



**HIT Policy Committee
Implementation, Usability & Safety Workgroup
Transcript
December 12, 2014**

Presentation

Operator

All lines are now bridged with the public.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Good afternoon this is Kimberly Wilson with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Health IT Implementation, Usability and Safety Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Please also keep your line muted if you are not speaking. I will now take roll. Larry Wolf?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

David Bates?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, David. Alisa Ray? Bennett Lauber?

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

I'm here, can you hear me? I'm using a Bluetooth speaker.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Yes, we can hear you, thank you.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Okay, great, thank you.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Bernadette Capili?

Bernadette Capili, DNSc, NP-C, MS – Assistant Professor, Associate Director, Division of Special Studies in Symptom Management – New York University

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Bernadette.

Bernadette Capili, DNSc, NP-C, MS – Assistant Professor, Associate Director, Division of Special Studies in Symptom Management – New York University

Hi.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

George Hernandez?

George Hernandez – Chief of Applications and Development – ICLOPS

George Hernandez here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, George. Janey Barnes? Joan Ash?

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Joan. John Berneike?

John A. Berneike, MD – Clinical Director & Family Physician, St. Mark's Family Medicine – Utah HealthCare Institute

Yes, I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, John. Michele McGlynn?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Michele. Michelle Dougherty?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Michelle. Mike Lardieri?

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yes, I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Mike.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Hi.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Robert Jarrin?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

I am here, unfortunately I'm going to have to drop off at some point and then call back in, but I'll be on the call.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Thank you. Steven Stack?

Steven J. Stack, MD – President – American Medical Association

I'm here, I think someone needs to mute their speaker in the background.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Yes, we are getting some background. Tejal Gandhi?

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Thank you, hi, Tejal. Terry Fairbanks? Betty Mims Johnson? Edwin Lomotan?

Edwin A. Lomotan , MD, FAAP – Pediatrician & Informatician – Health Resource Services Administration

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Edwin. Jeanie Scott? Lana Lowry?

Lana Lowry, PhD – Project Lead Usability and Human Factors for Health Information Technology – National Institute of Standards & Technology

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hello. Megan Sawchuk? And from ONC do we have Ellen Makar?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

I'm here.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Ellen, is there anyone else from ONC on the line?

Andrew Gettinger, MD – Clinical Informaticist – Office of the National Coordinator for Health Information Technology

This is Andy Gettinger.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Hi, Andy.

Kathy Kenyon, JD, MA – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Kathy Kenyon.

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Good afternoon. And with that I'll turn it back to you Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, thanks, and welcome everybody. I've been enjoying the pleasure of some time off so it's good to be back with a little bit of a sense of refresh and perspective and it looks like we have a very full day. So, I'm actually going to let David introduce our particular agenda and then I'll come back with some comments about future stuff.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Great, thank you Larry, could we go forward one slide and one more slide? So, today, you know, what we're going to be doing is be hearing about risk management and shared responsibility and then the HIT Safety Center Roadmap update.

I think most people probably heard ONC just released and updated strategic plan so that's a little light reading for over the holidays. And we also expect to have an NPRM to respond to by the end of quarter one of 2015.

In our January Workgroup meeting we're going to talk also about risk management and shared responsibility, we'll be talking about that some more and be going into that in some more depth and we're working on figuring out exactly who we'll have come speak with us in the January meeting.

So, that's a short summary of where things are. Ellen, do you want to say anything about the strategic plan in particular?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Just that, as you said, it's out there and we encourage public comment on the strategic plan and I think that folks will enjoy reading it, it's a good outline and there are links to it on our Buzz Blog on our ONC website.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Great.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

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David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Okay, Larry, other thoughts?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, so extending into looking at January, in the regulations there are actually two criteria that address safety. We spent some time talking about user centered design. There is a second one that looks at the quality management systems and this is specifically looking at the development process within the vendors environment where they're creating the EHRs and what they're doing to build quality in, if you will, to the product that they're creating and the current requirement is simply that they provide information about what they're doing and what they're doing could be nothing or what they're doing could be, here's the process we follow to provide quality software when we're done.

So, we want to review that, what has been done, what are the vendors saying as they take their products through certification. And also what standards are out there such as ISO 9001 that are intended to address quality development as it relates to healthcare software. And where are there other models it's sort of near cousins to that if you will. So, for example, the work done on CMMI, the capability maturity model and the institute that supported that out of Carnegie Mellon going back probably 20 years now.

So, what have we learned from that process what are the various ways in which people build quality into software and as we look forward to new Notice of Proposed Rulemaking coming from ONC and CMS sometime in Q1 perhaps or we don't when, but sometime in the not too distant future, to sort of be prepared to think about how's the current program worked and where might we be going with that.

So, those are things we have kind of in incubation seeing if we can actually have them ready for the group to discuss in January. And the reason to bring it up now is partly to solicit information from the members of the Workgroup. So if you have a strong connection to the development process and to quality assurance within that process to through e-mail and whatever other methods you'd like to get back with me and Ellen, and David about, you know, what you think we ought to consider as we go forward in this area. Anything you want to add to that David or Ellen?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

No, I'm set. So, any questions from the group? Okay, Matt, are you on?

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

I think so, can your hear me?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yes, we can, okay, good. Can we have the next slide? So, we've just been through the agenda. Next we're going to be hearing from Mary Logan and Matt Weinger from the Association for the Advancement of Medical and Instrumentation, and then after they finish up we'll be hearing about the HIT Safety Center Roadmap update, so now over to you Mary and Matt.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Thanks very much David. I'm going to...I'm Mary Logan, President and CEO of AAMI and I'm going to start with just a little bit of an overview about AAMI and Matt will then go and then he'll turn it back over to me.

We have two additional subject experts who are quietly waiting in the wings in case anyone has a technical question that Matt and I are not prepared to answer, we wanted to be sure that we were able to answer every possible detailed question that anybody might have and they are Sherman Eagles, who is one of the Co-Chairs of the Working Group that developed the draft framework that includes the visual with the pillars, the columns that we'll be referring to and he is a Software Consultant, and also Joe Lewelling who is the Vice President of Standards and Emerging Technology at AAMI and a long-term AAMI employee and Standards Development Expert. So, if you could advance to slide three, please.

There is a little bit more detail then I'm going to go through about AAMI and primarily that was because I wanted to be sure people who didn't really know who we are would get a little more context if they wanted it, but I think the most important thing is to get moving into this. So, if you could advance to the next slide, please?

I want to talk about what makes AAMI unique because I think that provides that best context for why we're here. AAMI is primarily known in the healthcare community as a standards development organization. We do a lot of other things but our core expertise is developing standards and that's really important because anybody can say they develop standards but it takes a special kind of expertise to develop consensus-based standards using a multidisciplinary approach where groups themselves decide what gets move through the process and we have deep, deep expertise in doing this work both in the United States and internationally.

And we're best known for our neutrality which also makes us unique, especially in the Washington, DC community, we don't take positions, we don't have any advocacy role and occasionally we will file comments in response to invitations to file public comments but there is a common theme through everything we do, it's either all about standards or all about patient safety.

And our tag line is, advancing safety in medical technology. So, that, if you don't remember anything else today about AAMI that's what I hope you'll remember. And if you could advance to the next slide, please.

Different people know, and sorry, go to the next one, different people know AAMI for different things and this isn't directly relevant to HIT safety but I wanted to mention this because I think it shows both the breadth and the depth of AAMI standards. A few months ago we were known as the expert on anything to do with sterilization or disinfection around Ebola and if you Google Level 4 Ebola gowns they're also known as AAMI Level 4 gowns because we have the standards for those gowns and also a lot of other standards that were called upon during the Ebola scare in the United States.

And folks who work in the OR and folks who do central sterile processing know us for the standards for sterilization of equipment. In Terry Fairbanks world of human factors we're known for our human factors standards and standards in our deep expertise with human factors which is also one of Dr. Matt Weinger's expertise.

In the dialysis community we're known for our standards on water quality and then with electromedical equipment we're known for a lot of different things. And since you mentioned quality systems earlier I'll just mention we have a very robust quality system standard and we teach it in a five day course and Sherman Eagles if there are questions about that later or in January, Sherman Eagles is the expert on the development of new work that we're doing on quality systems for software in particular. I know that's not the subject today but since it came up earlier I wanted to mention it. Skip to the next slide please and then one more.

So, why are we here today? We're here to propose an AAMI managed consensus-based process for a risk management standard or suite of standards for Health IT. And we want to show by the end of this presentation why it's needed and to illustrate what we think will be different in the future state if we have robust standards in place and then to talk a little bit about how to make that happen. And I'll turn...next slide and I'll turn it over to Matt from here.

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

It helps to unmute, thank you, Mary. I have a cold so forgive the changed voice. As you can see from the figure on this slide healthcare is a very complex non-standardized system that evolved organically over many, many years much of what we do is legacy and as new requirements develop they are, for the most part, bolted onto the existing system resulting in a healthcare system that is, at best, modestly reliable and certainly unsafe.

When we talk about HIT you could say the same thing, we have a very complex non-standardized system that evolved organically over many years that largely its legacy platforms each new feature is bolted on wherever and however it fits and these systems have issues with both safety and reliability. Can I have the next slide, please?

In contrast complex engineered systems are mostly quite reliable and if you think about bridges and boats, and processing plants we've had a hundred or hundreds of years to develop those systems. In contrast digital technology is relatively new which as an aside is why nuclear power is struggling to integrate digital technology in their legacy systems because the reliability simply isn't there yet. And so, can I get the next slide?

Across many industries it's recognized that healthcare or I'm sorry that software remains a lower reliability type of technology and that requires extra effort to get the reliability out of it that one needs and so across most industries, this is actually a quote from the esteemed Dutch Computer Scientist, Edsger Dijkstra, that "humans are not able to design and deploy complex software systems that are on time, within budget, meet specified requirements, satisfy their users and are reliable, maintainable and safe." Now he is talking about all software systems.

As we begin to talk about HIT, unlike consumer or business IT systems for example, these systems are overlaid onto very messy systems of diverse people processes, technology, governance and culture, and so the failures are particularly problematic perhaps for no better reason than people can be harmed. Next slide, please.

So, there was a 2007 National Academy of Science report, software with dependable systems and they stated that in contrast to our current approach to HIT that software systems should be considered guilty until proven innocent, that it should be the responsibility of the vendor to prove that software is reasonably safe and I would go further and say that self-governance by individual vendors has been shown repeatedly over all of human history to be insufficiently robust and reliable to assure general public safety.

In contrast, for example, nuclear power has a model of collective industry safety regulation through what's called the Institute of Nuclear Power Operations. And a consensus risk management approach is one way to develop a collective approach to safety and reliability. Next slide, please.

With regard to Health IT as I stated earlier the work that it's expected support is highly complex and context dependent and the figure you see here is from a paper that Kim Unertl, one of my former students is now on the faculty at Vanderbilt, and I, and others published looking at information flow in a clinic and you can see that it's very non-linear and that this results in quite a few issues when you're trying to design software that's reliable and safe.

And I'd refer you to our JAMIA 2011 paper about Health Information Technology Fallacies and Sober Truth to see some of the issues there.

Something else that we're beginning to appreciate is that HIT largely relies on a lot of underlying hardware and operating systems, and other types of software that were never intended for high reliability, safety, critical uses and that introduces additional risks that need to be considered. Next slide, please.

When you talk about other high hazard industries the overall culture is different than it is currently in the Health IT industry from nuclear power to chemical process control, maritime, etcetera, safety is the top priority it supersedes efficiency and cost, but to do that and still have effective products you have to have a process to know when and where in the safety issues you invest effort and where you don't and that's where risk management comes in.

Further safety is considered throughout the product lifecycle from the initial concept of the product to end of life management such as obsolescence and that's something that is integral to a risk management process. I mentioned the industry-wide standards of practice that's something that we don't yet have in HIT and some kind of oversight as I mentioned. Next slide.

As you all have played a key role, I believe, in integrating user centered design as part of safety enhanced design and that's really important but it's insufficient. When you look at a global human factors engineering process for safety and reliability user centered design is one component of it but equally important is risk management and when you look at the medical device industry it's taken 20 to 30 years to go from where I think HIT is or has been recently to where the medical device industry is now and so this is going to be a slow incremental process but it needs to be driven by the end users, the clinicians and patients who are both the participants and victims in the products that are being produced and society needs to be the advocates for safety and reliability. Next slide, please.

Oh, I'm sorry, I just wanted to mention, if you could back one, see if you're paying attention, this user centered design cycle, I wanted to mention that with software, modern software techniques tend to use agile type processes and when someone looks at this they say "oh, that's a waterfall process you've got to design everything up front and it doesn't allow for innovation."

In fact, user centered design and human factors engineering has begun to develop effective methods to integrate agile in a user centered design process but it still requires the step one there in orange to really have a thorough understanding of what it is you're going to build before you start building something. Thank you, next slide.

Now I wanted to talk a little bit about what this risk management thing is and perhaps many of you already appreciate it so I will keep this quick. The figure on the left I developed in the last couple of weeks to try and simplify it and basically at the highest level what one does in a risk management process is identify the system level risks of your software application, determine the or estimate the degree of risk of each of those and by that I mean the probability that such an event would occur and the severity of the harm that would result, prioritize those risks, develop mitigations for the highest priority risk that are unacceptable to the company and more importantly to society, and that's where a consensus standard comes in to help one of the potential standards is, well how do you decide where the cutoff is, assess whether your mitigations are effective, if not you do some more work and if they are then there is an ongoing monitoring process to see if risks have changed, if your assumptions are correct, if new risks have developed.

One of the core standards across all industries is ISO 31000, which is called risk management, and there is a series of sub-standards and perhaps the most important thing in that document is that the risk management process needs to be structured and systematic, and equivalently rigorous to other engineering processes. So, just like one would use rigorous, established best practice processes for designing your database that you're putting your data into you would do the same for you user interface and for the risk management process, and you can look at the rest of these later. Next slide.

So, starting to wrap up my part, no other hazardous industry deploys safety critical software without a formal risk management process. HIT risk, as I'm talking about it, is not just the risk to the direct user of their interactions with the user interface which is what we're mostly talking about here, but a risk management process includes risk associated with data integrity, cyber security, etcetera and there are already standards in place for security and privacy risks of health software and I suspect that most, if not all, companies already do that.

So, an important point that risk management is not going to be a new thing to them. Applying it to the user and the user interface and how their software interacts with the rest of the healthcare system that maybe will be new.

So, what we recommend from AAMI is an evidenced-based approach to developing and implementing a standardized risk management process for HIT safety. Next slide, please.

And as I said, there are many other standards in place and so this will not require starting from scratch, there is much that one can learn from other industries both their standards and their practices. And I want to point out the figure here, since it highlights a generic approach to one of the steps I mentioned earlier, is once you've identified the risks you try and use evidence in the world, both from your specific product and from the literature and other companies which is a reason to have a more open and transparent reporting of HIT risks, to estimate the probability of an event occurring of a risk and the severity of harm and you lay those out on a grid and then you identify those that are most critical and most common to address through various mitigations. Next slide.

So, what's missing at this time, as you all know a variety of entities have been advocating greater learning from HIT-related events, the FDA has begun to look at high risk software and how do we best assure safety. The ONC has begun to promulgate best practices and safety enhanced design and what we believe is critical is to begin to invoke a standardized and comprehensive risk management process for safety and reliability and that a consensus standard approach is the best way to do that and by the way, as a parting shot, what we're proposing is highly aligned with the objective 1B of the just released Federal Health IT Strategic Plan. And with that I will turn things back over to the Mary to describe our initial visions of how this might play out.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Thanks, Matt. Before you advance to the next slide could you go back to slide 18, please? I want to make one comment about the lifecycle. One of the things that I've heard a lot of discussion about from both the vendor community and the provider community is how difficult it is right now in the current state to learn from adverse incidents and from near misses, and from just bad things that happen that don't hurt anyone but they could and you don't want it to happen again.

And so the one thing about a standardized and structured, and systematic risk management process is you do learn as Matt said from what happens in the field and it's a continuous loop. So, when things happen in the, what we would call, post market, when something is out and being used and something happens in the field that information almost always gets back to the vendor and then it makes its way back into the standardized development process.

And I have two really simple examples from another space that AAMI is very familiar with, one, cardiac implantable devices, those are high risk, they're not in this lower risk space, cardiac leads for implantable devices have had a lot of problems.

And so the manufacturers of the cardiac implantable devices in the United States are working through an AAMI Standards Committee to develop better test methods for cardiac leads so that they can improve the design of the leads, that's risk management, that's information that came from feedback from the field and it's a continuous...what they do in the AAMI Committee will get fed back into the design and development process and so it goes, it keeps going.

All right, you can go back now to slide 22, please. This diagram and the one that is more detailed that we'll get to next came from international standards world from ISO/TC 215 and a joint working group with an IEC working group and I'll spare you all the jargon there, but it's an international working group and the big ISO/TC 215 is managed by AHIMA.

There is a working group in 215 that is managed by AAMI and Sherman Eagles, who is on the phone as a technical expert with us, is one of the co-chairs of that committee and it's in that committee that this proposed framework for health software and Health IT safety system standards or risk management standard came from and it was proposed to be developed in the international community, and there will be international work done out of this committee based on this framework regardless of what happens in the United States.

And you'll hear me say, in a few minutes, that what we're proposing is to start what we would call a parallel process that is US centric with this as a starting point but just as a starting point, because we won't know until we get into it what the needs are of the providers and the vendors in the United States. Next slide, please.

This is a more detailed visual and by the way both of these came from the pre-reading packet that we gave you as one of the attachments to the summary of what we were going to be presenting today. This is the draft framework which I also call a roadmap for what's needed with risk management standards.

And one of the other background materials that we gave you to read, actually two, were two articles about the 80001 standards. So, I want to just mention while we're right here, why we gave you those to read. The committee that developed the 80001 standards in the international community is the committee that came up with this framework right here.

And they started with the 80001 work several years ago because at that time the greatest need was for IT networks that connect with medical devices, it was happening and the vendor community could see that they were going to be huge questions and huge problems initially around roles and responsibilities because traditionally when technology lands at a hospital a box is opened up, sometimes there is training, it gets connected, people start using it and that's the end of it.

Where you start connecting anything to an IT network the roles and responsibilities become much more complex and they don't just belong to the vendor, they don't just belong to the healthcare delivery organization. There are some shared responsibilities and some different responsibilities. So, the very first standards that were developed in the 80001 group were all around addressing roles and responsibilities.

So, I think it's worth mentioning that in part because that's the committee that came up with this framework and in part to illustrate the work that has already been done in a simpler space but an evolving space, a related space and that committee has now seen that it isn't enough to address risk management for IT networks connected to medical devices a much more robust Health IT specific set of risk management standards are needed in part because the roles and responsibilities are even more complex than they were with IT networks connected to medical devices, and in part because it's so much more complex, and in part because you have so many more players involved in the process, and this particular slide illustrates all the different aspects that really need to be addressed in risk management standards. Next slide.

I think Matt really has done a great job of answering why standardizing the risk management process from looking at it from the perspective of what isn't working, but from a non-technical perspective and I'm not a provider I sit in the space between the vendor community and the provider community and so I think from a provider community one vendor at a time just doesn't work.

From a vendor community perspective one hospital at a time doesn't work, there are too many moving targets and we need a systems approach to complex, these are very complex sociotechnical challenges and right now we're not approaching this from a systems perspective. Next slide, please.

So, what are the implications if we don't standardize a risk management process? I think HIT progress will be like this illustration of dream airplanes where HIT continues to be viewed and designed, developed, implemented and used from the perspective of whoever's shoes you're in at that particular moment in this case it's an airplane with a fuselage group, the electrical group, etcetera. The same exact illustration could be made if I was more talented and creative I would have made it to illustrate but you get the idea.

Healthcare will not be safer from HIT it has great potential to be safer from HIT it won't be unless we standardize these processes. There will be big adverse events. One of the things about healthcare that's unique to other high reliability industries is accidents tend to happen one person at a time. HIT introduces, I think, for the first time in a real way the strong likelihood that there will be big adverse incidents involving multiple people because of all the connectivity. The cost will be higher, the finger pointing will continue and we won't learn from each other or from our mistakes. Next slide, please.

As I mentioned earlier, I have come to believe, very strongly, that this work needs to start in the United States and it has started internationally but I think that parallel work needs to begin in the US because the work in the international community is too far along with people who are really comfortable with the ISO standards development process, they use the jargon, they know the rules, they've been at the table together for a long time, it's very hard for new comers to just walk into that kind of a setting and feel comfortable that they're contributing, that they're being heard, that they understand what's happening.

And the meetings are all over the world and we're not going to get providers, especially, unless the meetings are in really nice places, we're not going to get the provider community to commit to participating in a standards development process that moves around all over the world. And we have some very large EHR vendors and component vendors and related implementation vendors, and providers that are US centric and we need to start there to make sure that we address the needs that are right now in the United States.

And then long-term it needs to integrate back with international efforts. AAMI has a lot of experience and expertise doing parallel work this way and we're confident in saying, it can be done, it should be done this way and we think we're the right organization to do it.

The way that our process works we're an ANSI accredited standards development organization and our rules provide that we have one vendor and one what we call the user or provider as co-chairs and committee membership balance so that you get diversity of perspectives and all of the stakeholders in the entire risk management cycle sitting together talking about what's needed to be done, what should come first, what are the greatest needs and then you build from there.

One big question, at the bottom of this slide that still looms and will continue to loom after today is what will get the vendors to the table. Next slide, please.

How to get started, there is a lot of process work that AAMI has to do, it's submitting paperwork to ANSI and internally getting things ready to go, but the first real step is forming a committee, getting the right people who have the right expertise and the will and the interest to participate.

AAMI is a non-profit organization and the way that we fund our break even standards development budget is that our rules provide that industry pays AAMI participation or membership fees and that allows us not to charge providers and we can also provide some travel support for providers whose organizations do not have travel budgets in this day and age for them to travel. That's our process and we would not be able to do this work unless we had the money to do it, because this is a huge project and we don't start big standards development unless we have the support of those who would have to pay to participate in order to make it happen.

The last really important point about getting started is a lot of people have asked me, well how long would this take and what would be the work plan and who would do the work, and what would be the agenda, and all kinds of detailed questions like that which are really important but the answer is very simple, the committee develops it's work plan. This is not determined by AAMI staff, it's not determined by anyone else. Consensus-based work means the people who are in need of the work decide the work plan, the pace and what needs to come first and it's all consensus-based. Next slide, please.

And in the desired future state what we predict will happen is you will have vendors and providers working together, vendors and vendors working together also, processes will be more efficient, there are some things that healthcare delivery needs to do to standardize, there are some things that the vendor community needs to do to standardize. They need to work together to figure that out. Assuming this can all happen that would free up money for innovation both for healthcare delivery organizations and also for the vendor community. Next slide.

And I think one of the most acute things that needs to happen very soon is clarity around governance and roles and responsibilities, and it's really critical for healthcare delivery organizations to have their culture and their workflow, and their technology all aligned and for everyone in this space to come at it using a systems approach because it is so complex and the sociotechnical challenges are so large.

In the end, healthcare will be safer and a full lifecycle view will give everyone what they need in terms of learning from what's happening in the field and feeding that back into a stronger design and development process so that these products can continue to improve and grow, and have the future that everybody wants them to have. Next slide, please.

It's a little bit simple as an analogy but I think it's a fair analogy of where we've come with ATM technology. The first time I went to Europe in the early 1980s I had to take Traveler's Checks there were no ATM networks that I could find. In the 1990s my card would work in some places and not in others because the network wasn't universal yet. Now, I can go anywhere in the world and get cash out of a machine from a highly secure little mini-bank called an ATM. That's where HIT will go. I believe we will be there, but we'll never be there unless we commit to development of standardization of lots of things most importantly right now risk management. Next slide.

Some have also asked me why would AAMI want to do this and I could say to...I have said and I could say to myself every single day, I'm not sure am I really crazy for AAMI to do this. I am convinced that AAMI is the only organization in the private consensus-based standards ANSI accredited community that would be well positioned and prepared, and have the expertise to get started on this now in the United States because we already are a leader in healthcare technology oriented, consensus-based problem solving in areas of high technology or complexity, sorry.

We already know human factors, we already know quality systems. We already have risk management standards. We have the expertise to be able to do this. The federal government actually prefers private consensus-based standards to fulfill government aims over regulation and I don't really believe that the federal government does the best job of developing standards because it's very...it's not...the federal government agencies are not standards development organizations, don't have the right core competencies to be able to do that, and don't have the multidisciplinary approach that private standards development organizations accredited by ANSI have. Next slide.

AAMI is known in our community as Switzerland for working on complex problems, because we're not an advocacy organization we're trusted that we don't have an agenda or positions and people feel really comfortable working in our space which makes it easier for people that don't agree on things to sit down at the table and try to work through the challenges.

In short, this is our core competency and we're confident that we would be able to do this. Next slide is just one of my favorite quotes "the future is already here it just hasn't been evenly distributed yet." We will get there it's just going to take some time and we have to have risk management as a core standards-base to be able to do what other industries have done before us. Dr. Bates, we would be happy to take questions.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

So, thanks so much Mary and Matt that was great and, you know, this is obviously ambitious but it also I think really clearly has a lot of promise. So, let me just at this point open things up. I have a couple of questions myself which I'll ask if others do not jump in, but let's go ahead and start.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, I have a...actually a number of questions, but my first question is, if I'm understanding this and first I want to say, thank you for the presentation I learned a lot about AAMI that I did not know before.

But, if I understand this right, this is sort of like a separate private effort to reduce risk in HIT systems and that's what's being proposed and it's certainly, you know, a terrific concept, but just what is ONC's role?

I mean, it seems like the government doesn't play any role at all in this. So, my question is what is our role as an advisor to ONC in commenting on this?

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

That's a great question, we have many other examples of government participation in our standards development process, we welcome it, we invite it. We consider government to be one of the players in any kind of standards development process.

I'm on the Board of the American National Standards Institute and there are government employees also on the Board of ANSI that's part of the stakeholder group. So, we would welcome ONC's participation.

Paul Egerman – Businessman/Software Entrepreneur

But you don't need ONC to do anything at all in order for you to proceed, right?

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Well, I think getting back...

Paul Egerman – Businessman/Software Entrepreneur

In other words there is no action from the government that will either help you or prevent you from going forward.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

That's a complex question. I think the most important simple answer I could give though is my biggest question about all of this is, will the vendor community participate simply if we open the door and say, come on we're going to start this work, what will get them here. And so I think any kind of either encouragement, nudge, push, whatever from ONC it would be very, very helpful.

Paul Egerman – Businessman/Software Entrepreneur

And...

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

Can I make...can I add to that? So, the ONC for user centered design did something along these lines in that they said, you need to have a process, we're not going to specify the process but by the way there is this...there are several standards 62366, 9241 that if you comply with those than for us that's good enough, that is evidence that you have complied with our expectations. The FDA does this regularly, they say to device companies, you must have a human factors engineering process and here are the standards by which you can attest that you comply with this standard, you're welcome to do other things, but if you do we're going to have to look at you a lot more carefully because you aren't saying that you complied with this consensus standard, which all of the people in your industry participated in developing.

Paul Egerman – Businessman/Software Entrepreneur

Well, those things already exist.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Also, the...

Paul Egerman – Businessman/Software Entrepreneur

I'm just trying to understand your risk management proposal and what you're asking us to do as a result of this proposal? I'm sorry; I just don't understand what we're supposed to do in response to that.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Well in a perfect world you would be either a driver or the driver to encourage, nudge, push, cajole, whatever it would take to have the vendor community participate.

Paul Egerman – Businessman/Software Entrepreneur

And just a comment, you talk about the vendor community but a lot of software is self-developed by providers.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Yes.

Paul Egerman – Businessman/Software Entrepreneur

And a lot of software also is distributed and produced by covered entities so there really isn't a distinction, a clear distinction between the vendor community and the provider community.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

It would have to be multidisciplinary, provider community, vendor community. The only reason I'm sort of picking on the vendor community, if you will, is I think the provider community...what I think of as in healthcare delivery is frustrated enough that I think it will be easier to get them to the table, it's the vendor community that I think would need help being convinced of the importance and the need.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

Lana Lowry, PhD – Project Lead Usability and Human Factors for Health Information Technology – National Institute of Standards & Technology

This is Lana Lowry, may I please ask a question?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Sure.

Lana Lowry, PhD – Project Lead Usability and Human Factors for Health Information Technology – National Institute of Standards & Technology

I'd like to agree with Mary's statement about the federal government and I represent NIST, definitely prefer the consensus-based industry standards, no question about that. And one of things mentioned is harmonization of those standards.

But I do have a question for Matt Weinger, because Matt Weinger is our contractor for the standards development actually usability framework and unfortunately this project has been delayed for four years for many different reasons, right now we are in the data collection state, I'd like to ask Matt to clarify to the committee how these efforts will be harmonized, these efforts with the government under the contract and his and Mary's proposal of the organization that is absolutely, in my opinion, the most superior organization in the country really to provide support in the risk management and usability because of the outstanding experience.

But my clarification...my respectful clarification would be, please describe how do we get from here to there and what is your vision Matt?

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

So, basically with regard to standardization there are three general approaches, one I sort of think of as the video tape approach, which is a purely market approach where the biggest player with the biggest market influences, dictates the standards.

The second approach, on the other end of the spectrum, is a government mandate approach where some kind of federal entity or occasionally a big state will end up doing this and then everybody else goes along because, California for example or Texas are big enough that everybody if they have to design for them they design for everybody.

The third is what we're proposing which is getting everyone, which would include the big players, the little players on the industry side, the people who are the subject of those products, the government and all of their entities together at the table, assemble all of the current evidence and that would include activities, partial standards, other standards together and say, we must come up with a consensus on a risk management standard that everyone will agree we'll all comply with and then the government's role at that point is to say, you all develop the standard, we'd like to see you comply with it and if you do we'll make your life, I'm going to say, easier, we aren't going to mandate it, but we'll make your life easier somehow if you do your risk management process this way versus some other way.

So, getting back to Paul's question, I think that the role of ONC will be to come out with a statement, regulation whatever you want to call it that says, we expect everyone to have a risk management process and this consensus process is one that we endorse and if you follow that that's terrific, if you don't then we're going to look at you and see what process you're using.

And by doing a consensus process the harmonization should largely happen on its own. If and when we go to an international level then it gets a little more challenging, but by the way, the big vendors are the ones that suddenly become very interested in international standards harmonization because they don't want to be having to build products using different approaches in different countries.

Rollin (Terry) Fairbanks, MD, MS – Director, Emergency Room Physician, Associate Professor of Emergency Medicine – National Center for Human Factors in Healthcare, MedStar Health Washington Hospital Center, Georgetown University

This is Terry Fairbanks, I just want to respond, I think what Dr. Weinger is saying right now completely, to me, resonates with what we heard from the vendors when we did those visits to look at their user centered design and to ask them about how the regulatory process that was going on at ONC was going to affect them or how it could help them because, specifically, I mean, the ones that were doing user centered design really well said, we wish that there was some standard by which they could just measure the fact that we're doing it well and then leave us alone so we can go on and put our resources into doing it well. And then the ones that weren't doing it so well were looking for advice on how to do it well and so the standards like Matt is describing I think help in both ways.

And I'll also say that, you know, I have been on the human factor's committee at AAMI for several years and Dr. Weinger was the chair for a decade and developed that and I do see, the way it works in medical device companies as being helpful I think for the vendors and for the FDA and the regulatory process. So, the model is there and works very successfully and the committee involves a large representation from the vendors, really all of the major vendors have representatives at the table. And so the standards are developed with a large influence from industry themselves.

Steven J. Stack, MD – President – American Medical Association

Larry? This is Steve Stack can you hear me?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yes.

Steven J. Stack, MD – President – American Medical Association

Oh, I'm sorry...so a few observations, I'm thinking back to the slide in the presentation about the ATM machines and how it's been actually over a 40 year journey to where we are, but I think one of the challenges a committee like this could potentially help in advising the HIT Policy Committee and ONC, and then CMS would be in our attempt to get it all done very quickly we have mandated a level of complexity, and I would be interested in the feedback on the presenters on this, I think, we have mandated a level of complexity that has markedly increased both the risk and the difficulty mitigating the risk.

And so perhaps some component of advising not do we create all new layers of complexity to manage complexity that's too big to manage, do we perhaps advise that perhaps some of the things we have mandated should be stripped away and we should focus on a narrower set of core outcomes and objectives that we believe as a nation Health IT and information exchange should achieve and then maybe we can design a system like this that will be more useful and have a higher probability of success.

Because I do have the concern that the current program our vehicle, Meaningful Use, has mandated a level of complexity well outside our ability to deliver and oversee the risk. And I'd be curious what either of the presenters think about that?

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

I hope you would want to participate in this process based on what you just said. Matt do you want to go first?

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

Sure. So, I...because of my experience with AAMI standards for 20 years now I've come to appreciate that government mandate that is too specific is not helpful. There is a clear role for government in setting boundaries and helping to identify issues but it has to be the industry and the people who rely on it, their end users, who figure out how to do it themselves.

With regard to standards, and I'm going to...I think I submitted a public comment at one point on this, but I think with regard to safety enhanced design that it's far more important to specify what are good processes and have the companies reliably do and be able to document that they follow good processes than to try and regulate their outputs.

So, I guess I'm agreeing with you that early in an attempt to change the wild west into a civilization that sometimes one can get too complex and the advantage of bringing all of the stakeholders together that this could be a model not just for risk management but for other aspects of Health IT and society, and that those entities could provide advice and guidance to government about when they have overstepped their bounds.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

And this is Mary, just one example that I think illustrates one of the reasons why we have such a mess not really picking on anyone, but just the whole system, is we haven't clearly identified a nationally-based standards-based whose responsible for what, governance and responsibility and that is at the core.

You can't build a house or a road, or anything else without having clear roles and responsibilities mapped out and people living up to their part of those roles and responsibilities. And I think just getting that going and getting that to be standardized across all health systems will help the vendor community and also the healthcare delivery community and that's just one little piece of what you're talking about.

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

Actually let me give you a specific example on the device side that you will easily see how it translates to HIT. An area that still hasn't been resolved on complex high risk medical devices is who is actually responsible for assuring use competency of the end user.

So, when an anesthesia machine is built and delivered it is still ambiguous as to where the responsibility lies between the person who built the machine, the hospital that bought it, the medical group or medical staff that's overseeing where it's being used or the end user, anesthesiologist or whoever and so there is processing going on right now amongst those various entities talking about how can we clarify who is responsible and how do we develop a competency-based approach to assuring that people can actually use the devices safely and effectively.

And you can't...if you think about that you can't say, oh, it's all on the vendor or it's all on the end user, it really is distributed responsibility. And only in a consensus-based, everybody is in the room talking about it, can you figure that out in a reasonable way that is scalable.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Great, other questions?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I just wanted to add, I'm sorry, this is Mickey and I've been in a little transition here from place to place, but to Steve's comment, Steve Stack's comment about, you know, I agree that there is a role for ONC in reducing the current complexity which is I would say adding to the risk and that's something we could ponder as a recommendation.

And then I also think I'm favorable to the idea of process standards versus specific, you know, functionality criteria that could play a role.

The other thing we can consider...well, I'll just stop there. So, I think the idea of advocating process standards is a new area like they did with QMM that's worth considering and usability practices just that the vendors are able to document what they're doing as it relates to a standard as opposed to all the detail and specifics that we run into challenges with.

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

And this is Joan, I just wanted to mention that many of the issues you've raised in your wonderful presentation here are those that we very, very carefully considered when we were putting together the SAFER guides and because we talked to so many stakeholders and involved so many people we came to the conclusion that we wouldn't come anywhere near calling these standards or mandates and in fact they're just sort of gentle pushes.

But the idea of risk is definitely built into them so that there are sections for each of the guides that talk about the risks if you do not follow these... and we're not even...we didn't even call them guidelines, these were just considerations. We tried to cover the same sort of territory you're talking about but in a very gentle push way.

And I guess my question for you is, you know, is the time right for making them standards which does sound a lot more mandated?

And my other question is, how would this work relate to what Doug is going to be talking about in the next presentation about development of a safety center?

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

So, I've read the SAFER guides, they're excellent resource materials and I would urge that they not...that those not be turned into standards because they were not developed through...they're an ONC document, as wonderful as they are, they are an ONC document and they were not developed by the community itself that builds on the ownership, there is something about having, in a consensus-based process, the people that do the work together than have a sense of ownership and they become the advocates, if you will, for the implementation and the use and if you don't have that it's much harder, it becomes...if those SAFER guides became a standard from the ONC it would be more like a mandate and I think it would spoil what they are, which are really, really lovely, helpful, well thought out guides.

And then related to the HIT Safety Center, there is a need for a feedback loop and a lot of folks have been struggling with how do you get that feedback loop and there are lots of different ideas and the HIT Safety Center is one of those, there are others that are being discussed and have been considered through the PSOs and etcetera, etcetera.

The key point is that the feedback has to be there to feedback back into the development, design and development and a structured risk management process allows that to happen, that's what happens in other industries, that what happens in the medical device industry and I gave the example with the cardiac leads where you learn from the things that happen in the field that aren't working and you feed that back into the Standards Committee or you feed that back into a...for a company back into the design process and if they have a robust risk management process then the feedback can happen. So, it is a piece, it's a post market piece, post market isn't enough.

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

Can I also comment on this? So, in fact, when one talks about national consensus standards there is another word that's put in there and that is voluntary. No one mandates that anyone use these or no one needs to. There are three kinds of levels of voluntary consensus standards in terms of whether a company complies one is that it's useful until they do it because it's there.

The second is, the industry as a whole develops a cultural or other type of expectation that one will comply with it. In the case of the nuclear power industry documents, you can call them standards, come out of info and there is such a strong expectation by all of the industry that everyone does comply with it.

And the third is, some kind of governmental or other overseen entity that says, we have some level of expectation that you will comply with this document with this standard. Even for the FDA they don't require any particular standard, they say, this is the standard by which you ought to follow but you don't have to, if you want to have a different process you're welcome to but we're going to want to see that it has the critical elements that we think are important to achieve the aims whatever it is risk management.

The other point I want to make is, once a committee is formed they have three kinds of documents they can put out. They can put out a process standard. They can put out like a design or technical standard, which could also be a guideline or they can put out what's called a technical information report which I think is similar to the SAFER guides.

And just using the Human Factors Engineering Committee, which applies to all medical devices that Terry and I are on, we've put out a process standard which turned into an international standard that said "thou shalt have a user centered design process that has these element in it" though there is still a fair bit of flexibility for each vendor it's intended to be highly scalable and customizable to the particular product and needs of that vendor but it has critical elements.

We've put out what's called HE75 which is a list of best practices which is really kind of a guideline. If you're building a device with an LCD screen on it, it needs to be this legible and from these angles, and there is no "shall" words in it, it's all "this is what we should and this is what we recommend."

And then we've put out a technical information report such as right now there is one almost finished in post market surveillance which is really guidance for industry.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

There are...just one other note on this, there are thousands of standards in the United States that are referenced in law, in federal regulations and in legislation from transportation, toys, ladders, snow blowers, Christmas lights, you name it there are thousands of them. Some of them get incorporated by reference into law, some of them get officially recognized in regulations and by law, there are lots of varieties of the way that the federal government recognizes that private standards need a government aim and they will actually go so far as to mandate.

We're not making any kind of comment about whether that needs to happen here at all, I just wanted everyone to know that there is a very wide range of ways that the government recognizes private consensus-based standards to meet their needs.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

This is Michelle Dougherty, I have a quick question. How...in some of the other industries of the medical device or international process, how do existing, let's say Health IT standards, some of those technical standards, how are they integrated in the process or referenced, or are they separate and this is focused in a different area?

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

It's very common for standards to have crosswalks or cross references, or footnotes, references to other standards. We have a very strong standards philosophy, as do other ANSI accredited SDOs, not to replicate or reinvent the wheel and we work very hard at that and ANSI tries to help with that also.

So, the document or the framework that's on the columns, the more detailed one that was on slide, hold on just one second, slide 23, actually assumes and in the longer document that explains it, it actually says there are a lot of existing standards that could meet the needs of some of what is needed for risk management and those would just be referenced as a part of the process.

So, for example, a risk management process might make reference to human factors standards that already exist or information management standards that align well but don't overlap.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Thank you.

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

So, if I can add to that two things, one is that every standard has a section called normative references where the committee that's developing it can say, oh, well, this standards, whatever it might be 14972 already has some critical aspects of what we want in ours so we're not going to duplicate it, so we'll list it as a normative reference.

The other point I'll make is a long time ago when we first started with the human factors engineering standards for medical devices, which was HE48 then we actually took a military standard and we essentially did a replace of all the reference to tanks and aircraft carriers and plugged in medical device and then re-wrote it from there. It went through several iterations but the feeling was why reinvent the wheel they had done 80% of the effort already and I would expect that there are many documents out there that would help to speed up a process towards a risk management standard of Health IT.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

So, this is Dave Bates, let me just come back to Paul Egerman's question and sharpen it a little bit and ask you, you know, what could this group do that would be helpful to you, you know, and in particular, you know, as you can tell from the questions we're somewhat impatient to get to a level of safety that, you know, that is higher.

Are there things that, you know, either the committee could recommend or that the government could do for you that would speed things up?

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Yes, get everyone to the table in whatever way, you would know better than we do what's the most effective way to do that. If you could get them to the table we'll take it from there.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Okay.

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

To be more explicit, if ONC said, you must have a risk management process and we intend to endorse a process that comes out of this consensus, this is one possibility, out of a consensus-based vendor participating process that AAMI is convening and will be starting tomorrow then that would get them to the table.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

This is Mickey McGlynn, I just have to make a...I guess maybe a personal comment, I think most of the vendor community just heard about this effort within the past 10 days, Kathy Kenyon brought it to our attention through a contact with the EHR Association.

So, I think individual vendors just need a chance to digest it, you know, so I don't think there is any hesitancy yet. I mean, I don't think people know enough. So, I think leaving some time for people to be able to consider it is worthwhile.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Yes and on that note I had a call yesterday with your Chair, Mark Segal, and we talked about the need for a face-to-face meeting with the leadership of the EHR Association just so that we can talk about it and answer the vendor community questions. If there are other vendor-based associations that are on this call and would like a meeting we'd be happy to do that.

And I've also had a couple of meetings with Russ Branzell from CHIME and his staff and I have Russ's permission to tell you all today that informally they're supportive of this effort and happy to help try to get their community to participate.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, this is Larry Wolf, I want to add to that CHIME is a great bridge to some of the earlier comments about, you know, Paul Egerman raised this and we've raised this in a lot of our earlier discussion, so the current state of the art is that the vendors whether they're self-developed or commercially developed, the product part of the Health IT is only a piece of the equation.

A lot of changes are created during the implementation process and a lot seems to hinge on that and training and policies and procedures. There is a lot that happens inside the health organization that seems to encourage or discourage good outcomes and safety in general.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And so I think that rather than acting like that doesn't happen it would be really important to include that phase of actually bringing the systems into use as part of the charge for the Workgroup and the Standards Group.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Absolutely and when I said earlier I sit with sort of one foot in the vendor community, one foot in the provider community, in the middle with a perspective of both, there are responsibilities, enough responsibilities and challenges to go all the way around and everyone needs to see it from the lens of the other.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Well and so what's actually delivered and implemented and in use.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

Yes, yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

We don't want this just to be a test bed exercise.

Mary Logan, JD, CAE – President & CEO – Association for Advancement of Medical Instrumentation (AAMI)

No.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

We actually...we want to get on the plane and fly somewhere and have assurance we're going to get there on time...

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

That's the problem...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And in one piece.

Matthew B. Weinger, MD – Vice Chair, Medical Research - Association for Advancement of Medical Instrumentation (AAMI)

That's the problem with the current summative usability test approach and all of the AAMI standards at least with regard to risk management quality systems, human factors take a systems approach which means all the elements interact with the product and a lifecycle approach from inception all the way to trying to, how do we get rid of this piece of software because we've bought something new and how to make that transition.

Steven J. Stack, MD – President – American Medical Association

So, this is Steve Stack...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

That would be great. Can we wrap this up guys, we have a second presentation and only about half an hour left for it.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yeah, so that's what I was going to do next. So, great discussion, thank you both. If we can it would be great to go over to Doug Johnston from RTI International who is going to talk about the HIT Safety Center Roadmap update.

Doug Johnston – Director, Health IT Policy – RTI International

Great, thanks, David. Good afternoon everyone, can you hear me okay, I'm on a headset, hopefully I'm not too muffled?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

No, you sound okay.

Doug Johnston – Director, Health IT Policy – RTI International

Okay, great. Well, good afternoon again, and thanks for providing RTI with the opportunity to update the Workgroup on an ONC project to develop a roadmap for a potential HIT Safety Center. I'm Doug Johnston, Director of Health IT Policy at RTI International and the Project Director for this initiative. Next slide, please.

So, the Health IT Safety Center Roadmap Project is funded by ONC lead by Kathy Kenyon in the Office of Policy with representation on the Task Force from Dr. Andrew Gettinger at ONC's Office of Clinical Quality and Safety.

The project started in October 2014 and most of the major work will be completed over the course of one year. And the work really falls into three main buckets, first is to convene a Task Force and develop a roadmap for a potential Health IT Safety Center. The others are to really develop a series of educational programs and to engage stakeholders in safety and safe use of Health IT, and finally to conduct a series of analyses and research on this topic. Next slide, please.

The project is led by a team of RTI staff with expertise in Health IT and patient safety and with experience in convening and managing Task Forces, developing roadmaps and conducting educational programs and actually conducting safety research and safety data analysis. Next slide.

The central goal of the project is to develop a roadmap for a potential national safety center focused on Health IT through engaging a range of private sector and government stakeholders. So, importantly, I just want to stress here that the project is not the center itself, it will result in a plan for a center, but this isn't the launch of the safety center itself.

The project also aims to promote awareness of Health IT safety and build private sector support for a safety center focused on Health IT for our work across the roadmap, education and analysis related tasks.

I want to note here as well that the project furthers the policy framework in the draft FDASIA report on Health IT, and ONC's Health IT Safety Action and Surveillance Plan all of which emphasize private sector leadership, engagement, shared learning and share responsibility.

Ultimately, at this point the Health IT safety center is envisioned as a public/private entity that promotes engagement, evidence and education around the safety and safe use of Health IT. Next slide, please.

So, in developing the roadmap the Task Force will be asked to consider what the activities, governance, funding sources and other areas should be for a potential national Health IT safety center. These recommendations and guidance will be informed by current ONC and AHRQ authorities, which is to say that the center isn't envisioned as an institution with regulatory power and not envisioned as conducting actual investigations of Health IT safety related events. The intention here is to build upon and not supplant current private sector activities in Health IT safety. Next.

The next two slides list the Task Force members as of December 5, 2014. The first slide has Task Force membership representing a range of private sector and government stakeholders including those from safety and usability research, patient advocates, providers and professional associations, Health IT vendors, patient safety organizations and accreditors, medical liability and health insurers, and representatives from FDA, AHRQ, CMS, FCC and ONC.

As a sidebar I just want to note that some of the Implementation Usability and Safety Workgroup members, notably, Terry Fairbanks, Tejal Gandhi and Steven Stack are members of this Task Force as well as Marilyn Flack who is I think Executive Direct of Patient Safety Initiatives at AAMI.

In addition to the Task Force there is a four person Steering Committee noted in red on this first slide who are going to be responsible for guiding the Task Force activities and overseeing the development of the roadmap. Next slide, please.

So, here are the remaining members of the Task Force, in total we have 28 members and since last Friday we've confirmed Task Force representatives from CMS, so it says TBD here but it's going to be...from the Office of Clinical Standards and Quality or OCSQ. And then from the FCC it will be Ben Bartolome from the Office of General Counsel or OGC.

So, in addition to participating in four Task Force meetings the Task Force members are going to serve on a series of smaller Workgroups related to potential Health IT safety center activities, governance, funding and so forth. So, a lot of the work as it is with the Health IT Policy Committee will get done in these Workgroups.

But it's important to stress here that the Task Force is not a federal advisory committee and the meetings themselves are not going to be public. However, RTI is going to post meeting summaries to a public website, the URL isn't listed here, I'm happy to provide it but it's www.healthitsafety.org and invite the public to review these summaries and to comment so that's how we'll ensure we get public input on Task Force related activities.

Also, want to note that the roadmap itself will not be put out for public comment as a federal agency might do with like a proposed rule. RTI instead is to deliver this roadmap to ONC and they're going to decide what they want to do with it.

And finally, a document that details the objective, scope, the Task Force members, the management of the Task Force, timeline and how we're going to get wider public input is all available at healthitsafety.org. Next slide, please.

So, in addition to the Task Force and roadmap we have, as I mentioned before education engagement related activities. We're conducting a series of 10 webinars on Health IT safety and the first one these is scheduled for Thursday, December 18th it's going to be on the current evidence of Health IT safety and features Bill Marella from the ECRI Institute and the Pennsylvania Patient Safety Authority, and Gerry Castro from the Joint Commission talking about their research and analyzing data for evidence of adverse events related to Health IT.

And RTI, with the input of the Task Force is going to develop the other nine topics over the next few weeks. The webinars are scheduled to occur once a month through September 2015 and if you're interested you can register at the bottom here, the link, we hope you can join us on the 18th and for others moving forward.

In terms of furthering private sector engagement we're going to be cataloging and promoting research, education and collaboration opportunities in Health IT safety. So, one important task here will be to collect as much as we can on what's really going on in terms of investigations, in terms of initiatives to form collaborations around Health IT safety and to centralize those in one place and to promote them to various stakeholders.

This work is just starting, we're happy to provide an update on our process, on our progress for this and other tasks in future Implementation Usability and Safety Workgroup meetings if it's helpful, but for now we're just getting started on this. Next slide.

And the third area of work really is analysis and reports. So, relative to this we're working with Crico Strategies to analyze their medical liability claims data examining cases where Health IT has been implicated and patient harm. The analysis results, the categorization of safety events by various system and user factors will be done using Crico's own clinical coding taxonomy and a report of this analysis is going to be made available publically.

In addition, RTI researchers will produce two reports, one on evidence of Health IT safety and interventions to promote safety and safe use of Health IT and the other on Health IT safety goals, priorities and measures over the course of this contract. These reports will be really developed and available by the end of the year so more towards the September/October timeframe.

And in addition we'll produce a series of four briefs that are going to help disseminate evidence and practices around Health IT safety. The first brief is going to align with our webinar on the current evidence and other topics are going to be defined moving forward. Next slide, please.

So, I have a pretty short presentation today and this next to last slide here shows a high-level timeline of Task Force meetings and roadmap development, educational sessions, engagement activities and our various analyses and reports, and the points at which we're going to work with the Task Force on these. I would note that the final roadmap is planned for delivery to ONC by April of 2015 and you can see here where we're going to be again, engaging with the Task Force and helping develop an outline, drafts and final version of the roadmap to deliver to ONC. Next slide, please.

So, for more information again, please visit www.healthitsafety.org and I'm happy to answer any questions and thanks for your attention.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Thanks, Doug, questions for him?

Doug Johnston – Director, Health IT Policy – RTI International

I would want to note that Mary's...the earlier question about how AAMI relates to the Health IT Safety Center, in addition to potentially providing a feedback loop, I just want to note that Marilyn Flack is participating in the Task Force and is going to advise on the roadmap development so that's one direct way that AAMI will participate here.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Doug, this is Robert Jarrin with Qualcomm, I have a question for you. Can you talk a little bit more about the funding mechanisms that you guys are exploring for the safety center?

Doug Johnston – Director, Health IT Policy – RTI International

Well, I can tell you what we want the Task Force to consider. Our first meeting is scheduled for actually December 15th so we've not yet met to discuss what funding mechanisms they think would be appropriate. The ones we're going to ask them to consider include in the scoping document that I mentioned a little bit earlier, we're going to ask them to consider contracts, grants, cooperative agreements and different levels of private sector and government funding.

So, scenarios in which the government would fund the entire center versus, you know, 75/50%, 25% funding from the government and more private sector funding there using a variety of different mechanisms.

Ultimately, though the Task Force would advise us on which mechanisms they believe will be, you know, best to pursue and at what levels of funding we should expect to have different types of activities supported. Does, that help, Robert?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Yes, sorry about that, I was on mute, yes.

Doug Johnston – Director, Health IT Policy – RTI International

Yeah, no problem.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Appreciate it.

Doug Johnston – Director, Health IT Policy – RTI International

Sure.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Great, other questions for Doug?

Doug Johnston – Director, Health IT Policy – RTI International

Well, my e-mail isn't on here but I'm happy to provide it if anyone has any further questions, happy to talk with you its djohnston@rti.org or you can reach us through the healthitsafety@rti.org as well.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Thank you, any other questions or comments? I will note that we'll have more time to talk about risks at our next call which will be in January. Okay, well hearing no further comments let me just...can I ask that we go to public comment?

Public Comment

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

Operator, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

Kimberly Wilson – Office of the National Coordinator for Health Information Technology

There is no public comment at this time.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Great, well, let me just thank all our presenters again both really interesting presentations and I want to wish...Larry and I want to wish everybody Happy Holidays and we will be in touch with the plan going forward.

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Thank you Happy Holidays all.

M

Thank you.

M

Great.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Bye-bye everybody, Happy Holidays.

M

Happy Holidays.

M

Happy Holidays.

M

Thanks everybody, Happy Holidays.