



HIT Policy Committee Implementation, Usability & Safety Workgroup Final Transcript October 24, 2014

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? Bennett Lauber?

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

Hello good afternoon everybody.

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

Hi, Bennett. Bernadette Capili? Betty Mims Johnson? George Hernandez?

George Hernandez – Chief of Applications and Development - ICLOPS

George here.

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

Hi, George.

George Hernandez – Chief of Applications and Development – ICLOPS

Hi.

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

Janey Barnes? Jeanie Scott? 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, this is John.

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

Hi, John. Jon White? Lana Lowry? Megan Sawchuk?

Megan E. Sawchuk, MT (ASCP) – Lead Health Scientist, Center for Surveillance Epidemiology & Laboratory Services – Centers for Disease Control and Prevention

Here.

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

Hi, Megan. Michelle Dougherty?

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

Here.

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

Hi, Michelle. Michael Lardieri?

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

I'm here.

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

Hi, Mike.

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

Hi.

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

Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

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 – Chairman - 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 Ellen Makar from ONC?

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

I'm here, thank you.

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

Hi, Ellen and with that I'll turn it back to you, David and Larry.

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

So, thanks so much Michelle. Could we have the next slide? So, and then the next slide. So this is just our meeting schedule. Today we'll be hearing about Health IT and patient safety, we'll be hearing from Ronni Solomon from ECRI and then Gerard Castro from the Joint Commission. And in our next meeting after that, which is November 7th, we'll be hearing about implementation science and certification.

We're still working out what we'll do with the two ones after that and then on Friday the 12th we'll talk about post implementation usability and safety, we'll get a report out from the Safety Center and we'll be sorting out what our timeline and goals are from 2015. And I will not be here at the next meeting; Larry will be doing that one solo. Next slide.

So, what we're going to do today, I'll just make a few remarks to provide a backdrop in terms of HIT and Safety then we'll have the two presentations, then we'll have a group discussion and then public comment. Next slide.

So, the backdrop in this area, this Institute of Medicine Committee, the Health Information Technology group was asked to report on this topic and what I'm going to do today is provide an ultra-brief summary of the IOM committee's report and I'll also summarize some of the recent research reports in this area. Next slide.

The IOM committee that worked on this area was asked to summarize the existing knowledge of the effects of HIT on patient safety and to make some recommendations to HHS regarding specific actions federal agencies should take to maximize the safety of Health IT assisted care and finally to make recommendations concerning how private actors can promote the safety of Health IT assisted care and how the federal government could assist private actors around that. Next slide.

And the very brief summary of the recommendations is as follows, the feeling was that current market forces were not adequately addressing the potential risks associated with the use of HIT and that all stakeholders needed to coordinate efforts to identify and understand patient safety risks associated with Health IT by first of all facilitating the free flow of information, second by creating a reporting and investigating system for Health IT related deaths, serious injuries or unsafe conditions.

And finally, by researching and developing standards and criteria for safe design, implementation and use of Health IT. This relates fairly closely to, you know, what we've been asked to do. Next slide.

So, you know, what does the evidence show about this area? Well, you know, we have some reasonably substantive evidence in a couple of areas that Health IT does make things safer. A lot of that comes from the medication safety arena and these are two meta analyses that looked at computer order entry and medication safety.

One study found a 66% reduction in prescribing errors on average. There have been very big reductions in prescribing errors that have been identified. If you look as an outcome at...harm at adverse drug events there are...in the Wolfstadt study there were 10 studies, five showed a decrease in adverse drug event rates, four showed non-significant trends and one showed no effect. Next slide.

And there is also some evidence that if you report that you have better medication safety related performance that you do better. Notably there is a paper by Leung in JAMIA in 2013 that found a 43% relative reduction in the rate of preventable ADEs for every 5% increase in your score on the Leapfrog test and in absolute terms that would mean that there are four fewer preventable ADEs for every 100 admissions for every 5% increase in your Leapfrog scores. This is a test that basically looks to see if you have a more important medication related checks in your system. Next slide.

For, you know, many of the other categories of harm that occur in hospitals in particular like hospital acquired infections, deep venous thrombosis, pressure ulcers and falls the evidence about whether HIT effects your risk is much less clear.

We do have a couple of studies that suggest strongly that if you slow providers down substantially that this results in worsen outcomes and the work of Joan Ash among a number of other people have demonstrated that many other unintended consequences can occur when you implement electronic health records.

So, that is just a very brief summary of the evidence. Larry, things that you would like to add at this point?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

No, I think that this sort of broad setting the base is exactly what we wanted to cover David. And I guess I should remind people as we dive into things to sort of look at both areas where IT is improving care and where it is creating its own problems. Thanks.

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

Great. Okay. So, any clarifying questions before we dive into the presentations?

Paul Egerman – Businessman/Software Entrepreneur

David, this is Paul Egerman, I didn’t understand the slide where I think it said recommendations. Are those like strawman recommendations that we’re going to talk about later? I mean, what’s the status of those things that we’re calling recommendations?

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

Those were the final recommendations of the Institute of Medicine Committee that reported on this process.

Paul Egerman – Businessman/Software Entrepreneur

Oh, I see.

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

It’s not our recommendations.

Paul Egerman – Businessman/Software Entrepreneur

Okay, I got confused, thank you for clarifying that.

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

Sure, yeah, yes. You know and some of those have been followed since then and some of them have not clearly. Okay, so at this point, Ronni over to you if that’s okay?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Sure, thanks David and good afternoon to everybody. I see you've got the first slide up and just by way of background, ECRI Institute is a not for profit organization. We focus on patient safety and quality evidence-based research and healthcare technology. And I guess most appropriate for this committee is that for several decades we've worked on patient safety reporting programs both mandatory ones and voluntary ones, both large and small ones. And these include approximately 3 million events and near misses.

So, we've been looking at HIT related safety events and hazards for the past several years and in fact we've worked with the ONC and we've worked with AHRQ on several Health IT safety projects. You have a copy of the white paper on how to identify and address unsafe conditions associated with Health IT which was published November 2013. And the information in that paper was largely drawn from a deep dive that ECRI Institute conducted in 2012 based on reports that we had been receiving from healthcare provider's organizations, mostly hospitals and by the way we'd be happy to provide a copy of that deep dive to the committee.

So, based on that work and based on interest from healthcare providers and from Health IT developer organizations, and others we convened a multi-stakeholder collaborative, a partnership for Health IT patient safety. We formally kicked it off in February of 2014 and I was asked to provide information to the committee on the partnership and in addition Dr. Clark will describe findings based on our review of Health IT related patient safety reports. So, you can go onto the next slide.

So, the purpose of the partnership, it's pretty straightforward, making Health IT safer together and our objectives are to establish a non-punitive environment for sharing and for learning to test a collaborative model for collecting and analyzing safety issues, it's collaborator and it's multi-stakeholder. It's to achieve robust stakeholder engagement, share best practices and lessons learned, evaluate two Health IT reporting taxonomies, I'll speak about those in a minute, and to inform the national strategy for Health IT. Next slide.

So, as you can see it's a collaborative effort, it involves many organizations, it involves healthcare provider organizations, Health IT developers, safety researchers and scientists, patient safety organizations, med mail carriers, medical societies and professional associations.

We've got about 15 healthcare provider organizations that are reporting data into us. So, essentially it's a collaborative that's small enough to be manageable but it's also sturdy enough to scale up and in fact we're still getting some new organizations signing on as we speak. Next slide, please.

Here are the three major activities that the partnership engages in, one of course is collecting data and you can see the list of the kinds of data that we're getting. And then it's doing the analytical work which will hopefully lead to leveraged learning and dissemination of best practices and some change. So there are the three big buckets of activity. Next slide, please.

Obviously, communication about the partnership is key so we established a web portal for the partnership and here are the kinds of things that are up on that web portal; there is a welcome kit that includes things like of course information about the partnership but guiding principles for participating, frequently asked questions.

We then have the actual web-based reporting system that we have on line and we've got two different Health IT specific reporting systems one employs the AHRQ common formats and one the Health IT hazard manager.

We also have a way to get insecure communications and this is for non-standard information. So, this is where hospitals or providers may give us things like investigation reports or root cause analysis or other sorts of data. We have training materials up on the website. We post the audios of our quarterly meetings, we post our partnership newsletters and we put resources up there things like the SAFER guides that ONC has created and things like the top 10 guides that ECRI issues every year, we issue a top 10 guide on tech hazards and on patient safety concerns. Next slide, please.

So, what are we getting? Here is a list of the kind of information that the partnership is currently receiving. So, the column on the left is standardized data. So, this is, you know, fielded data, they are web-based reporting systems and people who are reporting things in like incidents and near misses, and unsafe conditions. They're also reporting in hazards through the Health IT hazard manager.

And then you've got the items on the right which we didn't necessarily expect to...well the first couple of items we didn't necessarily expect to get but we're getting things like alerts that providers disseminate internally, we're getting help desk logs, we're getting, as I said, root cause analysis and then we review the literature.

So, we're looking at things like MOD and MedSun the general literature and we're doing some polling. Most of the data that we're getting is from provider organizations but there also is some that comes in directly from Health IT vendors. Next slide.

So, I mentioned those two standardized systems and, you know, you can see what those are and one is the AHRQ common formats, the other is the Health IT Hazard Manager and just by way of background, ECRI Institute had worked with Abt and Geisinger to beta test that hazard manager as part of an AHRQ project that we did back in 2012. So, we were very familiar with the ontology and how it worked. Next slide, please.

So, here is our flow chart of how we handle data that comes in and let me just make two points about this because it's a lot to look at, at first glance. One is that we get data from organizations that are participating in the partnership. They've signed up to be a part of that. But then what we are also getting is data contributed from ECRI PSO and from our collaborating PSOs that consist of all cause harm data and that can be a lot of data because it's what's usually coming into our PSO.

So, what we are doing is looking at that all cause harm data on a regular basis and then we're ferretting out the events for which Health IT was a contributing factor. Next slide.

On September 23rd we held our first face-to-face meeting of the partnership so here is the agenda and the desired outcomes that we had from that meeting of the full day meeting. We are in the process right now of compiling proceedings which will be disseminated, our plan is by the end of the year, but in the next couple of slides I'll provide you with some preliminary findings. Next slide, please.

So, to get the day started we used an anonymous polling technology to gather stakeholder perspectives and at the beginning of the day we asked a question which was, you know, what do you see as the top HIT safety issues and people were limited to three responses and you can see, you know, in this sort of messy cloud all of the kinds of responses that we got and the bigger the font the more times the topic came up. But you can see there were really so many issues listed and there was so much variation. Next slide.

Here is the same question at the end of the day with really very different results. So, there is a lot less variation. There were a lot less topics and there were really different topics. Next slide, please.

Here is another way of showing the data and this is a, you know, a chart that we developed from that first question of the day showing how many times a particular issue came up. And again, this was all through anonymous polling so that people felt comfortable speaking. Next slide.

So, we wanted to get a sense of how stakeholders were defining what they perceived to be an HIT event and we suspected that there would be a lot of variation and so we came up with 10 very simple case studies like the one that you're seeing on this slide provider documents care in the free text fields of the EHR, included in the documentation is a medication order and a lab order. So, this ended up in the free text field and not in the structured field, so, you know, we all know what could potentially happen then, which then those results may not end up in other important communications.

So, we asked the group anonymously to vote on whether they thought this was an HIT related event and you can see that there was a lot of variation in the answer, it was interesting. And then we also asked, would you report this or should this be reported internally to your IT organization, to the partnership and to the vendor and you can see the kinds of answers that came up. So, we did 10 of these case studies, they were all very different and got results on all of them. Next slide.

Of course the partnership is always striving to use a variety of methods for engagement, dialogue and sharing. I mentioned the case studies. We also held breakout groups at our partnership meeting. Each breakout group, there were six groups, each one of them was multi-stakeholder, we had two look at use issues, two look at hardware and software and two look at interoperability and it was a really robust discussion which we will be capturing for the purposes of those proceedings.

We also have videos. We do hold quarterly meetings with the exception of the one face-to-face they've been by telephone and we have a monthly newsletter. We have been involved in collaborator events at their annual meetings and so forth and so on. And then we're trying to also come up with engagement tools, how to help organizations get their frontline staff to recognize and feel comfortable about reporting Health IT related events. Next slide.

So, what are the next steps of the partnership? We will be issuing proceedings as I mentioned and would be pleased to make them available to the committee. We will be continuing to analyze the safety data that is provided by the participants as well as the all cause harm data that is provided to ECRI Institute, PSO and collaborating PSOs and we hope to publish the interim findings by the end of the year.

Then there was a strong interest at the partnership meetings for creating workgroups that would deal with specific safety issues for which interventions are needed and we are working right now with members of our advisory board on developing a list of those topics and we will be laying the groundwork for convening those multi-stakeholder workgroups. So, we hope to have that all happen by the end of the year and then begin to convene those workgroups in January.

And then the goal is to disseminate findings, strategies and best practices developed by the workgroups and hopefully we'll have something to report out by the summer of 2015. So, it's a tall order and a lot to accomplish in the next several months. Next slide.

So, I guess that's it and be happy...well, David do you want questions now or maybe we should just move right into John's presentation?

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

We can take...let's take any clarifying questions now.

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

Hi, this is Joan, and I was wondering if you could describe the funding mechanism for this. I mean, it's great work, thank you so much for doing it. I'm wondering how it's funded?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Well, it's funded mainly through the in-kind contributions of all of the participants. So, ECRI is making in-kind contributions in terms of setting up the infrastructure, you know, it's something that we've been doing for years so we know how to pull together these websites and reporting systems and get the data in, but we're contributing that, we're contributing analysis.

The vendors are contributing their intellectual know-how but money does not flow at all from the vendors to ECRI Institute. And the collaborating organizations the medical societies and the professional associations and our wonderful advisory board are contributing their time and effort.

So, it's a lot of contribution, we were very lucky to get some funding for the face-to-face meeting by the...Foundation which allowed us to pay the travel expenses for provider organizations to attend and for our advisory board to attend, I don't know if they could have afforded to do that without that funding. So, it was wonderful because we had about 60 people at the meeting and, you know, it was a nice number and it was all multi...and it was multi-stakeholders so we did get a variety of perspectives. We are continuing to look for funding.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, can I ask a follow up question to that?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Sure.

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

Sure.

Paul Egerman – Businessman/Software Entrepreneur

So, that's very helpful information I think and I appreciate Joan asking that question I was curious about it also. Since you're getting funding from vendors is there any concern that some of these vendors, especially some of the very large vendors are influencing your analysis and results...

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Oh, late correction.

Paul Egerman – Businessman/Software Entrepreneur

In any way?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Yeah, correction we accept no funding from vendors, did the no slip out of my statement before?

Paul Egerman – Businessman/Software Entrepreneur

It's no funding from vendors?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

No funding from vendors, no and in fact ECRI has a long history of looking at the safety of medical devices and it's always been, you know, one of our founding principles here not to take money from the medical product industry except if they buy, you know, and off the shelf publication or something. So, no we've not accepted any vendor funding. They are only contributing...they're contributing their time and their intellectual talent just like others are to this partnership.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Thank you for asking that question.

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

Okay, shall we move on?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Hi, this is John Clarke and I'm working with Ronni and I'm going to present the specific results of two of our patient safety organizations one is a PSO under federal PSO regulations and the other is a state mandated mandatory reporting system for Pennsylvania, the Patient Safety Authority. Now if I could have the slide. As David mentioned we know that the adoption of emergency, excuse me of...

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Go back one, yeah, go back one slide, there we are.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

No, we're fine. We know that the adoption of electronic medical records improves patient safety and the Pennsylvania Patient Safety Authority commissioned or cooperated with some researchers at Carnegie Mellon to document this impact and were able to ascertain based on reports to a patient safety authority that there was a 27% decline in patient safety events reported by Pennsylvania hospitals to the authority when they had implemented a level 3 electronic medical record.

However, as David has alluded to, if I could have the next slide, we have seen problems with electronic medical records and specifically those problems have been increasing with the adoption of records. This is a report from the December 2012 patient safety advisory and again you can look that up, but we identified over 3000 records in which there was some implication of the medical record, electronic record, and if I could just go over those in the next slide.

We actually published two articles. I apologize on the left-hand column that December 2012 annotation should be included in that, but as no surprise per David's comments that most of the problems had to do with medication errors and this was of course from CPOE systems. Laboratory tests there were also an issue, but not nearly as prevalent as medication errors.

When we looked at the kind of errors that occurred almost half of them were due to bad information being entered into the record. About 20% of them roughly were due to information not being updated in the record and this could be either manually or electronically from another system. And then in 10% an incorrect default value was used.

And in a subsequent patient safety advisory we looked in greater depth at the default values and so we found that two out of five related to failing to override a default with a data entry. In a few cases, however, the default over-rod the entry, in some cases the failure to enter the data resulted in a default being invoked and in some cases the default value was archaic and was no longer relevant and in a few cases they could not change the default value. So, some of these obviously were issues within the software or hardware I suppose rather than within the user interface.

Now if I could switch gears in the next slide and talk about an overview of the ECRI Institute PSO. We looked at 171 records in the deep dive and I'll give you just a few tantalizing specifics about that and then you can go to the document itself if you wish and I'm sure Ronni would be happy to provide that for you.

But about roughly half of them were interface issues and the other half were issues of either a computer or a computer interfacing with another computer. So, if I could have the next slide. We see that again entering the wrong information was a big problem. Another big problem that was identified here was accessing the wrong record and this occurred for a variety of reasons including multiple records being open at one time, multiple users on a terminal and so on and so forth and there have been people as you may know who have tried to solve this problem by doing such things as putting the patient's picture up and so and so forth. And in 16% the data was not incorrect but was just in fact missing.

So, with that tantalizing bit of information and this short presentation I'd like to move onto the next slide and just give you an overview of some of the general safety issues that we've identified through these two mechanisms of analysis, the ECRI PSO and the Patient Safety Authority.

The failure to link data across systems primarily lab feeding into general systems, accessing the wrong record, failure to get data or to put high data in the free text, entered it into the wrong field as well, and then failure to update the information commonly or frequently with a cut and paste mechanism just copying the old information, using the wrong units. Now if you enter the temperature incorrectly it's pretty obvious but if you enter the weight incorrectly then it's not so obvious. And then what we've identified as poorly constructed defaults.

So, if we get to the bottom line on the next slide and this is just a kind of a qualitative analysis on the next slide by myself. We can say that HIT improves safety but that if you have an error built into the HIT system this is going to be like a non-teachable provider that system is going to repeat the error so it becomes important to identify it.

And that I think there are two ways to look at all patient safety issues and that is that there are two kind of people in the world the ones who say, if everything works out and the other group are the people who say, what is the worst thing that could happen and obviously safety people are in that second group and I think some programmers need to be in that second group too. I certainly school people on how you can screw up a system because I do it on a regular basis, but HIT systems really need to expect and anticipate and check for errors in real time and that's really the goal I think of creating a safe HIT system. And that's it.

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

Great. Thank you, John. Questions for John?

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

This is Mike Lardieri, John, when organizations used a picture did that make a difference or did I hear you say that this really didn't make a difference in identifying patients?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

I think in the systems we saw there was a sense that it made a difference but I don't know that we have enough evidence to say that with confidence.

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

John this is David Bates, in the bucket where you have wrong information entered, that came up on one slide, what things went into that bucket? I mean, you didn't count it that way if it was the wrong patient.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Correct, well that might be they didn't list the allergies or they had the patient as having...there was one episode they talked about where the patient was said to have a PE because someone said PE colon and then described the physical examination. And it's the same kind of incorrect information that you could get creeping into a system because...a paper system because you entered the wrong information.

I'm a trauma surgeon and I was always amazed that the resident would say there was a gunshot wound to the chest and I looked at it and it was a gunshot wound to the abdomen or something like that. The breath sounds were decreased, they weren't decreased things of that type.

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

Thank you.

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

This is Michelle Dougherty, I have a question about the default fields and if you have any additional insights were they certain categories of information that you particularly analyzed in which data defaults created kind of a safety and error type scenarios?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

I can’t recall off the top of my head the specific things. They are mentioned in the article. I just can’t come up with an example right now of the kind of default problems but you could imagine for instance that if you, to save time, said the default was no allergies and then someone failed to enter the allergies that there would be then a statement that the patient didn’t have any allergies as an example.

I think a lot of these defaults were programmed in by programmers who may not have had a strong medical background and they were thinking about how to make things as efficient as possible without understanding the ramifications of the default answer.

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

Thank you I was curious if it was in some of the structured progress notes versus data entry fields for medications and other types of orders, so, but thank you I appreciate your insight.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Well, certainly a major part of it is when you do a dropdown menu for a patient on medications either by name of medication or by dosage of medication. In Pennsylvania we’ve seen for instance in CPOE systems where someone comes in with psoriasis is getting methotrexate once a week and the CPOE system doesn’t allow once a week entry and so it defaults to once a day entry which doesn’t work very well.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, first let me just say this is very helpful information. I really appreciate it. But I have actually two questions one is your sites talk about HIT but it seems like your examples are predominantly like EHR systems. So, are you really analyzing EHR systems or are you analyzing more broadly HIT systems? So, that’s one question.

The second question is, did your analysis include like solo physicians and various sized ambulatory practice groups?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Well, to answer your first question we we’re really looking at everything including...and I think primarily CPOE systems as well as electronic health records and some systems that are embedded into for instance programmable pumps and other programmable equipment. So, the answer is we’re looking at anything in which there is a programming component not just electronic medical records.

The second part of your question is, I think for the most part this...in Pennsylvania it's just hospitals, ambulatory surgical facilities, birthing centers, abortion clinics it is not office practices and the PSOs it just depends on whether they've subscribed to be members of the PSO. So, I really don't know but maybe Ronni might know the answer to that.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

I know that we do have physician practices that are participating in the partnership for Health IT safety. So, yes we're beginning to get that data but it's very much needed and...

Paul Egerman – Businessman/Software Entrepreneur

And then...I'm sorry; I didn't mean to interrupt you.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Well, just it's an untapped area. We've gotten far more from the acute care area than from the ambulatory.

Paul Egerman – Businessman/Software Entrepreneur

Yes and the reason I ask is as I look through your results I had a sense that these are the kinds of issues that you get in larger higher volume environments and there is a different set of issues that you get in ambulatory environments. So, for example the patient matching issues are very different depending upon the practice. I mean, a solo cardiologist has a different patient matching issue than, you know, an acute care institution.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

I think that...

Paul Egerman – Businessman/Software Entrepreneur

But at any rate that's helpful and I don't mean to broaden your scope any further than it is because it is pretty broad what you're trying to accomplish and I appreciate your other comments.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Hi, Larry Wolf, I've got a couple of questions. So, one is a presumption question that Paul's questions about patient identification made me think about. I've been assuming when I heard the stats on patients that this was mostly a, if you will, a jitter issue, you get a list of patients up like, you know, maybe patients on a unit or my patients or something like that and I go to pick someone who is on line three and I inadvertently pick the person on line four and I don't notice that I picked the wrong entry off the screen as opposed to, you know, I have lots of Larry Wolf's in my system and I pick the wrong one just because of, you know, confusion about who the patient is. Any sense of which of those patient identity issues we're running into when you say wrong patient?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

I think the answer is both but let me give you an example of the first which is perhaps not the jittery hand issue but is the fact that I'm sitting on the computer and I'm entering Tom Smith and then I walk away for a minute to talk to Mrs. Smith and then you get on, you've just come back from talking to Mr. Jones and you think that your record is up on that terminal when my record is up on that terminal.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Oh.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

That kind of stuff.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Got it. So, some of it might be issues like a shared device has its own risks different from others?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Yeah, I've gotten the usual issues of disruption. I mean, you know...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

This happens with charts as well you know and it's not just a matter of pulling the wrong chart out of the rack because there are two Mary Smith's on the floor at all, because usually those are pretty well flagged...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

But it's a matter of, you know, you have three charts on your tray and then you grab one and you write an order and it turns out it was the wrong one.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Got it. So, the second question really is more about the underlying information that we're looking at and if you could comment at all on your sense of the ability of people to even know that they have an adverse event let alone a Health IT related one and what your sense of the overall quality of the reporting is?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Well, it's an excellent question. I would say in Pennsylvania where there is a mandatory system we're thankful for everything we get and we use everything we get and we don't worry about what we don't get even though we know we don't get a lot.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

In a voluntary system you get less but it's different. There are different types of events. What we do know is this, that if you just tell healthcare providers to report Health IT events it's going to be a very tough thing to do and we are able to ferret out a lot of events where there was contribution, you know, by HIT in a broad way but they weren't identified as such.

So, we'd get lots of medication error events even surgical error events, you know, lab issues, diagnosis and when you actually...even though the healthcare provider might have checked off medication error or checked off fall, or checked off surgery and did not check off IT when our analysts actually go in and look at the report we may find that, you know, there is a gem of something to learn in there about Health IT and I think it is tough for people to recognize it at the front line and to report on it like that.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

To put this in context in Pennsylvania if you know that something is a computer problem let's say the computer goes down you don't even report it to us, you report it to the Department of Health and yet even with that caveat we received over a brief period of time over 3000 reports where in the narrative we were able...using a machine learning process, in the narrative we were able to extract that this was an HIT problem and we ourselves made that classification. In none of these instances did the person reporting it make an HIT classification.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

We learn a lot from the narrative, a lot.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess to oversimplify the situation your saying if people are generally reporting adverse events and then leave the actual analysis to some kind of look back that that's probably more helpful, more accurate than if they tried to do it in the moment in terms of their judgment?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Well, first of all let's take a very simple thing like lacerating a baby during a C-section, if you get seven people around the room they could classify it seven different ways maternal injury, neonatal injury, accidental laceration during an operation, etcetera. And then you can take any event and you can look at it in terms of different components.

So, you know, you can look at it as a distraction issue or you can look at it as a programming issue. So, I think that there is lot of value in coming from actually analyzing the case rather than taking it...not to mention the fact that most people who are looking at these problems are looking at them very, very simply and how many times have we heard that the solution to the problem is to blame and retrain the provider when in fact it was a system error.

And I give as an example a case in which someone gave the wrong isotope for a radio, for a scan and they fired the person for doing that and eight days later the same institution made the same error because in fact if you wanted to order this particular test you had to go into a gallium scan and then change the isotope on a pull down menu from gallium to technetium and only then would you get the correct study and obviously it was built into the system it was not a provider error and the institution had no insight about that.

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

So, this is Steve Stack, did either of you in this work find...what I find that the providers are very frustrated by...I think sometimes they don't identify it or they categorize it differently like you identified, I think those are very, very valid, but I also think there is fatigue from the stand-point that they stop reporting things as Health IT errors because they find that their response is inadequate, their response time is markedly prolonged and so I can just say our own experience is that we have to call a help desk in India go through a very arduous type reporting process and then maybe not get feedback for weeks or months or never.

And so, I mean, did you get any sense from the clinicians about frustration that they don't report some of these things perhaps because they find that there is never any benefit in reporting them and so they just create work arounds to try to survive or get through their day.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Yeah and I think that that's where local ownership really comes in helpful. I would say that's a very general issue and what we've found in Pennsylvania in 2004 when we started is everyone predicted we would fail but what we did from the get-go was we provided feedback on reports and when people see that there is no action taken they stop reporting. When people see that their report actually made a difference somebody paid attention, someone came up with the solution to the problem and the problem is available for a solution then people actually generate more reports.

So, one of the things we found in Pennsylvania in general was that if we reported on something typically we would get more reports of that type because people saw that it was making a difference but I think that there is no question local feedback is helpful and one way you can see it in Health IT is to just look at what the tickets come in on your help desk within your institution and make sure that those things are followed up that the people are acknowledged, you know, if we have a general Health IT problem or excuse me if we have a general IT problem at ECRI Institute someone is acknowledging our ticket, someone is following up on our ticket and that's what you have to do with HIT too.

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

I would just say, thank you, I would just...I think you punctuated that beautifully. I think there is a lot of learned helplessness because of the sense that it doesn't make a difference what I say nothing gets done and so I think that in the culture of safety and wanting to improve things I think that responsiveness that you identified as being so central is absolutely important to motivating individuals to participate in these kind of quality activities.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Absolutely.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Responsiveness is absolutely critical and so is confidentiality and trust.

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

Yes.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

So in Pennsylvania when confidentiality was extended in 2004 reporting went from something like, you know, 1000 reports a year to 200,000 reports a year.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

It was actually less than 1000.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

It was less than 1000 a year.

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

Well, thank you.

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

So, this is Terry Fairbanks, I want to thank you I think this has been great and I want to ask you a question and then emphasize a few things you've said that I think are important. When you showed the slide of human interface issues, and my interest is in human factors specifically with Health IT, one of the things that you said was 32% were wrong information entered and Larry brought up the good point that when you enter wrong information it can be that you have the wrong information to start and you do your data entry as intended or your selection as intended and that's one type of error.

The other type of error could be you have the right information and then your selection may be wrong and that maybe, in some cases, due to non-optimized interfaced design. And you also, you know, pointed out that you don't always have that information. I think we should emphasize that...I think you said how important a narrative is and I think we should emphasize that because some reporting systems don't allow a narrative.

But my question for you is did you have...are you showing us the broad data and do you have more data about the whys on this so that we could do more of a deep dive into how much of this wrong information entered or other classifications that you have may be due to design issues not because we want to name that and label it but more because we want to learn from it to optimize future designs.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Yes and I think that we did have more detail in both the advisory articles which I referenced and in the deep dive and we made some more specific recommendations but you're absolutely correct.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

And we'll be happy to provide those and also Terry as we, you know, do the analytics for the partnership hopefully we'll be able to find out more about the kinds of things you just mentioned.

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

Thanks.

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

Hi, everyone, this is Tejal Gandhi, sorry I joined the call a bit late so I missed the start of your presentation, Ronni, but I had a question for you...well I have a comment first which is I totally agree with the question about ambulatory issues and I do think the issues in ambulatory are going to be quite different from what we're seeing in hospitals so I think that will be a space we'll need to explore at some point.

But the question I had for you is I know as part of the collaborative you're starting to get information not just from hospitals but from vendors as well or that's the intent and it may be too early answer this but do you have a sense of whether the types of issues you're going to capture from vendors will differ significantly from what hospitals are providing?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

I'm looking at Lorraine who is the project manager for the partnership and we've gotten in some data from vendors. So, any thoughts or is it too soon to say?

Lorraine – Project Manager - ECRI Institute

It's a little too soon, it encompasses some of the same information but some of it varies a little bit because there are things that vendors recognize that providers aren't necessarily recognizing.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Yeah, Tejal that's something that we're going to look at and hopefully they'll...you know, we'll be able to have some information on that by the end of the year.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

But one of the things that I'm concerned about is that you put in a...take it because your system doesn't work and then they fix it locally for your own hospital system as, you know, a special favor without pushing that out generally to their entire system because of all the implications of work and implementation and so I could see this as becoming a very kludge system where we've identified our fixes, you've identified your fixes but no system has all the fixes built into it whereas when my Mac crashes, which it hardly ever does, but when it does crash you're reporting right to Apple and presumably somebody at Apple is saying, oh, yet another report about x, y or z and the next update fixes all those problems, in theory.

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

Thank you, it will be interesting to follow to see, you know, what the differences are and the value of the various data sources.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Yeah, actually that's something Tejal that the vendors are really interested in. They want to know for example whether we're getting information in the partnership that they're not picking up in their help desk system.

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

Right.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

That's a deep interest to them.

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

Hi, this is Bennett Lauber; I have a follow-up to Terry's question. How did you guys classify or did you think about when the correct information was entered in the wrong way? In some of the studies that we've done we've seen some of the participants, you know, enter an order but use the comment field to enter an order. So, would that be classified as an error or would that be the right information just entered the wrong way?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

Well, I guess you could do it either way but you are absolutely correct that a lot of the information gets entered into the comment field and then the doctor is upset that it didn't get propagated as an order or it just literally gets entered into the wrong field, I mean, you know, very simply you entered the patient's first name under the last name field and the last name under the first name field or something like that, but there is no question and I think the biggest culprit in that area is entering something in free text and then expecting it to be somehow magically propagated into the correct field.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

And yet, half of the people at our meeting didn't see that as an HIT issue which was interesting. So, there is a lot of awareness raising that needs to get done.

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

This is Steve Stack, if I could explore that point just a little bit. I think you're right it is shocking, it is an HIT issue and for a number of reasons and it's important to be identified as such. I also though think that part of the challenge...first of all there is obstinance and folks who just don't want to learn the new tool and that's a challenge and we have to overcome that.

But apart from obstinance though did you also encounter that it's really challenging, I mean, in the old days when you could just write on a sheet of paper please elevate patient's, you know, fractured leg at 30 degrees on the bed and check it every hour and make sure that the perfusion is good and there is no neurologic, you know, problems, you could in a couple of lines, if they could read it, you could very clearly state what you wanted done.

There is no way that the EHR can capture all that stuff in structured format and even if it does it has the painful feeling of trying to look for a specific order in a dictionary that's not in alphabetically order, it's very hard to find the specific word to search for some times or find and I could give more examples where our particular EHR you can search for a string that says contains a word or begins with a word but if you pick contains and it begins with the word it wouldn't find it because apparently beginning with the word was not the same thing as containing the word.

So, there are all these glitches that make it very hard for the clinicians to spend all this time trying to find which word to put in. You gave an order with the example with the gadolinium and the technetium and someone loses their job over an error that clearly is a system thing.

So, how do we address those things that it is...you can't just put a text comment and expect someone to do an order, I get that, but how do we address the need that there is still legitimate challenge with not being able to capture the full world of medical care perfectly in structured format and make it useable at the same time?

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

And yet Amazon does it beautifully. So, I would argue that it's possible because it's being done every day in the commercial world and we just have to do it. For instance in your particular order set that you just mentioned this is clearly something that would relate to emergency medicine, trauma, orthopedics and I could imagine that if it was an orthopedic case or a case admitted to one of those services that this order set would be very available, it would pop right up as soon as you put in that the patient had a fractured leg this would be one of the things that would pop up at the top of your order entry list in order for you to check it off or not off.

And Amazon is doing it every day. So, I think the vendors just have to be a little more sophisticated about what they're doing and put a little more logic behind some of their programming so that you can retrieve anything you want in three clicks.

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

Well, this is Terry Fairbanks and I think this...where the discussion has led to relates very much back to the last meeting when Raj and I presented about the cognitive support of work and I think Steve what you're talking about a lot of these errors can be avoided if we really can have a more sophisticated understanding of the different things that the providers need to do to function and a lot of these comment errors we've been looking at these as well here, a lot of them are because there is no other possible way to make the order that the physician wants to make in the system so they do the next closest order they can find and then modify it in the comment field not aware that in many cases, depending on the system, the nurse who is carrying out the order may not even have visibility of that particular comment field.

And I actually am glad that the discussion has gotten to this because I think this is a very important area to look at when we think about hazards.

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

I agree.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Terry, this is Gerry Castro from the Joint Commission and I completely agree with that last statement. That's exactly what we found in our data and, you know, when I get to my presentation I'll touch on that as well.

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

This is David Bates, this has been a great discussion but maybe we should just go ahead and hear from Gerry and then we'll open it back up again if that's okay with people? So, let's go ahead and do that.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

All right, great, well, thank you to everybody on the Workgroup for this opportunity to share with you the findings of our project and as you can see on the title slide that is the title of our project and if you could advance to the next slide please.

This project was funded by the Office of the National Coordinator and it is composed of four different components. One component is where we looked at our sentinel event data and tried to see whether or not we could find any Health IT related sentinel events.

The second component was where we went out for four learning visits to four different accredited medical centers and sought to find out a little bit more about how their Health IT information, Health IT system is structured, if they've uncovered any hazards or what are the types of methods and means they use to identify hazardous situations related to Health IT.

And the third component was to develop an education module which will be released probably first quarter of next year and then the fourth component is to develop some sort of I guess publication or other information to be made available to the public. So, next slide, please.

So, my objectives for my presentation today are to provide an overview of the sentinel event data and reporting process and really it's important to go over this because there are some limitations to our data and what we can say about it and the lessons learned from it. I'll describe the analysis process, share the results and then describe some of the themes from our learning visits. Next slide, please.

So, this is the definition for reviewable sentinel event and most of you are familiar with the term sentinel event but what I will point out is that reviewable sentinel events are those types of events that have caused death or major permanent loss of function. So, those are the criteria for the types of events that are actually reported to the...voluntarily reported to the Joint Commission and that's an important distinction because it's not...it is a very high threshold for that type of event. If you could advance to the next slide, please.

And in addition to those types of events that cause death or serious permanent harm are our lists of other event types that may not have caused the death of a patient. So, we talk about other events such as abduction or discharge of an infant to the wrong family and/or unintended retention of a foreign object. So, there are a number of different types of events that are also included as a voluntarily reported sentinel event. Next slide, please.

So, that being said, in your consideration of different types of patient safety events we've all seen the iceberg analogy before. So, in our estimation reviewable sentinel events are the very tip of that iceberg. We have all of the other adverse events and patient safety events and then everything else underneath the waterline, but again, so relatively speaking in a volume perspective we receive approximately 1200 to 1400 sentinel events reported to us every year, you know, compare that to, you know, ECRI or I was at the UAC conference a couple of days ago presenting where they are up into the hundreds of thousands. So, we receive a smaller volume of data but it is also of the more severe events. So, next slide, please.

This is just a brief overview of our sentinel event reporting process and it will give you some context to understand how this data is actually reported to us or how we are notified of the sentinel events that we receive.

So, there is an electronic submission process as well as a paper submission process and these can be from accredited organizations or from other clinicians within the organizations, individuals that kind of thing, they can be from government agencies. Also, we receive them from complaints. So, we can receive patient letters to the Joint Commission or there is also a formal complaint reporting process available on our website. So, we do receive those types of notifications as well.

And then also I should add if there is a notification in the media that we find. So, if there is a newspaper article or a TV report on a particular event we will follow-up on that if that's an accredited organization. And then finally, the last method is if it's referred to us from a surveyor on site.

When we receive notification of a potential sentinel event one of our staff, our patient safety specialist, who are primarily masters prepared nurses but we did recently hire a human factors engineer, they will work directly with that organization to determine whether or not it meets our criteria for reviewability.

So, again, if you think about the two previous or the few previous slides that had our definition for a reviewable sentinel event and all of the different event types to consider those are the types of criteria that they'll go through with that organization.

So, in working with the organization our staff will assure that they went through the root cause analysis process in a thorough and credible manner and that their plan of action is actually successful in remedying the contributing factors that they have identified during the course of their analysis. So, that's an entire process that will go on through the course of approximately a few months or so, but at the end what we have in our database are the findings from the root cause analysis both categorical and narrative and then also some information on their plans of actions. Next slide, please.

So, this is the type of data that we have within our database. We have the standard categorical information on patient age, range and gender. We have the outcome of the incident as well as the setting service event type and causative factors but we also have narrative data, we have an incident summary that is provided to us from the organization as well as a synopsis put together by our patient safety specialist. So, these are maybe something along the lines of a paragraph length, a paragraph long and length so that will allow us to, at a glance, look at it and see what type of event and what transpired during the course of the event. And then we also have the organization responses to the RCA framework questions. So, next slide, please.

The RCA framework is actually composed of 24 questions and this is the framework that our patient safety specialists work with in conjunction with the organizations to go through to assure that the analysis is thorough and credible and that they look at specific elements during the course of their analysis.

So if you look at the questions and I'm not going to read them to you, but what we seek to do is ensure that they looked at all the different aspects of, potential aspects that have transpired during the course of that patient safety event. So, we look at human factors, external factors and then also, you know, what was the intended process flow and then what did not occur as intended. So, next slide, please.

Oh, look at that the animation still works, okay. So, and going on we also look at other things such as the staff performance during the patient safety event, the accuracy of communication and the availability of information. So, next slide, please.

These are all questions that were very important in trying to determine the contribution of Health IT to the actual event and then finally the last set of questions here, I'll point to questions number 23 and 24 specifically, was the available technology used as intended and how might technology be introduced or redesigned to reduce risk in the future? So, those were two questions that were extremely helpful in helping us identify the contribution of Health IT. Next slide, please. One more time, thank you.

Okay, so, as I mentioned before we deal with both categorical and narrative data but the problem is we don't have a specific category for Health IT and as John and Ronni mentioned in their presentation the narrative is where we've really found the true lessons to be learned.

So, what we developed is a process that was somewhat adapted actually from Erin Sparnon and Bill Marella over at ECRI. So, what we did is we identified a subset of the data that we wanted to utilize so that's the sentinel events reported to the Joint Commission from January 1, 2010 to June 30, 2013 which accounted for 3,375 sentinel events. So, that's what we started with.

And then we used a two-step process of databased queries and content analysis. So, we used the electronic methods of searching and iterative search methods and then also content analysis, so that's actual person review. Next slide, please.

Okay, so here is where we started, we started with 3,375 sentinel events. Through the queries of the categorical queries and then the key word queries we identified 195 potentially Health IT related sentinel events and then finally after the content analysis of the full sentinel event incident reports we ended up with where we were comfortable that 125 Health IT related sentinel events.

So, there were actually two mastered prepared nurses and myself who did the reviews independently of the 195 potentially Health IT related sentinel events and then we came to consensus as to whether or not, well is there enough information to say, if in fact IT did play a role in this particular event or not. And so we agreed that of these events 120 of them did meet those criteria. So, next slide, please.

So, unsurprisingly, as much of the data shows other presentations and data has shown medication errors rise to the top, okay, so we found primarily medication errors, the Health IT related sentinel events resulted in medication errors, wrong site surgeries and delays in treatment. So, those were our top three.

Now you'll also see on this list suicides and falls. Now those are interesting because what we found is that for those types of events the risk assessment, the suicide risk assessment or the fall risk assessment did not behave as expected or it did not act, you know, there were no decision support when it was expected to happen or the suicide risk assessment or fall risk assessment was not up-to-date and so it spoke to the clinical contents of the actual tool itself or the EHR itself that they were using. Next slide, please.

So, here is our very familiar sociotechnical model that we used and so what we did in identifying the contributing factors is we created a composite classification system based on Dean Sittig and Hardeep Singh's sociotechnical model and I'm sure you guys are well familiar with this so I won't go over the different aspects of this, only to say that we used the dimensions of the sociotechnical model as the high-level categories for our contributing factors and then we used existing classification systems, the AHRQ common formats, the AHRQ hazard manager ontology as well as Farah Magrabi's classification system.

So, we...and then we hung those beneath each of the different dimensions and so what we came up with are shown on the next slide, there we go. Thirty-three percent of the contributing factors that we identified and there were 305 total contributing factors identified from the 120 sentinel events, 33% of those had something to do with the user interface followed by workflow and communications, that was the 24% and then the clinical content 23%, and then on down the line with the other dimensions of the model. Next slide, please.

So, these are the top 10 contributing factors and again I'm not going to read the specific contributing factors there, but you'll see human computer interface, workflow and communication, clinical content those were the top three dimensions that were found during the course of our analysis and so we can just kind of briefly look through the list on the left, we're talking about communication among team members, data entry or selection, entry or selection of wrong patient, wrong provider, wrong drug, wrong dose so on and so forth.

And, well, actually let's go to the next slide and we'll talk about that a little bit more. Okay, so digging deeper into the specific dimensions, so this is the results of the human computer interface contributing factors. So, in the previous discussion and what Terry mentioned this was identified frequently, data entry or selection and it's the wrong patient and the thing with these events is that it was the correct information it was just entered incorrectly in a way because the design of the interface itself did not facilitate a correct entry.

So, we did find a lot of those especially with the wrong site, wrong patient type errors where the specific procedure was selected correctly from the drop down list but specific details on the...or the entry point were contained within the notes and that component of that ordering system did not reach the actual operating room.

So, you can see the relationship between this data entry contributing factor and then the workflow communication contributing factor, you know, where both of these would be identified at the same time because the intent of this is to communicate what I want to happen to the procedural area and that communication just did not occur as had intended. So, that's the reason why communication was identified very frequently as well.

We also have different factors such as information was hard to find. So, those led a lot to the types of events that led to delays in...that resulted in delays in treatment. The information is fragmented so in one system you had to dig over here or it was found in a nursing...the relevant piece of information was found in a nursing note which is not accessible by the physicians because they didn't have the correct privileges or what have you. There were any number of issues like that so and then on down the line to information display, interpretation those had a lot to do with the display of the information was not in a way that was, you know, we dealt a lot with the PAC systems or there was also another issue where the ordering of information was not conducive to...well it actually facilitated the clinicians making mistakes. So, it's quite...and you can see how that would actually contribute to either a medication error or a wrong site surgery. Next slide, please.

So, these are the workflow and communications contributing factors and again, as I had mentioned before, you know, communications, it's all about communications with a lot of these particular errors. And then there is suboptimal supportive team work. So, those are the contributing factors.

When we put the contributing or we classified the contributing factors here there was a lot of hand off issues quite frankly, it's, you know, the hand off issue is of course very, you know, topical nowadays, but, you know, in these particular cases it was the health information technology itself that kind of hindered that process. So, that's what we found over there. Next slide, please.

And finally, the clinical content contributing factors, again, as I had explained earlier dealing mostly with the suicide and fall risk assessments, the clinical decision support primarily did not...it acted unexpectedly. The clinicians expected a particular support element or a particular stop so to speak and they were surprised when that did not occur. So, those were the kinds of contributing factors we identified there. So, you see that they are unexpected software design issue or decision support missing recommendation or safeguard. So, next slide, please.

So, we also used the AHRQ common formats to classify the type of technology it involved and so you can see the breakdown here most of them dealt with the EHR or the component of the EHR and you can see on the table there the breakdown primarily EHRs and CPOE systems and then, you know, on down the line, but after the EHR or component of EHR. We also found elements dealing with the PAC systems or the radiology diagnostic imaging system.

Now I will say that we did not find as many of the system to system issues. So, from the EHR to the PAC system or the EMAR system to the barcoding and, you know, on down the line, we didn't find many of those. There were maybe a handful of them that I can remember off the top of my head, but there are other studies where, you know...obviously the ECRI study and then the recent study performed by Meeks and I think Sittig and Singh are also co-authors on that one where they looked at the VA data for the patient safety informatics team or patient safety informatics data and they found more of that system to system issue. And I think that's just a nuance of the type of data that we are dealing with and then also of who is actually doing the analysis. So, it may be the case where they just didn't know that this could have been an issue. So, that's a very important point that I wanted to mention here. Next slide, please.

So, all of that to say in our analysis of these types of events the health information technology problems or limitations were distal to the patient because the event happened also not only because of the hazards posed by the Health IT technology but also because more proximal to the patient the medication double check failed as well or the universal protocol failed as well. So, it happened with every single one of those events that last piece of Swiss cheese right before the trajectory hits the patient those defenses also failed so to speak.

So, it is...in the patient safety events that we studied the failures were multifactorial and health information technology was always far, far away from the patient. But it was a progression that we did see frequently or almost with all of them, all the events. So, next slide, please.

So, from our learning visits, as I mentioned before, we visited four accredited medical centers and our discussions with the medical centers validated the findings of our analysis of the sentinel events. But what we did...what we also found though is that they were managing the hazards and the hazardous situations posed by the technology because IT was very well integrated with their biomedical engineering and patient safety.

So, I know earlier in the discussion we were talking about help desk tickets and I think it was John who had mentioned that, you know, we wish sometimes that the IT professional would be more sensitive to what could potentially happen or what's the worst that could happen and for these organizations the IT teams were sensitive to that and they were integrated into those patient safety discussions and early and often. So, that's one of the major learnings I'd say from our or findings from our learning visits that the teams were very well integrated into the patient safety context.

Some of the problems they did experience because they obviously still have their challenges was the loss of clinical context and what is meant by that is that they are finding...they are having difficulties just putting together an accurate picture of a patient because, you know, for one reason or another, one reason was that they find themselves too busy typing or they find that the information that they need is very difficult to find or it's ordered in such a way that the relevant information is not top of mind or, you know, right in front of their face.

So, they felt that it did not facilitate what they were trying to accomplish clinically. And then another quote, one of my favorites here is, documentation is not communication. And I know the group was discussing this a little bit earlier as well, that there was an expectation sometimes and they have to constantly fight against this that if it's documented on there, in the electronic medical record, that doesn't mean that somebody is actually going to read that.

And, you know, sometimes they do that and there is an expectation that okay my job is done, you know, I've communicated that but that is not the case. And then of course, one of the health systems we visited they were in the midst of implementing a...well, let's just say a new medical record system and of course they had been using their system for 20+ years, it was their home grown best in breed system, so for each of the different clinical settings and what they were trying to do is, you know, ensure that their workflow did not change significantly, but of course that was very challenging for them. So, that was something that they were very, very sensitive to. Next slide, please.

Okay, so, as I mentioned before the human computer interface and workflow those were the two major issues that we found during the course of our analysis from our analysis of sentinel events and from the analysis from our learning visits as well.

So, what we hope to do is to develop, well, one of the components of our project is to develop an eLearning module which we will make available for free, again, we're shooting for first quarter of 2015 and, you know, we will also be providing CE use for that. We will publish a paper and peer review literature as well as consider it as a topic for a sentinel event alert. So, and last slide. So, I will take any questions.

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

Gerard, this is Terry Fairbanks, that was a fantastic presentation and I think what will be ground breaking work, so thank you. I wanted to ask you a little bit more about the UI interface issue and relate it to what I think may be a gap between what you're finding and where some of the focus is.

So, if I understand right if you combine the workflow and communication and the user interface both of which would be considered human factors issues that's about 57% and you're familiar I think with some of the work that our group did that we presented last week where we looked at a cross section of vendors and found that about 1/3 were really ahead of the curve doing great human factors work and 1/3 were in the middle and 1/3 weren't really focusing on it and I think I want to point out that if we look at your work and find how prominent these are in errors it really emphasizes the need I think for this committee to find a way to increase the amount of human factors work that's going on in the vendor community.

And I know it's old now but a couple of years ago now at the IOM committee on safety and health IT there was one vendor that testified that they were not aware of any Health IT caused adverse events at all from their system. So, I think there is a real disconnect and I think that's why this...what you're finding here is so important.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Thank you for that and yes, I completely agree with you. So, again from our learning visits what the organizations we visited, obviously they are the well-functioning organizations because otherwise why would they invite the Joint Commission into their doors, you know, they have something to show us.

They work very closely with their vendors and they have that conversation and they have them very well engaged with them to make sure that those issues are resolved. There was one of the organizations did mention that, depending on the size of the vendor, there is, you know, different willingness to work with them so maybe a smaller vendor will be able to, you know, they're more agile, they're able to make those fixes whereas a larger vendor may not be as responsive.

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

This is Michelle Dougherty, I was wondering if during your learning visits if you picked up any best practices in terms of integrated teams that say analyze the reportable events and then have subsequent ways to, whether it's formal processes to address some of the HIT related and human factor issues as well. Did you see any...anything bubble up to you as some good practices?

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yes, actually for two of the organizations we dealt a lot with their IT folks and the IT folks they struck me as folks that got patient safety so to speak, they understood patient safety and so when they're looking at the help desk tickets that come in they know what are the potential downstream ramifications on, you know, on what are the potential effects on patients and so that of course comes with education, sensitization on what to look for and really having that means of communicating to the clinical side what you should be looking out for, how you can avoid this or, you know, what on the technology side what they can do to fix it, you know, what are the limitations and what do they have to do. So, it's a very organic process.

I would say that they...during those learning visits they were with us, it was IT and the clinical teams, the informaticists they were all together in the same room and they knew each other. So, I mean, that in and of itself is something.

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul Egerman, first I want to say this is a terrific presentation, thank you very much. I had a question about the slide where you showed what you called the device, HIT devices, where you showed which were the most prevalent.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yes.

Paul Egerman – Businessman/Software Entrepreneur

And showed the LIS, laboratory systems at the bottom...

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yes.

Paul Egerman – Businessman/Software Entrepreneur

Being at the bottom is good, okay, that's the fewest number. And my question is, why do you think there is that variation? Why is laboratory the most safe, safer than say radiology, safer than CPOE, how... do you have any evaluation as to why...because that's a fairly dramatic spread.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yes.

Paul Egerman – Businessman/Software Entrepreneur

Why is LIS so much safer than everything else?

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

See now I would actually say, I would not say that they were necessarily safer it's just what we found in our database and again, you know, given the limitations of our database it may be the case where since it's a LIS system they would report it to the pathology, what's...CAP I'm sorry or they would report it to the FDA that kind of thing.

So, it's, you know, we get a very specific type of data, it's primarily hospital related and mostly, you know, and I would say...yeah, less on the device related type of things. So, you'll also see on the bottom of that list, I know it's not on there, but I'm looking at the list right now. So, there is LIS at the bottom and then automated dispensing systems as well. So, those two are more on the device side. So, we would see...we would naturally see less of those types of events.

Paul Egerman – Businessman/Software Entrepreneur

Yeah and I have to say I don't see an LIS system as a device in the same way automate dispensing is.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Right, right, no I completely agree with you.

Paul Egerman – Businessman/Software Entrepreneur

I have a different interpretation which is...

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

I look at the LIS systems and those are the oldest HIT systems.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Right.

Paul Egerman – Businessman/Software Entrepreneur

They were one of the very first and they're ubiquitous, almost every hospital in the country has an automated laboratory information system and I'm wondering if you could look at that list and come to some conclusion that perhaps as systems become more utilized and more ingrained in processes there is fewer events because there has been a learning cycle.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

That could be interesting.

Paul Egerman – Businessman/Software Entrepreneur

At least that's what I would like to believe, I don't know maybe I'm taking my own interpretation and putting it onto your data.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Well...

Paul Egerman – Businessman/Software Entrepreneur

Yet CPOE systems are relatively new...

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yes.

Paul Egerman – Businessman/Software Entrepreneur

Relative to like a laboratory system.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

So that is a potential...I actually did not think about that, but, yes I think...I think that would be something worth investigating, yes.

Paul Egerman – Businessman/Software Entrepreneur

And I'm sure the improvements in the laboratory systems are due to years and years of efforts from the Joint Commission too.

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

This is Dave Bates...

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

This is Janey...go ahead.

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

This is David Bates, I wondered if you could just say a little more about the wrong site surgery ones, I was struck that so many came up. Was it just issues in which right was recorded as left or is that the usual sort of thing?

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yeah, actually it was a lot of the laterality issues as well as there was a specific, you know, specific details about the procedure that were not contained within the drop down list that were found in the comments. So, again, it was just many, many of those issues dealt with the detail of that particular event or the particular procedure where found in the comments and they just didn't reach the intended receiver.

John R. Clarke, MD, FACS – Medical Director – ECRI Institute

If I could jump in, this is John Clarke, I have the misfortune of being the world expert on wrong side surgery with 595 reports in our database. But there are two ways to get wrong side surgery and one of them is you have to add information and you can have bad information from not having it recorded in the field, so, for instance for every 10 scheduling errors where the site is incorrectly scheduled you'll have wrong site surgery. So, you can easily see where if it's not appropriately entered in the field then you can get bad information propagated right down the system.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

That's right.

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

This is Janey Barnes and so when you started talking about medical device reporting and as we hear these talks today one of the things we have to keep in mind is now everything is really under reported and it reminds me of a couple of years ago Bob North he presented and gave a paper about coming through the mod FDA data and looking for, out of this sample that he was going through, what could actually be attributed to Health IT and found many instances where reports were made to the FDA about a device but really if you read the narrative or if you looked at the details it was a healthcare IT and EMR problem.

And so, even with the two databases that we heard about today each one of you are under reporting and with so many reporting areas now that the magnitude of things being under reported need to be taken into account.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Yes, I completely agree with that statement and I think there is...this is why these kinds of conversations are so valuable to have folks, you know, such as ECRI and the Joint Commission and then, you know, to pull in the study from the VA patient safety informatics system so it will give you, you know, different perspectives on the particular problem but then it will also help characterize, you know, common things that we're seeing as well. So, yes, I completely agree.

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 again, and it seems what I've taken from these two presentations is that there are now pretty well-developed methods for gathering data and for analyzing the data so that we can learn more. I mean, certainly since the Institute of Medicine report on HIT safety in 2011 we've made great, great strides and it seems like, as Janey was saying, what we need are more data and so you are the experts, can you tell us how we could best get more data? Should we be thinking about mandatory reporting in some way or do you think voluntary reporting will eventually get there?

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Now that is an interesting question. Now if I were to say how can we improve the data that we're collecting is to really help, you know, help the folks at the frontline identify these problems and better characterize them because there were often times when we were reading through the accounts of what was going on and these are the findings from the RCAs we kind of wished they would have dug a little bit deeper, well, what specifically about that interface was the problem and, you know, we found ourselves wanting more.

So, to the extent that we could, you know, get that information and I know ECRI put out a great piece about identifying EHR related hazards...I think that's a great start but I think we should get that out there.

As far as mandatory reporting I would hesitate against that only because...well there are current mechanisms for mandatory reporting and I would say that, you know, for the Joint Commission, you know, the mechanism for mandatory reporting is that if we hear about it, you know, and you didn't tell us about it beforehand, if we hear about it in the media then we will ask you about it and then we will...and so in a sense that is quasi-mandatory. But, you know, the willingness to share the lessons learned is a lot less when that kind of relationship exists and that's just from our experience.

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

This is Terry Fairbanks, what about, and this I guess could be to you and to ECRI, but about using screenshots and building into systems the ability to do immediate screenshots when the user identifies a hazard and being able to integrate that into reporting systems?

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

That would be great because, you know...and in seeing some of your presentations Terry...because they show you at a glance exactly what's going on and how that difficulty could be characterized, you know, because trying to tease that out of a narrative and trying to figure that out is very difficult.

So, screenshots, yes, absolutely and I think even, you know, so I think of myself in my use and my technology I take a screenshot of whatever I'm having a problem with and I send that as part of the help desk ticket. So, you know, if we can instill that in users and reporters that would be great too.

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

This is Tejal, one of the things...I mean, as much as we want people to report, you know, we know how much it's a barrier to get people to report everything they're seeing and so one of the, you know, interesting studies I thought that came out in the last couple of years was Jason Edelman's work of looking for signals out there that identify the HIT issues without relying on the reporters to actually have to report it. We know there is a ton going on out there and if people reported everything they'd spend half their time reporting.

Gerard Castro, PhD, MPH – Project Director, Patient Safety Initiatives – Joint Commission

Right.

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

I think kind of thinking about innovative ways to do that sort of triggering method or other methods to detect the signal in the data that already exists as opposed to relying on reporters would be, you know, an innovative way to think about this.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, this is Larry Wolf, maybe I can jump in on that note. We heard some earlier comments about when confidentiality was improved that the reporting went up 100 fold, 1000 fold so big jump in the volume of information being reported.

Do you feel like we have sufficient confidentiality in place today to encourage more reporting or was that really a specific issue in Pennsylvania and we don't really have good national reporting with confidentiality?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Well, this is Ronni, so I'll try to jump in on that one. And just by way of background, ECRI has worked on a variety of programs for reporting so, you know, we are the contractor for the Pennsylvania program and been doing that for over 10 years and we do have a PSO which is completely voluntary information. And we have since 1971 run an ECRI voluntary program for medical...you know on technology and medical products.

But, you know, you get different sides of things with each kind of program but I think that to really get good data there is going to have to be confidentiality. We're doing the partnership under the umbrella of a patient safety organization and I would say that without that umbrella we would not have participants. And that's the just the state of things today.

You brought up, you know, cutting and pasting snippets of medical records that would be great but people are really concerned about HIPAA. Now arguably they can send us that data as a patient safety organization and we have a federal obligation to, you know, follow HIPAA and keep that confidential, but it's a concern for people and yet it would be a tremendous help in terms of, you know, sort of an outside independent body being able to look at things and evaluate them.

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

This is Mike Lardieri I have a question and again, thanks for both the presentations very helpful. My question is when you began to drill down and you looked at an event and you went to drill down were you able to go all the way back at the vendor and see if they had a...if they developed their software with user center design or safety design that we had talked about a couple of sessions ago?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

So, this is Ronni, we're just at the stage now, you know, we've been collecting data so now we have to do, you know, sort of what Gerry has done with that data and we have to, you know, sit back and analyze it all and it could be that some of the workgroups that we pull together will hopefully be able to do that. We recognize the importance of a shared responsibility and that's why we got the vendors sitting in the room at this partnership and we're not going to be able to make it happen unless it's a collaborative effort.

We've been working on medical products for years and, you know, we do, on the medical product side we end up in communication with vendors all the time and they want to hear about how their product can be improved.

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

Well, I'm just wondering if you're able to back up to get to the point where when they first developed their product, you know, was that on their mind versus now they're reacting and they'll, you know, talk to you and work with you but I'm wondering how much it was part of the development of the product and if...

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

This is...

Mike Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology

Yeah.

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

This is Janey Barnes, so last year or last meeting Terry talked about a vendor who was a part of their work and that they had analyzed their error data and looked at it, what could have been found where in the user centered design process that they have but I went back looking for a presentation that I saw from, I don't know if it was that vendor or a different vendor, but last year at a human factors conference one of the vendors actually presented their process, they went through their error data, they provided screen shots in their presentation and they also did the analysis all the way through to where could this have been caught in their user centered design process.

And so again that's certainly a vendor who is on the side of a very mature human factors and user experience team, but if we're looking for examples of where vendors are sharing and already very engaged in this discussion then we have an example that we...I'll be glad to send out the reference that points back to that presentation that the vendor made last year.

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

Yeah, thanks, yeah and I'm really more looking at the correlation of are there more errors from vendors who didn't have that as part of their design process versus vendors who did have it incorporated as part of their design process, was there any difference in the number of errors, you know, by that vendor. Okay, thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, picking up on that theme a little bit more, it's Larry, I wonder, we heard a lot about some of the, you know, you start with the vendor product and then it goes through changes as implemented, and then you have use and today we heard a couple of examples of the problems of information being entered by a user into a comment area rather than using a structured field and because it was in comments it got lost somewhere down stream.

So, it seems like we have at least three spheres of activity here, right, you know, the product itself, the product as implemented and then the product is used. Any sense of how to balance those three or how we might think about them as we go forward with our own work?

It seems like each of those has its own area of potential safety issues.

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

Yeah, this is Terry Fairbanks, I would agree with that and I think that I hope that all the presentations we've heard today I suspect have an ability to dive down deeper and I think, I hope that they think about that.

I would also make another comment around the discussion we've had about vendor user centered design processes and just remind folks that we did see that a lot of the vendors do have much more rigorous user centered design processes than are reflected in their current products because there is a significant time lag once they have the data and able to design the systems based on that information and then get it out there because of all the legacy systems, etcetera.

One thing that...to turn that comment into action that we could think about is that sometimes we can make immediate changes in the way interface design and usability impact safety with implementation and that's one area at the beginning of this Workgroup we talked about focusing on.

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

Great, any last thoughts? Okay, well, I just want to thank all the presenters this was a really great discussion. So, Ronni and John thank you and Gerry also. Michelle could we go to public comment?

Public Comment

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

Operator can you please open the lines?

Caitlin Collins – 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. We do not have any comment at this time.

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

Thank you everyone our next meeting is on Friday, November 7th. Have a wonderful weekend.

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

Great, thanks again.

M

Thank you.

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

Bye everybody, thank you.

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

Thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thanks, everyone.

M

Bye.

M

So long everyone have a great weekend.

Public Comment Received During the Meeting:

1. There is no easy way to report errors on our EHR.
2. I would like the Joint Commission to specifically target hospitals on Health IT safety, showing their formal processes for reporting errors, near misses, hazards, along with follow-up and feedback to those that want feedback. We have a real problem with Health IT governance, there is a huge skew to use Health IT for MU incentives and reimbursement at the total disregard for patient safety, workflow, and appropriate care.