

**HIT Policy Committee
Certification & Adoption Workgroup
Transcript
January 31, 2013**

Presenation

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good morning everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's Certification & Adoption Workgroup. This is a public call so there is time for public comment on the agenda. The call is also being recorded, so I'll just remind everyone to identify themselves when speaking. I'll now go through the roll call. Marc Probst?

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Marc. Larry Wolfe?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Larry. Joan Ash?

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

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Joan. Carl Dvorak? Paul Egerman? Joe Heyman? George Hripcsak? Liz Johnson? Charles Kennedy? Donald Rucker?

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Donald. Latanya Sweeney? Paul Tang?

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Here.

MacKenzie Robertson – Office of the National Coordinator

Good morning, Paul. Micky Tripathi? Scott White? And Martin Rice? And if there is any ONC staff members on the line, if you could please identify yourself.

David Hunt – Office of the National Coordinator

Hi, it's David Hunt.

MacKenzie Robertson – Office of the National Coordinator

Thanks David.

David Hunt – Office of the National Coordinator

And I also have Kathy Kenyon here with me.

MacKenzie Robertson – Office of the National Coordinator

Great. Thanks.

Mike Lipinski – Office of the National Coordinator

Mike Lipinski.

MacKenzie Robertson – Office of the National Coordinator

Thanks Mike.

Michelle Nelson – Office of the National Coordinator

Michelle Nelson.

Alicia Morton – Office of the National Coordinator

Alicia Morton.

MacKenzie Robertson – Office of the National Coordinator

Thanks Alicia. Thanks Michelle. Okay, with that, I will turn the agenda back over to Larry and Marc.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Larry, you put a really nice one-pager together kind of outlining our charge for the next – as we look at the safety plan. Do you want to go through that and then let's just get right into David?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Sure, I'll do that. So, that was the document that went out this morning and MacKenzie pointed out that it went out last week as well. So, the ONC published a plan on health IT safety at the end of December, and it was discussed briefly at the Policy Committee meeting a couple of weeks ago, and there were some open questions that they would like us to specifically comment on. So, these are what they're calling focus questions. One is on, or a pair of them are on meaningful use and safety risk assessment. This is about improving the safety of EHRs, should there be meaningful use requirements for providers to conduct a health IT safety risk assessment.

Let me point out, these questions are also imbedded in the slides that David Hunt's going to be presenting to us. And are there models or standards that we should look to for guidance. So, a couple of things related to safety risk assessment. Also a question about meaningful use and reporting, should there be any reporting or reporting verification under meaningful use, relating to safety. And finally, a statement of some of the things that ONC has included in the most recent regulations for Stage 2, the 2014 Meaningful Use Edition of EHR certification, and they're asking are there additional things that should be taken in terms of EHR technology certification. So, we have a few focused things for us to look at as we hear from David, and for those who are speed-readers, or need a refresher, there is some great material in the ONC plan as well, about the breadth of things they're looking to do. So, that's probably plenty for an introduction. Unless there are any questions about that one, we'll just hand this over to David.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

Okay, thank you. And, am I controlling the slides or are they remote?

MacKenzie Robertson – Office of the National Coordinator

I'm not sure if David has the ability to do that, but if you just say next slide, David, they'll advance them for you.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

Okay, that's what I'll do.

MacKenzie Robertson – Office of the National Coordinator

Caitlin, were you going to say something different?

Caitlin Collins – Altarum Institute

If he wants to control them, I can give him the rights right now.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

Oh, that'll be great. Thank you.

David Hunt – Office of the National Coordinator

Perfect. Okay, well thank you so much. I appreciate the opportunity to speak to the workgroup about, as you heard, the recently published Health IT Patient Safety and Surveillance Plan from ONC. And I do hope that so many of you did get a chance to see Jodi Daniel's exposition of the plan at the last full Policy Committee meeting, as was discussed. Now, this presentation will go over some of that material again, but I also hope to give you a bit of greater context for this work, as well as go into a bit more depth for some of the areas that directly relevant to the charge of this group, and the focus of this particular meeting. So, with that, I'll start by putting a spotlight on one fact that Jodi briefly alluded to, namely, how much we have yet to learn in this domain.

You know, this is a proper and inescapable place to begin. That is, with the unassailable fact that the success of our policies to promote adoption and the meaningful use of electronic health records, presents us with a fundamentally changed healthcare system. And most importantly, one that is materially, on a materially different trajectory than the healthcare system at the turn of the century. Now as we move to understand the implications of this new and accelerating course, one thing that we have all come to understand is that – sometimes we've learned this painfully – is that we have a tremendous amount to learn.

Now over the years as we've walked along this path to this brave new world, I've really been fortunate enough to present our programs and policies to a variety of groups, most often to physicians, and on so many occasions, I've found it fitting to conclude with this observation from Voltaire, namely that doubt is uncomfortable, but certainty is ridiculous. And rather than end my discussion with this, I think this is really a great place to start. But to do that, I also think that it's fitting to include a bit more of his letter from Prince Will, to Prince William of Prussia, namely that acknowledging our profound ignorance must inspire and animate our actions. If we did not have sufficient cause before, our need to learn has to serve as an underlying rationale, really for a renaissance of patient safety that relentlessly exploits the advantages and mitigates the risks associated with our IT-enabled healthcare system.

Now, as we'll see a bit later to that end, strategically we've translated this motivation in our Health IT Safety Plan as a first course of action, to learn. But first let's look at two of the major goals. They are to use health IT to make care safer and second, to improve the safety and safe use of health IT. Now, toward those ends you'll see that the plan explicitly addresses the role of health IT within the larger HHS framework of patient safety. In other words, Health IT is never a means or an end to itself, all of our work must translate into the larger work within the Department. And next you can see that these goals are a perfect first step to addressing the IOM report by building on existing authority. But, as much as we are in concordance with the larger aims of ONC and the department as a whole, this workgroup has really been charged to focus on a few specific questions within the purview of the meaningful use program. And this was alluded to just a little bit earlier, you've been asked to consider within the context of meaningful use, if any requirement for health IT – if there's any requirement for a Health IT safety assessment, whether that's in order. And if so, are there standards or guidance that we might look to inform that policy. And second, you should consider whether or not ONC should require safety reporting or verification, under the meaningful use program. And finally, what are the steps in terms of certification, in the light of our published rules requiring developers to publically identify a method of incorporating user centered design into their products and provide transparency regarding their approach to quality management systems.

Now, as you continue to think about those questions, let me provide a richer context for all this work. First, I think you all know that ONC's plan is really a response to a report that we commissioned from the IOM, a report in which we asked them to look at the question of patient safety through our lens of Health IT. The report had ten recommendations, and we respond to each in our response. I'll briefly outline our responses, but also point out that the narrative of our collective consideration of this intersection between Health IT and patient safety runs much deeper than this latest IOM panel. Yes, we have a tremendous amount to learn, but fortunately, we're not starting from zero. Our curriculum is not completely empty. Consider, for example, that this is not the first IOM report on health IT and patient safety.

Way, way, way, way, way, way, way, way back, in 2003, Paul Tang led a team that issued another IOM report focusing on patient safety and health IT. This one was commissioned by AHRQ and while he was also on the team for this latest report. I'd offer that despite being a bit older, he didn't have to be that much wiser than he was in 2003. And that's because while that 2003 report was not widely read, you'll find the formulation for the foundations for this work as sharp, as accurate, as crisp and as vital as the day they were written. In particular, they most clearly articulated the relationship between work and patient safety, and our work in the department and quality as a whole. When they wrote that patient safety is indistinguishable from the delivery of quality health care. Now, I want you to remember that because this is the key concept.

Paul, I quote this point dozens of times each year, because it really carves out an immediate home for our work in patient safety. It essentially acknowledges that in this model, all elements of safety are within the domain of quality, but it still recognizes that there are aspects of quality that are outside of the domain of safety. Well, it was this principle and a few others like this in the 2003 report, that helped me build the Medicare Patient Safety Monitoring system at CMS. Now, this is the backbone for the patient safety surveillance in the Department and the core for the partnership for patient's data that many of you may know about right now. Now, I'm spending time on this work and other programs that speak to the broader topic of general patient safety because I want to drive home the point that health IT safety must inform and contribute to the larger domain of patient safety, beyond the work of information technology. So, to that end, our program will remain concordant with the foundations of safety that have already been established, and the underpinnings of those programs. Such as a commitment to remain relevant to the proximate causes of harm to our patients, and to remain transparent in our efforts to prevent and mitigate those harms.

Now, I started this discussion regarding the history and context for our ONC Patient Safety Plan by pointing out that although this plan is being issued as a direct response to the 2011 IOM report, the world of patient safety did not begin in November 2011. So, if we are to have an irrevocable connection to the larger world of patient safety at large, we really have to recognize that the resonance of this field precedes my work or Paul's of over a half dozen years ago. It also precedes the landmark IOM report in 2001 to err is human. In fact, the composition and the requisites of patient safety long predate modern medicine, of course, as deeply rooted in the commonly held understanding of safety in general. That is, the condition of being free from harm, injury or loss. And our general understanding of patient safety is the act of freeing our patients from the risk of harm, injury or loss associated with their interaction with the healthcare delivery system and wholly independent of any disease process they may contain, they may have.

Now, for many of you, patient safety is synonymous with the tag line made famous by Claudius Galen, "primum non nocere," or "first do no harm." Now, most of us in patient safety are tenuously comfortable with this as a fundamental principle, simply because it allows us to dispel a regularly held misconception regarding patient safety, namely that patient safety is about the reduction or elimination of medical error. It is not. You will notice the Webster's definition of safety made no mention of error and likewise here, Galen did not write primum non errori, "First make no error," he said, "first do no harm."

Now I bring this up because there is a powerful temptation to believe that the application of information technology can close the book on patient safety by taking error out of the equation. Well, first off, computers don't eliminate errors, ask your accountant about that. And more importantly, no meaningful, and I use that work advisedly, no meaningful definition of patient safety includes any mention of error. You see, if we really expect to be patient centered, to be focused on the patient, then we can't have as our end-point of success a measure of provider activity. What a doctor may or may not do, we must have the singular consideration of, "What is our patient experiencing?" That said, yes, there is ample room in patient safety for error reduction, but the sole end-point of material concern must always and only be what has happened to our patient. Not only that, but if we are serious about making things better, we cannot expect a fulsome and a hearty partner in the provider community if we began the discussion with a recitation of the errors that they made. Our overly litigious world is best served when our common cause is the elimination of patient harm, rather than provider error.

Now, I said that we tenuously accept Galen's proposition, only because at face value it really is woefully incomplete. And we discussed this fact just earlier when I pointed out how wonderful Paul Tang articulated the relationship between quality and safety. That relationship is fundamental to patient safety, it is fundamental to our path forward in health IT patient safety and it remains one of the fundamental goals of medicine and healthcare in general. You see, Galen's abbreviation eliminates our original purpose, so I find it much better to go to the original source material, the Galen study. That is the Hippocratic aphorism that was written in the first book of epidemics, "As to diseases make a habit of two things – to help, or at least to do no harm." Now this formulation underpins all of our policies at HHS, and I believe this is what Paul Tang was writing about in 2003. And this is our strategy for health IT patient safety.

You see, it is our firm belief that the upcoming work in health IT patient safety is not solely a defensive game. We do not believe that our singular charge is "primum non nocere." No, we're committed to the proposition that health IT must have a direct role in making care safer, and that is exactly what we were told in the latest report. Namely that there is an expectation that as one growing part of American healthcare, health IT can improve patient safety overall. But to fully exploit its potential, and by extension reduce its attendant risk, we must work together to learn the proper place within the larger social technical system.

Now, having outlined our foundational underpinnings, I think you'll recall from Jodi's presentation, that we are approaching this work through three major lines of attack. Our immediate need is to understand this patient safety much better. A significant amount of resources will be used to increase the quantity and the quality of data regarding health IT in safety, in the hope that we might turn that data into knowledge. Now, we will gather this data from three primary categories; from providers, that is, from clinicians and facilities. Now – and to do this, we'll use, among other things, the bully pulpit to encourage the reporting of health IT-related safety events. We've already taken one step in place, and that was late last year when we were fortunate enough to announce the winner of our Health IT Safety Reporting Challenge. It was awarded to KBCore. They're winning application really proved quite impressive and very versatile. Next, we expect to garner safety related information from vendors as we encourage them to embrace a collective shared responsibility to prevent patient harm. From all of these channels, we will provide a variety of reporting mechanisms. I suspect that you're very familiar with the elements of Stage 2 that facilitate the flow of information from the vendor and accreditor community. That is, information regarding their use of quality management systems, user feedback and ACB surveillance. And finally, it'll be a pretty large list, but we will secure safety related information from existing resources at HHS. Now obviously that includes AHRQ and CMS. It is clear that this disparate data will need to be rationalized or normalized. We are fortunate that we have, that we might group apples with apples and oranges with oranges with the use of the AHRQ common format. It's an excellent indexing and categorization system for all manner of events.

Now this slide is busy, and I apologize, but it's used really only for reference purposes and I hope it illustrates the concept that we'll have a central processor of Health IT related patient safety information coming in from a variety of channels. So this just schematically shows some of the information flows. As we learn, we'll also begin to improve the system. To that end, we will leverage resources at AHRQ and CMS again, and our own offices here at ONC. Inherent in our plans for improvement is the expectation that some analysis and some synthesis of viable solutions will be managed at that central coordinator place or here at ONC. And finally, as with any safety enterprise, there is ample opportunity for leadership. I think I should point out that safe systems are first a derivative of strong leadership and in editing all three editions of the NQF safe practices manual since 2005; we were unanimous in selecting the creation of a culture of safety as the first practice requirement in a safe health enterprise. We have a great deal to learn in this regard, but if we are ever to have been recognized or considered a success, this must happen.

Now, I began with Voltaire and I'll wind up with one of the most respected and well-read researchers in the field of safety in general, Professor James Reason of Manchester. He noted that while "we cannot change the human condition, we can change the conditions under which humans work." This is yet another fundamental precept of safety and it sounds like our reason for being in meaningful use. The overarching question – Is safety meaningful? – was really meant to be rhetorical, but I hope you can see from this statement of Professor Reason, that the ball is clearly in our court. Our job will be taking the concept of safety in its current form, which is a tacit assumption of meaningful use, and making that connection explicit, obvious and non-trivial. And with that, I'll stop and I thank you all and I think that we're going to have a portion for questions and answers.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So David, thank you very much for the presentation. Any immediate response from the members of the workgroup?

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Well I just find it enjoyable always to listen to David. As you can tell, his articulation is more like poetry, so thank you David.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

Thank you. The check is in the mail.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

So, I'm looking at what Larry sent out, this is Marc Probst, and under Meaningful Use and Safety Risk Assessment, it talks about, we talked about these questions, that part of it says, "To improve the safety of EHRs, should there be a meaningful use requirement for providers to conduct a health IT safety risk assessment?" And as you said, and the health IT really is just part of it's a tool that's used within the provision of care. Do we – has work been done to really point out, what is what's unique in health IT? I mean, if it's a hammer, I understand that there's a nail, if it's screw, you can loosen and tighten screws and you can probably use it inappropriately to the wedge off a board. But, what is unique in health IT as it relates to safety? This is such – health IT is a huge category and safety is a huge category, and we could get lost in a discussion for, well, what's it been, since Paul started, 13 years in this topic. How do we narrow it down, particularly when we're going to ask people to do something in meaningful use and then there's certainly the potential for certification requirements.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

I can take a portion of that. There has been work on a number of fronts, mostly in the private sector, to look at this question. But I also have to point out that we at ONC have commissioned some work along these lines with the SAFER Guides, to begin to look at what is it that is unique about health IT that can one, make overall care safer and what are some of the unique risks that we need to prevent or mitigate or diminish in health IT. I think one of the most important things that I can convey that in looking at this overall landscape is that where we are today will need to grow exponentially in terms of our knowledge based on what this is. So much of what we do now has changed in the way that patients flow through our offices and hospitals that we're not completely sure all of the pivot points that health IT can cause problems with, and can help create some efficiency. So, there's a tremendous amount that we'll need to learn, so I don't know if there's a complete answer to that.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

David – I wasn't aware of the SAFER report, but, you know, if you looked at and said, can we build a Pareto Analysis that shows where the real challenges of safety in health IT is, does even something like that exist?

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

If I can speak up, this is Joan, and I've been involved in developing the SAFER Guides. And the first thing that we did was to try to prioritize the highest priority and riskiest areas for EHRs and HIT, and so that has been done. We have ten guides in the works right now, assessing the worst things that can happen. For example, one of them is strictly about downtime, which is one of the things that's very unique and different about Health Information Technology is that we're risking people's lives if systems go down. And so, Kathy Kenyon's been very involved in this as well. And if there's anything you need to know about the guides and the progress we're making with them, I'd be happy to share that.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Thanks Joan.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

And Marc, this is Paul. As usual, you have a very insightful and piercing question. I have a couple of things, and it piggybacks a little bit on what David said, and Joan. And what's unique about HIT is, unlike paper, which fails one at a time, HIT affects everybody in whatever locale. Downtime is a good example, like it goes out for everybody, but there are so many ways that it is ... challenges that may be an ... product or implementation affects everyone. One of the challenges is really usability and as you know, we've been trying to tackle that, but there is no one test of usability. So, that's one of the reasons ... but, how do systems improve, as complex as they are, you know this, that basically you need data to figure out, well, what are you doing and what's this result and can you improve on it and then do you get better results. So, one of the biggest deficits the ... committee quickly uncovered is, the lack of data and there were a number of impediments to getting data out there in an analyzable form. So, addressing one of the questions that ONC has for us is, should there be some kind of requirements under either meaningful use or certification that causes, that facilitates the reporting by the user of incidents of risks, let's say there's a button you push in the EHR that captures all the context and then you can describe, hey, here's what I'm worried about somewhere. And then the other piece is can it go somewhere so that it can be analyzed. So, those are a couple of ways that we could potentially use meaningful use as way of getting more data so we even understand the problem and can continuously improve our situation.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

And if I can just dovetail on that. That is incredibly important and one thing that'll be key as we begin to get this information provided is that it is provided in a, with a common taxonomy or common standardized way of reporting and that's where I'm hoping that we'll be able to leverage the AHRQ common formats.

Martin Rice – Health Resources and Services Administration

So this is Marty Rice from HRSA. Quick question, are we looking at this as – I always looked at HIT as a technology that's been placed on a process and so, are we looking at this to protect the patient process using HIT or protecting, or looking at HIT as a technology being efficient?

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

I think it's – HIT is embedded in our processes and we just want to figure out how are our processes doing in terms of mitigating risk to patient safety and ways to get data about that and so that we can improve, is probably where we're going, without saying it's only one or another.

M

Clearly ...

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

... processes.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

This is Larry, let me jump in for just a second and add a little bit of color to what Paul just said, which is, I think the notion of combining the safety broadly with health IT is really important. Because if you start looking at safety issues, you don't really know up front whether this was an HIT helped this, hurt this, contributed in some way, was neutral to the safety issues, until you actually look at what happened and do some kind of cause analysis. I don't want to say root cause, because I think there's typically many roots to the causes. And so I think that this is – there's a sophistication needed here, we can't just say report health IT safety events, because you don't know it was an IT event until you've looked at it.

David Hunt – Office of the National Coordinator

I agree wholeheartedly, that is a very important point. And with regard to the overall patient safety, I think one place that we can look to see where health IT might be able to help or reduce overall patient safety, is to look at the key areas that the department is already focusing on, in terms of general patient safety. And in that regard, the work of the Partnership for Patients, that have outlined our major patient safety challenges in general, at large, is a good place to look at has health IT helped these, has health IT actually inhibited some of the progress in this work.

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

Don Rucker. I think part of – a big part of the challenge is also that if you sort of dissect, even going back to Ross Koppel original article in JAMA, most of the things are either an interaction of sort of the vendor system and site customizations or more fundamentally driven by sort of site choices. And I think, how do you sort of get the flavor of the local install, I think is something that I didn't really see that in the plan, but I think that's sort of pretty central to the analysis.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, this is Larry, I'll jump in on that because I think the whole notion of the health IT risk assessment is something that's being asked of the provider, so that's how I'm understanding it, in the same way they do a safety ... not safety, a security and privacy assessment under HIPAA. So we're asking the question here is does there need to be a safety assessment and I sort of feel like that would capture the local things. But I think the real charge here is, maybe getting to the leadership question, culture question, of the value here is not formulaically going through some kind of assessment process, but actually looking to use the health IT to really achieve some outcomes, just have some goals for an organization, use the technology to achieve those goals.

There's been a lot of press lately about some of the shortcomings of the technology and I'm kind of amazed at the assumptions that are made by some provider organizations that simply by acquiring this technology, it will suddenly improve their quality or help them manage their costs or help them with the quality of their provider days. And none of those are achieved just by adopting the technology, all those have to become explicit organizational goals, they take effort, they take focus, they take data collection, they take analysis. And so I think this notion of having people do risk assessments is really important as a notion, but I think we have to figure out how to actually make it helpful and effective for the providers and not just add one more task to their to-do list.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

So Larry, in following up ...

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

So ...

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Okay, go ahead Joan.

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

If I can speak up again about the SAFER guides, the way they're being designed is for a self-assessment that would be done on a routine basis. And built into them they outline ideal goals and as a self-assessor, you say, well, we're just beginning this path towards reaching this goal. The next time you do your assessment you're saying, well, we're well along the path now, and this is the goal we're going to set for the future to reach the finality, the ultimate goal. So, it is a learning process and it almost forces planning towards greater safety.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Maybe I'll ... on that. So, a couple of things that are being asked of us and maybe these are the ways we can start this process. One is what Joan said which is; even to have ... raise people's awareness at the healthcare organization and the vendor, about the risk of using...the use of these technologies in patient care. But the second thing we need, the minute you have a plan is, well, we've got to get data and maybe another step we can take is to make sure that ... is to require data to be submitted, and that's part of the IOM recommendation. So, the ability to quickly, in the process of care, oh I see how this could cause a problem, be able to, for the user, just jot that down, capture the EHR context and send it in, so that they don't have to take extra effort to do that later on. And then the other part, as David referred to, the common format as a way of putting things in a standard format so they can be analyzed later. So maybe we can start with the thinking about it, the plan and then capturing data in a useable format.

M

Do the SAFER Guides work as a way to start prioritizing what we would focus on because, well, I guess I'll just leave it at that question?

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

That's a good point that it shouldn't create burden, an additional report or extra effort. It should be done on a regular basis and it should be kind of invisible to the user.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Well, it's not invisible to the user, we want to make it as convenient as possible, because the user has a lot of contextual information themselves, but they don't want to explain where they were on the screen, etcetera. They just want to say, hey look, I recognize this as a potential risk or something did happen, let me let people know about it so that it can be further investigated.

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

Well if it's a risk, it means it's a problem, and if it's a problem, it should be done in the background and not invisible, it should become as an alert that something's happening.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I guess I'm imaging what Paul's describing is, you're using your EHR and you notice something that isn't right, and it could be all kinds of things that make it not right. And you're saying there should be an easy way to say, at this moment, without really interrupting my workflow, I want to be able to tap on something that says something's not right here, maybe I key in three or four things about what's not right. It captures my context and then that's available for subsequent analysis and possibly passing on to a quality organization.

David Hunt – Office of the National Coordinator

In the application from KBCore helps with that to a large degree.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I'm sorry, what's this KBCore?

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

I can send you the link to the information on our app challenge. With KBCore, basically the challenge was to see what's the fastest and least painful way they can develop an app that will help you capture safety-related ... health IT safety-related events, and then pass them on. And I'm sorry; I should have shared the link with that beforehand.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So let me back up and say, given my earlier comments about it's not just Health IT, that it might be helpful if in any healthcare safety event, to consider how the EHR becomes a vehicle to help indicate that one has happened and that there might actually be useful context in the EHR beyond the immediate user context that's on the screen that would be helpful. And I realize I'm sort of blowing this really wide open by saying this, but if there's, for example, a medication administration error that it should be easy to say, and maybe this is more a tie-in to an organization's event reporting system, it should be easy to say, there's just been a patient safety event and there may be relevant context in the EHR to inform that, in terms of the process that was used to handle this medication, starting from diagnosis and orders through dispensing, administration and patient reaction. That there's all kinds of data that might be useful to capture at any point in there, there may be a contributing factor from the EHR technology or there might be mitigating factors from EHR technology. We've talked about concerns for near misses, and so it might be interesting to actually be collecting data about where the decision support provided useful guidance and where it provided not useful guidance.

Kathy Kenyon, JD, MA – Office of the National Coordinator

This is Kathy Kenyon. We certainly agree and the reporting app challenge allowed for all calls reporting using the AHR common format. That format captures the HIT presence in that, in any kind of adverse event in healthcare, including near misses. I think the underlying question is the extent to which that needs to be more integrated into a regulatory framework. We're clearly developing the infrastructure out there, but the workgroup and the Policy Committee may be able to then look at more closely around reporting. Last year you considered using the common formats, making the common formats much more integral into EHRs. I think that will be an important discussion this next year, but we have been making progress on the ease of all cause reporting out of the EHR that also captures the role of Health IT.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

That's helpful Kathy, thank you.

David Hunt – Office of the National Coordinator

And I think one thing that's important to remember in this is that when you look at the overall model of structure, process and outcome, that the EHR fits, actually straddles in two domains. It is a structural component of healthcare as well as an element of the processes involved with healthcare, so, we have to be able to identify both domains that health IT may be attributing to ... or contributing to.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

And I guess there's been a lot of statement of the potential for health IT to demonstrate great value and improve safety, and it would be great if in some of this we actually could see people not getting paranoid about how the IT is a problem, but actually getting engaged in making it part of the solution.

Kathy Kenyon, JD, MA – Office of the National Coordinator

I think that was very fundamental to the action surveillance plan and I can also so, and Joan can reinforce this, that we've built that into the SAFER Guides. It's both about making certain that when the clinician sits down to use the EHR, it is safe. It's also about making certain that the enormous potential that EHRs have to make healthcare safer is part of what we're doing in this safety effort.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So I wonder as a background, if ONC could send out to us the SAFER Guide.

Kathy Kenyon, JD, MA – Office of the National Coordinator

(Indiscernible)

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

... my inbox.

Kathy Kenyon, JD, MA – Office of the National Coordinator

We're in the – we don't have a final version of it, but I think that we could...

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Ah, okay.

Kathy Kenyon, JD, MA – Office of the National Coordinator

... certainly, we expect to have it in September, but I think in the interim if there's interest in it, we can certainly describe it in more detail.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

As we look at the charge that we've been given, do the SAFER Guides help us in defining what we're trying to do here, or are we just looking for a very broad scope, how do we collect safety-related information to HIT? I don't even know who I'm asking that question of.

Kathy Kenyon, JD, MA – Office of the National Coordinator

Well in the narrowest sense, I know that the committee is focused on Stage 3, and so, there is just the question of, to what extent can the technology help us with patient safety and how can we make certain that the technology continues to be safer. Just as what you can do through meaningful use and certification criteria on that. There is a much bigger picture for health IT and patient safety and the extent to which the committee is interested in that, certainly the SAFER Guides address both, but mainly the bigger picture. We're trying to do something that's helpful to the users of EHRs, who are adopting the technology that we're advocating.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So Marc, I guess I'm asking my question, I was thinking that our charge says should we be asking people to do a risk assessment and are there guidelines for that, and it sounded like that that is part of what's in the SAFER Guides.

Kathy Kenyon, JD, MA – Office of the National Coordinator

That is true. We will have the comments...we asked that question in the RFC, and I've actually read the comments, but – so, those will be available to you soon, for what ... and there was a kind of consensus opinion on that. I think that the SAFER Guides and some work being done by others will be very helpful to people who want to do a Health IT safety assessment as part of overall safety. Whether or not you build that into Meaningful Use is a different question.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

So Larry, I might suggest, this is Paul, given your time constraints, it's fine for the workgroup and even the committee to eventually recommend self-assessment. As you know, our input goes into ONC and then ONC can ... or ONC and CMS can later decide what guide to put as either suggestions or possible things to consider. So, we don't actually have to come up with a specific recommendation if we don't have one at this time, but the recommendation might be that we, that everybody perform this self-assessment.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So Paul, you're pointing out time, and we have 10 minutes this morning and some other questions that we need to be looking at. I wonder maybe if you could back up the slides to the question slides, so we can have those in front of us, and we could see if we can't get some key points from folks before our time is up this morning. So, we've been talking about meaningful use and safety risk assessment. Any thoughts or comments about repor – so, there were comments in the ONC plan for using patient safety organizations as a reporting vehicle, and engaging that whole process, including pointing out some issues that vendors might not be protected in that situation, but presumably provider organizations are. So, any comments about reporting aspects of this?

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

It almost seems like – Don Rucker – it seems like there's almost two things here. So, there's a safety risk assessment, which seems to me to be sort of a prospective thing. And then there's sort of the retrospective reporting. I mean, it seems like we have sort of two separate things here. As I was reading the report, also I was sort of curious in whether there's an understanding about what the overlap of usability and safety is. If you sort of look to aviation safety, certainly those two things in many cases seem to be related, maybe not when you're talking about...or batteries, some things are profoundly technical and don't really have a UY component to them.

But I was just sort of curious about that, because the stuff you see on the screen is certainly what the sites are going to be able to do and I'm not sure what the vendors are going to be able to do in terms of stuff underneath. Because it's sort of hard to imagine there's a big space between things that are unsafe yet actually work as software, you know, just from a computer bits and bytes thing. So, maybe focusing some definition on how much we think usability, how much we think prospective versus retrospective, might be a way of getting a discipline around it. It sounds like the patient safety organizations would really be a reporting mechanism and I think if we do the reporting mechanism step, then I think there's also the issue of – probably there ought to be one place to do it, whether that's the FDA ... or the PSOs or the certification things. But it seems like sort of a diffusion, or maybe even one of the international standards groups, right, because there's a bit of a reinventing of the wheel here. But it sounds like we should try to pick one place, rather than having three or four, for the reporting part.

Kathy Kenyon, JD, MA – Office of the National Coordinator

The information that comes in from PSOs goes to an AHRQ-run network of patient safety databases. So, there's potentially one central place that information is reported. It's de-identified at that level and available to researchers.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

So Larry, I think we certainly don't want to repeat the conversation at the IOM Committee, but leverage their recommendations and I think one of the primary missing factors is getting this data in a combinable way. So if we could require that EHR vendors have this, I'll just put it, call it a button for right now, this reporting capability that captures the EHR context, so that it's easy for users to report and then that report is generated in the common format, that's a step that I think we all need.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So that would be a pretty focused piece that could be in certification.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

So the certification for the vendor side and then ...

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Right.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

... this question on the screen is on the user side. You need to do your self-assessment and probably one ... assuredly one of the things that'll come out of that self-assessment is, gosh, I need to have more, a better understanding of what is going on in, and that's the data piece. So ... the IOM recommendation said that the reporting should be mandatory from vendors, so reports that they get in should go somewhere, PSOs is an example. And the user is a voluntary experience, but we need to help the user make it a convenient way to report.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

So is it the charge of this group to put the high-level ideas of what that assessment would be or just that there needs to be an assessment?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I think given the timeframe, we're really being asked to confirm or shape the priority of direction here.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Yeah.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

So that was the latter, that there should be an assessment?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Yeah.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

And then that second part, are there models or standards ...

(Indiscernible)

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

The group can choose to say, e.g. SAFER Guide or whatever they want to propose and eventually ONC and CMS will decide what to either suggest or state. But, we don't seem to have the time to go through it ourselves.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

... a general question – you may know this Paul – what's the environment for providers in reporting this? I mean, is it a safe part of the ... environment to do that or are there risks in reporting safety problems?

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Yeah. So actually, one of the things that did come out of the IOM report that David alluded to is the creation of PSOs, Patient Safety Organizations that was created in statute with protection. So one of the models was aviation safety, because the pilots are protected when they report. So they create a similar protected environment when providers report, hey, something either did happen or could happen. Yes, that has some potential liability, but that's what the PSOs were set up to do, we're doing this in the name of ... yeah.

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

Do the PSOs override state law? Like I know in Pennsylvania, where I practice, we have a requirement in the Pennsylvania law to do mandated public reporting.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

So no, it would not override that, because you're more strict ...

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

Right, so and that's true, I think, in a lot of states, because they sort of deals with trial lawyers on this, I mean, I think that was the politics of it. So, it might be interesting to see how many states would actually even be able to maintain this type of privacy.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Well, when you go into the Federal PSO, it's protected at the federal level.

Donald W. Rucker, MD, MS, MBA – Siemens Corporation – Vice President and Chief Medical Officer

Right, but if I'm reporting it to state as a doc, and that's where the malpractice action is, that's probably – I wouldn't necessarily see that Federal protection is helping me.

Kathy Kenyon, JD, MA – Senior Policy Analyst, Office of the National Coordinator

It does help you; it provides protection at state, in a state malpractice action. So, it's ...

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

So, a short answer to your question Marc is, yes, it's covered and there is a protected environment.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Okay, thank you.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I guess that really points out one of the concerns that would probably come from providers, which is, typically our event reporting applications are very separate from our EHRs, even if there's an entry point into them from the EHR, in order to have the information be seen as protected for performance improvement reasons. So, it may be unnecessary to restate that, but it sort of feels like one of those boundary issues of where does this information get recorded and is it in the EHR or is it something where we're capturing context from the EHR and then passing it off to some other place.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

It sounds like that reporting trail is pretty well defined, unless – I may be misreading what I'm hearing. If that's true, then, I mean, there sounds like there's also being technical solutions, I didn't write down the name of the one that you were talking about earlier, that was the winner. I don't know, I mean, it's all one environment. To me it was more important that there's a pathway where this information goes, one, so that it can be used. Secondly that it's protected, that we're not putting, that we actually get information that people have an incentive to do it, to submit it, and now it sounds like we've got to make sure that the...that we're asking the vendors to build the capabilities into the systems they're doing.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Sounds like a plan.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Was there anything unreasonable in all that?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I think I'd take that even back to kind of a step zero, which is, the risk assessment as a process, right? And then we have a way to identify things, right, identify events.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Yes.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

And then that it's protected, there's a mechanism to submit it and that's build into the products. That seems to actually address the questions we're asked to look at as well. So, maybe this is the place to pause, we have a follow up call tomorrow; and open this up for public comment. Does that make sense Marc?

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Yes.

Public Comment

MacKenzie Robertson – Office of the National Coordinator

Okay, operator, can you please open the lines for public comment?

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you are listening via your telephone, you may press *1 at this time to be entered into the queue. There's no comment at this time.

MacKenzie Robertson – Office of the National Coordinator

Okay. Thank you very much and Larry and Marc, our meeting tomorrow is 3-4:30, just to remind everybody.

Marc Probst – Intermountain Healthcare – Vice President & Chief Information Officer

Thanks for everybody's input and David, thanks for spending the time presenting that to us.

David Hunt – Physician Steering Group on Trusted Identity, Office of the National Coordinator

Thank you.

Paul Tang, MD, MS – Palo Alto Medical Foundation – VP & Chief Information and Technology Officer

Thanks David. Thanks Marc and Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

... more thoughts tomorrow and if anyone's inspired to circulate some notes in advance, that would be great, too. Thank you.

MacKenzie Robertson – Office of the National Coordinator

Thanks everybody.