



HIT Policy Committee Implementation, Usability & Safety Workgroup Final Transcript October 10, 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

Present.

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

Hi, Bennett. Bernadette Capili?

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

Here.

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

Hi, Bernadette.

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

Hi.

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

Betty Mims Johnson? George Hernandez?

George Hernandez – Chief of Applications and Development - ICLOPS

Here.

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

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?

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

Janey Barnes is here.

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

Hi, Janey. Jeanie Scott?

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

I'm here.

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

Hi, Jeanie. Joan Ash?

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

I'm here.

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

Hi, Joan. John Berneike?

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

Yes, I’m here.

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

Hi, John. Jon White?

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Hey, Michelle.

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

Hi, Jon. Lana Lowry?

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

Here.

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

Hi, Lana. 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

Here.

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

Hi, Mike. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

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. Tejal Gandhi?

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

Here.

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

Hi, Tejal and Terry Fairbanks?

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

Here.

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

Hi, Terry.

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

Hi.

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

And from ONC do we have Ellen Makar?

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

You do.

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 over to you, Larry and David, we have a full group today.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yes, we do, it's Larry, I'd like to welcome everybody. I'd like to thank you all for joining us. Your participation is what makes these things work so it's great to have everybody on the call. And as you probably sense we're a pretty big Workgroup so looking forward to the discussion and to your feedback as we proceed ahead. So, speaking of proceeding ahead why don't we move ahead to the meeting schedule slide?

So, you'll notice that the first thing we're trying to do is to keep a sane schedule so at this point there are no crises driving our work we know there are going to be things coming from ONC towards the end of the year or next year in addition to the roadmap that is about to be released but we didn't want to overload ourselves around Thanksgiving so the two meetings that were previously scheduled right before and right after Thanksgiving are currently likely to be canceled so just a heads up to folks about that.

We're going to continue down our plan to get oriented to this vast and rich space of safety and usability and so today is going to focus on some of that and then we've got follow up information coming from ONC more about the certification program I think on the next call is the current plan. So, there is an overview of where we're going. Next slide.

So, today we're going to go over a few slides about the certification framework that ONC is working within and then we'll mostly focus on care of usability presentations. That's the plan. Let's continue, next slide.

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

We're getting a little bit of background noise, I don't know if it's you Larry or somebody else, but if you aren't Larry if you could mute your line that would be wonderful.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I apologize I'm trying out a new set of earbuds and a mic I've been having problems with the prior headset I was using, so hopefully that wasn't my background noise and this is okay.

Anyhow, so we currently have in the Stage 2 certification criteria two elements that sort of address the general areas of usability and safety. So, one is the user centered design piece and the second is quality management systems.

Also, some of you may recall we had some discussion about reporting of safety events and things like that so that is not generally in the current technology base.

So, we're going to be talking on a future call about what ONC is learning from this initial round of requirements around user centered design. Let's go to the next slide.

So, as far as safety-enhanced design this showed up in the 2014 criteria and it looks to say that we need a process and we need an assessment of how you're doing and that's very over simplified the framework that's here. In addition a few key areas were pulled out to focus and I guess we didn't get that as listed in the slide. Next slide.

Oh, here they are, thank you. So, the focus was to look at areas of interaction checks, medication allergies and clinical decision support, electronic administration of medications, ePrescribing and information reconciliation. So these were areas that felt like with design would make a difference in terms of safety and usability and that these were key areas. So, it was a place to get people engaged where we thought there would be high value. Next slide.

So, before we dive in to the specifics that we're going to inject today, any comments or observations from the Workgroup?

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

Yeah, this is Megan, I have a question.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Go ahead?

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

Some of the reports, I'm thinking of a past, you know, ECRI deep dive report indicated that laboratory reports were I think number four on the list of like safety issues. So, I wondered if laboratory data came up as a consideration.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I don't recall that discussion. I don't know if any ONC folks can comment or we'll have to pick that up in the future?

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

Yeah, this is Ellen, that's something that they're looking at for future so that's one of the things that as a Workgroup you may want to recommend, it definitely was included in some of the comments that we got when we put it out asking for comments.

So, it's not included in the current regulation or the voluntary regulation which is going to go into effect in October, but certainly as we're looking now to make recommendations for the future that might be something that you would want to include.

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

Thank you.

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

And this is David, there are other things like that, you know, we should try and be thinking about them. I think that definitely would be a good addition.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul, I have a couple of questions. It says the Stage 2 user center design and quality management talks about increased transparency. In the 2014 edition, is this an optional certification or is this mandatory?

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

It's not optional.

Paul Egerman – Businessman/Software Entrepreneur

It's not optional. And my second question is, it says that ACBs can conduct surveillance in live environments, I'm taking a guess, but I'm not sure it's right, that this is limited or is it limited to healthcare organizations? Do they have...do the ACBs have any authority to do any kind of surveillance or auditing of vendors?

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

It is the technology in use in the field.

Paul Egerman – Businessman/Software Entrepreneur

In the field, so that would only be healthcare organizations?

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

You know, I don't know that it's limited to that and I think when we get our presentation on certification we'll take note of that question and ask that to Alicia Morton who is the Director of the Certification Program.

I think the goal and the intent is to have it in the live clinical environment but I don't know if the regulation prohibits it from being done in a laboratory or vendor setting. Good question.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

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

This is Alisa Ray I could add some clarity if we don't want to wait for Alicia.

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

Sure, if you know the answer go right ahead.

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

Well, so just by way of introducing myself as a former head of a former ACB, the ACBs have authority, they have contractual relationships with the vendor to oversee the compliance of the technology, right, so the developers or vendors with the technology.

But the surveillance as you noted really is only useful if you see how it's implemented in the field. So, you could request or ask the provider to allow you to see a particular installation and see how the product is performing there, but I think it's sort of a goodwill, it's as consented from the provider to let you in and do that demonstration. Does that help?

Paul Egerman – Businessman/Software Entrepreneur

Okay, it does, but the ABC doesn't have any authority to really audit or check as to how a design process is occurring by a vendor?

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

Well, they do through their evaluation of...exactly as the safety-enhanced design criteria is written here and the test procedure. The EHR developers are required to have a safety-enhanced design process that in particular covers how they develop the software, the technology that addresses all of the bulleted criteria in the slide here. So, they have to have...especially for CPOE medication list, allergy list, CDS, etcetera, the ones listed here.

We could go through the test procedure, the criteria but they do have to have a process that at least develop these criteria. So, it's a modular testing process. Any developer that's bringing one of these criteria for a modular certification such as CPOE they would also have to come along and meet the requirements of the safety-enhanced design criteria as well. I hope that helps.

Paul Egerman – Businessman/Software Entrepreneur

That's helpful.

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

Thank you.

Paul Egerman – Businessman/Software Entrepreneur

Thank you that's very helpful.

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

This is Megan, I have a follow up question. I just wondered if these are the certification criteria from ONC are there also companion performance measures tied to incentive payments under Meaningful Use for CMS?

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

This is for certified EHR technology so they must use certification EHR technology to attest to Meaningful Use. Meaningful Use also has the other measures in performance benchmarks that are with the Meaningful Use program, but this is the certification requirements as it applies to user centered design.

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

Okay, I think that answers my question, thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I'm going to take silence as an indication we should move on. Okay. So, Raj or Terry you are up next.

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

Yes, this is Terry Fairbanks, I'm going to start with a brief introduction and then hand it over to Raj. And I'll just briefly...I think I know most of the people on the committee, but I just briefly will tell you our setting in the project that we're going to report on today.

So, I'm the Center Director and Raj is our Scientific Director of the National Center for Human Factors in Healthcare which is part of MedStar Health which is a 10 hospital system in the Baltimore and Washington, DC area and we're the academic...we're the clinical affiliate of Georgetown, so Georgetown University Hospital is one of the MedStar Hospitals and we have an 18 member human factors group embedded and we do applied work so we're on the ground a lot doing work in the hospitals, and we also are an AHRQ and NIH supported research center, we have five principal investigators who are doing a lot of research as well in the area.

And one of focuses is Health IT and what we're going to talk about today was work that we did for the ONC through the SHARPC mechanism about a year ago. We were a late addition to the SHARPC team when they opened up funding because they wanted to look specifically about how the safety-enhanced design was impacting vendors and have a group go in to talk to the vendors and get a better idea, essentially we looked at is a usability study of the regulations thinking of vendors as the user of the regulations.

And the overall goal I think of the regulations around safety-enhanced design is to move the end products in the right direction so that they are produced in a way that enhance safety and so our job was to go in and kind of gather information so we could act as advisors to the ONC in terms of how the current state is effecting vendors and develop some recommendations on what we could look at in the future.

So, what we're going to...Raj and I are going to talk about today is, I'm going to give you a very brief overview of something I introduced in the last call and that is the two bins of usability so you can see the framework from which we went in and then Raj is going to tell you the results and tell you what we did in our project and what we found.

Raj was the principal investigator for the project and myself and another...I'm an emergency physician with a human factors background and Zach Hettinger another physician who is an informatics specialist, the three of us plus a fourth human factors member were the ones that went and did the visits to the vendors. So, Raj will tell you about that.

So, this slide that's in front is a picture taken by Bob Wears of his ED about a year after they implemented the Health IT system seen on the right there and you can see that all the workers are still using the whiteboard and as opposed to most places when they put up the Health IT system they didn't take down the whiteboards here, and so what this demonstrates, you see how young these people are you see it's not because they're not computer savvy that demonstrates kind of the crowd effect of people using what they find most useful.

And if you think about it from a human factors stand-point those whiteboards were developed over years of time by the people that needed them to support their cognitive work so they're very useful to them in helping them do their work and often times the Health IT systems do that in many respects but miss other respects of supporting the work.

So, this demonstrates what we are calling the second bin of these two bins, the one on the right and that is cognitive task support and I think often in Health IT and IT in general when we talk about usability everyone focuses on thinking about the bin on the left, the bin number one we call it, which is just straightforward user interface design like the clicks and the controls, and the colors and how many clicks do you have to make and the very basic user interface design stuff which is very important but it's not the only key to making a system safe and useful to its end users.

The other one is how well the system actually supports the work of the people trying to do the work things like smart data, visualization, do you give the people the right information at the right time in the right form so they can get the most insight and can they then immediately and easily do the function, execute the function which that information would lead them to.

And so we tried to look at both of these when we went in but I think for the sake of the discussion I'm just going to take two minutes to show you examples of these two bins because I think it's really important for this committee to understand these two and understand why a successful system from a safety stand-point has to have both in place.

So, if you go to the next slide this is a straightforward example of two different user interface designs for selecting x-rays, the one on the left you see which is the older one has a separate column for left and right, and very easy to distinguish and these two...when we looked at these two there is a much higher error rate in the one on the right for a couple of reasons, one is it's harder to distinguish left from right they're not as clearly delineated, but also you look at the simple...it's a single pixel mistake to select left versus right, because there is no separation of space where the function won't click on something and so we saw a big difference in those.

So, that's just a good example of bin one, user interface design that can lead to errors, facilitate errors as you see on the right or decrease errors as you see on the left. I wrote the left and right in there in red just to clarify it.

So, if you go to the next slide, this is an example of a very basic way that supporting cognitive work can reduce errors. This is a system where when the...it's domain specific so in this case it's for an emergency department, if the physician types in Bactrim, because this is a prescription writing system by the way, they want to write a prescription for Bactrim up pops five different choices that are most common in the ED and then they can choose one of those. So, it reduces all of the potential errors that they could make in making choices. Now if they want to choose something else they can.

But a more advanced bin two problem, if you move to the next slide, I think to show you that, to demonstrate that I'll show you the transition that we studied in a past work between a whiteboard in an ED and a system. So, the whiteboard is up in the ED there is a picture of it and if you go to the close up on the next slide you'll see that one column there that I blew up shows a column that has these circles and x's and slashes, and this is very common in a study that Bob Wears actually did at five different ED's throughout the country, he found that the different icons and signs that were used are different throughout different regions and different EDs, but the things that they represent are consistent. So, people had similar needs in each ED.

And one need that we find in teaching hospitals is there needs to be a way for the attendings to track who their...which cases are theirs and where they are in their workflow. So, what they do here is they put a circle once they've heard about the patient they put one slash when they've seen the patient and a second slash when they have finished their documentation.

And what happened after implementation of this particular system if you go to the next slide real quickly there is no mechanism in the IT system that was implemented to allow that cognitive function need and so what happens on the next slide is the physicians did a work around to that, they still needed to track their workflow so they put it on an index card which they kept in their white coat pocket.

And in this ED that we were studying that resulted in a large increase in patients being discharged without being seen by the physician, because what was happening was the nurses and residents were...while the attendings just thought they were using that to track their workflow it turned out to be an asynchronous communication method so that the residents and nurses were aware of which patients the attendings had already seen.

So, that's a very straightforward example of how a system can support or not support a cognitive workflow need of the physician. And we recognized when we look at this study it that we're talking about something that's very complex because this is one type of physician in one environment and think of how many permutations there are across. So, it's a very challenging...it's a challenging ask of vendors to know and understand the cognitive needs of all their different users so well that they're supporting at this level.

So, I'm making two points here, one is demonstrate what we mean by bin one, the straightforward usability and bin two the complex supportive cognitive work and then also to recognize that that's a challenge and it's difficult to do.

The next slide just makes a point that in aviation they had a similar challenge the air traffic controllers were using, if you go to the next slide, paper and the NextGen Project that's been going on for decades now is trying to computerize that and you see similarly all these handwritten icons and notes that the air traffic controllers put in their strips to communicate to each other these subtle details and it's been very, very difficult for teams that include lots of human factors engineers to be able to reproduce this so it supports their work well in an IT system.

And so aviation has delayed the implementation of this and in contrast in healthcare we didn't delay the implementation until we got it right so now we're faced with trying to move things in the right direction after implementation.

So, with that my goal was to give you an introduction and give you a sense of what we were looking at when we went into the vendors visited them as representatives, contactors of the ONC to learn about their user centered design process to see at what level they were doing the kind of work that integrates this.

So, on the next slide I'm going to turn it over to Raj Ratwani and Raj are you on?

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

I am, yes.

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

Okay. But is it...would it make sense for me to entertain questions about my introduction before Raj goes on to talk about our work or do you want to go to the end?

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

I think it makes sense.

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

Okay, are there any questions or thoughts about what I just talked about, about the two bin philosophy?

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez, this is...I want to thank you for the presentation but this is exactly what I was talking about last week when we come in, like for example we bring in a new EHR and the department already has a workflow and we can't enforce the current system, our system onto them because they already have a workflow and we know we don't want this to reinvent the wheel, but it is sort of us trying to make them reinvent the wheel because they have the workflows that they've been using for years and they've got all these fast iconic uses of little symbols and little...the little conventions they use and it's very important to, as far as implementing things, to get them on board with that we're not going to throw away all the knowledge and advantages that they've achieved by creating this system over the years. We can't just throw that all out.

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, that's a great point George and it brings up a really important issue that I appreciate you highlighting and that is that we're talking about two different things here and the workflow...it's good actually if the workflow changes in some cases and we're not talking about workflow in terms of the order in which people do things and the way in which they do them, we're talking more about supporting their needs in their daily work in managing patients, what do they need to know, when do they need to do it and what functions do they need to execute.

And we're talking about trying to learn all the subtleties we need to know to design a system that supplies that functionality not...it may supply it in a different way than they're used to doing. So, it may end up changing their workflow and what we find is that's okay, people aren't resistant to changing the way in which they do things as long as they get the information readily available that they need at the time they need it and can execute functions based on it.

Are there other questions? One other point I'll make just in terms...I don't like using the word workflow because there is a lot more to this. A lot of it is cognitive task support, for example in multi-tasking there are ways that people have cognitive artifacts without IT that helps them remember the tasks during interruptions, remember things they're supposed to do, track where they are with patients and those kinds of functions often we hear providers say they have lost the ability to do when they move through the IT systems and I think IT systems are the answer in the end to making us safer but in order to do that we have to be able to meet those needs.

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

Terry, this is Ellen Makar.

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

Hi, Ellen.

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

As you guys know because we talked, Lana, from NIST will not be able to speak today because she is a victim of the flu and it's so great of her that she's listening in and she is going to provide us with her insights but she has lost her voice.

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

Oh, I'm sorry.

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

So we do have a little bit of additional time and you had mentioned that perhaps you would be able to in this section address the recent events that occurred in Texas and just kind of put some context around that within the frame of what you've just told us.

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

Sure, I mean, the...obviously none of us really know what the true contributing factors were in that case. But in general in our work...well, so let me first comment that many EDs throughout the country have, and this is my specialty so I'm a little more in it, but...and I'm involved in the Ebola preparations for MedStar at the moment so I have...but many EDs around the country weeks ago implemented protocols so that when a patient came in and was screened positive that it set some activity into action that would have precluded what happened at the hospital in Texas from occurring at least in theory.

And so I think it's important to say it's difficult to...and I think those processes and procedures that were implemented did not include this asynchronous hopeful communication via the IT system from nurse to doctor.

And so I think when we talk about the Texas case it's important not to say that anyone should rest their only safety around Ebola on an IT communication, however, we have in our work seen many cases of a common problem where I think the people entering data perceive that data is being communicated to certain groups of people or certain individuals and the individuals on the other end are not receiving the communication often because of different ways that it's transmitted in the design of the system and I'll just give one quick example.

We had a recent case here in our system where a CPOE was entered for a drug dose but in the comments, text comments, the physician wrote "do not give this if the patient is going to the OR in the morning" or something like that. And it turns out that those comments are not viewed in the order that the nurse receives unless it's double clicked on which is not in a normal routine not something necessary for them to do and so it was this latent hazard that we didn't realize existed.

And so I think what we heard about in Dallas sounds like one of these things where the nurse thought that by typing it in there the physician would get the data and the physician it sounds like didn't get the data. But, we've heard conflicting reports so it's hard for me to speak specifically to that case, others on the line may have more insight.

Paul Egerman – Businessman/Software Entrepreneur

Well, this is Paul Egerman, I don't have any insight into necessarily what happened in that one case except to make an observation that a lot of the workflow in terms of how the physicians and nurses, and people work together is determined uniquely by each institution and also a lot of the systems are configured uniquely by each institution and so user centered design alone is not enough.

Even the example you gave is not enough to make sure that you don't have these kinds of problems. A lot of these things are simply learned once the system is in operation.

So, you learn once it's in operation about the issue of the comments, because it's very hard sometimes to come up with very many of these things in the design process.

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 that...Paul that brings up I think a really important point that Raj will probably touch on. Something that we came out of our project with great enlightenment on was just how prominent the implementation issues are and how much I think this is a direction ONC needs to take is to help guide both vendors and organizations in ways to do implementation in a better way, because I think that's what we're having and I think that's one reason...one of the limitations of our current certification process is if you do a summative usability test on a product that's going out the door from the vendor it could be dramatically different from the end product once implemented. And that's one of the things we were hearing the vendors say as well.

Paul Egerman – Businessman/Software Entrepreneur

That's right and I'm involved...I sit on the Chair of Patient Safety and Quality Committee at the Safety Net Institution and one of my other observations is a lot of times when issues arise they arise when the staff is under pressure, you know, when you have a waiting room full of people somebody else has something happen to them that is out of the ordinary, it's the end of a shift, there are a lot of things happening at once and often those are also very difficult to simulate in any kind of a design process.

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, good point. With that I don't want to eat into Raj's time so unless there are any other pressing questions maybe we could let Raj go and then take other questions at the end.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

Okay, great, so this is Raj Ratwani I'll get started. Thank you for the opportunity for speaking with you today. I'm going to tell you about the work that Terry originally introduced, the work that we did that was sponsored by ONC and SHARPC making 11 in depth visits to different vendors across the country to learn about their safety-enhanced design processes and specific challenges that they've faced.

And I'm also going to talk about some of the work that we've done looking at those safety-enhanced design reports that are on the CHPL site and what we can extract from an analysis of those reports and then I'll touch upon our perspective on certification and finally I'm going to touch upon some of the work that we're doing looking at patient safety event reports that are Health IT related and how we can use those to better inform user centered design processes. Next slide, please.

So, this is the project that was sponsored by ONC SHARPC and as I described what we were really focused on was understanding the user centered design processes that are being employed by vendors, specific challenges that those vendors have faced and these were very in depth conversations that we had, it was usually full day visits. I went on each of the visits and either Terry Fairbanks or Zach Hettinger accompanied me both with the emergency physician background and some human factors background as well.

And just to clarify when I talk about user centered design there are several user centered design recommendations including the recommendations by NIST that are referenced in the certification guidelines. We broadly categorized user centered design as any formalized process for incorporating user's needs throughout design, development and implementation. So it was not the case that they necessarily had to adhere to the NIST guidelines or ISO guidelines they could have developed their own guidelines. The key component was that it was throughout the design development and implementation process there.

And so as we made each of these vendor visits we spoke with usability experts when they were available, business analysts at each of the vendors, product managers and had very open discussions with them and for the most part the vendors were very welcome to our visit and really provided us with incredible detail on the current processes as well as the challenges and that's what I'm going to describe in more detail. Next slide, please.

So this is intended to give you an overview of some of demographic information for the 11 vendors that we visited. As part of the visits we promised that the names of the vendors would stay anonymous.

What we did try and do is get a good sampling of the vendor marketplace, as I'm sure everybody is aware the vendor marketplace is incredibly diverse, and we tried to touch upon tiny vendors with estimated revenues of \$300,000 and total estimated employees of 10 all the way to some of the largest vendors, multi-billion dollar corporations, with 6000+ employees.

On the far right side of the slide you'll see the estimated usability team size if usability folks were available there and so I'll leave it at saying we did our best to attract a diverse representation of the current vendor markets.

If we go to the next slide I'll describe sort of what we learned from the vendor visits and we were able to roughly categorize each of the vendors into three broad categories based off of their user centered design processes and roughly 1/3 of the vendors fell in each of these different categories.

So, the first category up at the top is a category of vendors that really have no true user centered design process in place. These vendors are primarily focused on customer requests and in fact have pretty intricately designed methods for soliciting customer feedback and then implementing that feedback but it's actually not a true user centered design process. They're not looking at cognitive workflow and cognitive processes to design and develop their products from the get-go rather they're developing a product taking feedback or reviews on those products and then implementing those changes to enhance their system.

The next group, and I'll come back and talk about the challenges of each one, the second group is a group that has a very basic user centered design process in place. These groups of vendors understand what user centered design is which is a start and important. They understand that their product will succeed, is partially...the success of their product will be partially based on the usability of it and the user centered design process being employed. They are striving to implement UCD processes but generally have very specific challenges which I think can be tackled. And so the group as a whole doesn't fully have user centered design integrated into their design and development process, mainly their development process. There are sort of sprinklings of user centered design here and there but it's not completely formalized.

And the third group is a group of vendors that has a very well-developed user centered design processes and has really crossed a lot of the boundaries that come up when you think about implementing user centered design in rigorous development and really had some impressive methods in place. So they have a rigorous user centered design. They've figured out efficient testing methods which might include things like remote testing and importantly they have an extensive infrastructure of participants that they can use in their usability testing and this ends up being critically important. So, they have expansive networks of clinicians of all types that they can very quickly show rapid prototypes to, have discussions with, conduct informal usability testing and summative usability testing to accomplish their goals.

So, that's sort of a rough breakdown of the processes that we observed in three broad categories and again each...roughly 1/3 of the 11 vendors that we visited fell in each one of these categories. And importantly we were able to identify specific challenges for each of these category groups.

So, going back up to that top category of vendors that have no true user centered design process in place they really lack an understanding of what user centered design is and importantly the leadership, the highest level leaderships of these particular vendors don't quite buy into the benefits of user centered design. So, there is a dramatic shift that's going to be required I believe to push this group to really employ rigorous UCD.

The basic user centered design group, the middle group on this graphic, had some very specific challenges and in fact some of these challenges that much of the SHARPC Program focused on addressing and I think we'll hopefully see the fruits of their labor as those spread, importantly those were primarily focused around resources. So, these vendors don't quite have the full usability staff that they would like and they're aggressively hiring and in fact we've seen some vendors grow their usability staff from two or three to 15 or 20 over the course of the last three years.

Specific challenges also include things like participant access. That might sound like a very small thing but in fact if you don't have clinicians and experts that are willing to perform...to participate in the user centered design process it's quite hard to get any meaningful feedback and this includes resources like use case development to develop Meaningful Use cases to test your systems requires experts to develop those use cases and for some vendors, particularly smaller sized vendors, that are really operating under tight resource constraints having those resources, having folks that can contribute to use case development can be challenging.

And for the well-developed UCD group challenges here include things like developing very detailed workflow analyses for a lot of the subspecialties, as Terry described early on with the examples that he gave in the emergency department, to perform a true analysis of cognitive process in the clinical environment takes a significant investment and often times what vendors do is they make the business case for why they should make that investment if they do so and will concentrate on where their product is likely going to have the highest impact in terms of revenue and so forth. And so environments like the emergency department will often attract researchers from the vendors to understand workflow, smaller subspecialties likely will not because it's difficult to make the business case.

And related is safety data that's coming out of the hospital systems and providers, vendors express the challenge of getting that data and analyzing that data to better inform their products and improve their products. So, those were two of the major challenges that were coming from the well-developed UCD group. Over to the next slide, please.

So, I think what we can...one of the conclusions we can draw from that previous slide is there is a tremendous amount of diversity in the user centered design processes being employed by vendors and we saw it across those three categories.

In addition to that work what we've also done is we've looked at the safety-enhanced design reports that are on the CHPL site, the ONC CHPL site. So, as we saw at the beginning of the agenda here in the review of the certification requirements each of the vendors is required to attest to a user centered design process and then also to provide the results of their formative testing and those results were intended to be public and are posted on the CHPL website, it should be noted that not all of the ACBs have actually provided all of the summative testing results and in fact only about 20 of the vendor reports are actually available on the CHPL website from the last time that our research team had looked at that which was a few weeks back so I'm not quite sure if that's changed.

So, when we talk about transparency we're not quite there. And accessing those reports is incredibly difficult as well and so as we talk about usability at all levels we should think about making that process more usable.

Once we were able to actually download those 20 reports we did a systematic analysis of what was contained in those reports from a summative testing stand-point and it was quite disappointing to learn that several vendors, at least a few vendors had as few as three participants participate in their summative testing, their summative usability testing and in fact some vendors had participants that had no clinical expertise whatsoever and were in fact employees of the vendor organization. So, when we think about what this does in terms of the marketplace, well when we talk about as few as three participants by certain vendors, there are other vendors that have an incredibly rigorous process in place and have made substantial investments running something like 20+ participants. And so what that does is it creates a double standard there where some of the vendors that are making tremendous investments in the UCD process to meet the certification requirement are looking at other vendors that haven't done so and are wondering perhaps why they're making such a substantial investment and of course three participants violates all the usability standards that we know of.

I talked about the limited clinical expertise that we're seeing with some of these vendors, very diverse experience levels, several of the vendors aren't quite reporting all that demographic information so it's very, very hard to compare processes across these vendors but what these reports do tell us is that again it reinforces the tremendous variability that we've seen by our vendor visits and I think it identifies specific challenges that we're seeing with this safety-enhanced design process.

And I think it also points to the fact that we need to look to some of the authorized certification bodies, the ACBs, and examine their criterion guidelines under which those ACBs are operating, at some level it's incredible to see that...a vendor that's running three participants in their summative testing is being certified for safety-enhanced design. Over to the next slide, please.

So, I want to provide a couple of additional perspectives on certification and these have come from the research work that we've done and also from direct feedback from the vendors when we made those visits. Terry touched upon information on the implementation processes.

So, as we've looked across different hospital systems that have adopted new EHRs and have gone through implementation we're seeing incredibly variability in those actual implementation processes and the types of communication and support and teamwork that's happening between the vendors and providers, we're seeing some EHR products that aren't the strongest that actually end up being pretty successful when implemented because you have a strong provider group, a strong information service team at the provider level that's able to dramatically improve the product.

Likewise we're seeing EHR products that are not necessarily the strongest, sorry that are quite well designed that are not so successful in the clinical environment because you have information service teams and provider processes that are not exactly efficient and effective.

In this space in general there are few guidelines, the ONC has sponsored SAFER guides which I think are a step in the right direction to provide some guidelines when it comes to implementation but I think more can be done to provide some specific guidelines and there can be more sharing of best practices between vendors and providers.

And as Terry also mentioned we have to really focus on and think about what it means to actually certify an EHR product when we see dramatic customization at the level of implementation.

The push for summative testing I believe is to say that we have sort of a safety check once the vendor completes the product, but if many of those things that are considered safe elements are then undone during the implementation process we're not really certifying anything at that level and so we have to think about where certification happens and what we're actually certifying and what the stamp is going on.

And it's also important to realize that many of the vendors expressed concern over the summative testing requirements and it's not that they don't want to be integrating a user centered design process, I think there is some discomfort in the resources that are required for summative testing and the fact that summative testing is occurring very late in the usability process and so if you're catching safety issues at the point of summative testing vendors are very unlikely to change their product at that point it's too far down the development cycle to actually change the product. So, in fact what happens is vendors will release the product and then attempt to make those corrections in the next update.

So, if we go to the next slide, I think it's important to think about how we might be able to modify the certification requirements to meet some of the challenges, to address some of the challenges that the vendors have expressed and so one of the methods that our research team is proposing is that...one of the processes our research team is proposing is that we think about having options for vendors, one is that you can...when you attest you can attest to UCD process and provide summative testing results just as the current certification requirement suggest and is in place.

In addition to that you could also have the vendor attest to UCD process and provide evidence of the UCD process actually being employed and this actually has tremendous benefits at some level, because vendors that already have a rigorous UCD process in place are able to catch many of these usability and safety issues early on and make those changes.

Forcing the summative testing requirement actually takes tremendous amount of resources and if you're a vendor with fixed usability resources, and I'm speaking very generally, if you're a vendor with fixed usability resources and you have to contribute a tremendous number of those resources to accomplish summative testing you in fact can't advance your product in ways that we'd like to see them being advanced.

And so what we should be aiming to do is to push vendors that are not quite performing UCD at the level that we like we want to elevate those vendors but not at the cost of hindering vendors that are already doing a really good job with user centered design and I think by providing these options we would be able to achieve that in the marketplace.

And so if we think about this additional option of attesting user centered design and then providing evidence of the UCD process what that does is the byproducts of UCD process, which should already be there for those vendors that have a rigorous process in place, those byproducts would serve as evidence of the UCD process being in employed. So it alleviates the burden on those vendors, it allows those vendors to expand their usability resources as desired and I believe we would see greater impact on improvements in the marketplace if we allow those resources, those usability resources, to be expended as desired by that particular vendor.

So, I want to close with some of the work we're doing looking at some safety-enhanced or sorry, some of the patient safety event reports that are coming through the MedStar system. If we can go to the next slide. And talk about how we can actually use this information to support user centered design and in fact more clearly delineate what user centered design processes should be employed.

So, within the MedStar system we have a patient safety event reporting system like many healthcare systems do and some of these get explicitly flagged as Health IT events by the people doing the reporting and many do not. I don't think it should be the expectation that the reporter has to do that kind of flagging.

What we've done is we've used a natural language processing approach to process through many of the free text descriptions, the open free text descriptions, of these reports and we've begun to look at which ones of those are actually Health IT related through an NLP process and so if you look at this description here the example I have here this was actually initially input as a medication-related event and our algorithms were able to flag it as a Health IT related event so we're able to better understand the information of patient safety event reports that are coming through our system.

And the reason this is important for several reasons, but most relevant to this Workgroup I believe is that we can actually use these safety events to think about how the UCD process could be modified or enhanced and this is actually not an idea that we came up with this is an idea that one of the vendors that we've worked with came up with, they went back and looked at many of the safety events that were reported to them from doctors of their software and they then categorized each of those events and tried to determine where in the usability process, if at all, those errors or those issues would have been caught.

And so if we do this at a larger level it would essentially be developing an evidence-based approach or a particular UCD process. You could take several of these Health IT related issues that we're seeing across several systems and we could begin to determine where in the user centered design process those particular issues would have been caught.

And on the preliminary data that was analyzed by the vendor it turns out that a majority of those concerns would not have been caught at the summative testing phase rather they would have been caught well earlier in the process and in fact, very few would have been caught in the summative testing phase alone.

So, there are certainly methods that we can employ here to develop a more evidenced-based user centered design approach and I think vendors would certainly welcome that and that we'd be providing clear guidelines and I think we would trust those guidelines.

So, thank you so much I'm going to stop there. I hope there are some questions here and I'm happy to talk more about any of these issues and we can go to the next slide I think.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, this is Larry, let me jump in with a quick clarification question, maybe ONC can help out here. My understanding is that the certification requirements in Stage 2 2014 edition around this stuff was to surface the processes that the vendors had in place and not to set a bar of a pass/fail around the actual results of the testing or any judgments of that good testing/bad testing or good product/bad product but just to start the process of surfacing user centered design and putting in place the summative testing as a specific element to look at, but using it more as a place to begin rather than a stand-point. Do I have that right?

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

Someone from the ONC want to comment on that?

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

Larry...

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

Yeah, this is Ellen, you know, I think there is always what you think is what's going to happen or the intent and then what does happen. I know that over prescriptiveness is not something that is usually the way that they want to go.

So, I don't...there is no pass/fail, really what it is, is to see what people are doing for user centered design, but I believe that the intent is that good valuable information is what's used in user centered design and I don't know that the CHPL website reflects that all of the different testing that was done was kind of equal in that way. So, that's the transparency piece.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

So, I'll comment as well, I mean, I believe you're right that there is no specific user centered design process that was...there is no prescriptive user centered design process in the certification requirements, there is a reference to NIST guidelines and ISO as well, but certainly, I would hope that there would be...there should be some minimum criteria for what constitutes a user centered design process because otherwise it's virtually irrelevant.

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

And this is Terry...

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

So...

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

I'll add that when...in one perspective you may think that the vendors would appreciate the flexibility but what we found in our visits was that they were very frustrated by what they perceived as a lack of guidance and so they were scrambling to find standards that they would be expected to adhere to for the summative test.

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 mean, my interpretation is that 2/3 of them are getting scores that would be failing so that suggest that we need to come up with some approach to, you know, to make that work better whether that's just to reveal what their scores are and make those transparent that would be one approach.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

I mean, I don't...I think 2/3 may be an aggressive estimate, but certainly there is a subset of vendors that do not have a rigorous process in place that are being certified and I think that making the actual UCD process that's being employed and that information more transparent would be a step in the right direction.

Ultimately, it would be great to be able to make some more meaningful comparison across the vendor products that's challenging. Currently, as it stands, as I mentioned, not all of the reports are public and the ones that are public are incredibly difficult to access and so there is certainly some easy steps that could be taken to make it so that information is more transparent.

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

So, this is Janey Barnes and so a couple of things, in the regulation it does say that you need to use a nationally recognized user centered design process or if you choose something that's not nationally recognized to describe it and provide the rationale of how it, you know, fits to be an acceptable UCD process and so human factors professionals that...we can identify what's a good UCD process and what's not a UCD process.

And I think that one of the areas that needs improvement is to have the certification boards also understand what's a good UCD process and what's not and then when they read the reports or read where folks attest and describe the activities that they conducted that the certifiers have guidelines that they can follow so that they can also recognize what's a UCD process and what's not, not what doesn't fit into a UCD process.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, I just want to make an observation, which is that this is a fascinating discussion first of all, I mean, I just want to say thank you to Terry and Raj, really very helpful and I really appreciate the amount of work that went into this presentation.

The observation I want to make is we're talking a lot about vendors and what vendors are doing right or wrong and we're talking about what we would like vendors to do but there doesn't seem to be any vendors on this call or on this committee and isn't that inconsistent with the fundamental concept of user centered design if we're going to be designing and talking about processes that vendors need to perform shouldn't the vendors be involved in these discussions?

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

So, Paul, this is David Bates, you know, we're thinking of you in part as someone who has certainly substantial expertise in terms of, you know, having worked with a vendor and we're actively trying to identify an additional vendor to join this group. So, I agree with you they should be involved.

Paul Egerman – Businessman/Software Entrepreneur

And I thank you for saying that David, but, I do think that I can't...I don't feel like I represent the vendor community in particular because I don't have the...you know I'm not currently going through the process of getting an EHR system or a module certified and so I don't understand all of the details, you know, it would be as if you were talking to a clinician who wasn't currently in practice and tried to tell them...and that person was to give you some advice on things, you need to have people who are like on the ground and actually doing this work.

I have heard feedback from my vendor friends that this certification itself is causing usability problems and it causes it from the stand-point of putting people under intense time pressures that they have to get things done in too short a period of time to do the testing that they would like to do and also that a lot of what's been in the 2014 edition was overly prescriptive and sort of suggested certain workflows that did not always work out for their customers and that those are important concepts that I think we also should be considering.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

This is Raj Ratwani again, you reminded me of an important point, touched upon an important point that I should have stressed here. The vendors that have the well-developed UCD processes in place have really figured out how to incorporate user centered design into these rigorous development timelines and that's a really important aspect here because as we think about making suggestions on user centered design processes and we think about perhaps modification or not and certification requirements it's critical that we take that industry perspective and understand the timelines that they're operating under to get a product out the door. And I think in the past perhaps we haven't quite provided...we haven't quite taken that stance and it hasn't worked out.

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, and I just wanted to...you know, I completely hear what Paul is saying but it seems that Raj and Terry really are representing the vendors here, they've done a really sound study and they've put themselves in the, you know, really in the footsteps of the vendors.

But I have a question about their recommendation, which sounds very intriguing, about certification of the process in a different way, in other words these byproducts would be available to provide transparency and so my question is, what would those byproducts look like?

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

Well, so let me clarify the suggestion of the modification to certification requirements allowing either the summative testing or the byproduct option are suggestions that were made by some of the vendors and then formalized a little bit more by our group, so there is no specific vendor that is suggesting exactly that.

Now to address your question specifically about the byproducts I think that there would need to be some work done there to determine what those byproducts might actually be. I think that's work that could be done directly with EHR vendor partners and engaging organizations like the Electronic Health Record Association, the EHRA.

An example of what those byproducts might be is some of the results of their formative testing. So, they're going to be...if they have a rigorous UCD process in place they should be documenting their formative testing results which would include demographics of the participants, results of the studies, etcetera.

All of that information, since they already should have that already collected, if you make...if that becomes the evidence that's required for certification it reduces the burden on the vendor and it provides clear evidence of that process. Now that is just one example of the kind of evidence that could be provided.

There are several other forms that could take, it could be well-developed personas of the kinds of users they're anticipating, there are lots of other byproducts there that could meet the need I think.

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

Thank you.

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

And this is Mike Lardieri, and is this what you were talking about before that are hidden or not easy to get? And my question is, is it not easy to get because it's embedded so deep in a website someplace or it's not easy for people to understand once they get to it meaning a layperson understand?

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

Sure, I think it's both. So, first not all of the ACBs are reporting this information, right, so out of all of the vendor reports that are out there only 20 of the vendor's information is up there about the attesting and the summative testing results. So not all the information is actually available through the CHPL website.

Then in addition to that it's incredibly difficult to actually navigate to those reports and in fact the only reason I was able to find them was Janey Barnes, I ran into Janey Barnes at a conference and she was kind enough to tell me how to get there and so she sent me the long path to get to those reports.

Each of those reports if we talk about just the format of them is in a...it's in a PDF document so you have to navigate to the specific vendor, open up the PDF and then find where that information is and then there is not a tremendous amount of consistency in the way that information is presented.

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

Okay that's what I thought.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

So, I think it's all of the things that you just mentioned.

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

Okay.

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

And this is Terry, I just want to echo one thing that Paul said and also respond that I, like Paul, I don't feel comfortable suggesting that as a member of the Workgroup I'm representing the vendors actually among the Workgroup I think there are others who probably have a much closer view like Janey Barnes of what the vendors are toiling with each day.

And I do think if you think of the three different types of vendors that we found the ones that don't get it yet and haven't really embraced usability probably wouldn't benefit us on the committee but some of the ones at the higher level that are really doing this well I think might be able to provide good insights into the struggles and we found that they were very enlightened and up front and honest about acknowledging the need for certification but trying to be realistic about the way that it could impact usability most effectively in the end.

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

So, this is Janey, just a couple of things too, so the other thing about the reports are the reports are required to be written in the common industry format developed by NIST which is a very formal usability report and that again, me and my team and human factors professionals kind of like you learn how to read journal articles you learn how to read these very formal usability reports.

Anybody, layperson that wanted to open those reports up and to try to do an apple to apple comparison you would probably fall out of your chair, you know, before you got out of the third page, and so I don't think that the format is in a way that is meant for real people to read and glean good information out of the report and that's an area that I think this committee can address.

And then I don't think that we can at all underestimate like the three groups that Terry and Raj's research identifies, those are true user groups in terms of the way that we think about vendors and user centered design and their needs are different, and their processes are different in much of the same way as we're talking about the places where EHRs are implemented and that becomes really important.

And I know for a fact that there are some of the folks in that very mature usability group that they would love to be a part of this committee and we just need to reach out to them and ask them if we want them to be members or participate on a regular basis.

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

And I think that we all recognize it maybe beyond the time we can add Workgroup members but we'll do our best to represent them but I think it's important to acknowledge that the contribution was important we really, I think, Raj and I would...I think Raj would agree with me, we really learned a lot from them and their struggles.

Many of them really have the right idea and are trying to do it well and as others on the call have pointed out implementation is a huge piece here but I think that it's not us or them when we talk about implementation I think that there is also just as much as the organizations sometimes fail to recognize all of the issues with implementation also on the other hand sometimes the vendors don't take enough engagement as they might be able to help.

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

Hi, this is Janey Barnes again, and the other thing that we see, we've seen before is just like those different levels of usability, maturity in the vendors there are different levels of usability, maturity at provider sites and hospital sites, and that we know of hospital sites and provider sites that take the software from the vendor and as they're doing their own customization and their implementation they're doing their own user centered design and usability testing some of them with, you know, very mature usability programs.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

Janey, that's a great point, I think related to that, I think earlier on the call we were talking about some of the customization and things that implementation and then how you could actually discover where some of the safety hazards may rest and there may have been some comments about sometimes you just have to implement the system and work with it for a bit and I don't know that's entirely true, I think if we begin to look at if there is a role for simulation here and how simulation can be used for testing these systems, you know, where it's post that customization phase so we have a product that's more well-developed and is going to be going into the specific provider environment and test that in a simulation environment to discover whether there are some serious safety hazards that need to be addressed.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Terry, hey, it's Jon White, Joan Ash is on the phone so I don't know if she wants to speak up about it, but Oregon is doing some EHR simulation work.

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

Well that's right and we've developed some scenarios specifically to test EHR errors and whether users see them or not. So, I'm glad, I don't know who raised the idea of simulation but I'm glad that you did mention it and, you know, we're thinking that by developing these scenarios they will be available for people to use in testing in the field which is something that I think we're all agreeing has to be done we just...and I wanted to actually ask Terry and Raj what their ideas are or maybe what the vendors ideas were because I'm sure they heard about this, about how oversight or testing could be done in the field?

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

You know, Raj can comment, I don't remember the vendors talking a lot about testing in field, there was a lot of...in the field I mean, there was a lot of discussion about them feeling like what they were testing was not all that similar to the different products after they were implemented. It would be challenging though because the implementations are so different. I'm not surprised that they didn't suggest implementing them or doing them in the field, testing them I mean.

There was not discussion about simulation that's something that we've started to look at a little bit here and we'd love to learn more about what you're doing, Joan. But, Raj, are you remembering something I'm not?

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

Yeah, just so, Joan, thank you, this is Raj, and I was the one that originally made the comment about the simulation and so just to touch back on your response. I really appreciate that you're developing use cases that would be made public because I think that addresses some of the challenges that vendors explicitly stated about having informed use cases and so the fact that you're doing that in simulation is fantastic and I'm really happy to hear that's being done.

In terms of what vendors are doing now we did not hear much of vendors doing anything in simulation really that doesn't mean that it's not being done it simply didn't come up.

There are vendors that are at various levels of sophistication when it comes to surveillance, all right, so once the system has been implemented and is running, how a surveillance process is working and what's going on there and like everything else there is tremendous variability when it comes to that surveillance.

One of the big advantages we see with vendors that have a cloud-based system is that those vendors are able to conduct safety surveillance considerably more quickly and they can make changes to their system more rapidly once safety hazards are identified. And so I think that's something to recognize from the cloud-based systems and is not necessarily true for some of the other systems.

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

Hi, this is Bernadette from NYU just more from the clinician perspective, I haven't heard anyone mention as far as mobile or digital patient engagement in EHR.

And also I think with some of my clinician colleagues some of the things that they complain about is that it's difficult sometimes to track referrals and consults, and when do we know it got done and this way we can prevent any, you know, safety loopholes with patients not getting referrals done and audit trails, and, you know, the systems being able to communicate across venues I think is another problematic issue among my clinician friends just as a comment.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

This is Raj Ratwani, I think that's a fantastic comment I think it's a recognized problem across several of these systems as we look at transitions of care and where the information flows. And I think that's another one of those components that is very difficult to test in isolation but if we think about a simulation environment we can begin to test some of these things that otherwise go untested. So, I think it reiterates perhaps the value of simulation testing.

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

Also, I would say that the bin two, what you're talking about is really bin two, understanding the cognitive needs and how things that can't be remembered, you know, we're not computers and robots, how the IT system can help that process work seamlessly and with no errors.

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

This is Megan Sawchuk and I want to make two comments, one is I'd like to just acknowledge the good work that these select vendors in your survey, especially the ones with 15 and 30 people in usability teams, you know, that they actually have these teams and are using them to work on a process to benefit safety of electronic health records. So, I want to acknowledge those vendors even though we don't know who you are today, you know, that you're doing that work and that that's really appreciated.

And the second question I have is earlier this year Medscape published a survey of, I think 18,000 physicians, on EHR satisfaction which included some usability components and the system at the Veterans Administration consistently scored quite high as far as usability as measured by the users and I was just curious if that system or any representation happened to be a part of this particular report and investigation?

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, I would just...because they're affiliated with one of the vendors and because we were...it was so important to the ONC and to the vendors that we don't give any indication if it's okay, although I feel like I'm like a CIA agent or something, but if it's okay I'd rather not answer that question directly. But I can say that we did not look at the VA implementation specifically.

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

Thank you.

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

Hi, and this is Jeanie Scott from the VA I can tell you that our current system is not one of the certified products we're actually going through it with our newer systems. We do have a whole history of...and I was listening to, you know, the no true UCD and the basic UCD, and the well-developed UCD, and I was thinking well where...my question actually is where is the VA in there. We've had a couple of those components but as far as formalization what's been presented here from some of the better practices it would be interesting...I'm not quite sure if we actually could fit in any one of those buckets. We're kind of unique.

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

Hi, this is Janey Barnes; I just wanted to say...

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

We have components in there that have to be done along the way.

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

This is Janey Barnes and I want to say that, you know, Jeanie, when you started trying to place yourself into one of those buckets and you said you're unique, based off of work that's been done by the HIMSS Usability Task Force with their usability maturity model usually what you find is you can't say like "this vendor or this organization is represented in one of those buckets."

What you're going to find is you might have a human factors or user centered design group that is very high in usability maturity but a product team who is very low in usability maturity.

And so as we look at groups and institutions and start seeing how can we meet different needs of usability maturity that it's going to be different inside of each and every organization based off of work from the HIMSS group.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul, these are interesting comments, Paul Egerman, the comment about the Veteran's Administration made me also think that not all certified software comes from vendors that there is...there are people who have self-developed software and there are people who use open source software so they are basically using the VA system and they get that certified for their institution, and when you do that they're basically using...they may be designing software themselves or they even be using some design that somebody else did and offering it and it just seems to me this recommendation on design needs to somehow accommodate and make sure that the people who are still using open source software or doing self-developed software are able to get certified.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Hey, so it's Jon White, so very good discussion, Terry and Raj excellent presentation, so that leads me, you know, in my evidence-based mind to the question of so, you know, I think user centered design and, you know, good usability is important I would agree.

What is the evidence at this point that links use of user centered design, virtuous use of user centered design whatever you want to call it, to either increase user satisfaction for users of certified Health IT or to, you know, better outcomes in one way or another?

I'm thinking I'm not sure off the top of my head that there is good evidence for that. I know that there is evidence about user centered design in other industries but I just wasn't sure about our industry. Thanks.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

This is Raj that's a great point and it's I think, you know, I would basically be just repeating what you said and answering it. We have not made that connection. It would be the next step of our research work is to begin to tie the work that we've done here of understanding processes and then tying that to the actual usability of the product being developed but we haven't done that yet. I don't know of other groups that have done that and I could not point to explicit evidence within the healthcare domain that links a user centered design approach to actual usability of a product.

However, if you look at the boatloads of work that's been done in human factors usability in several other industries I think that connection is there and so I think we do have to ask ourselves the question of how important is it to make that connection given the evidence from several other domains and the science itself.

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, Jon, there is one other piece I'd want to point out about what you're saying and that is that you're right that although I think we can all agree it's kind of like the parachute to say having a really good usable system will be safer and better, but your point is that, is it a good user centered design process that leads to that that we haven't really shown the connection for and I think that's important especially as we look at how we implement it and I think to your point right now we're asking people to certify that they have a user centered design and we clearly see that just the presence of it or them attesting to the presence of it clearly does not lead to better usable software or better outcomes.

And so, I would just emphasize your point that it's not just having any user centered design but it's having a good one and an effective one that's our real goal. I don't think we should wait for evidence-based studies to do that because I think we'd delay it, I think it's clear from other industries where there is good data but I think we have to do it in a smart way and make sure that the user centered design processes are good.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

This is Raj, I'm going to add one other comment there, Terry reminded me of this, so the work that we did was done last year and looked at...took a vendor snapshot at that point in time and we have to keep in mind anecdotally people might be saying, well, if 1/3 of these...some of the vendors that visited that have these true UCD processes in place we can look at their products that are on the market right now and maybe to do some of what we're talking about here but in fact we have to keep in mind that it's not quite the case that there is a dramatic...there is a large lag between when the...how the UCD processes are being deployed and when that product actually gets released.

So, while I'm optimistic that several vendors are integrating a rigorous UCD process and are growing their usability teams we're not going to see the fruits of their labor for many years down the line.

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

So, this is Janey and just touching on this part of the discussion, so the reports that are available and the ones that, you know, ONC has access to through the certifying bodies, those are supposed to be reporting their errors and doing an error analysis that were found in summative testing and just based off of our work we know that we identified critical errors some of which a vendor would go back and actually do a software update to fix the problem and retest it so that they didn't have to go public with it.

So, the idea of transparency it definitely resulted in that was the reason that something got fixed before it went out the door to fix it later as part of our work with the certification of and the summative usability test.

And then the other thing is just to look to the FDA where medical products as part of the FDA's human factors process where teams have to provide objective evidence that their mitigations to identify problems are effective and that again, trying to make that tie the transparency and then identifying problems and mitigations and providing evidence that you have a more effective mitigation to a problem that was already identified I think that again it doesn't speak directly to what user centered design process that you're using but having that transparency of these are critical errors in the EHRs and these are...here's evidence that the mitigation is appropriately addressing that mitigation of that issue.

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez, is there a possibility of ever making like you mentioned the scores of the EUPs for example or any of the SAFER programs of...and not just an App of a vendor but the implementation public?

Like for example if you go to the App store or Google Play you can go and you can check on an App and you can see it's score and you can see user comments. Would there ever be a possibility of doing that as far as EHR vendors where here's how they scored on their usability test and basically holding up a mirror and then making it available?

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

This is Dave Bates, I think that is a possibility, I mean; we can recommend things that we think would be helpful. The vendors have not been terribly interested in that sort of approach.

George Hernandez – Chief of Applications and Development – ICLOPS

If you have a listing of hotels and they're rated from two stars to five stars there is a tendency to go to, well depending on the price of the hotel, to the higher star hotel.

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

No, I agree.

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

Hi, this is Bennett Lauber; there are some websites out there now that already do that they're just not affiliated with ONC. There is one called EHR Selector that I know for sure and there is a bunch of others where they go and they review the EHRs and they report on them to help you create a select...help you select the EHR that you're interested in. But I think it's a fantastic idea, you know, summarizing the usability studies and putting that inside there.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

This is Raj, I agree, I think it's a great idea and there, as the speaker just suggested, there are other websites out there that do that. I think if we...I think improving transparency around the usability of these products is going to be critical to moving the market.

Of course the devil is in the details of how do you actually do those kinds of comparisons and that's really what would have to be flushed out and would include things like having a standard set of protocols that are to be tested by each vendor and coming up with the appropriate measures there of what you're actually going to be output, right, because time alone is certainly not going to be appropriate and other error data may be appropriate. So, I think, there is a lot to be done there but it's a good path to pursue.

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

This is Joan and I'd be a little bit skeptical just based on some work one of our doctoral students did a few years ago where he did usability testing within three different organizations and a number of hospitals and it was, you know, in C2 usability testing very, very thorough, analyzed the data three different ways everyone thought this would be a bakeoff among three different large vendors and the upshot was that some were good in some areas, some were bad in some areas, it was almost a tossup. All were strong in some areas and all were weak in some areas. So, I'm just saying that sometimes the reporting could be misleading.

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

This is Megan Sawchuk and I have just a similar comment maybe in a different way, but I think we need to be cautious about recommending publication of an actual score because it will lead to debates on whether, you know, is it significantly different if one is an 85 and another one is a 90 for the reasons that Joan just cited, it may be a level of complexity involved with that EHR or particular module and it may not reflect the entire product or it might reflect just a portion of it.

So, I definitely though would support some type of indicator of the robustness of the UCD process or some type of categorization I think absolutely appropriate. I would just express caution on an actual score.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul, one thing I want to add is a comment, you know, Joan says that some vendors are sometimes good at usability in some areas and not so good in other areas. There may be many reasons for that but one of the things that affect's usability is the technology that the vendor is using and so that could be one of the reasons why you get that kind of variability.

I mean, for example, if a vendor is doing a lot of things with mobile devices and tablets they might have a high level of user satisfaction for some functions but for other functions there may be too little real estate on that tablet or mobile device to accomplish what is needed.

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

Can I get in on this discussion, this is Lana Lowry, I just would like to remind us that usability is a variable term and scoring and other specs, and user acceptance is extremely important criteria, however, usability that pertains to safety this should be the focus of the regulation and the government's involvement the rest should be taken care by the market. I think it's just impossible to cover the whole broad spectrum and give the, you know, specific scoring.

I think the focus has to be that these systems would not cause inadvertent errors and that's what really needs to be validated and that has to be priority. And everything else really should be left to the market to sort out, that's just my opinion.

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 there is one I think, pertains to both Lana's comments and the comments Joan's and others were making about the variability. I think, that in order for us to move the vendors forward I have started to believe that the market can't do that as effectively because as opposed to other...in terms of usability I mean, as opposed to other markets the decision makers in healthcare systems are not the end-users and there is often a large disconnect between the hazards that the end-users see when we're focusing on our safety discussion and the hazards perceived by the decision makers who are choosing the EHR systems.

There is a wide disconnect and so systems are not bought on usability and safety, they're bought on all the other things that matter to the decision makers and I think to move the needle...Raj brought this up a little bit, but my subjective assessment after our project about how we can move the needle is to incentivize senior leadership to put importance and resources into user centered design because user centered design takes resources and there are some large vendors out there who have zero usability resources in terms of people, nobody qualified with qualifications as we would see them and so there is a large variation.

There are other vendors where the leadership has really bought into this and they have, as Raj mentioned, they greatly expand their usability teams. So, while I agree with you Lana that the market should I'm not sure the market will move this needle very quickly.

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez, it seems like one of the general problems is that you've got an EHR and let's say it's made by technical folks but they're not the clinicians, they're not the ones out in the field and so it would be good to get scores that are based on the actual users like one vendor might make a good oncology department suite but their emergency department suite is lousy.

And so it would be good to have users not just of the specific components but also the specific implementation because I think we've all discussed like for example if you've seen an install of Epic you've seen one install of Epic because one install of Epic is completely different from another install of Epic somewhere else so it's entirely implementation specific.

So, you would need to have users in specific departments giving that score and I think it's good to have very componentized scores like that because a simplified, here's an 85% score is not very helpful when you're trying to fix something more specific.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul Egerman, I would just like to make an observation, as I listen to the discussion I'm starting to lose track of what we're trying to accomplish, especially what we're trying to accomplish with certification.

I mean, one of the questions that was asked in the slide is, what is the role of certification when there is customization and variability in workflows and implementation, but I'm trying to understand what does certification mean, it seems like we're trying to use certification as a tool to change vendor behavior and to get...improve usability and I just don't understand why that's a function that the government should be doing and how that fits with what the HITECH Act says.

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; I'll answer it because I think that was largely to my comments. I think the focus on safety it's usability as it pertains to safety I think is my understanding of the focus and that's why it's called safety-enhanced design. And certainly that's where our group focused when we were doing our project.

Paul Egerman – Businessman/Software Entrepreneur

And that's an excellent answer and I guess I'm comfortable as long as we start to understand that that's what we're trying to do and we're not just trying to improve the usability of these issues, it has to be limited to safety related 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, good point.

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 mean, I think that should be our main focus but, I mean, the fact is that if the usability is really bad in general it does slow people down a great deal and then that, you know, in and of itself can become a safety issue. We see all sorts of usability issues with various products. I think our main focus should be on the ones that are safety related.

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

And this is Mike Lardieri, is there...I’m just thinking the vendor may do very well, you know, out-of-the-box in certification but things change once it gets implemented. So, would there...would we have any way to follow up once an organization implements it?

I know I’m dealing with that in my organization. We implemented something and we didn’t do a good job, we asked the vendor to make changes and now some of those changes are not good ones and now we have to go back and retool, any way to catch that on the backend?

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

Does somebody like Janey want to comment?

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

Well, I mean, I think that again, part of that is going to come with the vendor and the organization’s usability maturity and what kind of user centered design process goes into customization at implementation.

I know coming out of the summative usability test that when we would start having our error analysis discussions with the vendors they would say “well, that’s not our problem that’s an implementation problem” and that would be things like very basic safety problems like truncation of drug names and truncation of doses.

So, things that I like to go back and point to the NIST EUP where they have the heuristic at the end that has some very specific watch for these error prone places in the EHR and so I think that as you try to get the gap of once things are implemented it’s the place where this group should be talking about, you know, how do we get user centered design and a focus on safety farther down the line at a time when changes can be made to make improvements.

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

Okay, thanks.

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, I would, this is Terry, I would echo that and also add that one of the things...one of the conclusions we drew at the end of our project was that there needs to be more resource and guidance to systems about how to implement and I don’t think we can put it all on the shoulders of the vendors.

Earlier I said, I think the vendors need to take more responsibility in guiding this but I also think that we need as a community better resources to help guide how to do it well, because we have 3000-5000 hospitals or however many there are doing this each trying to learn it on their own and redoing, you know, reinventing the wheel over and over again.

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

Right.

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

But that maybe beyond the scope of our Workgroup's conversation but I think it's relevant to where the discussion has gone now.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Hi, it's Larry Wolf, I guess I want to jump in and agree that this discussion of how do we effectively bring this to the providers is really important and to some of Paul Egerman's comments that we should broadly consider options for doing that, that certification may not be the appropriate vehicle for everything and we should be judicious in thinking through as we progress in our work of what the right methods are going to be to move forward broadly on this...we need to look at both, the parts that the vendors can do and the parts the implementers are doing inside of individual hospitals and physician practices, and the other care settings that have Health IT.

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

Are we at a point where we could...where we are essentially done with this discussion, do you think?

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

Hey, David, it's Robert Jarrin; I just wanted to say a couple of things. I've been silently or quietly rather listening to the discussion and we are a vendor obviously, Qualcomm Incorporated, but we're not an EHR vendor nor certified to a module at least not yet.

Our medical device subsidiary has a software component to it but, you know, having said that our medical device subsidiary obviously when we created our medical device had to follow human factors testing and usability studies as part of what we had to have on file for FDA and there a number of guidance documents that the FDA has pertaining to human factors testing and a number of other standards bodies for example AAMI has a document, I believe it's HE75 on human factors which has several sessions on software and user interface design.

So, I just wanted to make sure that everybody was cognizant of that because that might be a good place to look as well.

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

Good point, thank you.

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez, as far as the safety goes it seems like when you have...you look at these vendors and you have three categories of no UCD, basic UCD, well-developed, it seems like the great danger in that are the ones that have no UCD.

So, it seems our process should be one to look in a mirror to show, okay you have no UCD, you're missing your pants altogether and two once they have their mirror there should be some little best practices there, okay when you wear pants you should have your belt and your shoes should be the same color.

I mean, that basic thing of one, just showing that there are problems and two here are how you fix that problem. Simply providing a mechanism to be aware that you have problems and then giving them tips on how to fix the problems seems to me like the basic mechanism.

Raj M. Ratwani, PhD – Scientific Director – National Center for Human Factors in Healthcare, MedStar Health

This is Raj Ratwani, I agree that some very basic criteria are important and I think Lana could probably address some of that information as well.

If we look to other industries, particularly if we look to the FAA and the guidelines that they provide around certification or at least what would be equivalent to certification for technology that goes into the cockpit there is very clear guidelines about the kinds of fonts, the size of fonts, the types of colors, etcetera, which bridge both bin one and bin two.

So, I think there is certainly work that can be done there to provide those basic guidelines and in fact some of the work that's been coming out of the SHARPC Program has been these I think well crafted, one page guidelines for different aspects of EHRs that begin to address some of those issues and while they're not certainly required for certification I think they're in a nicely consumable format that could advance some of the vendor practices.

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

Hi, this is Bennett Lauber, I want to continue with the analogy this time a little bit to the automobile industry where in 1968 the automobile industry was required to put seatbelts in and they said that it was going to bankrupt them, well, obviously it didn't and I think there may be some other opportunities for the government to be a little bit more forthcoming in having requirements so that the electronic health record system is able to provide a safe system for us to use.

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

Okay are we...Larry, are we at a point where you feel comfortable going to public commentary?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Exactly what I was thinking.

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

Great, so...

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, I just need to...apologies in advance, I'm going to stay on, Raj has to give a presentation that was prescheduled before this meeting, so I just wanted to speak for him and say, you know, he's going to get off probably before the public comment.

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

Sure, no, we appreciate it, this was really, really helpful, thanks to both of you for presenting a lot of very provocative stuff, we'll...this was great. So, Michelle, if you could take us to public comment that would be terrific.

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute
Operator, can you please open up the lines?

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.

Okay, it seems like we do not have any public comments so we truly appreciate you all joining the meeting here and just have a wonderful weekend. Thank you.

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

Thanks so much everybody.

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

Thank you.

M

Bye everybody.

W

Thank you.

M

Bye, thanks.

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

Bye-bye.

W
Bye.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Bye.

Public Comment Received During the Meeting

1. It is true that many of the new FACAs have little to no vendor representation. I believe the EHRA has communicated this fact to Dr. De Salvo.
2. In addition to the resource issue of Usability professionals for many vendors and the cost involved in that, the timeframe to develop certified products is often too short when one looks at the time final rules are published and when the end users must be using those products..