



HIT Policy Committee Health IT Implementation, Usability and Safety Workgroup Final Transcript November 7, 2014

Presentation

Operator

All lines are 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? Larry Wolf?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Here.

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

Hi, Larry. Alisa Ray? Bennett Lauber?

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

Hello everybody.

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

Hi, Bennett. Bernadette Capili? Betty Mims Johnson?

Elizabeth Mims Johnson, PhD - VA Medical Informatics Fellow – Department of Veterans Affairs

Hi, good afternoon.

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

Hi, Betty. Ellen Makar, I'm sorry, from ONC?

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

Yes, I'm here, thank you.

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

Hi, Ellen. 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 and 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? Joan Ash?

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

I'm here.

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

Hi, Joan. John Berneike?

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

Yes.

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

Hi, John.

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

Hi.

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

Lana Lowry? Megan Sawchuck? I know Lana's on. Megan Sawchuck? Mickey McGlynn?

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

I'm here.

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

Hi. We're going to call you Mickey because we have Michelle Dougherty, too.

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

Okay, that will be great.

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

Okay. Michelle Dougherty?

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

I'm here.

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

Okay. Hi, Michelle. Mike Lardieri?

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

I'm here.

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

Hi, Mike. 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? Steven Stack?

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

Here.

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

Hi, Steven. Tejal Gandhi?

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

And...oh, hi, Tejal. And Terry Fairbanks?

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

Hey there, it's Robert Jarrin. I'm here, I was on mute. Mute is a terrible thing, so happy Friday everybody.

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

Hi, Robert. And I think we have Terry Fairbanks, too, I just...

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

Yes, hi Terry. Are there any other ONC staff members on the line besides Alicia Morton and Ellen Makar? Okay, with that, I will turn it to you Larry.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay. Well, I'm going to give a little bit of context for what we're doing today. And we're continuing our discussion about the implementation...I guess that's right, we're going in the right direction, those are the right slides. We're continuing our discussion about the certification process, so in many ways this is a foundational piece and mostly for our information. So we'll be doing a little bit of a look back at some of the things that happened recently and a little bit of a look forward.

So, a reminder about where we are with our current schedule; we've had three meetings so far, we're doing one today. There were a couple that were originally scheduled that have been cancelled and our next one is going to be Friday, February 12, so almost a month out. And we expect, actually, the engagement and the pace to pick-up early next year because there will be some expected results coming out of ONC for us to review and provide comments on. And also we will have covered the things that we wanted as a shared foundation for everybody. So, that's the plan. Let's go on to the next slide.

So, we have two presentations queued up for today, one is looking at the certification process as a whole that Alicia is going to report on and then some specific things around usability and EHRs, mostly coming from Lana and the work at NIST. And then, of course, we'll have public comment. Let's go on.

So, a reminder, or maybe news; I don't think its news for anybody, but the 2014 edition of the Certification Criteria introduced this notion of safety-enhanced design as part of the certification process. And so our goal here is really just to remind people of what is in that and that it was really about getting the software developers to describe what their current process is and if there is one, to do an assessment of it and if there isn't one, to state that there isn't one and that the results of that would be posted on ONCs CHPL as a way to create some transparency around this, as a way to just start to learn what the vendors are actually doing and begin to get some insight into what might be a helpful process and what kind of effort it takes and what the results look like and really establish a baseline.

And so in the context of that, the certification bodies also have a surveillance piece that they can go and see how the systems are working in live environments and ONC has asked them to take on that charge, so they're beginning to do that as well. And particularly given some of the concerns about how it's possible, given that the systems are all very highly configurable, that the thing that passed certification is not anything like the thing that's being used and particularly with issues of usability and safety, that could actually be things got better because of adjustments made in implementation or things got worse because of adjustments made in implementation. And at this point, it's really a big unknown. There are anecdotes out there, not a whole lot of actual research looking at the differences. And finally a link to the CMS FAQ sheet on their flexibility on the current go-round with the current certification and Meaningful Use Program. So, next slide.

So this is what's currently there. So we have a variety of areas that are covered for if your product is certified for any of these criteria, then you should address the design aspects. And then that list was expanded in September of 2014. And the next slide translates all those numbers for us, so let's go on to the next slide.

So, here we are, the optional ones I believe are all the new ones and the ones not flagged as optional are the ones that we've had before. And there's also a link through to the test procedure around this. So I think this is actually a pretty useful list that people might just want to hang on to as we consider what the current certification program is looking at and as we start to see what people are doing, where these are actually key areas...to be focused or maybe an area where we want to be more parsimonious and say, more tight focus on a few or broader or build in more flexibility in terms of where people pick things. So, we'll have plenty of discussion about this, I'm sure, as we get deeper into the end of this year and early next year. Next slide.

There also was an aspect...another piece that ONC was looking for input on in terms of quality management system and this is really looking at the quality of the software and what's being done for quality assurance around the software. And this also might be a place where feedback from use might be valuable. We've talked already on some of our calls about in the use of the EHRs and other health IT to collect information about problems with the technology or problems in the care and how that might feed in, so that's a very tiny piece of really feedback on the quality of the software. So quality management system here is really about the software development process and feedback around the software. Next slide.

Okay, so that's it for my piece of background and context. We sent out earlier today a link to the Certification Hearing, and that really is just background for people on some of the input that was received this past spring. And there's also a link which I guess we're going to distribute from the June Health IT Policy Committee where there was a report back to the Policy Committee on the summary of the hearing and some recommendations on focusing things for the future. And that's really all context that was input to ONC and so we should welcome Alicia as the new lead on the Certification Program.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Hi, thank you. Can everybody hear me okay?

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

We can hear you.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

All right.

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

It's Alicia Morton, just so everybody knows.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Yeah, Alicia Morton; brief background on me, been at ONC pretty much since the beginning, a little over 9 years now. And I have come full circle, I think; so when I joined ONC from CMS, by training I'm a nurse informaticist and I was at CMS running some programs and came down to ONC to run the first contract for the first formal Certification Program, which was at the time, just CCHIT. This was, of course, all pre-HITECH. And then transitioned that contract at the time, the previous Director, Carol Bean and went off and did all kinds of other things in ONC, had a Workforce Development Grants. I've always kind of done a lot of the CDS activities and now I'm back as the fairly new Director, it's been about 6 weeks now, of the Certification Program.

So, happy to do that, happy to take on the challenge, it is quite a challenge, there's a lot...with the program. It was good to produce these slides because I kind of learned more as I was going through and I think I'll be on the steep learning curve for a while, but I'm happy to share what I know...with you guys and hope that it helps you in your deliberations going forward. I'm glad that Larry mentioned the Certification Hearing from the spring; I think that that's valuable.

I don't know if this group is aware, I'm going to assume so, but if not, there was also a Visibility Hearing that was prior to that, I believe. Michelle or Ellen, you can let me know if you've let the group know about that, but if not, I think that's something worthwhile for them to take a look at as well. I know they previously received some presentations from Raj and team, so perhaps they already know about that.

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

Alicia, we just shared them as background materials before the first call, but we didn't really walk through them.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Okay. So we can go to the next slide. So, I just wanted to set the stage about what I was asked to present to you guys today. I was asked to talk about just a brief overview of the ONC Health IT Certification Program and the current 2014 edition, which products are being certified to, and mention that the CHPL site, which is the list of the certified products that ONC maintains for folks to be able to check and see if the product is certified and if that individual or hospital is a participant in the EHR Incentive Program, otherwise known as Meaningful Use Program at CMS, that's how they get their CMS certified product number for attestation. And then to talk about the surveillance program, which is a component of the ONC Health IT Certification Program and our relationship with the ACB, the certification body. You can go to the next slide.

I thought this was a helpful slide for lots of reasons. First, it's my UK wildcat blue M Corvette made in Kentucky, but two cars, same year, same manufacturer. Both of these meet baseline safety standards, they've met functional conformance testing. If you took them to the vehicle emissions testing, they'd both pass; let's hope at least they'd both pass. So they've met some of the basic criteria, right, but they're obviously not equivalent because they've met some baseline standards and those weren't the differentiators between these products.

There are lots of different differentiators, right? It could be how many people do you need to travel? What's your budget? What are some of the additional bells and whistles that you would like? Which one would you be satisfied with? Which one meets your purposes? And so, just wanted to set the stage that when we talk about the Certification Program, we're really talking about meeting baseline standards and conformance criteria. We're not talking about all the bells and whistles. And I think we would probably all agree that nobody would probably want the government specifying what the best agreed product is and holding everyone's feet to that fire. We really are at the minimum functionality, baseline standards for certification. So we can go to the next slide.

So the ONC Health IT Certification Program; so I will just take you through this process then I have another graphic that will build on this. So it starts with regulation, right? So ONC issues a regulation, we go through the rulemaking process that includes what the proposed and then final certification criteria are and associated standards. For...of rulemaking process there's plenty of public input, FACA committees also participate in some of that and that then specifies what's required of the Health IT product and also within the rule talks about the establishment and the structure of the Certification Program.

And then, once the rule is final, the Health IT product developers create the products that meet these minimum standards and certification criteria that was adopted by HHS in the regulation. And then the testing laboratories test the products that developers present against these standards and certification criteria that were adopted by HHS. The certification bodies then issue certification to those tested products.

They also conduct surveillance and when the products are certified, they share that information with ONC and on the Certified Health IT Product list so that everyone knows that yes, this product is indeed certified, what it was certified to. And we're also improving that site with additional transparency so if you go there now, you will also see some of the reports with exactly what was tested to include usability testing for those that did provide that information. And then the purpose of this is that so providers and hospitals have some assurances that the products meet these specific certification criteria and standards and if those hospitals or providers are participants in payment programs, such as the EHR Incentive Program, then they have a manner to attest that they've used a certified product. We can go to the next slide.

So I think if you've been to our web site you've seen this graphic, kind of a nice little map of the program itself. So ONC has a process for approving the approved accreditor and the approved accretor, which is ANSI right now, they accredit the authorized certification bodies of which we have three right now. And then on the left-hand side we have NIST, the National Laboratory...Voluntary Laboratory Accreditation Program. So NIST accredits the lab, which are the ATLS, the Accredited Testing Laboratories and they're the organizations that perform the conformance testing against the certification criteria.

So the developers submit their products to the ATL, if it passes testing then they will present it to the certification body for their certification and then we make that public via the CHPL. And there are standards, the pink boxes there on the left and right are the standards that guide the conformity assessment and the requirements and procedures for accrediting a certification body. Okay, we can go to the next slide. Oh, there are 5 ATLS and three of those ATLS are also ACDs.

So the next slide just shows what...certification criteria within the rule, there are like seven categories. Those that are highlighted in green are part of the base EHR definition, I just thought that would be valuable for you guys to know and to note that on the right, you'll see safety enhanced design and the quality management system, which are the ones the criteria that are focused in the areas that I believe you are focused on, and those are not part of the base EHR definition, although many of the functions, the safety enhanced design focus on are, such as CPOE. And we can go to the next slide.

This is something that I wasn't really acutely aware of until I took over this job, so I thought it would be valuable to kind of clarify the terminology, and I know we kind of change it up on everybody every so often, so it's probably hard to follow. But...so, base EHR, it subsumes the term qualified EHR, which some might have noted from the HITECH rule, and that was what was in green on the previous slide. And then we have the Certified EHR Technology, and people have seen this term a lot, it was actually on some early draft slides for you guys, and that really is a term that's specific to the Meaningful Use program. It's not...it's more than the base EHR definition, so it's really about leveraging the certified technology in a manner that's specific to the Meaningful Use Incentive Program.

And then complete EHR definition, which if you guys have read through the 2014 edition, release 2, is a term that will go away in future rulemaking. So it's the one that specifies use in the ambulatory setting or an inpatient setting and its base...a lot more. We can go to the next slide.

So kind of still building on the relationship between Health IT certification and Meaningful Use; so you know ONC adopts the certification criteria that specify the functionality and capabilities of the technology, and we give an example here of a few things. So we might say that SNOMED for recording problems or you must be able to do CDS. But then CMS talks about behavioral aspects of the Meaningful Use piece, so an EP must do this with certain functionalities; they must e-prescribe 40%, etcetera. And then to demonstrate the Meaningful Use, they provide them the metrics, the results of the measures and they attest to performing those behaviors in a manner that meets the expectations of the Meaningful Use program. We can go to the next slide.

So I've talked about the Certified Health IT Products list, I have a link here if anybody want to go take a look at what's there. It's not the most user friendly, we are making improvements, and we will continue to do so. Feedback is very welcome. There is a lot that's there and it's kind of...it can be a bit challenging to navigate.

So when you go the website, you'll see products that are certified to either 2011 or 2014, and we also have this mixture...2011/2014 to facilitate the Flexibility Rule option that people now have. When you go to that site, we have been and are improving the transparency through the ACBs to ensure that there's a test summary report where purchasers, researchers can read what was tested, what the results are and for those that did provide their QMS, you'll be able to note what they state there and their usability assessments. So, it's interesting to take a look, I have...the hyperlink that I have there is actually will link you, if you have a hard copy or original copy of the slides, will link you to one of the test reports so you can get an idea about the detail included.

So later this year, there will be a release 4.0, we've kind of improved the user interface of CHPL. But also going forward, we really are planning more of an open data, open CHPL development process for late next year where the information that's contained won't just all be PDFs, which make it very difficult for folks to be able to do the kind of research that I think your group might want to, looking at the different reports provided by the vendors and the ACBs...well, the ACBs. And so going forward next year, the goal is to have all of that data in a database that services researchers, interested parties, perhaps even consumer advocacy type groups can take that information or that data and make some meaningful information.

The next slide, please, is...I just lost my connection...Health IT Surveillance. So, we've talked about this briefly and I just wanted to kind of go over, and I have some links there that I think will be helpful for you guys to look at, at a later date. So the ONC-AA performs surveillance as part of their accreditation of the ACBs, they perform surveillance and technical assessments. And then the ACBs also perform surveillance of the products that they certify, and both reactive and proactive.

And the proactive areas ONC has specified in the last years, the priority areas for that which were exchange, safety, security and population management for quality measurement. I will note that the safety part are the criterion related to CPOE, drug-drug, drug allergy and med reconciliation as part of the clinical information reconciliation criteria. It's also important to...did someone turn this...very good.

It's also important to remember that surveillance is based on certification criterion, they perform surveillance when...well, reactive, when they've heard from either a consumer or ONC that a product is not performing in the manner that was expected based on what it was certified to, that kind of limits the scope of their surveillance activity. They can also perform surveillance if we've noticed that there are a large number of inherited certified status requests as well.

So like I said, ONC has provided guidance to the ACBs, the priority areas for surveillance, and I've provided a link here. We...this was fairly recently established, so, they're wrapping up their first year of surveillance in response to our guidance, at the end of this calendar year. And ONC anticipates receiving the reports of those activities in late February.

So, as Larry mentioned at the beginning of the call today, there is still quite a bit of unknown because it's a fairly new component of the program and they've been doing surveillance this entire year and we'll have a much better idea at the end of February. Also they're very responsive and reactive to consumers, purchasers of the certified products as well as ONC, whenever we've had a concern; they've been very willing to conduct their reactive surveillance. And then important to note that the NIST National Voluntary Laboratory Accreditation Program performs the surveillance of the authorized testing laboratories.

And then on the last slide, I...to, of course, if anybody has any questions or follow up, feel free to send us an email to the ONC.Certification@hhs.gov. There's another link to the CHPL, the product list. Take a look at that, let us know if you have suggestions, and send them to us on the certification email box. As I said, next year we're looking to move toward a different format, a more open data format. And a like to the ONC Health IT Certification program web page. That's it for me, I don't know, Michelle, if we want...we were going to have discussion with the workgroup members after my presentation or you should wait to do that until after Lana; either works for me.

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

Larry, what would you like to do?

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, how about if we do if there are any clarification questions, we'll do those now and if it's more general discussion, we'll pick that up after the second presentation.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Sounds good.

Paul Egerman – Businessman/Software Entrepreneur

So Larry, this is Paul, I have a comment and question. First I'm going to say, Alicia that was an excellent presentation, you described what is actually a fairly sophisticated and complicated process and you provided a great deal of clarity, so I appreciate the presentation. And you mentioned...you described how the CHPL works and the question I have is does ONC spend any time really doing any statistics on how the CHPL itself is used, and in particular, do you have any information about these things that Larry explained, that the vendors are providing the test results and their development plans? Are people actually looking at that information? Do you have data that says people are looking at it or that purchasers are using that information as part of the purchasing decision?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

I don't have that on hand, that's a good question. I will ask Scott Purnell-Saunders who is a Senior Advisor on my team who runs the CHPL. I know that we could probably get that data. I think presently what folks, and I'm sure it's quite difficult if I'm thinking about a small practice provider who is just trying to get through the process, right? It's a little bit difficult to navigate and so I think when they access it, they're really accessing it when they need to fill up the cart. Because it's kind of like a shopping cart thing, if you haven't looked at it, fill up the cart with all the criteria their product is certified to so that they can make sure they get their CMS certification number for the attestation for Meaningful Use.

So I don't know if folks are being proactive, I'm going to guess not, but who knows, and taking a look at the data that's there when they're considering purchasing products and saying, okay, well what are the results of this products certification, did they provide the usability report? What does it say? I don't know that people are doing that, I think that would be wonderful in the future if we can kind of educate providers and hospitals that this is yet another piece of research that you should perform as you're going to purchase an EHR or health IT product. I don't have the data on when people use and what functions they use or how much time they spend on opening all the PDFs, because unfortunately, they are PDFs right now. But that is something I can look into.

Paul Egerman – Businessman/Software Entrepreneur

Okay. And again, the reason I ask that is, I'm just curious to know if this is of value, I mean, if rather than arguing whether or not the user-centered design is a value, the question is, is having this information in the CHPL, the process of getting vendors to provide this information, is that of value to anybody? Is anybody actually using it? That seems like that would be an important thing to know and sort of interrelated with that is simply an observation. If I understand the description right, you have these surveillance capabilities, but the surveillance doesn't relate to the vendors, in other words, there's no way to find out, for example, if the vendor really is following the development plan that they've put forward.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Yah, so the surveillance is related to the developers and to the products, but the surveillance is tied to the certified product, the certified criterion.

Paul Egerman – Businessman/Software Entrepreneur

But it's tied to the use in a live environment, in other words, you can't go into the vendor's shop and actually interview developers and watch them while they develop the product.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Well, I guess they could, I mean, the scope of surveillance could be really broad, but we have to note that it's got to be related to the certification criterion. So, we don't have a criterion that state, you must use this UCD principle in your development, so there are no teeth there.

Paul Egerman – Businessman/Software Entrepreneur

Right.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

It's just right now their surveillance is either reactive, you know, I purchased a product, the product was supposed to be able to do transfer of care summary, but I can't, it's not working in the live environment. And then the ACB could determine well, is it something that was done in implementation that's not related to the certification criteria or is this product not what was presented for certification or has something changed with this product from when it was certified. And that...

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and those are helpful comments because in effect, there has almost become like two categories of things that are in the CHPL now; one category is things that passed the certification testing process, and that's a very objective process and the surveillance is related to, well gee, how can something pass the certification that's not really working correctly in a live environment. And the second category that we now have is this information about development and testing processes that vendors do, but that's not objective, that's just sort of like a one way street where it's submitted and there's no validation process to see if that's accurate.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Correct. So at this point it's provide us that information, because previously they didn't have to. But now it's if you're doing that, tell us how you're doing that.

Paul Egerman – Businessman/Software Entrepreneur

Great. Thank you.

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

I know we were waiting for discussion, this is Terry Fairbanks. I do have comments about that, but if you want to wait until we open up for discussion, I can go then.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So...

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

Hi, this is Bennett, I have one quick comment. Is there any regulation or control from the certification bodies to the level of transparency that they're supposed to be providing because the different certification bodies are putting different things up on the CHPL site?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

So, I'm...I think I need more information to be able to answer that. For instance...

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

Well, okay, but my question, I guess is specific to some of the usability tests...

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Yes.

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

...because if you look at the ones that are put up by Drummond, they always...tend to always have the summative usability test included and if you look at some of the ones from ISC Labs, they typically do not have the usability test included.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

So my understanding of that, and if I'm wrong, I'll send a note and clarify this. My understanding is that earlier in the program, at least one ACB did not provide that format that you're talking about, that 30 page long or so PDF and so we're kind of retroactively trying to get that information up, but they did not originally provide that information. And why, I don't know, but it's something that we are aware of and trying to retroactively get those records up there.

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

Okay, great. That's great because we've done some tests that they weren't a Chevy Vega, they were actually a Chevy Corvair and the usability test wasn't posted, so if anyone was actually searching, they would not be able to get the information.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Thank you.

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

Larry, is it okay if we continue this discussion, while we're on it?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yeah, I think we should.

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. So this is Terry Fairbanks, I...even beyond what we're talking about with surveillance, I just want to add some data that since we presented the other day, our group has done a pretty extensive analysis of the CHPL reports of just looking at approved EHRs. And of the 62, we looked at 62 summative testing reports and we found concerning data that I think beyond the surveillance piece, I think raises a question about how robust the evaluation of the submissions really is.

We found the range of participants in the usability studies was from 2-24 and 2 is 100% certainty not enough participants in a usability study to have any value, but yet it was certified. Twenty-five percent of the reports we looked at had no physicians at all as participants, which really raises the question about the user...about whether you're covering appropriate user groups. And beyond that, there were several vendors that did not actually attest to having a user centered design process, they simply stated that there was a summative test that was run, which also is a requirement. And so I think even at a more basic level, we need to look at how these evaluations are being performed and really if these standards, as published, are really being met.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So...

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

Hi, this is John Berneike...oops, sorry.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Go ahead, John.

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

Yeah, John Berneike of St. Mark's Family Medicine, as a primary care provider, I want to reiterate the comments that have already been made, primarily by you Larry and by Alicia, about the need for the surveillance to be done in a live environment. For instance, if the surveillance is done at the developer's site, obviously they're going to have an environment, a configuration set up that's going to continue to work and achieve the desired results.

But I ran into a situation myself having recently upgraded to my Meaningful Use 2 version of my vendor's software which is certified and supposedly has the functionality for all of the required elements, but once I got it installed and for a variety of reasons that I'm still trying to work out with the vendor, some of the functionality does not work. So something unique to my environment having gone through multiple software upgrades or who knows what at this point, but again, bottom line is it has to be done in a live environment, as has already been pointed out.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Yeah, we are hearing a lot of that and...as you know, you're still trying to figure out exactly why and that's really the challenge on our end as well. I mean, there...is it because what was certified is not what's in place? Or is it many of the other things, you know, version, implementation, configuring interfaces with other products? But it's something that we're definitely committed and the ACBs are required to look into, so I'll say it here, and this is for everybody. If you have an issue with a certified product where it's not performing as anticipated, according to the criterion for which it was certified, please send us an email on that ONC Certification mailbox with the product's name and the product's certification ID and a short description and we will work with you to try to address it this is a certification issue or another issue.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

And Alicia, this is Mickey McGlynn, I have a question on that surveillance process. You mentioned that surveillance has been going on all year and then I think you said you were expecting a report in February.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

Yes.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Is there any, what I’ll call close loop at the time of a report? So, I’ll just use the example that was given a minute ago, if that provider’s having trouble with his software and then that comes to...should come to the notice of the vendor, but a request to have it surveilled, is there kind of a working discussion or is it just a report? I’m not sure how that works.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

I’m not either because I haven’t had to experience this yet. So what’s coming to us at ONC is a report of the surveillance activities of the ACBs for the entire calendar year, according to the guidance that we provided them and any reactive surveillance that they perform. So that’s what I’m anticipating at the end of February.

We have encouraged them to make public their surveillance plans and these reports, well, I don’t know if and when they will and I don’t know...I’m sure that we will, at ONC, at least digest the three ACB surveillance reports we receive and share, at least at a high level, what we learned.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Okay.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

As far as the unique activities, a complaint comes in and we forward it, I hope there’s a...I mean, we close the loop. I will. I mean if anyone sends me information about a product and I engage the ACB, we will make sure that we close that loop. Like I said, there is just a lot of unknown on my part, but I’ll know a lot more by the end of February.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Thank you.

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

Alicia, this is Joan and I understand that the ACBs can also do proactive surveillance. As far as you know, have they done any of that?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology

I'm pretty sure they have, I don't have any numbers, I don't know how many percentage wise they've done surveillance on and what types and in what settings but I believe they've all done some. If you look at our guidance, we didn't provide specific expectations about a percent of their product, but I know that the ISO guides that they follow as certification bodies do suggest a specific percentage of the numbers of certifications they've issued.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, it's Larry, let me jump in, maybe I can make a comment to wrap up this section and transition us and then we'll come back for some more...conversation. My sense is that these particular areas that we're looking at, the usability testing, the quality measures and even to some extent the surveillance are all areas where the regulations created a structure, but did not really create hard criteria, as Paul was saying. Unlike some of the other sections that are very specific in the certification criteria, these were much more, we're looking to learn what vendors are doing, we want to get experience with a process, we don't want to be prescriptive until we can understand and be descriptive.

So we're starting with the description level and as people are commenting, it's raising lots of questions, which is perfect but hopefully we can actually get, in this next cycle of getting feedback and learning from what's been done. And that's going to actually be critical to the next rounds of regulations and as we think about where we can provide direction to ONC on how to leverage certification to improve usability and safety and hopefully not get in the way of innovation and true improvements in both of these areas where we really want to see things get better.

So how about if we transition to Lana's material, and then we'll come back to the discussion.

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

Ah yes, this is Lana and it is kind of hard to present after such an interesting discussion on certification, but I'm going to deviate from the policies and the certification discussion and the topic that I'm going to cover today will be very technical and this topic is about measurements, about usability as a science and as the evaluation tool and this is for the focus of NIST, because NIST is the National Institute of Standards and Technology.

So the title of my presentation is "How Usability of EHRs and Workflow Impact Patient Safety." And I'd like to ask to jump not to the next slide, but to the slide after that, it's under the title, focus of the EUP. Thank you.

So, NIST developed EHR usability protocol. It's a standards tool that addresses standard methodology in evaluation usability that impacts safety. We have been having a lot of discussions about usability in the past year, so me in leading this project, we had many different comparisons to the iPhone, to the innovation, to the market regulating usability versus government regulating usability, so I would like to provide a few clarifications.

Yes, usability is a very broad term as defined by the ISO, but there are certain aspects of usability that cover and study the human performance and interaction with a user interface and the error-free and successful performance is the ultimate goal of any user-computer interaction. So, the position that NIST has that it's very important to clearly distinguish between usability aspects that pertain to user satisfaction and usability features that impact clinical safety.

So our focus of the research and development has been on those aspects of usability that potentially can impact clinical safety. We believe that limited critical usability aspects that pertain to clinical safety must be embedded into the system and must be required as a core functionality, not a competition feature. And the barrier to entry the marketplace on safety is basically an expected outcome.

Typical measures of clinical safety are adverse events, which is wrong patient, wrong treatment, wrong medication, delay of treatment or unintended treatment. And accepted usability safety standards should be considered industry standard practices. Any company should be free to go above and beyond the basic standard; however, the minimum standards for usability in safety enhanced design should be established and articulated to address patient safety.

I was very impressed with Alicia's example about the emission and the safety inspection of the cars. All of these cars on the road and they are there because they pass inspection, the design, the luxury, any other features of the car is the subject to innovation, subject to competition, subject to the consumer choice and this is very important not to stifle innovation; however, we have very minimum benchmark on the safety, on emission that prevent unsafe cars to enter the road. Also, we do have a post-market surveillance and we have problems with Toyota, Toyota is recalling the product because we have surveillance, we know what goes wrong and then we can correct it.

So EUP...if I could please go to the first slide which is the core validation tool, can we just please go back? Ah, yes, thank you. So the usability evaluation protocol is the tool that is designed to help vendors, hospitals and other stakeholders to ensure that electronic health records users are minimized. So basically we are focusing on the human performance, we're focusing on the prevention of use errors and also evaluating effectiveness and efficiency. It's very important that the time of performance would not exceed some benchmark as well, because if the user performs on the task for excessive amount of time, it's just as dangerous as the user committed the error.

So the other purpose of EUP is to provide technical guidance for summative usability evaluations. We do require the summative usability report for the Stage 2 certification; however, it's a very rudimentary level when Larry already covered it and I don't need to repeat that, when the industry basically attests to the fact that they have the user centered design and that they tested the products with the end-users for the 8 safety related functions. But we do not identify any specific scenarios, any specific events where they should be tested to ensure the error-free interaction. So, EUP kind of expands the direction or the technical guidance on this particular issue, so the summative usability testing is meant to be independent from factors of...creativity, innovation or competitive feature of the system, and I already said that. These focus should be solely on the system to be safe for the end users.

Examples, as I just mentioned, of safety related usability issues that have been reported by healthcare workers include poor designed EHR screens that slow down the user and might sometimes endanger patients. Warning and error messages that are confusing and often conflicting and alert fatigue; basically it's a level of saturation of the human interaction when human does not react any longer on very important alerts and that happen because they designed without the consideration of the human limitations and human attention span and many other aspects that basically constitute the poor design. Can we please move to another slide?

The next slide is basically the usability evaluation protocol consists of three steps, and again, I already mentioned it, it's a pretty standard methodology that is one of the best practices in human factors of all of the complex systems evaluation, especially systems that are safety related. So the very first step includes usability application analysis where basically developers and human factors experts who identify those areas, those scenarios that pertain to the specific functionality of the system. It could be the pediatric functionality or it could be the imaging functionality. So the analysis needs to be done to specify what is the best way to evaluate this specific product.

Step two is also a very standard step and its expert review analysis of the application. So basically we have the expert that has enough experience...expertise and knowledge and qualifications to evaluate the application against the deficiencies. The end users are not involved in that application. And step three actually involves end users and that step three is actually usability testing, basically summative testing. The difference between summative and formative testing is that summative testing is for the end product, before the product is fielded. So basically after you do the summative testing, there should be no changes done to the application because the changes, if they are presented, they have to be tested as well. Okay, can I please go to the next slide?

The next slide is just the chart that...basically visualizing the three processes that I just listed. Can we please go to the next slide? So the main objective of the EUP is on ensuring necessary and sufficient usability validation and that remediation has been conducted so that user errors are minimized and use efficiency is maximized. As I explained, user errors are just as equally important to analyze as to analyze the time and duration of the human performance to execute the task. So the usability issues that can be uncovered by the evaluation should be mitigated. So the intent of EUP is to validate the applications user interface is free from critical usability issues and supports error-free interaction. The next slide, please.

In the course of developing EUP, we identified what we called "never events." And again, these are the events that constitute the critical usability issues; those events that must be eliminated and that would constitute that usability of this system will not impact the safety, identification of the areas for potential UI improvements and record user acceptance satisfaction. We do recommend in the course evaluation, to collect the data on the user satisfaction. It should not be the factor for the certification because it's subjective; however, it is a very important feature for the marketing purposes and it should be probably known, but it should not be the subject for certification. Can I please move to the next slide?

This slide is just a description of the user centered design where on the left we have test and evaluate. So the usability evaluation protocol that I'm covering in my presentation today would be the integral part of the user centered design. Next slide, please. I'd like to skip this slide; can we go to the next one?

So, how to measure performance? I probably will repeat myself, the performance can be measured by the accuracy and the error-free interaction, and it also can be measured by the efficiency and effectiveness and the time of the performance. And the goal of the validation test is to make sure that critical interface design issues are not causing patient safety related user errors; in other words, that the applications user interface supports error-free interaction. The next slide, please.

In the next couple of slides I'm just bringing very abstract examples of the potential scenarios that can be created for the evaluation protocol. And this particular task and the next slide as well are basically setting up the conditions that you have two patients with the same last name, with a similar first name and basically the task would be to observe the user ability to select the right patient and not to confuse with the patient with a similar name. In this task, it's also certain conditions are designed to trigger the CDS, the clinical decision support in the form of the alert and also study how the end user actually responds, successfully or not successfully to that alert. Can I please move to another slide?

This is just the theoretical example of the findings and if you can see on the right, it's a severity rating. Severity rating is given from 1, as the least to 4 as the most by the expert and depending on the severity and probability of the impact of that error, the 3 and 4 have to be addressed for mitigation immediately. The next slide, please.

This is the usability safety framework that was the core of our research and this is exactly what I'm trying to present today that the usability safety framework has to be the core of certification and validation, and not the other usability features and aspects. In the center severity, frequency, deductibility and complexity, these criteria are most critical in human factors in usability. Severity, it can be a very infrequent event but with the most dangerous outcome and it has to be addressed because the consequences potentially are very serious.

The frequency, it may not be that critical outcome, but the frequency of events also require attention because the probability of the error is very high. Detectability; detectability is basically, in my understanding and my expertise, the most dangerous factor. It's when the end user commits the error and doesn't even understand that the error has been committed because the end user cannot detect what went wrong.

And complexity, in the case of EMRs, complexity is the patient factor; when you have a newborn, when you have people with multiple illnesses, so the complexity of the patient also impacts the effect of the user-computer interaction outcome. On the left it's the user error root cause; on the right are adverse events. This is what we called the "never events," the events that should be eliminated and mitigated before any system will be fielded. And, can I please move to another slide.

There are several more examples. This slide, wrong patient record open, because many of EMRs or maybe all of the EMRs right now allow multiple records to be open at the same time. There are cases when let's say the imaging of patient A will be displayed on EMR of the patient B, and we're hearing it's not a very rare event. But I would say that is quite a high severity of this type of error for anyone to understand. Can we please move to another slide?

So another example is wrong mode for the action. And we had one of our colleagues, Dr. Brigg presenting in our workshop several examples how crucial that is in pediatrics to identify the right mode and the right dosages. And some of the EMRs basically changing the mode without the clinician even realizing that and again, the consequences...unintended consequences can be extremely crucial. The next slide, please.

The incomplete data display. If you look at this screen, there is no intuitive indicator of what that is but basically it's the example that menu cuts off the doses, so you're looking at the medication but apparently in order to see the dosage, you have to click on this medication. It invites the error. So can we please move to another screen?

And that's a very similar example, it's basically an example on the taper of the dose and in order to be able to see the chart or progression of tapering the dose, you have to click on the comment field. So, that's yet another example when the screen almost invites the user error. The next slide, please.

And this slide I just would like to re-emphasize again the usability and the definition of usability, the workflow and workaround because a couple of other slides at the end of my presentation, I'm going to cover another technical guidance that was recently released by NIST and it's basically the guidance in the ambulatory workflow. The next slide, please.

The reason why we looked into the ambulatory workflow is because we realize the end users having issues that the EMRs workflow not necessarily reflects that clinical workflow that is intuitive for the clinician. So, in order to support and provide some technical guidance to the industry, we had discussions...multiple discussions with the subject matter experts to define the end user requirements. And based on these end user requirements, to build the workflow of the...that would support the main...the clinical workflow, not vice versa; so this way the EMR would become of assistance rather than destruction from the workflow that is most important. And, next slide, please.

The technique that we use for that was the process map and goal-means decomposition diagrams. And these diagrams precede the GUI design, so basically they are identifying the workflow that is optimal for the clinical users and based on this workflow...if we can move to another slide. And based on this workflow, the GUI design would be reflecting the needs of the end users. And again, this has...this subject not has anything to do with certification, I'm just covering to inform about the available technical guidance that was released by NIST. And of course we placed different buckets in ambulatory care, like before patient visit, during patient visit, physician encounter, discharge and visit documentation. Next one, please.

And these are just examples how we were building these workflows. And again, all of these workflows and decision making diagrams were built based on the end user feedback and identification of the end user requirements. The next one.

So, you can see the balanced workflow we learned from talking to the subject matter experts that one of the factors that are critically important is the situation awareness and knowing your workload and knowing your schedule, and then you can identify your task based on overall picture. And this way the interaction would be optimized and EMRs would become extremely useful tool in balancing the workflow during the day. That's before the patient's visit...and the next one.

And the other feedback that we received that during the pa...I'm sorry, before the patient's visit, it is very important every time when physician reviews the lab work or the imaging, the simplicity and clarity is extremely important to be pres...in the right place, in the right time. And this is one of the examples of the simple chart of the lab work. The next one, please.

And the other request and requirements from the end users is that ability to take certain notes in a free format in the EMR that they can store for the next visit for their own recollection of the encounter with this patient. The next one, please. And these are basically examples of our final workflows. And the next one.

So, in the course of this research, we provided recommendations to the industry and basically the recommendations are increase efficiency by reviewing results with the patient, drafting the pre-populated orders to be formally executed later, supporting drafting documentation with shorthand notation without a keyboard. Design for empathetic body positioning/eye contact. Support dropping tasks and delaying test completion. Verification of alarms and alerts and data entry without hard stops; hard stops is a big, big subject. There should be no hard stops anywhere in EMRs because the final decision making must be up to clinician, not up to the computer, even though even medications are contradicting, it still has to be only clinician decision, not the computer of administering or not administering.

And the final slide, please; recommendation for the ambulatory care and...but these are basically recommendations for the providers. Well, thank you so much for the opportunity to present the NIST work. As I said, I have deviated from the policies and just provided the introduction of our technical guidance.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, this is Larry, maybe we can sort of think about framing our discussion in two parts. So the first part of what you presented was around the notion of testing in general and then the second part was some specific recommendations that came out of some work that you've done looking at where there are high frequency problems and some things that might address them, is that correct that there are really those two parts to what you presented?

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

I apologize Larry, can you please repeat?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Sure...

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

I'm sorry.

Larry Wolf – Health IT Strategist – Kindred Healthcare

...it seemed like there were two parts to your presentation, that the first half looked at testing in general as a structure and we might want to talk about that and then the second part was some work that you did specifically the recommendations that are now up on the screen, about ambulatory care and places where specific kinds of problems surface and some suggestions, guidelines about what might be done to address those...

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

Right, it's not the guidelines...at least the meaning of the word guidelines...standards. This is just the technical guidance.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Right. So, that's what I'm trying to do is separate the structural piece of what you looked at in terms of the importance of testing...

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

That's correct.

Larry Wolf – Health IT Strategist – Kindred Healthcare

...the kind of testing and how it might be approached. And then some specific findings that you've got and some...recommendations.

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

That's correct.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So maybe as the workgroup responds, people could use the first...like say the next 20 minutes to look here at the structural things and then the following 20 minutes to look at sort of any additional things that came up from the NIST presentation.

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

Yes, this...

Larry Wolf – Health IT Strategist – Kindred Healthcare

So with that as my...go ahead

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

Yes, this is Mike Lardieri, so I have a question that is about testing in general. So how would you...how do you differentiate with the folks who are doing the testing those providers who actually like check boxes and drilling down using check boxes versus people who their brains don't work that way, they'd rather have free text and do everything in more of a free text mode? So when you're doing the testing, if someone is really proficient, they like the check boxes and they get...and they're in front of a system that does that, but you have another person who doesn't really like check boxes, how do you ferret that out when you're evaluating whether this works for them or not? It's usable for one person versus not usable for another.

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

It's question for me, right?

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

Yes.

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

Okay, this is a very good question but I just would like to reiterate what I said from the beginning that the protocol that we developed do not really identify or emphasize the user preferences. If they can complete this task without errors and ensure safety, that's what this protocol is all about, the user preferences, the different aspects of design, this should not be really regulated or certified or required. What's more important, it's not the design features, what's more important is the user performance.

So our attention is on the user performance and if you can...whether you don't like check box or you like the check box, but you complete it error-free in a reasonable amount of time, that's the bottom line. As I explained in the very beginning, the benchmark is very low because we are talking about the certification, right? Market will define which system is more accepted by the users or the users are more satisfied, that really should be up to market...

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

This is Terry Fairbanks, I just want to agree with Lana, but I want to add a reassuring note about it that if a good user centered design process has been used, then the designers would have learned about the different preferences of their end users and they would have presumably built a system that accommodates those different preferences. And so then when the summative testing occurs or the testing occurs, then the users...the participants can use the preference the way they would use the type of interface that they prefer. So, I agree with Lana that if this is designed correctly with a good user centered design, then that should not be a factor.

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

And this is Janey Barnes; I would just like to give a concrete example for a testing that we conducted on behalf of vendors. We had that exact task for many of them and so when the physicians were doing their tasks, they had a task that was related to CPOE and they had to give special instructions to the nurse about how to administer something related to the medications in the CPOE. And so some people did the check box where it was intuited for the product for them to be able to provide that messaging and others wrote in a comment field.

So then when nurses came in, nurses had to do a task where they had to administer medications that had been ordered and they had been ordered by physicians who were in the same usability test at a different time. And so the physicians who went through the intended design with the check boxes, those nurses who had to follow up with...CPOE order that they were able to see the special instruction and carry it out. Those nurses who ended up getting paired with the physician who wrote it in the text comment box, it turned out that the nurse didn't even have a view of that comment box; so the software didn't support that.

So, on one product in particular, there were a lot of failures on behalf of both ends because the doctors couldn't...didn't carry it out in a way that the software intended and the nurses didn't find it. We did the same task with other products where the designers, as Terry had just described, that they knew about those different ways that people might enter that data, there were not as many fail...not as many task failures because all of the nurses could discover that note to them and administer it based off of the special instruction. So that's the example of how usability testing would highlight the area that whoever asked the original question, that's how the testing would handle that.

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

Okay. Thank you everybody, that's very helpful.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul Egerman; I have a couple of questions. First is, Lana in your presentation you made a number of references to vendors and the marketplace, but what about self-developed software? Does your...how does your protocol relate to people who are developing their own software for their own use and not for the marketplace?

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

Huh, that's a good question. I mean, I apologize I really don't see much of a difference. The end users...an end user requirements, this is what drives the user centered design, so everything has to be designed according to the end user requirements plus the functional requirements. So I really, I may be using the terminology of the industry, vendors, developers, but the applications that are developed for the internal use, I don't see any difference.

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

This is Janey again; I'll give you just another example. So we were testing for vendors with CPOE that they had orders that the vendor had set up for the usability test and then when we went out in the field, then of course we knew and people said, well we don't like the vendors order set so we customized our own and so then we asked about what kind of usability testing was done with their own order sets and hospitals that were...hospital systems that were very mature in their usability programs, they actually did a user centered design process around their customized order sets.

And those who were hospital systems that were not mature in usability did not and that one of the things that we found was that some of the common errors that are identified in the EDP related to order sets, that the immature places...vendors and hospital systems, that that's what's being implemented and its errors that can be caught as part of a very simple risk management program that's a user centered design process you follow.

Paul Egerman – Businessman/Software Entrepreneur

So I didn't quite understand what you're saying about customization, whose responsibility is it then to do the user centered...to do this protocol if a user wants to customize their system? Is it the user's responsibility of the vendors?

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

...I mean it's a shared responsibility, right? I mean...

Paul Egerman – Businessman/Software Entrepreneur

I'm sorry? It's a shared responsibility?

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

Yeah sure it's shared responsibility if the vendor creates the baseline product and then a hospital system or a doctor's office is going to customize that, then there are like two kinds of exchange. It could be that the vendor creates the software so that the customization cannot be made to put the software in a place where it would be prone to errors. Or it could be that the vendor lets full customization take place, and somebody might customize themselves into an error-prone software, but the vendor should be providing guidance so that they don't put themselves in a bad place like that.

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

Well, and also...

Paul Egerman – Businessman/Software Entrepreneur

So, in the example of alert fatigue that Lana gave, it's the vendor's responsibility to make sure the hospital physician doesn't set up too many alerts? Is that what you are saying?

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

I mean the vendor makes all the alerts available, I think, and the hospital system that they would have a committee that would determine how are they going to handle alerts. And so many hospital systems would say, we're going to be very conservative and every provider is going to see every alert, high, medium and low. But then there might be other provider systems that say, our providers have different levels of needs related to alerts, so for example residents are going to get a lot more than specialists who have been practicing for 30 years and that we might turn off the low and medium alerts for the more experienced provider.

And so again, it's a shared responsibility and in the end, it's that hospital system and their policy that's probably driving what's going to get displayed.

Paul Egerman – Businessman/Software Entrepreneur

So I still don't understand how that relates to the shared responsibility. Does the vendor have responsibility for those situations or is it really on the customization solely on the hospital side in your example?

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

Well I would pick a vendor that would provide me some guidance.

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

Right, it should be default settings, it should be some guidance, it should be some warning of the customization that can cause unintended consequences. And government has released, ONC, I believe, has released the SAFER Guide and basically there are guidelines right now on the potential safe and unsafe customization. So, if before we didn't really have any formal technical guidance coming from the government, right now as I said, we have the EUP from NIST and we do have SAFER that was released by ONC.

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

This is Tejal Gandhi, I just want...

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

This is Mickey McGlynn; I would add a comment here as well. I mean typically at time of implementation, there is implementation resource who is focused and in combination with a provider, to make those decisions, at time of implementation. But then, in some cases, hospitals have big IT staffs and then years may go by and then they might do customization on their own, or they might have a vendor come back in and make decisions with them. It kind of varies depending upon, in my experience, depending upon the customer and how autonomous they are and how much expertise they have on their team related to IT.

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

This is Tejal Gandhi; I wanted to add to that. I agree that it’s highly variable right now and I do think there needs to be guidance because based on that expertise, people often do go with defaults that may not be really set optimally for safety. Often the defaults are, show every alert and then it just minimizes the impact of the alerts because they get ignored by everyone. So I think there needs to be some level of guidance, especially to help organizations that don’t have a lot of this IT expertise, but really for all organizations.

And also to achieve a standard around some of this critical safety decision support so that if a physician is going between hospitals, he or she isn’t getting certain alerts at certain hospitals and different alerts at other hospitals and expectations for what they might be getting alerted on may not match what they’re getting alerted on. So, I just think that there needs to be, especially for things that we think are critical to safety, more of a real, I don’t want to use the word standard, but real guidance for where the safety optimization will lie.

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez, I have a question about...I’m not sure if this is a safety issue, as far as...to make something a little more consistent, because the user, for example, may be able to drill down into a patient by clicking on something, but then in the same App, another page, they have to double click and then elsewhere they have...there’s a button instead. So, they can use the software safely, but because it’s inconsistent, some users will think that oh, this feature doesn’t even exist on this page because I’m usually double clicking when I’m supposed to find some button. Is this a safety issue or one that when an App...is there...as far as an App being consistent and say no, they do a similar task?

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

This is Lana Lowry. This is a very good question. When we standardized the features right, we are stifling the innovation. I mean basically by being so prescriptive and say that here has to be a single click, here has to be a double click, here has to be the drop-down menu, this way we will never achieve the true innovation because it’s so restricted. So I am totally in agreement with you that consistency supports successful user interaction.

But we have multiple, multiple systems and they’re different and they have every right to compete so my answer will be still the same, if it’s validated in usability testing and the user can perform the task without error and successfully, that has to be the focus of certification. But the optimization of the feature and consistency and better user satisfaction, again, that should be driven by the market.

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

This is Janey, just to follow up. So what happens in the case that you just described is that, I'll just call it a "golden path." So typically what happens is the vendor identifies what is the optimal path to complete this task and that optimal path is based off of both effectiveness and efficiency. So if it's the case that then sometimes the system has people single click and other times it has them double click, what we've seen is that when people go down the "golden path," sometimes when it's supposed to be a single click, if the system isn't responding, then they start double clicking and double clicking and double clicking and in cases on testing that we've done, that gets marked as an error, so now it has to undergo an error analysis.

And this either becomes it's an efficiency issue in that those double clicks are contributing to poor efficiency or sometimes it creates a safety problem, so its created duplicate error messages, in terms of drug and drug interaction warnings. So instead of having a one drug to drug interaction for when you single clicked, you actually have five because you single clicked and then double clicked twice. And so that's contributing to alert fatigue and now that's no longer just an efficiency problem, it becomes a safety problem.

M

Hmm.

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

I want to just, if I can, tie back to the first presentation. So, our experience is that having these reports be public is a differentiator from all the other safety related industry. So for the FDA, there's very similar process that's required, but the summative usability test isn't required. And then also in transportation, there's a new guidance document out related to being able to provide evidence about driving distraction. But again, the report isn't public. Our experience has been the threat or the regulation of a public report it made a big difference for vendor organizations that had an immature usability program. So in those immature organizations, usability testing number one, it happened, it might not have happened otherwise. And then it got the attention that it should have gotten.

And then the other result of it is, when you do the error analysis related to what was observed in the usability test, that those reported errors and their mitigations, I think they become a pool of important information for surveillance. So for example, the kinds of critical error examples that I've been given, that those are out in these reports and they weren't mitigated before it went live so the systems are out there with those errors, then the ACBs, if they're going to be proactive, then they can go and follow up on those reports to see what's the vendor's timeline for mitigating the errors in the way that they said that they were going to mitigate them.

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

This is Mike Lardieri and when you're getting into the subsequent reports, when there is an error and how do you differentiate that it was an error because the user modified the system, even though the vendor may have counseled them, hey, don't do that, they did that anyway. Now they're getting errors, they report that error up, how is the vendor going to be protected and not make it look like it was their fault because it really wasn't?

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

This is a tricky question. If the system is modified based on what vendor allows to modify, it's one thing but if somebody literally breaks into the system and changes the configuration and makes certain features quite unsafe, this is a totally different story. But again, I would like to repeat what I said in the beginning that post-market surveillance should determine...and when system functions not as it was certified or intended based on what? Based on the fact that we did the best simulation for the evaluation and certification, we still simulate, because system is not fielded and then we field it and some environmental factors made certain things not functioning as intended and they need to be mitigated. Or somebody configured system in an unsafe way. So these have to be a part of the analysis.

And again, I'm bringing analysis from out of the industry and from aviation. Before the airplanes are released, they are tested and tested and they test it with the pilots and in a simulation in the lab. But when something is happening in the air due to the weather, due to other factors, so whatever is happening is recorded and analyzed to make these systems safer. EMRs are safety-related systems so we need a very sufficient mechanism to do all of the possible validations before we field the system, but also continued surveillance and making sure that they are functioning as intended.

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

Um hmm. Yeah, I think I'm just concerned that on the continuing to function as intended, it may not have anything to do with the vendor because if I'm a provider and I have staff that I don't necessarily need to break into the system, but I can change the system. And even if the vendor provided the guidance that, hey, don't do that, I do it anyway, now I report an error; just want to make sure that when we're doing the collecting the error reporting we're asking that question, did you modify the system after you got it from the vendor, so that it doesn't look like a vendor didn't provide an adequate system when they really did and somebody changed it.

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

Yes, and that's what exactly is included in the analysis.

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

This is Terry Fairbanks. I would just add to that though that I think that we've had a lot of discussion about the implementation piece and even today we're talking about there needs to be a partnership in implementation because the vendors may have had an experience at prior implementations where they've seen that an error can occur because of a certain customization that occurred. And I think the question is where does the responsibility lie for guiding the next place they implement?

And so I don't know if I know the answer, but I'm just raising the issue that I don't think it's as black and white as that and I think that that might be a place our committee should focus when we're thinking about safety.

I do want to just bring up one question though for Lana. One thing that you said, Lana, earlier on in your presentation was that after the summative test that there should be no further changes to the application. And so that related to my point I just made, that raises the question of what happens with both the implementation and how much implementation change and impact on the usability should the vendor anticipate and guide? But it also raises questions about the different functions because right now we're only evaluating eight functions, so how does a vendor grow functions if there can't be a change after the summative test?

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

Yeah, Terry. Your question is great and you're always raising the most insightful issues; I definitely would like to state that. But, to answer your question is, the user centered design involves different stages of evaluation and the formative testing will uncover some usability issues that need to be fixed and they should be fixed. And some of the vendors...doing the user...a blind user centered design in doing the formative testing in a consistent way. All I was trying to say that the summative testing it's the testing that's executed on the final product and, as you know, if any changes are presented, they are not always for better, they also need to be tested. So summative testing is just to verify that the product that is about to be certified or fielded is usable in a sense of the relation to the safety. And what was your second question, I'm sorry.

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

Umm, my second question was...

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

The first one was about summative, 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

...functions, yeah, growing functions. I guess overall I'm just making the point that the summative test you do one freeze frame of the product before it goes out the door and then it evolves into many different things. And so I think...I guess it comes back to a point that Raj and I made when we did our presentation, what we learned is we think that for the vendors that are really good at user centered design, not necessarily the big ones, because we found, as you know, it didn't correspond with their size. But if they're really good at user centered design, maybe summative testing isn't the best thing for them to focus on, because it has limited value.

And I think one of the studies that one of the vendors did looking at their summative testing, they found very, very small percentage of their usability safety related issues were actually found in summative testing. So they were actually questioning the value, which I think is a reasonable question.

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

I know. Terry, I cannot agree with you and the only reason why I cannot agree with you, it takes very long years and a lot of effort and a very collaborative effort to establish a standard. And then to become a national standard and then to become the international standard and the summative testing is the international ISO golden standard to validation. So if you and your team and other colleagues of mine disagree, that's fine, you need to join the ISO standard group and definitely present your opinion, and if the colleagues agree...I have to joke, I cannot agree with that because this is the standard.

Paul Egerman – Businessman/Software Entrepreneur

So this is Paul Egerman...

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

This is Janey, I think that...I mean I think the thing that happens with healthcare IT is people separate the summative task from the user centered design process and the summative test is just one part of the user centered design process. And so I mean, I don't think that Terry is saying, don't have summative usability testing, if we just change the...if we brought in the focus and people who say that they are attesting to a user centered design process, that also means that they are doing a nationally recognized summative usability test. And so, if you have a strong user centered design process, all of the components are important.

Maybe for this first step, the summative usability was really important because it was something seemingly concrete that you could say, you have to do it, you have to do it like this and here are the results of it. But there's great...like that identified usability at that point in time on that one configuration and whatever in the environment that that particular usability test took place and it's one instance in time and it needs to be over a process and a lifetime of a product.

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul Egerman, I still want to understand this summative testing part some more. So like maybe two weeks ago, the National Coordinator, Karen DeSalvo, did a conference call with the CEOs of the major EHR vendors and said, we've got a huge problem with Ebola and she asked them to immediately respond in their EHR systems, and they did. And so within the last week or so, all over the country there are computer systems now and I actually observed one last week where there are new questions being asked, people are asked if they've been to West Africa. So...but there wasn't time to do the summative testing, so was that...did the National Coordinator make a mistake in doing that? Do we make all of our EHR systems unsafe by pushing through some workflow immediately relating to Ebola?

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

I don't think that you can answer and say did that request or requirement make every EHR system unsafe. But I what I would do if I was betting woman, I would bet a penny that the people who went through some kind of a user centered design process, and it doesn't have to be long and laborious, it can happen really fast, the people that looked at how that fit into the workflow. And then the people that did some kind of evaluation of it that their systems are probably more effective, more efficient and safer related to checking for Ebola compared to EHR systems where the folks and the provider systems where folks did not do that.

Paul Egerman – Businessman/Software Entrepreneur

I thought you just said...

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Yeah, and this is Mickey I...

Paul Egerman – Businessman/Software Entrepreneur

...you can't change the product after the summative 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

Right, I think...

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

Right, even though request came from the National Coordinator or if the request comes from any other sources, the end users ability to interact safely can be only determined by validation and testing. And if the testing is not done, now we have anecdotal evidence that all of the users are successfully accomplishing Ebola functionality, we don't have the evidence of that. And the fact that request came from National Coordinator or from any other source the only confirmation is the ability of end user to successfully complete the task. And if we didn't validate it, we just don't know it. We are assuming that they are very successful in accomplishing it, but none of us knows if they are or if they are not.

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 I think that this is, I think this is an important discussion and therein lies the problem really because there are lots of things like Ebola that we have to move quickly on and I think the main point I think we need to look at is, where do we want our vendors to be in the future? What we want is we want them all to have a very robust user centered design process. If they have that, we wouldn't even need summative testing because we could have good certainty that their products have a good, safe, user centered design in the end.

And I'll just bring everybody back to what we learned from the vendors that have great user centered design processes is that they're spending a tremendous amount of resources on doing the summative testing. And while you have hundreds of thousands if not millions of permutations of different functions and end users and environments, you're only testing eight in the summative testing so it's only giving you a very, very small snapshot or very small picture of the overall usability of the system whereas a good user centered design should result in a robust system in the end.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

So this is Mickey, I wanted to comment on a comment that Terry made right before this Ebola discussion about the sharing best practices at time of implementation, the role of the vendor in that with the provider. So I'm not sure if you're familiar with the EHR Developer Code of Conduct. It was developed about a year and a half ago, we lead it in the Vendor Association but we worked collaboratively with many physicians and other partners to do it. And we had extensive discussion about the implementation and the role of the vendor and the role of the provider and what we came away with, and the feedback was, if I'm a provider, I've done one of these, right and you, Mr. or Mrs. Vendor, you've done a hundred or more, you've got to help me be more successful because you know better than I do, I mean generally about best practices at time of implementation.

So as a result of that there is a section broadly on patient safety in the code of conduct, then there's specifically an item that says, we will share best practices with our customers for the safe deployment, implementation, maintenance and use of our products. So any vendor that adopts the code, which is up to 21 vendors now, commits that as part of their implementation, they'll have a set; they'll have process...to help do that.

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 Mickey, this is Terry. I do know about the document, I don't know the details of it as you are just describing so I'll look more closely at it.

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

Don't take that to say I think it's completely covered, I just wanted to point out that there's been some discussion on it, I mean certainly more work could be done there, but I'm agreeing with you that that's an important thing that should happen and best practices should be shared.

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 and I think really when we talk about these best practices sharing, it brings up the problem, if we just in the future had summative testing of all of our products, we couldn't do summative testing on all the functions that they do, so we'd have to continue to choose some. And I'm not convinced it would actually change the overall usability and safety of the entire system, because I think it would focus efforts on those eight functions and I think that the Ebola example is a good one that brings up the need for us to really think about the big picture and what we're trying to push for here. And I would argue we're trying to push for a more robust, user centered design process in all of our vendors.

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

I agree with you. I mean, the vendors, and we've had a lot of discussion on this recently in the Vendor Association that the vendors that have robust, up front processes feel that that summative testing is not...doesn't add as much value. Let's just say, just using a simple term, if they had a \$100 to spend and they had to spend \$60 of it or \$40 of it on doing summative testing, those \$40 would be much better spent in the front, up front doing user centered design because it could address things more broadly. Now, if you don't have robust, up front user centered design process, and then it's certainly better than nothing, right? So I think it's the rising tide lifts all ships, right, we have to increase the level and amount more broadly across the vendor community.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So it's Larry, I feel like we have good and excellent chasing after each other here, that summative testing in some ways is a validation step, a minimum bar. We recognize that we're not going to be able to do it across every aspect of the product and that in some ways it's essential that you know are you actually being successful in what you've done, but that actually it's the user centered design that's the process that's going to give you performance improvement, is going to let you actually raise the tide, as it were.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and...

Larry Wolf – Health IT Strategist – Kindred Healthcare

So, I feel like there's a balance that we're talking about here.

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

Yes.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul and I agree with what you just said, Larry. My point in bringing up the Ebola example was to sort of suggest that that stuff happens all the time, not necessarily you have pandemics all the time, but there's just, whether...

Larry Wolf – Health IT Strategist – Kindred Healthcare

(Indiscernible)

Paul Egerman – Businessman/Software Entrepreneur

...it's the National Coordinator or the Chief of Surgery or somebody, there is lots of pressure and these systems dynamically change and frequently just an additional question occurs and there's this constant, incremental change and it's actually that incremental change where each individual increment is not a problem, but the sum total over a period of time is what can make these systems very difficult from a usability and a patient safety process. And in fact, that's one of the sources of the alerts that they give people, incrementally add more and more alerts and my comment there is that the user centered design does not address that kind of an incrementalism that is, I think, the source of a lot of these issues.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Well, it actually is a pretty interesting question, Paul, about whenever you make a change, how open are you to actually getting the feedback that would be part of user centered design? And how much is...we do all kinds of testing before things are rolled to production, given priorities and scope of change might be a small checkpoint, it might be a major checkpoint. So I'm wondering if this is in some ways no different than the extent to which systems have regression testing when the change is made, you make a risk assessment about the scope of the change and periodically you do a major regression test to make sure you haven't broken anything fundamental. But a lot of changes are made with the assumption that their scope is limited and you don't need to retest everything. So do you think this is fundamentally different?

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

Larry, this is Ellen Makar, just to share with the group. This past Wednesday we did have a webinar that ONC sponsored with Texas Health Resources about this very question, about the changes that they made due to the Ebola response and then what kind of follow up processes they did to ensure that the system is working as intended. So what we can do is provide to the workgroup the link to that webinar.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and that...this is Paul, this is helpful but what I'm trying to suggest is, I'm not trying to argue against user centered design, user centered design is great, a lot of arguments for it. I'm trying to suggest that there is a real world activity that goes on with these EHR systems where there's a ton of incremental changes and that that incrementalism, don't know if that's the right word, but that evolution of the system can be the source of a lot of the problems that are talked about here and that, I don't know, it just happens slowly over time, but these systems are in place over a number of years and that's how it happens. And that's an additional issue that I don't think we're thinking through and this protocol I don't think adequately addresses.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So Paul, let me see if I can restate what I'm hearing which is, right now we have sort of a major waterfall approach, if you will, with certification and testing but the reality is that in use in the field, that there's a lot of incremental change over time that we can't assume that it's a stable product. And if we're really worrying about safety, that this has to be an ongoing responsibility that the providers take on, and I think almost all of them do. I think there's an awareness of they can be introducing issues when they make a change and a question of how do you then formalize that into the kind of regulatory work that ONC and others are doing? Because you're right, I mean, the incremental changes are huge over time and sometimes they're huge in a really good way and sometimes like piling on more and more alerts could be change that's really negative.

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

This is Joan and I'd just like to reiterate what we were talking about before about the dual responsibility of the customer as well as the developer and I'll tell a little story. When we were developing the SAFER Guides we did a site visit at Geisinger as one of the models of HIT safety and I was completely shocked when Jim Walker there told us that when they did an upgrade, they had EPIC and when they were implementing an EPIC upgrade, they did 50,000 hours of testing before they actually went to that upgrade. And my thought at the time was, that's amazing, but I also felt very sad about all of the hospital systems that don't have the resources that Geisinger has to be able to do that. And so I know Tejal mentioned that the more immature organizations really need some help here, it's not all on the backs of the developers.

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

Joan, this is Terry, just as an aside to that comment. That may be a place that ONC or another...or someone else could have a role in that the lessons learned from Geisinger and their 50,000 hours of upgrade that was presumably the same upgrade that many other hospitals dealt with. And I think that's one area that there's a gap right now is there's no one helping one hospital learn lessons learned from another hospital.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay, I'm going to have to be timekeeper. We're four minutes to the top of the hour. I hear that there's a lot of value in continuing discussion, which is good, we've got some upcoming meetings in December and then next year, so let's keep this dialogue going into our next calls and maybe we can open it up...public comment.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Larry?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Yes.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

This is Mickey McGlynn, I’m new to the workgroup today, I was just wondering if I could introduce myself to the group, just so they know my background?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay, a quick introduction is welcome, thank you.

Michele “Mickey” McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Okay. I’m Mickey McGlynn, I work for Siemens Healthcare. I also am the immediate past-Chair of the Electronic Health Record Association and still remain on the Executive Committee. Kind of just some specific topics in my background that relate to the work of the committee is that I was the lead in developing the EHR Developer Code of Conduct and worked with a number of stakeholders across the industry and a number of the topics do...are covered...are mentioned, I wouldn’t say fully covered, but are discussed in the code of conduct.

I also as the point kind of for the vendor association on the certification hearing and some recommendations and continued collaboration we are having with ONC to look at potential opportunities for improvement on the certification process. And then lastly, I’m leading an effort or a collaboration I would call it, with the provider community, specifically AMA and ACP and a few others, on the topic of usability and how we can work together more collaboratively to kind of improve the usability overall on EHRs. I’m happy to discuss any more about any of those topics at a future meeting and I look forward to working with all of you on the committee.

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

Can we maybe...

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

Thanks Mickey. Operator, can we please open the lines?

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment, please press *1 at this time. There seems to be no public comment.

Larry Wolf – Health IT Strategist – Kindred Healthcare

I'd like to thank everybody for the discussion today, a lot of good material presented, a lot of really good discussion about how we actually try to achieve the results of safer systems and the fact that it ain't easy and that there's benefits to be had at various checkpoints and there are also cost-benefit tradeoffs to be looked at. So, clearly no simple answers and we've got some runway in front of us before we need to report out, so that's all really good. Our next call is December 12, is that right? Yup.

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

Yes it is.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay, it's up on the screen so, see you guys in about a month.

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

Thanks everyone.