



HIT Policy Committee Implementation, Usability & Safety Workgroup Final Transcript February 6, 2015

Presentation

Operator

All lines bridged with the public.

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

Thank you, good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT 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. I'll now take roll. David Bates?

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

Here.

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

Hi, David. Larry Wolf.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Here.

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

Hi, Larry. Alisa Ray?

Alisa Ray, MHSA – Executive Director & Chief Executive Officer – Certification Counsel for Health Information Technology

Hi, Michelle, Alisa is here.

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

Good morning or good afternoon.

Alisa Ray, MHSA – Executive Director & Chief Executive Officer – Certification Counsel for Health Information Technology

Yes.

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

Bennett Lauber?

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

Hell, I'm here.

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

Hello. Bernadette Capili?

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

Here, here.

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

Hello.

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

Hi, here.

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

Betty Mims Johnson? I heard you, thank you. Edwin Lomotan, sorry?

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

Here, that's okay.

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

Hi. George Hernandez?

Elizabeth Mims Johnson, PhD – VA Medical Informatics Fellow – Veterans Administration

Betty Mims Johnson.

George Hernandez – Chief of Applications and Development – ICLOPS

Here.

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

I'm sorry George.

Elizabeth Mims Johnson, PhD – VA Medical Informatics Fellow – Veterans Administration

Hi, this is Betty Johnson, I'm here.

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

Okay, thank you. Janey Barnes?

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Here.

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

Hi, Janey. Jeanie Scott?

Jeanie Scott, MT, ASCP – Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics - U.S. Department of Veterans Affairs

Present.

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

Hi, Jeanie. 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.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – 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.

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

Hi, John.

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

Hi.

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

Lana Lowry?

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

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Megan Sawchuk? Michelle or Mikey McGlynn?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare
I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Mikey and Michelle Dougherty?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – 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, here, hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Mike. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur
Yes, here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Paul. Robert Jarrin?

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

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

Hi, Robert. Steven Stack?

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

Here.

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

Hi, Steven. Tejal Gandhi? Terry Fairbanks? 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.

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

Hi, Ellen. Anyone else from ONC on the line? Okay, I will turn it over to David and Larry.

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

Great, well, thank you, Michelle and welcome everybody. Today we're going to be hearing about presentations...we're going to be hearing about quality management systems which are used in HIT software design and then we'll also hear about the AHRQ special emphasis notice on research and health IT safety.

We'll spend about a half an hour on initial presentation then we'll have some discussion then we'll hear about the special emphasis notice. And presenting about quality management systems and principles for HIT development will be Sherm Eagles and Alan Kusnitz from SoftwareCPR. Larry, anything you want to comment about?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

No just a very quick comment before we hear from our folks at SoftwareCPR, we've got a one slide reminder of what's in the current certification criteria, I don't know that it needs a whole lot of review at this point but it's there for your reference.

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

Great. Okay, and let's see are Sherman and Alan are you ready to go?

Sherman Eagles – Partner – SoftwareCPR

Yes, this is Sherman ready to go.

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

Great, so over to you, thank you very much for doing this.

Sherman Eagles – Partner – SoftwareCPR

All right, well, thank you. Just before we get started let me say a few words about who we are. Alan and I are partners at SoftwareCPR which is a small consulting group that provides quality risk management and software consulting to the healthcare industry.

Before joining SoftwareCPR I was a technical fellow at Medtronic working in the areas of software development, reliability and safety, and since the mid 1990's I've been involved with standards for medical devices and I've chaired all of the international working groups that have developed software standards specifically for medical devices such as the IEC 62304 medical device software lifecycle processes.

And today we're going to talk about software, about quality system principles and practices and the need and possibly application of those principles and practices to the development of Health IT software.

So, I'm going to be making the presentation, Alan will be available to help answer questions and elaborate on some of the items during the discussion period. Next slide.

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Yeah and I would just interject Sherman that our perspective is not to promote the medical device standards, I think we've seen all sides of medical device regulation and so what we're trying to do is present kind of our perspective on what's important here and what could work.

Sherman Eagles – Partner – SoftwareCPR

Okay, thanks, Alan. Next slide, please. So, you've probably all seen some version of this cartoon like most cartoons we find it funny because it's really an exaggeration of situations that we can recognize. There is some truth to this.

We know that Health IT products can be very complex and are used in a very complex environment. Problems in communicating and not understanding the use environment in the clinical workflow can lead to products that don't completely satisfy the users this leads to work arounds that can undermine the efficiency and the benefits of the Health IT products and I particularly like the "as installed" picture in this cartoon, I think it shows the creativity that many sites use as they implement Health IT products to fit in their particular unique environment. Next slide.

To achieve the benefits that have been promised by Health IT and to address the problems that might occur the draft FDASIA report proposed that the Health IT products that provide health management functionality should look at these four areas as priorities for improvement.

The draft FDASIA report suggested that these health management products don't need FDA regulation but that they could pose some risk to patient safety. So, it proposed these four priority areas as important to minimize these patient safety risks while not impeding innovation in Health IT that can bring substantial benefits.

So, today we're going to talk about the first priority area the use of quality management principles and also some about the need for standards and best practices in utilizing these quality management principles. Next slide.

As the slide states the goal of using quality principles is consistency. It's not enough to have a one-time inspiration or a heroic action in order to achieve a great result. Those great results have to be repeatable so the goal is consistent excellence. Next slide.

The way we achieve consistent excellence is by continually improving our execution of the quality principles. So, this idea of continual improvement underlies all of the quality programs that have been developed. Next slide.

So, first I want to give a brief background on quality systems and quality principles and then look more specifically at applying the quality principles for Health IT. Next slide.

Shewhart and then Demming championed the use of data to drive reduction and variation of manufactured products. Demming's success in Japan in the 1950s and 1960s led to a worldwide quality movement. Other quality leaders like Juran and Crosby extended the use of Demming's ideas to areas outside of manufacturing and over time the idea of quality evolved from meaning the ability to build consistently...build products the way they were designed to mean consistently producing products and services that meet user's needs and exceed their expectations. So, a change from manufacturing to more design and service quality. Next slide.

Most of you probably encountered one or more of these quality management programs. There has been a great deal written about them and they and other quality management tools are being used around the world in a wide variety of industries. Millions of companies utilize one or more of these quality management approaches. Next slide.

These are the principles that ISO, the Organization for International Standardization, have documented as underlying their quality management system, the ISO 9000 series of standards. These quality principles are not a set of technical practices they focus on people, relationships and ways to use data to manage an organization to consistently produce excellent results and these are the principles that are general and used in all of the different industries. Next slide.

There have been a number of standards derived from these quality principles not only the generic standards which is ISO 9001 but also standards that apply to particular disciplines like the ISO 90003 for software engineering and also to medical devices, ISO 13485 for quality management systems, IEC 62304 for medical devices software development. Next slide.

So, with this background then I want to take a look at why the authors of the draft FDASIA report proposed to promote the use of quality management principles for Health IT. Next slide.

Better information and less human error resulting in improved patient care is the promise of Health IT. During the past week I spoke to two MD's in Family Practice, doctors in large healthcare systems one in the Midwest, one on the West Coast, both of them in their early 60s, both of them had been using electronic medical record systems for several years. So, I asked them how they liked the system and what they thought of it and I got the same answer from both of them. They both said it was very hard at first they had a hard time getting used to it, neither of them thought of themselves as particularly computer savvy, but now they said they don't think they could do without it. The availability of information, the ability to consult with others quickly and easily about that information has become extremely valuable to them.

This type of Health IT that implements health management functionality is where we can see the greatest benefits can be realized. But at the same time it can also introduce new risks that are hard for a clinician to detect and both of the doctors I talked to are not questioning whether the information is correct they assume that it is going to be correct and they're writing orders based on the information that they receive. Next slide.

The authors of the Institute of Medicine Report on Health IT and Patient Safety concluded that quality management principles are critical for the safety of Health IT and therefore should be a high priority for design and development activities, and that their use should be standardized to provide confidence to healthcare organizations in the public that the Health IT products would be safe.

So, standardization here is intended to set a minimum level not to restrain or limit the Health IT developers from taking different or additional actions to create safe, reliable and usable systems but to bring everyone up to a certain level of quality. Next slide.

As mentioned earlier the draft FDASIA report proposed four key priority areas and the first of these was the use of quality management principles. The report concluded that the application of quality management principles is necessary for safe design and development of Health IT. Next slide.

In the 2014 certification criteria for electronic health record technology we saw up there at the very beginning the vendor is required to identify the use of the quality management system. The test procedure asks the tester to check if the vendor has specified an industry standard quality management system, a homegrown quality management system or no quality management system. Any of those answers is acceptable.

A list of example industry standards is provided in the test procedure and that includes the FDA's Quality System Regulation and the standards that I showed on a previous slide. There are problems in using the quality system regulation or the other example standards for Health IT. The FDA's Quality System Regulation doesn't really fit what is needed for Health IT. It was specifically developed to implement US medical device laws including requirements for premarket review, facility inspections and post market reporting. So, the authors of the Institute of Medicine Report did not believe that it was the correct quality system for use by the Health IT industry although they said that using a quality system was critical for safety. Next slide.

As was mentioned earlier there are also existing international standards for quality management including standards for medical devices. These standards may work for repeatedly developing similar types of devices but they may not work as well when innovative ideas are used to produce new software that is unlike any software the developer has created before and these cases focus on best practices rather than repeatable processes may be more appropriate to develop high quality Health IT software.

Also, the existing standards are written using terminology from the quality movement because that is what is used in the regulations. They do not use terminology that's familiar to software development. This results in a need to interpret the standards for the software developers resulting in disagreements and confusion over what is really required by the standard.

Writing the standards in terminology that is used and understood by the users of the standards, in this case the software developers can make the implementation of the standards much easier. Just as Health IT developers that don't understand the clinical workflow of their users can create products that are inefficient and hard to use also quality professionals who don't understand software development can create standards that result in inefficient development processes and possibly more defects in the software. So, Health IT standards should be written in the language and terminology of the users of the standards. Next slide.

While it may be possible to use the quality regulations and the standards that have been developed the differences between medical devices and Health IT make it challenging. So, I've just listed some significant differences on this slide. Medical device software that works with complex hardware to actually deliver therapy has significant complexity related to managing and controlling that hardware. In most Health IT products the complexity comes from the domain content rather than from the hardware that the product is being used on.

The lifecycle is different, conventional medical device technologies have a very long lifecycle. The Health IT products may need to be changed much more frequently. The Health IT products will also tend to evolve over the life of the product to a different scope perhaps a different actual use. In general medical devices have a particular intended use that doesn't change over their lifecycle.

And probably one of the major ones is that the design of medical devices doesn't change after they're released whereas Health IT may have to be changed during implementation to fit a particular healthcare environment where it's being used. And the medical devices may have easier work arounds if there are problems whereas a broadly used Health IT system needs to be fixed quickly if there is a need for a change or a fix. Next slide.

So, while the ISO quality principles that we saw earlier can apply to Health IT some of those seem especially important and there are a couple of important principles that are missing. A patient safety focus and creating a safety culture have been recognized as being especially important in developing healthcare products.

I first joined Medtronic about 25 years ago and during the first month I was there I was sent to a hospital to observe a pacemaker implant and to meet the doctors and nurses who used the products I was working on. Once or twice a year during the time I was there we stopped work for a few hours and gathered to listen to patients who had received the products we made talk to us about their experiences, mostly good, but some not so good.

These activities were intended to create a culture where the product developers were always conscious of the patients and users of the devices that we were developing and that kind of safety culture and focus is something that is a key principle in developing products in the healthcare area.

Another principle that I think is missing from the ISO list is a focus on best practices. We need to be aware of and look at how we can adopt best practices. This is particularly true for rapidly changing environments like Health IT. We can see this need very clearly in the emerging awareness of the need for identifying and implementing best practices for cybersecurity. We can't expect every vendor developing HIT to discover what controls are necessary for cybersecurity, we need a way to incorporate best practices that have been identified and created by others. Next slide.

So, the principles that are needed in the development of Health IT products for quality are not really different from those that maybe already familiar to healthcare providers. The implementation will be different and we probably can't expect a single quality standard to cover the entire lifecycle and all of the stakeholders so we need to focus on particular pieces and particular uses but they should be familiar, the quality practices and quality principles should be familiar to all of the stakeholders. Next slide.

I want to take a look at the key principles that were identified and some of the practices and benefits that have been recognized and documented or observed in working with Health IT and developers. We've already talked some about safety culture. One of the key practices in a safety culture is doing risk management early during the development not just for regulatory compliance but to actually reduce risk to the patients from the Health IT product. So, this, risk management is another key area and this is how it integrates into the quality principles by looking at this in terms of patient safety focus. Next slide.

A general customer focus is another area that is very important in the quality principles and another one that is really important in the Health IT area. The involvement of the users, the clinical domain experts, the people who understand the workflow is key to developing good products.

Another aspect, another principle that is a key one that has been identified is the idea of user centered design and this is where user centered design integrates in the quality principles with this idea of customer focus. Next slide.

Knowing that top management has set goals for quality and safety and is reviewing progress toward them is an important motivator for the staff and the development organizations. It communicates that quality and safety are important to the organization and helps align the staff's activities to achieving the safety and quality. It helps to minimize miscommunication amongst the staff members that are doing the development. Next slide.

Engaging the people doing the development of the Health IT products is also essential. Individuals need to recognize their importance in developing products that ensure patient safety and they need the training necessary to make them successful in fulfilling their roles so they can be committed and engaged, and fully participating. Next slide.

And as mentioned earlier, the idea of continual improvement is the foundation under all of the quality management systems. A key practice for this principle is the gathering and use of data to make decisions about what needs to be improved. So, being able to quickly react and to get data and quickly react to problems is a key result of this. Next slide.

Best quality practices must include means to establish customer expectations and inform customers of the implementation and maintenance needs and services. These best practices may come from other Health IT vendors or from outside the industry. Focusing on best practice is necessary to create a learning organization that can continually improve its safety and quality. There are many ways that we need to look outside of just the development that's going on to bring best practices to bear on our work. Next slide.

This is an example of how best practices can be adopted and spread throughout the industry. This is from an AAMI technical report on using agile practices for medical device software. It targets medical software development and it was created by medical device software experts. It adopts agile practices that have been found to be useful in general software development and then adapts them for use in the regulated medical device industry including how they can be used to satisfy regulatory requirements.

The agile practices and how agile practices should be applied for Health IT development will probably differ from the ways in which they're applied for medical devices and they should be documented and described by the HIT software development community and the users of those products.

But identifying best practices and then making them broadly available is a community-wide activity, it needs to include both the vendors and the users, and it can increase the overall quality of the Health IT products and increase the user's confidence. Next slide.

So, what we see being created in healthcare quality...healthcare product quality standards is a continuum across different levels of risk that are inherent in the different products. For the high risk medical devices where software directly controls therapies or directly is responsible for supporting life we have existing standards and regulations that apply for quality such as the quality system regulation in ISO 13485.

The International Medical Device Regulator's Forum is looking at creating guidance for software that is used to manage life critical decisions. So, the kinds of things that would be regulated as a medical device under the draft FDASIA report would fall into this category but it's products that are software only not without the hardware, specific hardware that is created.

A third level is being looked at and worked on by an AAMI software committee, this is software that's I'd say on the border of medical device classification, it may be considered a medical device in some countries, it may not be in others. So, it's less safety critical but it still has to tilt towards the regulatory aspects of medical devices.

And then finally, what we don't have, but I suggest we need, is some standard for Health IT quality principles and practices that applies the software intended for health management that is considered to be lower risk. These Health IT software products have to integrate and interface with regulated devices and regulated systems, such as laboratory information systems, across all levels of risk. So using similar quality principles and appropriate quality practices will facilitate developing quality Health IT products that can interface safely.

So, this standard is not under development at this time but AAMI has initiated a process to develop such a standard and with participation by Health IT vendors and Health IT users a quality standard could be created that will satisfy the recommendations of the Institute of Medicine and FDASIA reports and benefit the Health IT community. Next slide.

However, when we look at this we want to make sure that a new standard is not prescriptive or burdensome because it won't be successful if it is. And it shouldn't contradict existing quality standards, it should build on the quality principles that are underlying those existing standards. So, organizations that have already successfully used or tailored existing standards should continue to be able to use what's working for them and also meet the new standard, but a new standard should be easier for Health IT organizations both to implement and to then follow and comply with. Next slide.

So, finally, for this standard to be successful we have...there are some things we need to avoid. We shouldn't repeat the problems that we saw in trying to use existing quality management standards. So, the difficulty is that the legacy of these existing international standard organization working groups who have invested a lot of time and thought into creating these standards is going to make it difficult to create a new standard that doesn't repeat these same problems.

A way perhaps to do this is the creation of an entirely new committee of Health IT vendors and users that can take the quality principles and apply them in a way that's meaningful to the Health IT community and that's the end of my presentation and we'd be happy to take questions and discussion.

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

So, thanks so much. Alan, anything you want to add before we open it up?

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

No, I think Sherman has done an excellent job. I guess the only thing I would stress is the last two slides that in the absence of Health IT specific quality system guidance there are certainly companies doing Health IT that have invested a lot in making that challenging crossover to where they have tried to use and maybe even successfully used medical device standards or general quality standards, or general software standards outside the medical industry and it's very...we believe it's very important that anything new be structured in a way that would allow them to map those things and not necessarily reorganize and learn a whole new terminology unnecessarily.

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

Great, okay, so questions?

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman I have a question. Hello?

Sherman Eagles – Partner – SoftwareCPR

Okay.

Paul Egerman – Businessman/Software Entrepreneur

It's interesting to talk about a standard for development and I looked at some of the standards that FDA uses back when I had to do a 510K approval process for a radiology project I was working on and your comments about terminology are certainly correct, I mean, I remember at the time I had no idea what the FDA was talking about in a lot of places.

But the concern I have about establishing a standard around development processes relates to simply the rate of change. There is a lot of change that is going on in terms of what people consider appropriate techniques to do rapid development and software development can't be separated from the technology itself, in other words the technology technique that...the techniques that are used today are different than the techniques that are used...were used like 10 years ago or even 5 years ago and so isn't there a risk if you established any kind of development standard that it will, in some sense, become out of date fairly rapidly and as a result possibly be either not useful or possibly hold back some organizations?

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

Sherman, do you want me to take that or would you prefer to take it?

Sherman Eagles – Partner – SoftwareCPR

Let me answer shortly here, quickly and then you can add on if you want to Alan.

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

Sure.

Sherman Eagles – Partner – SoftwareCPR

It's interesting, the key here is to keep the standard flexible and not prescriptive particularly in terms of techniques. What we would hope to see is a standard that talks about what could be done and not how to do it so at least to allow that "how" to be left open. In some cases we may think that it's necessary to have a development organization describe how their implementing the standards or "what" requirements, but I think the idea is to not...it would be to not do a prescriptive technical descriptor, technical standard that has specific technical requirements in it. Alan, you want to add to that?

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

Yeah, so, at least in our opinion this would not be a software development methodology but it would require maybe, and again this would be part of developing the standard, it would require each HIT developer to define their software development process and it might have some minimum requirements for that process not how to do it but for instance certain things that have to occur like some sort of safety analysis, some sort of testing, some sort of specifications at some point, some post market use of data for feedback and improvement, patient safety organizations, you know, for example.

So, the only other comment I would add to this is I always think it's important to look at the maturity of an industry at a given point and so 5 or 10 years from now this standard might evolve and become a little more prescriptive in the areas that are shown to be necessary based on actual healthcare safety information. And so...

Paul Egerman – Businessman/Software Entrepreneur

I don't understand why might they be different 5 years from now than they are now? I mean, some parts of HIT...

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

Well...

Paul Egerman – Businessman/Software Entrepreneur

Are very mature, right, when you look at laboratory systems those are like over 30 years old.

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

Yes. So, there are also...a lot of these systems for electronic medical records, health records that include automation of formally manual healthcare sort of checks on and crosschecks, some may be mature in a given organization but some may not be mature in terms of the whole industry and we may not want to standardized methodologies at any point but industry by industry what can be standardized tends to change over time partially because technology is changing, partially because we get new information about what's absolutely critical to sort of constrain. And so all I'm saying is these things can evolve over time. Right now there is no Health IT development quality system standard.

Paul Egerman – Businessman/Software Entrepreneur

Well, maybe you're saying something I'm misunderstanding, when you about Health IT are you referring to electronic health records or are you referring to a broader...

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Broader.

Paul Egerman – Businessman/Software Entrepreneur

Laboratory systems, retail pharmacy systems, you know, systems that do scheduling of healthcare staff. I mean, what is your...the way you're using HIT?

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Well, I'm using it in a fairly general sense but I'm not necessarily saying that this applies from a sort of regulated perspective, you know, the scope can be defined. I'm not sure personally I would have this apply to scheduling I'm thinking more of things that effect safety and effectiveness.

Sherman Eagles – Partner – SoftwareCPR

And I think the draft FDASIA report makes it clear that their proposal, the recommendation for using quality principles applies to Health IT that provides a health management functionality.

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

This is David Bates, let me just ask a question that I was thinking about that relates to what Paul has been asking, which is, you know, clearly we want to do things like enabling agile approaches as you've discussed, how do you think that this would differ between the device approach and HIT software?

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Sherman, do you want me to start?

Sherman Eagles – Partner – SoftwareCPR

Go ahead.

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Well, in the medical device arena there was a long period of time and actually it continues to some degree where medical device manufacturers did not think that they could use agile practices and still be compliant with the medical device regulations. So, some used it and used it in ways that they believed complied and were able to convince FDA others simply didn't use them.

AAMI initiated guidance that FDA participated in on use of agile practices for medical devices which attempted to give explanation of how one could use them in a compliant way and stated kind of ways to articulate that, things to do, not to do.

For Health IT one doesn't have the same, potentially the same regulatory constraints that are in medical device law. So, whether it's agile practices or other new development practices there is a lot more flexibility available because you're not trying to shoehorn it into also meet the medical device requirements in the quality system regulation and other regulations. Sherman?

Sherman Eagles – Partner – SoftwareCPR

Yeah, I think that's a good answer. I think the differences here really need to be looked at by the people who are doing the Health IT development and the people who are using those products in terms of...those practices or which practices of agile would be the most appropriate and would provide the most benefit to the developers and the people using the products. It is going to be different for the medical device industry because the quality system regulation is something that by law the developers have to follow, we don't have that kind of regulation for Health IT.

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

And we also, you know, for large IT systems the large software development IT contracting firms are highly utilized and IT in general, right? And they often...part of what they do is say, we have our proprietary lifecycle and approach to software development and implementation, and in the medical device industry there is the question if we were to use that would it be compliant but it's not a big question because that's not typically how medical device software manufacturers find their development in process resources.

But in the Health IT industry one could imagine or at least I think one could imagine that if there was a Health IT standard guidance than these large IT vendors would invest in saying, either here is how our process meets those requirements or possibly enhancing their processes to ensure that there is that safety focus which is not universal for general IT. And so that could further promote whatever is trying to be promoted in this new standard.

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

I'm sorry, this is Michelle, we have a heavy breather on the phone, if there somebody that has their mic kind of close to them if they could move it away that would be great, thank you.

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

And this is Mike Lardieri, I have a question.

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Okay.

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

Go ahead.

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

Okay, so it's along the same lines, so I'm assuming that there may be some HIT developers who may already be doing this and if they are they may not need to have a regulation or have a process to go through again and if they are how do you balance them not having to do extra work, pass on extra costs to the consumers versus those HIT developers who haven't used such a process?

So, I wouldn't want to make somebody do it again and pay extra money if they're already doing it but I do want the folks who are not doing it to actually participate.

Sherman Eagles – Partner – SoftwareCPR

Yeah, well, I think that was the point of the last couple of slides which I was hoping to say is that we need to develop a new standard to bring everyone up to a certain level but we shouldn't be penalizing the people who have already figured out how to utilize the quality principles in a way that's effective for them. So, they really need to be able to continue what they're doing if that's what they choose to do where they can meet that standard and that's why we need to have them participating in the development of the standard so that we can make sure that we can do that in such a way that they can continue to use standards that they have already been using that implement these quality principles without having to make major changes in their development process.

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

And one way that this occurs with standards in general is those that already have a process that meets or mostly meets whatever the standard is requiring there is a relatively small task where they create a little trace or map of, here is what the standard requires, here is a reference to where or how we do that. And so, yes, there is a little bit of work there but if they really are meeting general quality principles and the software development, sort of good engineering practices then that's a very small task.

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

And then the cost that they would have to pay for somebody to review their activity, I guess I'm concerned about that as well, because usually with the standards you have to pay something to get reviewed to begin with.

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

Well, I understand your concern and I guess some of that depends on how this is enforced or not enforced, in other words, no one is saying, yet, that there is a body that goes out and inspects and certifies these companies. So, for instance in the ISO world in the medical device world in Europe there are many devices that are what are called self-certifying so the manufacturer has to meet the medical device quality system standards but they get to determine that on their own and certify it and then later if there were problems I suppose, you know, a regulator could challenge that. But I can't say there would be no cost because obviously somebody has to read and understand the new standard...

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

Right.

Alan Kusinitz, MS – Managing Partner - SoftwareCPR

And map it to the old standard whether that's internal resource, external experts or some regulators coming in.

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

All right, thanks.

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

So, this is Joan, I have a question. I just...you're obviously experts in this area and I'm wondering exactly what your recommendations would be. It sounds like you're recommending the development of more or less gentle flexible high-level standards and it would be done by AAMI and then what would your recommendation be after that? Should this be a requirement for certification? What are your thoughts about it?

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Sherman, do you want to go first or would you rather...

Sherman Eagles – Partner – SoftwareCPR

Go ahead.

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Okay. So, I would just add to our recommendation in terms of your summary that I think Sherman said it would be very important that the group, the AAMI working group, consist of the right representation. So, we're recommending that it not just be medical device people or just IT developers but, you know, it consists of Health IT representatives including user representatives and so on.

I personally don't know if my opinion would be that this be a voluntary, you know, a guidance that's out there and it's one way to meet the regulatory requirements for a quality system, you know, that was summarized at the beginning, one of the slides, or whether it's worth going beyond that and making it a requirement.

I personally would say, well you have a requirement to have a quality system for development testing, etcetera. You could state that conformance to this new standard is one way to demonstrate that and leave open the possibility of demonstrating it in other ways or you could make it more stringent where companies would have to show how whatever they do meets that or get it certified independently. Sherman, do you have a strong opinion?

Sherman Eagles – Partner – SoftwareCPR

I guess, my only opinion here would be that the current certification requirement says that companies can say they used no quality system or development of some functionality. It seems to me like the first step would just be to say, let's take away the "no" option and say you have to use something for quality systems. And hopefully this standard would then be the easy one for them to introduce rather than going to something that has more regulatory flavor such as the quality system regulation or the existing standards, international standards.

So, I don't know that it's necessary to say you have to use this standard as a criteria but the use of some kind of quality principles as a criteria seems to me to be the next step in the certification requirements.

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

This is John Berneike, I have another question. You know we’ve talked a little bit about, you know, HIT software certification and development standards relative to medical devices but how about, you know, following development standards, you know, a lot similar to ISO 9000 and whatever else and everything we’ve been talking about here, but relative to other software industries, you know, on-line banking stuff or on-line, you know, merchant stuff where obviously there is going to be a lot of incentives and motivation for having, you know, high quality software for privacy and security, and everything else. What are the current industry feelings from some other industries that this might apply to?

Alan Kusnitz, MS – Managing Partner - SoftwareCPR

Well, I think the key difference in this particular area is the patient’s safety consideration and the fact that the benefit accrues to the patient if the product gets used. So, it’s unlike some other domains where you have the option to say, if I’m concerned about the quality I don’t have to use the product, but you don’t really have that option as much here and the patient safety piece is probably not in most of those other industries and if it is it’s in it in a more regulatory prescriptive manner.

So, but I think that question is one that should be looked at by the people who are trying to develop the standard. If there are other standards that can be used and that apply to this domain and people, both the users and the developers say, yeah, that’s one that makes sense then let’s just include it in the list and maybe we don’t need to have a new standard. But I think we need to have the right people looking at that before we make that decision.

Sherman Eagles – Partner – SoftwareCPR

So, for instance in the development of the medical device software lifecycle standard 62304 one of the early discussions the working group had was, are there other standards, can we use an IEEE standard or the Australian standard or IEC 12207 for IT, would that...would any of those serve adequately for the medical device industry and there was discussion and investigation and so on that, and there were reasons why that wasn’t a path taken mainly that there wasn’t an ability to find a standard that focused adequately in the same terms on safety of software. So, although there were other safety standards for nuclear and aviation and so on there were some technical reasons why they really weren’t appropriate directly for medical devices.

So, that’s a question to be answered or dealt with in the working group as to what’s useful, what can be referred to, what shouldn’t be referred to or voila we found this amazing thing in another part of the world that should just be used for this.

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

Hi, this is Mickey McGlynn; I have a follow on question to Mike’s of a few minutes ago. So, I happen to work for a company that has an extensive quality management system in place, we’re certified by ISO and we have taken the existing standards and adapted them to, you know, the HIT business to get at those issue you were talking about earlier.

In addition there is an ISO technical report 17791 that did an analysis to say, do the existing...do we need new standards or do the existing standards satisfy the ability for the health software to enable safety and quality and my understanding is this report has said in the software development area the existing standards do suffice there may be some gaps in implementation and things such as that, but that the existing standards would suffice. So, could you comment on that and how that relates to the proposal?

Sherman Eagles – Partner – SoftwareCPR

Well that technical report referred to the existing medical device standards such as 13485 and I think in the situation that you mentioned where a company has adapted that to their products and use in Health IT that probably does cover what you need.

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

Okay.

Sherman Eagles – Partner – SoftwareCPR

I think that, you know, what we're really looking at is the people who haven't done that, how do we encourage the developers to find a way to incorporate these quality management principles into their development and make sure that they have done the risk management that's necessary and the user centered design that's necessary and kept that customer focus and safety culture that we really want to see in the development activities.

So, we've also done a report...I Co-Chaired a group that did an ad hoc health safety, health software safety report that was a combination of ISO and IEC, and we basically said there is a series of things that need to be a foundational level and then we need to look at what is additional for development for implementation and for use, and deployment.

And we...as 17791 pointed out its implementation seems to be the place where the largest gap is. So, at the international level I think we'll see much more interest in looking at implementation and how do we share responsibility between development organizations and the implementation organizations in terms of assuring patient safety.

In this case I think we're looking at trying to identify the things as I said, the people who aren't doing anything now would be able to do...to bring them up closer to the level of the people who have fully implemented a quality system, you know, for their development.

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

Okay, thank you.

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

So, other questions? I'll just ask one then, this is David Bates again, essentially everything that you've talked about relates to what happens after the...before the software sort of goes out the door. Is there anything analogous for around what happens post implementation?

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

Did we lose you?

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

I'm still here.

Caitlin Chastain – Junior Project Manager – Altarum Institute

On mute perhaps?

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

Did that question come through?

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

I heard you David, but...

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

Yes.

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

Yeah, it’s been a little bit of silence.

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

Sure.

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

Did we lose Alan?

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

Alan are you there?

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

It sounds like we lost him.

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

Okay. Okay.

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

Did we lose Sherm?

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

Sherm are you there? I think we were essentially at the end of time anyway. Let’s see if they come back on.

Sherman Eagles – Partner – SoftwareCPR

Hi, sorry, this is Sherman Eagles I got disconnected there.

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

Thanks, Sherman.

Sherman Eagles – Partner – SoftwareCPR

Do you want to repeat...I don't know if you got an answer from Alan on the question that you had, but...

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

No, let me go ahead and ask it again, this is David Bates.

Sherman Eagles – Partner – SoftwareCPR

Okay.

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

I just wanted to ask, you know, so, you know, many of the issues that happen with HIT really only manifest themselves post implementation and, you know, it seems like most of what you talked about relates to pre-implementation. Is there anything analogous that we could learn from this about post implementation?

Sherman Eagles – Partner – SoftwareCPR

Well, I think that the principles, the quality principles can apply just as well to post implementation. It's likely that we would need some different standards I think just because as we mentioned in the last question we're into the area in post implementation where we've got shared responsibility; it's not just the development organization that has to make certain that the patient safety is protected.

So, while I think the principles will apply I think we'll be needing to look at some different implementation of those principles in a different standard. That is an area that's been identified in the international activity as a...actually as probably the largest gap in terms of standardization. So, there will be work that starts internationally on that. It may also be though that we need to follow up the idea of having some kind of a development standard with additional work perhaps by the same people in saying, so what do we do now with implementation.

So, I think the principles are pretty consistent but the actual standardization might need to be different for that post market, post deployment kind of activity.

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

Great.

Sherman Eagles – Partner – SoftwareCPR

Does that help?

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

Yeah, that’s very helpful, thank you. Any last questions? Okay, well we just want to thank Sherman and Alan, we want to thank you both that was really terrific and very helpful. We’ll be hearing some more about this I think on our next call from another group, but next we’re going to hear from...Teresa, are you on?

Teresa Zayas Caban, MS, PhD – Chief of Health IT Research – Agency for Healthcare Research and Quality

Yes, I’m on, sorry, I was on mute.

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

Yeah, no problem, so next we’re going to hear from Teresa Zayas Caban who is the Chief of Health IT Research. AHRQ has just released a special emphasis notice which we’re very excited about and we think it’s directly relevant and we wanted to hear from you today.

Teresa Zayas Caban, MS, PhD – Chief of Health IT Research – Agency for Healthcare Research and Quality

All right, well thank you for inviting me, we can advance to the next slide. As David mentioned AHRQ published this special emphasis notice on January 27th and through the notice we were letting the research community know that in fiscal year 2015 the Health IT portfolio at AHRQ is interested in supporting research regarding the safety of Health IT systems. If we could move to the next slide.

And so as you all know Health IT has been shown to improve quality and safety of healthcare but as was alluded to in the previous presentation it may also cause new errors which are sometimes referred to as technology induced errors. Design including usability and implementation of Health IT can impact how the systems are used and lead to errors.

And there have been calls for improved approaches to Health IT system design, usability and implementation. There is a need to understand how users interact with the systems to carefully monitor the systems use and performance post implementation, as David was alluding to with one of his questions, and to understand how to address causes of errors.

In addition many have called for the user centered design, human factors and ergonomics those technical systems vary, human computer engineering and usability engineering and other related frameworks and approaches to improve Health IT safety.

And so we published this special emphasis notice with the goal of funding research on the safe Health IT practices related to the design, implementation, usability and safe use of Health IT with the goal of generating new evidence...Health IT practices that could inform certification and other forms of policy guidance. Next slide, please.

As specified in the notice we were asking for applications to be submitted through two different program announcements one of them was the R01, those applications were due yesterday, and the second one is an R21 that is a funding opportunity announcement that is Health IT focused and is really meant to fund exploratory and developmental research projects that include three different types of research projects that sort of pilot the small focused studies, secondary analysis and economic analysis. So, we can really get a diverse group of grant applications. Next slide, please.

I just wanted to highlight that for R01s in particular we were asking the personnel from Health IT vendors and healthcare delivery organizations to be part of the research team and we were also strongly encouraging patient safety organizations and industry to be partners in the grant application. Next slide, please.

And in terms of each of the two mechanisms the R21s are limited for two years in length, the projects are, total cost cannot exceed more than \$300,000 for the entire project period and they cannot exceed more than \$200,000 for any given year. The R01s are limited to no more than \$250,000 per year total but can last up to 5 years. And with that I'm happy to take questions about the special emphasis notice.

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

Yeah, thanks so much, we'll be excited to see some more evidence coming in about this. Questions for Teresa? Okay, so, you know, as we've discussed it will be really helpful to have some more evidence about this and we're very excited to see this moving forward. Larry, anything you'd like to add before we go to public comment?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

No, just that I think Michelle or Ellen had suggested that we were actually going to announce opening the lines to public comment before we did our final wrap up so there is time for people to get on, so let them do that and then see if we can have a couple more closing comments.

Public Comment

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

Thank you, Larry. Operator, can you please open the lines?

Caitlin Chastain – Junior Project Manager – Altarum Institute

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

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, my thoughts in wrapping up is I found the conversation about work on standards around quality measures pretty interesting, the fact that AAMI has already started some work in that area is certainly something we should be following given ONC's stated interest in having some standards that they can refer to.

I thought the discussion around the need to bridge the language from the existing work in the quality measures world to the work in the software development world was really important. Paul Egerman talked about some of his problems and having to try to wade through regulations that were speaking a whole different language and I think that a lot of people have been experiencing that in this whole area so I think that will be actually an important piece to see the bridge and I was very encouraged to see that there was some work already done looking at agile as a methodology and how you would apply that because I think to some of the discussion about the need for innovation to happen in software development but still not create prescriptive requirements that don't allow for the innovative activity.

And in terms of the grant work it's great to see that there is an opportunity to support more work on looking at safety issues. So, I think that wraps it up for me.

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

Great, so, yeah, just a couple of thoughts on my end, I agree with what Larry has just said. The first presentation was really helpful, a couple of points that I found to be specifically, you know, really useful were, you know, one changing the terminology to terminology that would be understood by the users of the standards and then actually, you know, moving forward with development of these quality principles and practices.

And I think we'll need to think as a group about how use of the standards should relate to certification that was a good discussion I was very glad that Joan asked the question that she did. And, you know, I would just second Larry's comments about the special emphasis notice from AHRQ. So, do we have any public comments?

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

We have 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, all right, well, just want to thank everybody, thanks to our presenters, good call.

Teresa Zayas Caban, MS, PhD – Chief of Health IT Research – Agency for Healthcare Research and Quality

Thank you.

W

Thank you.

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

Yeah.

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

Thank you, everyone.

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

Thanks, everybody.

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

Have a wonderful weekend.

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

You too, bye-bye.

M

Thank you.

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

Take care.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Bye.

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

Bye-bye.

M

Thank you.

M

Bye everyone stay warm if you are in the DC area.