looks like and an ORU looks like and an ORM looks like, etcetera, that drove lots of interoperability specific use cases and data sharing arrangements.

So our conclusion is that basing the healthcare Internet hourglass on the context...on the construct of core composables, generally core composables for data and a limited set of orchestration patterns will lead to a high degree of heterogeneity. And that was probably far too abstract, which is why David's now going to take it now and make it a little more concrete.

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

So in case you missed it, that odd shape is the top half of the hourglass, done by engineers not artists with the bottom of the slide representing the narrow waist. And the previous slides had in a different color the reminder that the implementation of all of this stuff is vendor-specific but the exposure to the outside world via these APIs and these orchestrated constructs is, in fact, standards-based. So we'll focus on the top half of the hourglass here. And at the narrow waist, as Arien described, is basically the Internet...the core Internet standards, HTTP and TLS, the building blocks of everything that happens on the Internet. I will also comment, before I dive in to these, these are exemplars; these are not exhaustive of even necessarily correct. This is just our snapshot of how we look at this based on the depth of our understanding today.

So the layer above that is really the key layer that the JASON Task Force addressed with their notion of the public API, which they specified as contains standard set of services and a standard set of data profiles to flow over those services. And what we've done is to mix in a couple of other standards that are necessary in the real world to do anything, which is basically the security standards around authentication and authorization.

So you have, in the core compostable category, basically profiled FHIR, and it's not all of FHIR and it's not all profiles, it's a core subset of FHIR and a core set of profiles useful to get enough agreement around the industry the people would say yes, I'll implement those. The Argonauts are attempting a first cut definition of that, for example. OAuth 2 and OpenID Connect to address the authentication and authorization needs and then HTML 5 to carry any user experience that's needed. We don't need a new forms language, we've got one, it's called HTML 5. We don't need a new user experience toolkit, we've got one, it's called HTML 5.

Then above that, I think our key insight, and this was arrived at with many different iterations in our group and discussions about the proper terms and we landed about the notion of orchestration

patterns. Pattern picks up the notion of software development pattern and orchestration picks up the notion of a sequence or an interchange of back-and-forth handoffs in some kind of a choreography.

So these orchestration patterns would include our kind of exemplar of a very powerful but nontrivial pattern, the SMART App platform, which as most of you know, is a way to plug a web App into a container that could be running in an EHR or in a researchers toolkit such that the plugged in App uses HTML to give you the visuals, it uses OAuth to authorize itself into the data source and it uses FHIR to move data in and out of the data source. So you have the combination of data plus authorization plus visuals and that's all a standard orchestration that can be replicated for literally thousands of different use cases.

So that's the layer above, is the various use cases, each one of which would be mapped to a well understood, well-defined, possibly even standards-based orchestration patterns. And open question is whether orchestration patterns are something that SDOs should produce or some next generation convening authority, used to be known as S&I Framework should produce. But the orchestration pattern is beginning to vary out from the core of the narrow waist, but it's not so broad as to be use case specific; you try to accomplish as many use cases as you can with each orchestration pattern.

And then at the top, we kept coming back to the notion that these things make sense in the context of some kind of data sharing arrangement. You can't do this one size for the whole country, certainly not one-size for the whole world; you do it in the context of well understood data sharing needs which involves trust frameworks, business arrangements, business drivers and sustainability models and the like.

So you could imagine, for example, to take the SMART App strategy and run with it a little bit, a vendor may put together an App Store that hosts standards compliant SMART Apps, but it only hosts the SMART Apps that the vendor has certified to be consistent with their safety philosophy, their visual design philosophy, etcetera. So you could have, in fact, a governance framework around that particular App Store. Someone else may put together a more generic app store that crosses vendors, go create partnerships amongst vendors to have a higher level App Store and that would be another data sharing network.

But they all use the same orchestration pattern and those in turn all use the same core API services. So when somebody gets a great idea for a new app, they don't have to go to the vendors and start arguing about a custom feed of data in and out of the EHR, they can just plug in to that orchestration pattern and run with it.

So here's an example of a little bit more detail on this pluggable apps, which is just a generic name for the SMART Apps. And I'll just call your attention to the second part of the slide that there are a lot of different use cases that could take this same exact orchestration pattern and do things with it with minimal to minor work on the vendors part. You could have disease-specific visualizations, diagnostic clinical decision support such as differential diagnosis tools, visual diagnosis tools. You could use this approach to do the RDF and SDC, but more generically than those approaches currently use and you could use it to bring in data from outside sources like HIEs or population health management programs.

Now we said, all right, let's just test our hypothesis as a group and say, could we come up with...oh, actually before I go to that, this is an example of what the SMART App orchestration pattern looks like. So this is the handoff between the container, the SMART App and authorization service that does the

OAuth work. And you can see it's not trivial, but once it's agreed upon, people can take advantage of it fairly quickly. So this would be the way you might publish or expose this particular orchestration pattern.

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

Just to add one more thing, we mentioned a bunch of clinical use cases, patient-oriented use cases would follow exactly the same orchestration, relatively the same orchestration as to whether it's pluggable web app or a mobile app. The power of this is that once you defined the core composites and the orchestration pattern, a diabetes care management application that gets its authorization from a patient and a diabetes decision-support application that gets its authorization on the provider side use exactly the same underlying data and orchestration framework. So that is, from a vendor perspective, you do this once and you're generating the whole set of use cases on top of it.

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

That's exactly right. So we took it on ourselves at our last meeting to say let's craft another orchestration, a different orchestration example just to test our hypothesis and make sure we're not just saying SMART Apps is the answer to everything. So we floated the notion of what we're calling here remote clinical decision support with optional conversations. And we struggled to come up with a catchy phrase for that, but we couldn't come up with one that was useful in public, so we're going to just stick with remote CDS with optional conversation for the time, until somebody comes up with a better name.

And the idea here, and this is driven out of the real world need that all vendors in this conversation, so Janet and George and I, all admitted we have at least a dozen companies coming to our companies and saying, we want to plug our decision-support into your product. We've got these cool things to do, pharmacogenomics or advanced pharmaceutical recommendations for complex drugs or expensive drugs or appropriateness screening for radiological procedures.

There are literally dozens of companies out there with very sophisticated technology to do this and they all want a custom API into each vendor and that's incredibly expensive for the vendors, for those little small companies, some of whom won't survive if they have to do that over and over again. So we said, could we zoom out and create an orchestration pattern that fits that general use case? And so this is what we came up with with our first cut at it. And this is not detailed enough to go live on, but it's compelling enough so that George and Janet and Josh and Arien and I all felt that it was a good starting point.

So the basic idea would be that the EHR uses an internal tool to recognize the opportunity to invoke that decision support. So that vendor's got to know, when is it relevant to invoke that decision-support. It then authenticates a back channel conversation using these core composites with the remote CDS. The remote CDS then uses FHIR to query the EHR for whatever data it needs to answer the question that's being posed. It can go back and forth and ask for more data. If it discovers that it doesn't have enough data to answer the question, it can ask the EHR to open a SMART App, in front of the physician.

So at this point now the physician's workflow is invaded with a question that he needs to answer to capture the missing data. At that point the remote clinical decision service can make a recommendation and push that back into the EHR using FHIR to do something like, for example, suggest an order that the physician can then go ahead and validate and sign, or push a note into the chart documenting a rationale for the decision that was made or to push a token in that can be exchanged with the payer to justify the payment for the procedure.

And that model, we sort of zoomed out and said, that model would fit all 10 of these companies that want to interact with our systems, if we built a general-purpose orchestration like this. So we look at this as a very promising way to craft the next generation of interoperability use cases. I think it's your turn now.

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

So if you follow us down the yellow brick road, what we're saying is that an hourglass model should actually be a framework for an interoperability roadmap. That is that a roadmap should define elegantly the least invasive set of activities that generate the most clinical and workflow benefit. And our belief is that the hourglass model that we've proposed offers such a framework.

And so on that basis, if you follow us down that yellow brick road, you get to the following general recommendations which is to move towards, and I wish John were here to hear me use the word again, use...move towards the parsimony of transport and security content via profiled FHIR and common orchestrations. And that that move towards is driven by a deliberate policy of what we termed rebalancing the standards portfolio towards that level of parsimony. That is not a blanket mandate for everyone to turn on a dime and go do something else, but to think an appropriate rebalancing exercise to drive, and now that Jon's here again, to drive the standards portfolio towards parsimony; so, I can say it again.

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

One of the reasons that I was so impressed with the presentation.

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

We did have to supply a definition of parsimony on one of the earlier slides, I don't know if you noticed that at the bottom of the slide; for the uninitiated.

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

And then corresponding with that rebalancing, allowing an appropriate time to develop, adopt, use and allow for success during that period. We also have to give some general recommendations to avoid use of terms like SOA and REST in the interoperability roadmap as being at a level of abstraction that's hard to understand in the context of the roadmap.

So our general recommendations for 2015-2017 are to create a glide path to core composites and orchestration patterns and here are some of the activities that we would recommend; supporting SDOs and public-private work to define the core composites and define security components. Those would include the work of the Argonauts, DAF, SMART and other activities. Support future work to define other core key high-value orchestrations and security components. So for example, as David mentioned, peer-to-peer may be a generalizable framework. Dixie and Josh and I have put together a use case that calls for peer-to-peer data exchange; getting that orchestration right may end up opening a lot of cases. Pub-sub, I think was pointed to particularly in the example of ADT-based notifications if there are more generalizable pub-sub orchestration, you could build a high degree of interoperability components on top of them. So here, the general recommendation is let's find the other high-value orchestrations and associate security components, get those defined right and make sure that you have the fewest number of those possible.

And then the last recommendation is, when you have a priority use case that wants to get done, push for that work to get done in terms of the core composable and orchestration patterns. So when the next PDMP comes along, I think people will find that PDMP is a perfect application of a SMART App. You invoke it, it goes off and looks at the PDMP, compares that to medications that are being proposed to prescribe and provides some alerting. So it's either a conversational CDS or it's a SMART App. Likewise, radiology clinical decision support, structured data capture have some of the same patterns as well.

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

And what I was mentioning this morning in the presentation on eLTSS was exactly this thought, when those use cases are settled, let's look at these orchestration patterns to see if any of them fit that model because you're talking about really complex interplay with lots of players, so let's see if we can do it with core composables that everyone is going to implement. And if we can't find an orchestration for LTSS then what's missing? Maybe we need another orchestration that solves for a slightly different, broader set of uses.

And so I think as a workgroup, we'd be happy to take a look at that work, John Derr and I just talked about it earlier over lunch, that when those use cases are solidified, the API group could take a look at that and sketch out whether or not it fits one of these orchestrations. And if it's missing, we'll come up with another one.

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

And then again subject to the consideration that you followed us down the yellow brick road this far, you would then, as part of that rebalancing effort, want to reduce friction and distraction for adopters and implementers during the rebalancing period. And you do that by minimizing certification requirements to allow ample time to pilot, adopt and refine core and orchestration. Ensuring the government incentives, Meaningful Use, alternative payment methodologies and others can be met using newer approaches, even if not formally certified as certified HIT or even if it's an alternative way of achieving the outcomes established in the incentive program.

Continuing to support, and this is a key point, continue to support production adopted standards that are not based on core, while minimizing changes and new uses. So for example, if you've determined that a standard, for example consolidates CDA, where there's existing HL7 work to do document-based standards on top of FHIR, is an important production adopted standard that's in wide use. We'd want to make sure that we continue to support it, but put most of the effort into new things that you'd want to do into the standards core...that are based on core and orchestration patterns.

And then you'd also want to avoid endorsing new standards that are not based on the core and seek alternatives that are based on core. There's an inherent cut over period where you've got some activities that are well adopted, that don't fit the long-term direction that you're going; you want to keep those supported, moving along and be successful. You've got some that are new and pretty clearly want to steer into the core and composable and then you've got an odd transition period. So we called out three things that were listed in the best available standards list that to our knowledge had not actually had any production use or adoption outside of Connect-A-Thons and brief pilots; HPD Plus, CSD and HIEM as examples that might fit that crossover point.

Then for the 2018-2020 period you'd refine and extend your core composable list, expand the number of piloted use cases that are based on the core composable. Address needs for national scaled services, this actually starts to look repetitive, which is great because a lot of us have been saying the same thing in different workgroups. Consider mature APIs, orchestrations and use cases as candidates for addition

to certified HIT. And begin the transition from non-core orchestrations; we've got some examples of that in a subsequent slide

For the 2021-2024 period, keep doing all that stuff and address complex data profiles that might require more robust models. Another key consideration here is that, and there are some words that got lost here in the update here, but since this is a 10-year roadmap, we need to be prepared if we think this hourglass model has legs, we need to be prepared that 10 years from now, we may be in a world where quantum dot-based semantic interchange is the going forward standard for the 2024 period and so we need to start preparing the way for quantum dot approaches for semantic normalization, where FHIR may be the legacy standard 10 years hence. And that's just the reality of, if you look at the lifecycle of standards adoption and deployment across the internet, we should be preparing for doing it all again 10 years hence.

All right, so here's an example of what a path from production adopted standards to approaches based in core composables, and this is purely a draft. In the area of directed exchange in 2015, there is some core work that's going on right now that is orthogonal or independent to...into this work. So for example, the criticality of the EHR workflow that drives coordinated referrals, transitions of care, incorporation of information from external settings of care; that workflow is an important part of interoperability and is orthogonal in many ways to core composables.

Some of the trust framework issues, the DirectTrust and others are engaged in, again, are critical and important and layer very nicely on top of OAuth and OpenID Connect. In this same time frame we should also be piloting FHIR-based content packaging and edge APIs in addition to or in replacement to or transitionally in replacement to, for example, XDR XDM and the Internet message format work that Direct is currently based on.

In the 2018-2021 period, we should start adopting those FHIR-based content packages and edge APIs and start to adopt native FHIR-based directed exchange end-to-end. In the area of document-based exchange, XCA XDS, likewise consider...continue interoperable trust in EHR workflow. There's a...IHE has MDHDv2 based on the FHIR document model, so we should start using that in parallel with XDS and XCA and pilot the use of FHIR for discrete data exchange along with the document-based exchange.

And likewise in 2018 to 2021, start to prefer the new approaches for new go-lives, start adopting discrete data-based exchange and start the process of phase-over. To Wes' point, this will be asynchronous and bilateral. And we need to plan for and be planful of making sure that HIT works during that transition period.

So that's a framework for thinking about how we could affect that rebalancing approach towards the notion of core and orchestration. Again, the critical part here is that you follow us down the yellow brick road, that there's a minimal set of core data composables and security composables and a minimal set of orchestrations that leads to maximal generality for use cases. And that by being smart and wise about selecting that set, we can make the...we can make all the new use cases that we have a lot of excitement about...don't care for HIT vendors and provider adopters because they are merely straightforward applications of the existing orchestration patterns and existing core composables.

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

Okay. Well, was that impressive or what? So, you know the great thing about Jon and I's yin and yang here is that I am a private sector guy who I am not bound by any constraints, and so I can say things like. Congress, over the last couple of weeks has set a lot of peculiar things about, oh, we've got this roadmap and it lacks detail and actionable this or that.

Well here we have actually a framework laid out by ONC that has now enabled us, a Federal Advisory Committee, to add a lot of those details. And sure, I am...we'll have many comments today and going forward over the next few months, I'm sure polish that here or there, but what a perfect actionable set of steps you guys have outlined today. I mean, I could easily assign my staff to working this and getting the kind of forward progress we all need. So it's alignment of JASON, it's alignment of the interoperability roadmap and it's alignment of what we all need in our various...each of us, in our sectors. So Jon, I know you wanted to comment.

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

Yes, and just be clear, that was not a recommendation from the..., it was just a comment. So I was just...all I want to say is, it is almost a year since the first JASON Report was released the robust health data infrastructure. And to go from there through all those discussions in October to the recommendations of the JASON Task Force and then to go from October to here, it's just...it's not an unusual experience but it's definitely a different experience to have a vision for the future and be involved with that and then to watch it unfold in front of your eyes, in this kind of way. So, it's really cool, thank you. I'm almost a little verklemmt, thank you very much for doing the work.

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

Thank you very much.

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

So again, trying to go in the right order, we have Wes, then Cris and then Anne. So Wes.

**Wes Rishel – Independent Consultant**

So, I have to say up front I'm sad that I had no part in producing this but it allows me to say without fear of self-interest, this is a brilliant piece of work. And more than what Jon said, unprecedented specificity in terms of any recommendation I've ever seen from any of the Federal Advisory Committees I've been involved with. So let's hope that specificity doesn't shoot you down. You mentioned in the oral presentation, you mentioned Josh Mandel; I didn't see him on the list of contributors.

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

He's on the workgroup.

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

If he was missing, that's a huge oversight on my part when I typed it, because he...

**Wes Rishel – Independent Consultant**

Oh, he is on the list.

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

Oh good, because Josh is a major contributor to this.

**Wes Rishel – Independent Consultant**

All right, I'm sorry that I missed that first because of his brilliant contribution, second because he brings...he comes from the healthcare organization side of the interest groups so that represents some important balance. For the last 15 years before I retired, I worked for a company that made its money by explaining technical issues to decision-makers, who typically aren't technologists. And this is the closest that I've seen of an acronym laden presentation that actually did a good job of phrasing the issues in a way that it can go to a decision-maker.

And I particularly want to emphasize that this hourglass metaphor is not something these guys thought up in a phone call, it represents kind of the summation of a whole lot of insight into why the Internet succeeded so much more than the various networking, remember DECnet, and IBM had a network, everyone had a network that represent this hourglass phenomenon is seen as the key to success of the Internet over all of that stuff .

We talk about this being an example for potential consumer applications connecting to the EHR. I think it's important to recognize that to a great deal, this is also the model that consumer applications use today without connecting to the EHR. It therefore represents the path of much lower resistance to integrating those things that are still sold from big-box stores and so forth into a meaningful national healthcare network. And finally, with regards to the yellow brick road metaphor, those of you who are going to HIMSS should check to see if for the third consecutive year, Janet is wearing her ruby slippers.

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

Thank you.

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

Okay, actually it was Dixie who was next, so missed her in my blind spot here, go ahead.

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

Sorry, I'm easy to miss.

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

Always turn left before making...

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

Yeah, this is really, really good. This is my kind of presentation. This is great...really good and I agree with much of what you're saying. I just wanted to mention that the OAuth 2 and it's OpenID Connect profile address identity sharing and authorization only, but that they don't address authentication...the whole identity and access management set of things. So I think that, you still, I believe what still belongs in this picture are things like ID proofing and credentialing and authentication, as well as non-repudiation and auditing and accounting of disclosures because all of those would be part of this.

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

Yeah, completely agree. Thank you.

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

Cris?

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

Same comments about brilliance of work; I can hardly imagine the average SAT score of the participants in this task force, it must be pretty amazing.

**Wes Rishel – Independent Consultant**

It's bounded at the high-end.

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

What's that?

**Wes Rishel – Independent Consultant**

Bounded at the high end.

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

Bounded at the high end, yeah, I think that's exactly right. So the similarities between the seven layer OSI model for networking and this is pretty obvious. Since we're attempting to be limited in our comments about public action, I'd be interested in your comments about private action. That task force represents three of the largest EHR vendors and a significant vendor in the interoperability and connectivity space and I don't know how else you'd characterize everybody's business.

These kinds of models work best where there's congruence between the technical model and a competitive model. And I'm curious, just given all the kind of speculation, some of it overheated about the intentions of vendors to not interoperate in certain ways and in certain fashions, I'd invite comments about what your thoughts are around whether this is...how would this be received and actuated in a competitive environment amongst these various companies who would have to act on it? And in a particular, the folks who helped write this? I'm optimistic, it's intended to be little bit of a softball question, but I'm curious, do you think that this will be congruent with the competitive impulses of the companies who are going to have to implement this?

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

It was funny, in our last call this topic came up and I think the sentiment...so first of all, I think Michelle would want me to say that we started out with a workgroup that had a much broader balance of interest and what you see on that slide were the people who stuck through us, thick and thin and were seeking to get more done.

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

The sharks devoured the more gentler, kinder, slower?

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

I think it was more that some people just opted out of the conversation. But the sentiment of the folks on the call is, you know, this makes so much sense that we're just going to go do this and we'd love to do this with ONC's blessing and participation; we'd love to not be hindered and blocked. But our sense is this makes so much sense, this solves so many business problems for, as David mentioned, the myriad clinical decision support vendors who want to integrate in, this solves near-term business problems. So,

at least the sense of the 3 to 4 folks who represent the interest of developers and vendors is, we're going to go do this.

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

Yeah, I would agree. I think competitive forces can be forces for good as well as...

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

Exactly.

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

...forces for confusion or counter purposes. You don't want to be left out if your competitors doing something and it looks really sensible and rational, you're going to better be there and do it, too. So some of that's what's going on, some of it is, we are all architects, we like building things that work and that's much more satisfying than building things that don't work. So that's part of it. I think there's just pride of ownership of wanting to do good work that I know that particular group of folks, it drives them all.

And then, oh, I had one other thought but it escaped my mind. But anyway, yeah, so I think this is competition actually working for the...oh, yeah, no, I remember my thought now which is, if we don't do it well, somebody might do it badly...

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

That's right.

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

...so let's get up there and do it well.

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

I think maybe a last comment, just to echo John's earlier comment that his team could get to work on this right away. I mean, as a consumer of this stuff from multi-vendors, to be able to purchase and implement against this is pretty powerful. I think behooves those of us who are buying this stuff to pay attention to it and endorse it.

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

And Jon is out of the room, but...so I make the comment to Steve Posnack and Jodi and Michelle that of course we have no idea when the certification and MU staff will exac...will arrive, but let's hope over the next days to weeks when it does, that we could overlay what was described by Arien and David to that, because who knows, Steve, if CMS is up to FHIR and API thinking, but let's hope whatever they come up with is not so prescriptive that it is at odds with what we've heard today. Because this is such an elegant roadmap, I think our industry would be invigorated by saying, you at ONC, you at CMS, have outlined a set of policy goals and the kind of roadmap that the Federal Advisory Committee has advised, which is very executable, aligned with those goals. And, time will tell. Okay, Anne.

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

Thank you all for running the marathon to get us here because it really is, to everybody's point, an actual framework we can start running the business use cases against. And David, I encourage us to follow your advice and run as many as we can against it to try to round it out. But I hope and I think clinical decision

support is an excellent one from a provider standpoint, but I hope from a consumer standpoint, whether it's long-term care or some other, we run against it, too, to be sure that there are no holes.

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

Yeah, I...anyone who listens to me when I am at Cerner talking to our other teams, they...I'm constantly coming back to the fact that the game changing thing for the next generation is going to be Apps in the hands of consumers that are connected to these systems to help manage chronic disease. And these orchestration patterns are perfectly optimal for those use cases, they're just waiting to emerge.

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

I fully agree. And to John's point, we need to be sure there are no constraints on this work to getting to this future state, because I'll be surprised if we get to 2018 before some of this is needed.

**M**

That's right.

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

Yeah, I think it'll be happening faster than we can predict. And to Arien's point, the SMART Apps, I mean phone-based Apps, which is for better or worse where people are going to interact with computers in the future is in their phones...on their phones, supports all these core building blocks because they're based on Internet standards and that's where this convergence has come full circle. And all of the enterprise architecture approaches like DCOM and CORBA and stuff are now basically irrelevant because you've got to talk to that phone and it speaks one language.

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

Oh absolutely, and we know for poor and vulnerable that that's one route we can get to them.

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

That's right.

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

Um hmm.

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

So, we have limited access otherwise.

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

Yup.

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

And I just wanted to point out that the Argonaut project includes consumer access to their own health record both through web Apps and through mobile Apps as one of the adopted core four use cases. So it is definitely top of mind for the thinking that went into here.

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

Well, excellent; thank you so much...oh, sorry, Leslie?

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

I just wanted to also compliment you and to build on Anne's point, the Secretary has challenged us to come up with, as an industry, computable consent. And right now we see efforts going on that are organization to organizations, individual to organizations, patient consents that don't mean a whole heck of a lot and so I think your framework is also quite informative. You use this, the combination of OAuth 2, so let's think about how we could develop a privacy consent framework that could work in this environment and leapfrog all of this just difficult and complex solutions we have to come up with now. And I'm wondering Jodi, if this is a way that we could potentially look at, as we did in the past, the Notice of Privacy Rules? Could we look at this as construct to help define the requirements for computable consent? And what could we do to accelerate that process going forward?

**Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology**

So, Lucia Savage isn't here, she's our Chief Privacy Officer and she's actually working on...she's been the one who's been thinking through computable consent. So I'm going to punt that and suggest that it would be a good to have a conversation with Lucia, and get on her radar screen, because it's something that she's been tracking and leading.

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

I'd only add that that model is a model, as somebody else mentioned, that consumers are already very familiar with, the notion of delegating access to your Facebook account for a specific set of limited purposes that are specific to the application or use is a model that is familiar and seems to be relatively scalable and comfortable to consumers already.

**Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology**

Yeah, yeah thank you.

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

Build on it.

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

And there is, Dixie's participating in it, Josh I know is participating in a workgroup called HEART that's exploring something called User Managed Access, which is essentially a layer on top of OAuth that allows for more granular control. It's complex, it's not proven yet, but it would open the door to that kind of highly granular control managed by the consumer for those few percent that actually want to take that control.

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

But in tandem with that technical effort, we could have the actual policy language recommendations coming out; we could really move this agenda, as Anne's point, much faster than 2018.

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

It just needs to be proven in the real world before we policyize it.

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

Well, yeah, I agree.

**Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology**

Yeah, I mean, I'll just say, the one thing I'll say is, as we always talk about, I think we're in a much better position when we are developing the policy and technology in tandem so that we're making sure that what we are putting forward in technical requirements, specifications are aligned with the policy directions. And sometimes we've done a good job with that, sometimes we could improve on that, we've done that. And I think in this space particularly, it would be very important to be having the policy construct on top of the...or as a key driver of the work. So, I would agree with that.

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

So, Michelle I believe you don't need any consensus statements for this one, correct? So maybe our colleagues in the press can note that today, we heard this wonderful work and so, we all applaud marching down this yellow brick road to you've outlined with courage and the notion that what we have outlined ahead of us is our greatest opportunity for success.

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

Thank you.

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

So thanks. So let us now hear from Julia about quality improvement standards evolution.

**Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

**Julia Skapik, MD, MPH – Medical Officer, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

I'm Julia Skapik, I'm a Medical Officer in OST at ONC. I'd like to thank Steve Posnack for suggesting that we present this work to the Standards Committee. Part of this work is sponsored through a contract with CMS called Tacoma Contract and Steve's counterpart at CMS, Kate Goodrich and Minet Javellana, who's my counterpart send their regards and are sorry they can't be here, but they look forward to feedback and participation from the Standards Committee in this work moving forward. So next slide.

Oh, I have the thing. So our objectives today are to talk about the 2015 measure update standards. I would call those the current state, even though the measures aren't out yet, then to talk about the need for CDS and eQIM harmonization. I hope to the Standards Committee that's an easy sell. And then to learn about the planned pathway for CDS and quality measurement standards harmonization, specifically a couple pieces of that have evolved recently and I wanted to let the committee know about that and to have the opportunity to ask questions.

So the 2015 quality measure annual update will republish all 93 of the quality measures in the new HQMF R2.1 format. We're expecting that on or around May 1, 2015. That means the current measure authoring tool will no longer support the previous version of HQMF. Along with the changes to the measures, the value sets will be updated to later code systems. There will be corrections to logic to incorporate feedback, and I'll put a plug in for the JIRA issue tracker, which we've used to resolve over 1500 comments from the community about improvements to the quality measures.

And then finally I wanted to mention the Bonnie testing tool which creates QRDA libraries. CMS has agreed, actually, to require the use of Bonnie to pretest all of the measure specifications prior to releasing them as of this year. It's our goal as part of this work moving forward that testers in development will be the norm for artifacts and that testing will be a part of any standard prior to release. And I think that that echoes some of the comments we've heard today. Bonnie also has the ability to import and export test libraries and it can be imported into a system internally or used by users externally to do this kind of testing. It also does complexity analysis; those are all new features.

So the motivation for HQMF R2.1, I think actually the intention of HQMF R1 was that people would be able to import machine-readable artifacts. But I think due to timing and technical limitations that actually didn't end up happening in the fields. We do know now, actually there are a couple of systems that can import HQMF R1 and are working to update to import R2, but R2 should be a lighter load to lift, it's easier to parse, it's simpler to execute. Our goal in having a simpler execution model is to enable that automated machine import so you could literally take in the new package of 2015 measures in sort of an instant with a minimal amount of manual work. Currently we know people do a great deal of manual work to put in every change in the measures.

So here I wanted to show you of an example of the difference between and HQMF R1 measure and HQMF R2 measures. The colors actually just tell you which piece of the measure it comes from, which population. The is a 2014 measure logic for CMS 135 which looks at whether or not patients with heart failure are being discharged on ACE or ARB medications. You see that the 2014 version is eight pages, the 2015 version is a page and a half. Part of the reason for this added simplicity is changes to the quality data model which is the underlying data model and logic expression language for the current HQMF. It involves the use of in-line comments, the addition of variables, simplification of temporal operators and you see that that's already made a significant impact on the complexity of the quality measures.

So moving forward I'd like to address the issue of quality improvement standards mismatch. Here I've just shown that when we talk here, in this context, when we talk about clinical quality improvement, CQI, I'm specifically referring to the activities surrounding quality measurement and clinical decision support. I think it would be easy to argue there are more activities that could be considered quality improvement, but here we're sort of focused on that scope.

Right now, clinical decision support and electronic quality measurement in the field are closely related. They share a lot of common requirements. The data needed to support them is very similar as well, but currently we can't support sharing of that information or those artifacts across the two use cases. And this is because the standards for the two are fundamentally different; it actually added more detail in slides in the background section on exactly what standards are involved in each. But the reason for this actually when you investigate is not that there was a failure to want have these two things aligned, it was rather that the quality measure program was moving forward, the standard was being rapidly developed and there wasn't time to put in the kind of sophisticated language and expressions that you would need to do clinical decision support.

So they're technically more complex pieces to the way you need to express ideas in decision support and that's because quality measurement is largely a retrospective activity. Right, so decision support needs to be able to have a higher level of confidence to provide recommendations. We know that because of the fact that the two are not aligned. Many systems have gone to the effort of manually

building decision support artifacts to support every individual quality measure, and they've done that at great expense in many cases.

So our goal is actually to allow quality measurement to be sort of a byproduct of decision support that we take evidence-based medicine, use the patient's own data, provide timely feedback to the provider to enable them to do the evidence-based action. That then there's a log sort of generated of those activities which tells you what the quality measurement performance would be. I think that's sort of an ideal world and I'm a provider and I would think that would be the way that ideally we would do it.

So in terms of the current harmonized quality improvement standards, again, current's sort of an imminent current, we're in the process of publishing a big portion of this content now. So when we first talked about how we would achieve the goal of shared standards between quality measurement and decision support, it was felt that the best approach would be to modularize the standards, look at where the content was the same and unite it. Look at where the content differed and bring the missing pieces in and then where the content differed and was overlapping, to sort of adjudicate the differences and to harmonize them.

So we've done that in three layers; a metadata layer, a data model standard and an expression language standard. So the clinical quality metadata conceptual model that actually has already been published in February of this year; I won't take credit for it as part of the Tacoma Contract, I think it was more of a community led activity. A total of 18 different standards metadata requirements were consulted to come up with a single standard that could be used across all of them and it includes all of the standards in the box on the right, which as you can see, are widely implemented in systems and widely used in programs, such as the QRDA and CDA.

So this is already out, so I think we've made a major step forward in terms of getting to that future state of harmonized standards. The next piece is the clinical quality language. The DSTU was balloted in the January 2015 cycle. It builds on the functional requirements defined already in the two existing standards. So leverages additional computability that was existing in the clinical decision support standards; it also leverages the focus on measure author understanding or sort of a human understandable component to the standard. And the focus on that is going to be important in helping people to actually create artifacts that conform to the standard correctly.

So here I have to two examples again. I should mention that we have seven ongoing pilots as part of this work. One of them is this one, chlamydia screening and our goal is to pilot in cycles, so as we make each a stepwise improvement to standards, that we re-pilot using the newer standard to demonstrate success. This chlamydia screening is already moving into its second phase. I'll also mention, we do have a radiology appropriateness of use pilot with ACR.

So you can see on the first slide CQM and the second slide CDS, they're almost virtually identical sort of format and content between the CDS and the CQM the matches it. And this reflects sort of a really nice achievement of the goals that we had set out for, to have the two things dovetail very nicely. And at HL7, the clinical quality language was described as both simple and elegant, it's because the way that it's set up is that it has the very sort of author friendly, consistent kind of language that faces the user. And then that has a one-to-one representation in a machine-readable ELM. And then that ELM is relatively easily translated to any one of a number of a different languages and that facilitates, I think, for the interoperability that we're looking to achieve in this space.

So in terms of what our next steps are for the harmonized quality improvement standards, and I apologize for the dimness of this slide, I think that happened when I blew it up. Currently we have the HQMF R2.1, which incorporates the newest QSM logic and data models. Our proposal, and this decision was made in an HL7 workgroup discussion, one of you was present at that discussion; was to move as an incremental step to replacing the QDM logic with the CQL logic that we just discussed.

A lot of the reasoning for that was the thought that making a huge, 100% shift in all of the standards could be potentially disruptive to the field, that it would give people the opportunity to have more incremental implementation, would give us the opportunity to do more testing. And also importantly, since our data model is FHIR-based, it allows us to move forward without having to worry about sort of shifting sand as the FHIR core is solidified.

It also allows us to continue to use the QDM data model, which means that no significant changes to QRDA need to be made to allow us to continue to use the current measure reporting architecture at CMS. And the cons are that it does delay a little bit that full integration of the two quality measurement decision support pieces; but I think some external factors would have limited that anyway.

So this is the final step proposed, sort of the outcome we're seeking in terms of our standards work. We'd like to move from this intermediate step with the CQL to actually a FHIR-base structure that uses the QUICK data model. So QUICK was originally thought of as the data model that would result from bringing together the quality data model in the VMR. Intentionally they had decided to make a UML-based logical model. That sort of aligned a little bit better with the previous RIM versions of the data models used. And the plan was to actually map back to FHIR. So in the stack I have on the right hand of the slide, sort of starting at the top and moving downward.

When we first brought that to the HL7 community and the FHIR community, they pressed us to sort of reverse that, to instead start with FHIR to try and push as much of the quality FHIR content into the FHIR core to then generate the quality FHIR Profiles built off of that core and then to auto generate the QUICK model from those profiles. So hearing that feedback from the community, we reversed course and opted to take the approach, that's the approach we're currently working on. And so QUICK is separate from the quality FHIR profiles again, because it's the data model that's generated from the FHIR profile. And the plan for that is a ballot in 2015, and we're looking towards the May ballot cycle if possible.

So there was one more sort of monkey wrench that was thrown in the whole works which was realization that there's a really high percentage of overlapping content across quality improvement and some of the other ongoing initiatives and work inside S&I and outside. Starting in May or June of last year we started an S&I coordination effort to see the all the initiatives were converging on the same point rather than diverging and there was a realization that the Data Access Framework, Clinical Quality Framework had a great deal in common in terms of their FHIR profile.

We continued to actually reach out to other models in the community and discussed this in the HSPC team and found that they were interested in collaborating with us to try and harmonize, bring together as much of the common content as possible. And therefore our approach is that we've created sort of some core profiles that are shared across all three use cases and then, for each use case, you can further constrain and/or extend the content in the core. And that...we'll skip ahead real quick...so that's displayed here.

One thing I wanted to point out is that these three initiatives actually have relatively different scopes. Data Access Framework focuses on meaningful use data, it focuses on queries, it focuses on the US realm whereas the CIMI initiative and HSPC focus more on international realm content, it includes a much broader scope including information that's not fully clinical, like administrative data. And yet those three different groups are able to come to some agreement on basic content with, such as an observation profile or a patient profile.

I think it's the ultimate goal that over time that core will continue to grow and we can pull additional data models in so that where content is common or similar, you can reference only a single source. And I think that as the core becomes a stronger and better demonstrated, there's a real argument for pulling the QI core into the core of FHIR. So I'd like to thank you all for listening. I hope that you have questions and feedback for me. Up here I'd just like to thank again the HL7 sponsors who worked with us, CMS who wasn't able to be here and all of the people who have worked very hard on the S&I Framework initiative.

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

Great. Well thanks so much, very well done. And because I know David you may have put your card first, but Floyd has to go first because he is the quality maven in the group.

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

Actually, I had mine up before she started to talk, so I could get on early.

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

So this the downside of the glaucoma, it's a peripheral vision thing?

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

Actually thank you, Julia, I think that was a really nice description of how all of this is moving to fit things together and expresses some of the discussion this morning that Stan and Arien talked about, the future for how the S&I Framework and HL7 can work together in a better way. And I think that kind of was partially informed by some of the fits and starts that occurred in this initiative. But I think it's come out very nicely.

A couple of things that I do question and you didn't mention where VSAC comes in here, the NLM Value Set Authority Center, to help coordinate across value sets that are used. And one of the issues when you looked at slide 15, your example of what is...how do you determine sexually active. And I don't want to get into how that was decided, but other folks would decide it in a different way. So, if there were a method to understand metadata about the phrase, not just the value set, to know the intent, the exclusion and inclusion, they'd be more easily interchanged, and I think that's important to address.

I agree that JIRA is a nice place to share and capture information, it's very challenging to navigate, search and figure out how to put something in and whether you actually got an answer. So it needs a bit of work to...but, it's a good approach to try to get there.

I also think to get Bonnie to do what you're suggesting needs some conventions as well, to be able to use those cases as samples to import, just something as simple as a naming convention is really

interest...important on the samples you put in. So that's basically what I wanted to address and it's been very nice working from the HL7 committee with the group as well. Thank you.

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

Thank you. David? And then Leslie are you...is your card up?

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

A couple of observations and they're going to come off sounding negative, so first let me thank you for the hard work to summarize an incredibly complex space and a set of readable slides. That's not easy to do. And second, is...even with my reservations and criticisms, I think this is really important work to be able to develop the ability to unambiguously declare what some of these measures mean in a way that two different groups of people who are experts would understand and agree exactly what you mean when you clarify that.

That said, I'm not sure that all of that complexity and clarity is going to translate very well to something that vendors will be able or interested to do something with. And I say that based little bit on the phylogeny of the standards efforts that led to where you are today, most of which were never deployed at any wide scale, a couple of pilots basically, DSS, VMR; I mean, I'm aware of one or two limited pilots and that's it.

So the fact that you're basing it on existing standards doesn't mean very much if those standards didn't work. And by didn't work means didn't get uptake, which is not to say that they were bad standards, but they didn't get uptake so they haven't been tested. So and a number of the key drivers of this project are the people who put those standards together, which again means they know the field really well, but they don't have necessarily a track record of success with deployment in real-world settings. So that's number one, that the phylogeny raises concerns.

Number two, the notion of...that CDS and CQM are essentially two sides of the same coin; CDS in the sense of, this is something the physician needs to be aware of and take into account, I would agree. CDS in the sense that this is a rule that needs to run in the EHR and put a pop-up in front of the physician, I would strongly disagree. So physicians are going to achieve quality output by whatever means they can and the degree that the vendors help them with their products, we will go as far as we can out of our way not to do it with rules that fire alerts in front of their face to remind them of quality measures, because they hate that.

So it's tempting to see CDS meaning that and if you look at these things in their written-like rules, then that's what I'm thinking that you're thinking that you mean, in which case I am getting concerned because we're not going to put those in as rules that go in FHIR. Something like an order set, for example, that constrains your choices to wise choices is a much better way to influence the physician's proclivity, choose something bad, is don't give them that choice upfront, rather than letting him pick it and then putting up an alert that fired by one of these rules that said, you shouldn't have picked that because it's not the best choice. So just, I get nervous about the notion that CDS is, in fact, the other side of the quality output. I think it's an important consideration.

And then third, the learnings from the Health eDecision work and I think any of these other efforts that have tried to encode complex clinical knowledge is that it's much, much easier to send the data to the knowledge than it is to send the knowledge to the data. So it's much more likely for a remote decision support service to be able to say, here are the data elements I need to make this decision than it is to

say, here's this incredibly complex rule language, yet another one that we've invented last week and some...I mean, we have dozens of these now in HL7, balloted ruling coding languages that have never been used, and not dozens, but we have at least three that I can name. So it just doesn't work to push the rules down into the vendor's products. It's going to make much more sense to push the data to someplace that then can execute the rules in whatever language they prefer.

So producing drools or SQL or JavaScript is, to my mind, sort of a, who cares and why would you do that? Because it won't work in our system and it won't work in any other vendor's systems, because it's the curly brace problem all over again; all the other things that will be impedance mismatches, even if you kick out a bunch of drools, and we have a drools engine, it's probably not going to work.

So, the data, on the other hand, we can agree on what those are over time, some of these profiled FHIR resources will get us there. CIMI, if it catches on and we get finally some uptake around agreement on more complex information models, once we get past meds and allergies and problems, then that has a chance of catching on and being useful. Push that data into the engine and have the engine come back and say, here's your quality score for that measure.

So I just think this is one of these places where you have to be really careful about the real-world implications of what looks like an elegant model in the balloting process, but in fact, doesn't translate well to the real-world.

**Julia Skapik, MD, MPH – Medical Officer, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Sure, so if I may respond to some of your points.

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

Please.

**Julia Skapik, MD, MPH – Medical Officer, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

In terms of your first point, I maybe misspoke if I implied that we were directly sort of reusing the content from the previous CDS standards to incorporate directly into these standards. I think really the goal was to see that the functionality existed that would enable all different kinds of clinical decision support. It was felt that if you looked across all of the existing standards, there was in some enough content to actually do most of anything it could realistically think of doing in clinical decision support. I don't think it was so much that we used exactly sort of those standards or elements from those standards as much as focusing on having their comprehensive functionality.

There are some pieces of the model and the expression language which went back and forth a number of times across the community in terms of, is this approach the right approach, is this approach the right approach and I think we'll expect to see changes as we actually test CDS using the standard.

I don't think that rules are intended to be the major or only use of the standard. I think that it's our goal to create building blocks that systems could use in a multitude of ways, order sets are a good example and they are incorporated into the content in the standard. I do think there...if we can establish these kinds of standards, potentially we could allow CDS to fire at people who aren't the physician, but other members of the care team or even the patient and to incorporate data from other sources. But until we

have sort of a well thought out and demonstrated sort of way of representing the information, it's going to be really impossible for us to reach farther out to bring in new data.

And then again, to your point about sending knowledge to data, I fully understand and CMS and ONC have not committed to actually investing in the creation of CDS tools. It's actually our goal to enable the community to participate in that effort, that they would be able to allow CDS to specify anything they need for their local purpose. And as part of the work moving forward we anticipate creating both an editing environment and a testing environment to enable community members to do that. But we haven't actually seen a sort of pathway the creation of federally sponsored CDS.

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

I understand and I would assume that the private market would in fact take the definitions and then find ways to make a business around running that. My concern is more that if you look at the Health eDecisions use case, we're on a kind of what, this ECA notion, which is an abstract syntax tree that represented decision logic. And the assumption was the vendors would build engines that could execute ECA. And you could have, and I think one vendor actually did, although the ECA was based on that vendor's existing product, so they had kind of a head start and I'm not sure that was a real test of anything, but it hasn't gone anywhere because it didn't address the myriad other things that determine how CDS works in a vendor setting.

The rule if then else logic is usually the trivial part. It's...the rest of it is all of the complexity of the triggers and where in the workflow and to whom is it delivered and when and how and what happens if it's overwritten and all of those things.

So you look at these things that are encoded in what looks computer readable declarations and the assumption, if you're not careful is, oh, the vendors are going to suck that in and run it and I'm saying, probably not. And so if writing it in computer pseudo-code is the best way to capture the exact meaning of the measure, then that's a good idea, although well...precise English might be just as effective as something with...at least you got rid of the XML, so that's a step in the right direction. You can read it a lot easier as something that's pseudo-JavaScript. But...so, be precise in the definition but be careful to not just jump to the assumption that the precision actually makes it machine executable in a vendor setting, because of probably won't be.

**Julia Skapik, MD, MPH – Medical Officer, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Sure.

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

Well thanks very much for that. I know Jon White had a brief comment and we're running a little bit behind schedule now, we do want to do public comment. But...so Jon White and then Leslie and then Stan, you finish us up.

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

Okay, I'll just try to be quick. So generally speaking, David, appreciate the thoughtful comments. You and I have talked about this many times, so, not new. What I would say is that I think that, and I hate to get less practical than this committee is very good at being, but I am going to be just for a second, which is

that there is a lot of interest and sometimes pressure to move knowledge into practice using our information systems.

I'm open...very open in the ways in which we do that and I'm happy, I actually really looking forward to engaging, because basically at the end of the day, I want the knowledge in the hands of the clinicians who are not sure what to do in a given situation. I mean, I want it in the hands of the patients that are visiting those clinicians and trying to make those decisions with those clinicians. All right, so I'll get back out of the clouds for second, but that's kind of generally where we want to go.

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

...what we were talking about with this orchestration proposed around remote decision support with option of user interaction was an attempt to get at that exact problem in a way that decouples the dependence on the vendor and the knowledge maintainer and the executor so that you agree on a fairly lightweight, well-defined handshake between those two worlds so they can iterate on their own without complex interdependencies. And we're likely to get there faster and hopefully it's still usable, I mean, it has to be proven. Don't have a proof point yet.

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

...way to put it.

**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 an example of simple and used millions and millions and millions of times in a very short period of time has been the InfoButton standard. And although it's URL based and not scalable as we'd like it to be, converting it into a FHIR type of a structure can be very, very helpful and informative. And NLM has...is up past I think 6 million use cases in less than a year. We're a little non-profit, we're over a million and a half; implementation is less than a week. So it's not trivial.

And it also incorporates the idea that patients can participate in clinical decision support or shared decision-making. So let's not make it so complex that all the stakeholders are removed. In addition, beyond the use cases in real world decision-making, the quality reporting patient reported outcomes data will be very, very important. And in the early work in Health eDecision, the patient was considered one of the stakeholders, but the use cases have gravitated towards all provider use cases. I think that's a mistake and as we work more on value-based care, the patient will be more active in participating in decision-making, although probably not in the ICU and probably not in very complex clinical cases, certainly decisions that relate to cost and quality like referrals, imaging where a third of the cost for CMS take place, have a significant applicability to patients involved in decision-making. So please expand those, please also look at simple; it can be good.

**Julia Skapik, MD, MPH – Medical Officer, Office of Standards and Technology – 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 to give you hope, the Moore Foundation has funded Hopkins, UCSF and Beth Israel Deaconess to do ICU-based family decision support, so...

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

Really?

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

Exactly, it's coming.

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

I want to know more about that.

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

Stan.

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

So first of all, just I applaud the effort to try and bring groups together and end up with a single solution and so, that's great. And I guess I would create a little different picture than...and I don't know that this is all shared or understood, but the heart of all this, or maybe the first step, not the end of where we want to get to, is having a way to unambiguously and very explicitly reference data that participates in the rules and that's what I see is a real valuable part of what people are working on here.

And then the thing that I think is still sort of an unproven hypothesis is whether we can share knowledge in some representation that you can then interpret into other languages. The more important thing that and the way I saw this moving forward David was not that actually, but that because of the work that you guys were talking about, I see this evolving to where these explicit profiles, and especially the FHIR profiles that result from this, are then the basis for the standard APIs for accessing data and it enables what you said that you can have the logic executing in the cloud and for now you ignore how...if that's a black box, if I'm consuming it, the thing does what I want it to do, and I don't care. And over the next 10 years, people will do it different ways and then we'll have a real basis from which to try and standardize or figure out how to share between the drools representations and an Arden representation or some something else.

And so I see this as a very important first step in becoming explicit about data representation which then enables all of these other steps. In some cases they're just experiments, but I really like the fact that we could get value out of it as executable forms without worrying about the logic representation so much as the first step.

**Julia Skapik, MD, MPH – Medical Officer, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology**

Thank you Stan.

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

I mean I certainly agree with that, I think the gaining factor in the long run is going to be what is the clinician capturing in a structured fashion that's necessary to drive these algorithms. And since we don't have an agreement on what that is, we have to all go to these very complicated lengths to try to guess that this is the disease that was present or whatever. So the degree to which we can get modeling approved for information models approved by medical societies in the specialties that are affected by these measures, so that they're members would agree, this what we all have to grunt and groan and mumble and growl about, but if that we don't capture it, we aren't going to get our quality measures.

Until them, all of these rules are just going to drive us all crazy. So we really ought to be focusing on the data, send it to the cloud, let the decision be made based on the best guess of whatever rule it is this week, because it could change. And decouple those two worlds, but get that data settled because right now we're...look at the definitions in here of, that example in there, does the patient have syphilis? Well, how do you determine that? Right now there are a lot of different ways that you could infer that and the rule doesn't say anything about that. And when was it and is it old or secondary, or tertiary or primary or active or just an RPR that's elevated...

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

Is this personal experience or...

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

...or what do you mean?

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

Well with that, Michelle I know we wanted to get to public comment. And thanks very much for a wonderful meeting so far today. I think this is going to be one of those meetings that goes down in history as a major turning point. And look forward to seeing your reactions and your organizations and press reactions and I will be fast at work on a blog about it on the flight back to Boston. I do apologize for my relative lack of coherency, because I haven't actually been in a bed list since last Thursday, so...Michelle.

**Public Comment**

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

If there's anyone in the room that would like to make a public comment, please come up to the table and I'll turn it to Alan to open up the lines for public commenters on the phone.

**Alan Merritt – 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.

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

While we wait for commenters on the phone, I do want to thank all of the Chairs of the workgroups that have been working so hard on the interoperability roadmap. It's been a lot of work. And I also want to echo the thanks to Arien. He has...I've seen it, because I've seen the emails. He has been working

remarkably hard for us the past few months and with great appreciation, thank you so much, Arien. And it looks like we have no public comment.

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

Well with that, I guess, has Jon left the room? So I will do the closing benediction. I will, I’m sure be chatting with all of you over the next days to weeks, as we might see some regulations, some NPRMs and other things appear. And look forward to our continued work and the alignment of those with all of the frameworks we’ve outlined today. So safe travels everybody and see you next month. Thanks.

**Public Comment Received During the Meeting**

1. Isn't this the same EH data shown last month? Where is the preliminary EP data?
2. I believe that Critical Access Hospitals may have a closer relationship with their EHR vendors. I know as an EHR vendor worked very closely with every client for many months in 2013-14 to assist them in achieving the workflow changes and processes to meet the MU2 thresholds.
3. Despite their weaknesses, eschewing OWL and RDF could put ONC on a potential rabbit hole of creating an alternative technology and associated standards to support HIT while the mainstream of Big Data (think Apache stack) is moving ahead with existing ontology tooling
4. The architecture group's roadmap for composable design patterns is attractive. That said, it would be useful to review the history behind composable services work in DoD, which faced a similar uphill adoption battle due to legacy systems interop, developer mindset, weakness of software engineering models and many other challenges not wholly dissimilar to those faced in HIT > 1 decade later. (A RAND report suggested the composable approach in 2003). Most existing IT systems lack flexible, pluggable, web-enabled workflow, which is a core component for composable systems,. The lack of workflow stds is partly due to a coherent agreed-upon version of the models associated with domain-specific systems. Health care applications face similar challenges.

Meeting Attendance							
Name	03/18/15	01/27/15	12/10/14	11/18/14	10/15/14	09/10/14	08/20/14
Andrew Wiesenthal	X	X	X				X
Anne Castro	X	X	X	X		X	
Anne LeMaistre	X	X	X	X			X
Arien Malec	X	X	X	X		X	X
C. Martin Harris	X	X	X	X		X	
Charles H. Romine	X	X					
Christopher Ross	X	X				X	X
David McCallie, Jr.	X	X	X	X		X	X
Dixie B. Baker	X	X	X	X		X	X
Elizabeth Johnson	X	X	X	X		X	X
Eric Rose	X	X	X	X		X	X
Floyd Eisenberg	X	X	X	X			

James Ferguson	X	X	X			X	X
Jeremy Delinsky	X	X		X			
John Halamka	X	X	X	X		X	X
John F. Derr	X	X	X	X		X	X
Jon White	X	X	X				
Jonathan B. Perlin	X						X
Keith J. Figlioli	X		X			X	
Kim Nolen	X	X	X	X		X	X
Leslie Kelly Hall	X	X	X	X		X	X
Lisa Gallagher	X	X	X	X		X	X
Lorraine Doo	X	X	X	X		X	X
Nancy J. Orvis	X	X				X	
Rebecca D. Kush		X		X		X	X
Sharon F. Terry						X	X
Stanley M. Huff	X	X	X	X		X	X
Steve Brown			X			X	
Wes Rishel	X	X	X	X			X
<b>Total Attendees</b>	<b>26</b>	<b>25</b>	<b>22</b>	<b>20</b>	<b>1</b>	<b>22</b>	<b>21</b>