



HIT Policy Committee Implementation, Usability & Safety Workgroup Final Transcript April 21, 2015

Presentation

Operator

All lines bridged with the public.

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

Thank you, good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Health IT Implementation, Usability and Safety Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. David Bates?

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

Here.

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

Hi, David. Larry isn't here. Alisa Ray?

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

Alisa's here, hi.

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

Hi. Bennett Lauber? Bernadette Capili?

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

Here.

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

Hi, Bernadette. Betty Mims Johnson?

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

Hi, I'm here, good morning.

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

Good morning. Ed Lomotan?

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

Here.

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

Hi, Ed. 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. Janey Barnes? I know Janey was on. Jeanie Scott?

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

Here.

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

Hi, Jeanie. Joan Ash?

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

I'm here.

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

Hi, Joan. John Berneike? Lana Lowry? Megan Sawchuk? Mikey McGlynn?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I'm here.

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

Hi, Mickey.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Hi.

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

Michelle Dougherty?

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

I'm here.

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

Hi, Michelle. Mike Lardieri?

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

I'm here.

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

Hi, Mike.

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

I'm just on the phone.

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

Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here, it's Paul I'm here.

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

Hi, Paul. Robert Jarrin?

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

Here.

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

Hello.

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

Hi.

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

Steven Stack?

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

Here.

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

Hi, here, Robert Jarrin here.

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

Hi to you both. 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

Hello and Terry Fairbanks? And from ONC do we have Ellen Makar?

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

I'm here.

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

Hi, Ellen. Okay.

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

Hi, Bennett Lauber is here, my phone battery died and I dialed back in.

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

Thanks, Bennett. I will turn it over to David who will get us started.

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

Great, well thank you all the goals of today are simple and they're basically to go through the recommendations of the two groups about the Certification NPRM comments and we're going to start with Group one.

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

Well, thank you, do you want me to jump in?

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

Yes, please, over to you Steve.

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

Thank you, so this is Steve Stack and thank you to my colleagues who joined me on this Workgroup and I'll jump in here. I'll just go through this one after another. So, we were asked to comment on "in the field surveillance and maintenance of EHR certification" and so we have the collective comments of the group here.

I think I would say overall we had pretty good consensus across all these comments so I think what was included here generally was agreed upon. There was not much in the way of disagreement. We do believe that new types of surveillance and in the field ways of assessing EHRs in actual deployed settings is important and we therefore have suggested that we be supportive for this concept as proposed in the NPRM.

We do raise some challenges because it will require some precision in defining how that certification works. There are major updates or version changes over time and at some level of substance those things would need to be almost looked at as a new version and probably require some kind of ongoing surveillance.

On the other hand there are all sorts of routine patches, updates, bug fixes and the like which obviously if we were to require surveillance through those kinds of changes it would be utterly undoable. So, we identified the need for some clarity for under what circumstances such surveillance needs to occur and at what level of transition or change.

We also raised the issue and the challenge about using a different example here Microsoft Windows obviously produces or Microsoft produces numerous or one version of Windows but it is deployed in innumerable different environments and one could effectively argue, I would say, that a deployment in one hospital is not the same product as a deployment in a different hospital, which would mean that if you use the unit of measure each discrete implementation you have, again, probably an insufferably unobtainable burden for the vendor community to ever hope to participate in and yet there are clearly wide variances in the success or lack thereof for how the same product is performing in different settings.

So, there is the suggestion here I believe that there is an additional need for clarity in the NPRM how that would intend to be addressed and at what level they would set that.

So, we have also suggested here...there is so much complexity in here, so forgive me it's hard to determine how to distill it. But so those were the two things I'll highlight and we do talk about the difference versus having an audit versus self-reporting of issues and challenges, and that's a third part I would identify in here. I should have asked, is David, are you chairing this overall call or is it Larry?

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

I am.

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

Okay, do you want me to go through all of them at once and then leave it for you to run the individual comment or go one item at a time?

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

Let's go one at a time I think it's just complicated enough that this will be easier.

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

Okay, so, I guess I'll leave it as that's what I've intended or what I chose to highlight and of course there's a whole page of text there with more details.

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

So, comments or questions for Steve?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

So, this is Mickey, just a couple maybe questions. So, I totally understand where this is coming from and I understand it. My questions come about the actual implementation of it. So, we have, you know, a complex process today where vendors go through a ton of work to prepare for certification and the certifiers go through a complex process that, you know, in some cases can take days and there is very high-level of expertise.

So, I'm trying to think through what this would look like as actually implemented. So, if ONC is doing the surveillance or, well I guess it's the certifiers, but the level of expertise that is required to do it and the assumption about the availability of the vendors and the providers to participate in it.

I have a concern reminiscent of the Meaningful Use audits and I know that some of you probably went through them as providers but there was, in some cases, almost a whole other set of requirements that was looked at when the auditors came to the sites and a whole new set of requirements that came onto the vendors.

So, I know in the case of my company we had to pull tons of resources off development to respond to the audits because there were questions, clarifications, in some cases new development that needed to be done. So, when I read what's being asked for here it reminds me of that, which I would say I'm not sure I would agree was a good thing, because there was not clear...there was a not a one-to-one correspondence between what was being audited versus what was being certified.

So, I think we just need to either question or request clarification about the assumptions about what would be expected from all the parties involved and their level of expertise and what that really looks like as its being implemented.

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

Mickey, if I may, I don't think, based on...and my group members can correct me if I'm incorrect, I don't think any of us would have any disagreement with adding the need for that clarity.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Okay.

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

I think...

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah...

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

And if others disagree please speak up. I would say though that I think that the group overall felt fairly confident in the need for something like this because, now I'll personalize and give my example, I have a large well-known vendor who provides our EHR it is kicking people out regularly and causing all sorts of problems and all sorts of glitches, but whether that is the fault of the vendor, the platform that it rides upon, the server farms, you know, all the...I don't know where the problem is and honestly I think that the physicians say "we really don't care, we've been compelled to use this and it's dangerous and we need it fixed."

But that doesn't mean I think that any of us want to unfairly create a construct that is, you know, chaos and uncertainty which I think you just reasonably described. So, I think we would accept very constructively what you just offered.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, Steve, and I...like I tried to say...I totally get it, I get where the feeling about this is coming from. The implementation of it is not clear to me you know what I mean?

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

I get it.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

So...and the idea of having it through the ACBs is a little...well through the regulatory process is a little uncomfortable to me because I think it's not...like let's just say, as I read through some of the comments, there are no standards yet, I'll call it standards loosely, as to what constitutes a good implementation.

I feel like we're at the best practice stage versus the standards stage. So, how do you evaluate what's good, what's bad, what the bar is. So, you know, and then just the scenario you just described that's real I get how important it is, that's a project, right? Getting someone in there, figuring out all the causes of that and I agree it's not clear who should bear the burden of all that, but is this the solution to that problem I'm not sure.

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

So, Mickey, what we're proposing here is a more rigorous and protocol-driven complaint process would you have problems with that?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Well, I guess I have a little problem with the way we're saying "complaint process" just like what Steven said he has...in his site he has a real and serious problem, right? So, it's an analysis, right? It's a "what is the problem?" It could be 100 things that are causing it. I agree that it needs to be solved and the right smart people need to get involved there and figure it out. Personally, I'm not sure I see this process as solving that problem.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul, I just wanted to chime in on this discussion and simply say, I hear what you're saying Steve about the problems you have, but I don't necessarily understand how certification is either the source of that problem or this sort of, you know, audit could help solve the problem. I mean, that's hard to know and I kind of wonder if part of the issue here is there's an unrealistic expectation about what certification does and what it means. I mean, certification doesn't mean that necessarily these computer systems are systems that providers are going to like.

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

Well, I think it's a...

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

Yet...

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

Oh, I'm sorry, there was someone else who wanted to speak there I don't want to talk over them, who is it?

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

Yeah, this is Mike Lardieri, I'm wondering if it needs to be more than just a complaint process but a complaint and documentation of the resolution, because a complaint is one thing once you delve into it you may identify that it's the servers, it has nothing to do with the program like in your description there.

So, then on the documentation side you might just document this was the problem, it was resolved at this level and then organizations, other folks who are reviewing this stuff would at least know that it was or wasn't the EHR, whether it was these other configuration issues or it might have been an implementation issue, but I think to document that would be very helpful for folks. I don't think it can just be a complaint process I think they have to do the follow-up.

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

So, this is Steve, if I can...so this is so dense to go through...the only item I was presenting right now was a standardized or pseudo-standardized structured way to do planned regular surveillance which is the number one in this bigger document, that the complaint issue is number five down below, which is two issues down later, which I think we do acknowledge or at least we acknowledged it verbally, I have to re-read this and see if we got it in the text, Mickey's concern that, you know, they can take complaints of all sorts and varieties but it needs to focus on the certification because otherwise you have a test and you are holding people accountable for something off the test. So, there is an identification of that tension.

And Paul to the concern that you raised, it is an interesting discussion about how all these pieces interact but if we look at certification as the tool that is supposed to ensure that a certified electronic health record can perform the tasks required for a Meaningful User to successfully demonstrate Meaningful Use and if the Meaningful User, the aspirational Meaningful User, is using a certified EHR and finding that they are not able to successfully perform Meaningful Use then certification has not...could perhaps be one reason why that it was not sufficiently appropriate to make sure that the product was going to work properly when they deployed it.

And so, I think the whole paradigm we could assert, and I'll only make this comment once on this call today, is that we've had a bar of expectations set beyond where the technology currently resides and the principle party that is subject to that misery is the eligible hospital or eligible provider because we've set a bar higher than what the technology currently provides.

We didn't write this Reg, as you all know, ONC did and they proposed this language so we were just reacting to it as a Workgroup I think saying that having in the field surveillance of some sort done in a fair and reasonable way so as not to unfairly injure EHR vendors or unfairly hold them accountable for things they were never asked to do we get that and I think that Mickey there's no discomfort including that sentiment in here about being reasonable and transparent, and fair but having some kind of in the field surveillance to see how these tools are actually performing in the real environment not a certifying lab which is a sterile and controlled environment would add additional input and insight into the overall process we have here with Meaningful Use EHR adoption and use.

Does my Workgroup...David you were on the Workgroup, have I represented fairly as far as you're concerned what the Workgroup has commented on this?

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

I think...

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

This is Alisa; could I add some comment Steve? Alisa Ray, could I comment?

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

Oh, yes, by all means, yeah.

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

Thank you and I want to build on something that Paul stated and also Mickey. You know I think we kind of go back to what are they trying to do with this and clearly everyone supports that ONC and CMS need more information and I would warrant they're trying to understand if the criteria are the right criteria, right, that's part of it. If they're being tested correctly but there are other ways to do that. And then also to get input from the providers, as you stated, is the technology doing what they it to do.

And I just am now sure this is the most efficient way of getting that information that important information. Going out in the field doing extra testing, there are a lot of resources involved in this, someone is going to have to pay for it, you know, certification bodies can do lots of repeat testing, you know, is the incremental value, is it really getting, you know, more for all dollars spent, are the providers going to pay for it, are the vendors going to pay for it, and again, you know, is that the most efficient way to get the information folks need and that could include information on complaints, this all could be rolled into a much more, I think, efficient data collection process that didn't involve significantly really expanding the scope of what the certifying bodies are supposed to do. I mean, the Regs are written that their scope is to, you know, check out the products in the lab.

Now part of the accreditations that delegated authority to ANSI and NIST, and the lab there are surveillance mechanisms in there so, you know, if ONC wants to, you know, protocolize that or make that happen in a different way that authority is already there. Do we really want to make a regulation or a law that, you know, burdens with more detail on that?

So, I just think...I support the notion but I think we're really not being crystal clear on why we're doing it, the information we're trying to gather and I also question the efficiency of how we're approaching it. So, thanks for letting me have the floor there.

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

Thank you. Let me, if I can do this, because I know we have a hard stop to move onto the next group at the top of the hour. If we look at number five, maybe the staff can pop that one up there, there is the complaint reporting process here, it might make more sense to logically go to that real quickly, where the rule proposes that there be a list of complaints received on a quarterly basis and that those be posted publically and be available and I think that the Workgroup was generally supportive of that. That is different and it's actually separated by over 30 pages I think or about 30 pages from the topic we were just discussing in the proposed rule.

So, do people have more comfort with this? Now we raised concerns here that it has to be carefully thought out where there is well-defined objectives and clearly documented methodology and I think everyone, Alisa and Mickey, I think you would agree with that it should be well thought out and clear, and it should be fair and transparent not sneaky and confusing.

But we were generally supportive that there should be a way to have complaints received and publically shared and reported and that some kind of trend analysis could be done on that to see where problems are arising we hadn't anticipated or failing to address. Would the group be generally supportive of the feedback we offered here in the complaints reporting area?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

So, this is Mickey and I'm sorry I only got about half way through this so I haven't read this section yet. So, yeah, so what are we publishing the resolution or the complaint? Meaning...

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

I'll make a comment. Mickey when you're done I'll make a comment after you okay?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, I mean, so, you know, let's just think back to the last...Steve I know you were listening and involved with that, of the hearing we had with...about the certification program probably 18 months ago, there were many, many recommendations made there some of which have been implemented some of which are not, but I think if anything was pointed out it's the complexity of the program, the complexity of the implementation and there is, you know, one problem manifest itself in a lot of ways and, you know...I guess one...I would say can we focus the amount of time we would put on the reporting on solving the problems we've already identified as a group with the program, with the reporting, with the transparency, you know, there's a 100 things, there's vendor issues, there's regulator issues, there are provider issues and we really haven't spent any time on that and now we're saying, okay, let's just document the problems that I think we already know exist.

So, I guess I'm more...I'd love to see us spend more time focusing on the solution, which is really outside of this report, you know, responding to this Reg. So, that's my concern, I think the issues have been...many issues have been surfaced, some have been addressed, many more need to be addressed. And I think the complaint process will continue to point some of them out.

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

Okay, Alisa was that you who wanted to jump in?

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

Yeah, I wanted to comment and I think again, it's really important to get more information to understand from providers what's working for them and what's not and I think, you know, we're talking about an efficient information gathering approach to that and so understanding your complaints is one thing and it's probably, you know, fine to ask the ATLS, ACBs to be the point on that and again, in fact the ISO and ANSI rules require that they...each of them that they have a mechanism to log and capture complaints and their status.

So, again, that's already there but again, sort of are they all doing it in a different way, have there been requests for reporting or analysis, I mean, I think we're just overdoing this, I think there is probably a very simple way that ONC could provide some leadership to the multiple organizations that are doing this on capturing that information.

And I will share with you anecdotally as someone who used to run an ATL/ACB but does not anymore so I really don't have a, you know, personal interest in this other than I just have experience or knowledge to offer, my organization tracked complaints but we had a database, we had a set of categories that we marked them into but by far the biggest number of complaints were related to customer service or things that were not within the realm of authority at the certifying body, you know, or they didn't call me, the vendor didn't call me back when I asked them to or the vendor...we asked them to make this fix and I need it next week and they said they'd do it next quarter, well that's interesting information and I think, you know, ONC should hear about things like that, but that's not necessarily something that you could decertify or it's within the scope of the certifier to do anything about.

So, again, let's, you know, let's find an interesting way, let's manage and coordinate the resources we have kind of think about...be thoughtful up front about the kind of reports we'd like to see then that should be a pretty easy process for the ATLS/ACBs to get that to ONC and share that publically, put some transparency on it that's fine, let's learn from it, but let's not...

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

This is...

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

I mean, do we really need to make a regulation out of some of these simple operational types of maneuvers.

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

This is Ellen, I just wanted to jump in for a second because I think what's happening a little bit is folks are...these are broken out into individual answers and I think some of them do influence each other but if you look at them one at a time for example the complaint process and the decertification process are two separate questions. So, I think maybe Steve if you look through or maybe even just read out the answer folks can say whether or not they can support it or if they want additional bullets added.

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

Well, you should also understand what is currently there in the regulations and the accreditations, and are we duplicating it in a regulation...something that already exists. So, I think that's important.

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

I got it. And Ellen I was struggling with this because we don't have for all of these like a final recommendation just as a summary at the bottom, but...

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

Well the summary is generally at the top where you're supportive of the idea but then the group had put caveats on that.

Paul Eggerman – Businessman/Software Entrepreneur

Yeah.

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

Oh, I'm sorry, I'm sorry, okay.

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

This is Mike...

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

Well, so let me ask this, because I think we can...some of these, once we get through this initial step some of these other ones hopefully will follow more quickly. So, who was...someone said "hi" in the background I don't want to step on someone's...

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

Yeah this is...

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

Thoughts.

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

No that's okay, this is Mike Lardieri, I was going to say are these reports going to be aggregate or are they going to be by vendor? I just guess I'm...because of the complexity of when a problem is a problem if it rises up in, you know, the vendor's name is attached to it, I guess I feel less comfortable with that until it gets resolved as opposed to having aggregate reports and not necessarily naming the vendor I think that's helpful because then providers can say "oh, yeah, I'm having that and I'm having that" you may have different vendors having the same problem but that then helps the vendor community focus on the problem as opposed to naming the vendor and it might not be the vendor's fault as everybody has identified before.

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

Right.

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

So, I think that might be something we look at. I think the transparency is important even though, you know, Alisa says that's out there now, but is it required for it to be transparent, does everybody get to see it, maybe it just needs to be more visible than it is now.

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

I think that's...I think the data are there it should just be sort of figured out how to aggregate it and display it, yeah.

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

All right, so Ellen, I see what you're trying to...because where I had the confusion the blue language though is the "we" there is ONC it's what ONC is proposing in the Reg. All of our comments from this Workgroup are in the white text beneath. So, I guess if I can, because I've heard similar concerns raised both on the in the field part and on the reporting which is can we come up with a rational way to do it first of all.

Two, if we come up with a rational way will it actually be doable or will the burden of work be excessive.

And three is, if we can even come up with a rational way to do it, and even if we could design it in a way that we could do the work, is doing this work actually of value or is it misapplied effort that would be better delivered some other way.

Mickey and Alisa did I capture some of what you two were saying?

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

I like how you summarized that.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, I think that was well said.

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

Okay, hopefully ONC recorded that because I couldn't do it again. So, that would...does the rest of the group feel that we are supportive of the concepts I think of getting better understanding of how the tools are actually being used in the real deployed environment and both of these, in the field surveillance and complaint process, would aspire to find out better what is really happening in the real world and use that information or at least make it available to people who might use it to improve the deployment of these tools. So, that I would say is the overarching purpose for these two items.

Then the question is, can we do it rationally, can we do it reasonably and sustainably, and then is it the right thing to do in the first place? So, do people...and then we have specific comments here for if ONC decided to go down this path where we have said there is a need for more clarity for more precision to scope it into what would be at least a reasonable and discrete way to do it so we were responding to what ONC's proposed language was raising as a Workgroup concerns or thoughts for what would need to be addressed.

So, for others who...not to exclude anyone but Mickey, Alisa and me we've heard from all of us, is there anyone else who has any other general concerns or would you feel it is okay for the group to at least make the high-level comments that I just summarized for what we understand to be the desire we're trying to achieve but the three major problems that need to be better addressed.

And then I think there is good language in here from this little, whatever we call it Task Force/Workgroup, that we had that give more discrete examples that ONC could pull out or, you know, that Ellen and others could pull out if we're going to have a comment letter that gets submitted to give some examples. Does that sound like a reasonable approach for these two items and are there any other perspectives that are not incorporated by that that we should hear?

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

This is Michelle Dougherty and our Workgroup Three also had something similar that was in one of the sections that we were assigned to and as your group noted that your Workgroup members were generally supportive our Workgroup members were as well. I know we had some important input that was, you know, slightly different than that.

We did two things that came up, we recognized that some of the sharing, some of the blocking that may occur may not be at the certified product level it could be a decision made by providers so I think it's important to have some of those nuances be addressed that there is still that more development as well as perhaps, I think what you last said, the discrete examples, you know, it reminds me of some type of like a health information exchange bill of rights sort of thing like...that are the practices that we know today, you know, are just not something that's appropriate and I think that is maybe consistent with the leadership you've mentioned from ONC on the types of practices that are contrary to sharing and, you know, slowly being able to exchange information.

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

Thank you.

Paul Egerman – Businessman/Software Entrepreneur

Yeah and this is Paul I have just one comment. My comment is we don't necessarily have to have like complete consensus on everything sometimes if there is some levels of disagreement just expressing that, you know, most people thought one way but there were a couple of people who thought something different and here is why that's useful information for ONC also to hear. I mean, again, we don't have to necessarily come up with one single unified recommendation. If there is some level of disagreement simply explaining that is useful data for ONC.

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

I wouldn't disagree with that at all Paul I think that's reasonable although to the extent we can give clarity it's probably more useful because they're going to get disagreement from all sorts...

Paul Egerman – Businessman/Software Entrepreneur

I agree.

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

Everyone who submits stuff.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey just one comment that wasn't covered just food for thought, so, you know, this ONC asking for feedback. I think we've kind of said, from your summary Steve, that, you know, we're in the information gathering phase here in a lot of these areas, you know, learning more, understanding what are the best practices and we're being asked by a regulator about how to do that. So, is ONC, as a regulator, the right organization to be looking at this and maybe is there a more important more research oriented body that would be more appropriate.

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

Okay, thank you Mickey. Let me do this because I'm going to give David his meeting back here at 1:00 o'clock so we can get onto the next Workgroup. So, let me do this and I'm going to wrap this up at the end so give me five minutes.

I'm going to jump us real quick to the decertification Health IT part and I'm going to ask people our high-level input here was that, while we understand that people see this as a lever to get, you know, vendors or whoever to do the right thing and make sure that stuff is working properly, if you decertify an EHR and they have a big...I don't care if it's an install base of one or an install base of 40% of the market, you have decertified the vendor and obviously caused problems for them but you now have an EP or an EH who is using a tool that they bought that was certified at the time of purchase and who now finds themselves, at whatever point in time they are, using a non-certified product which therefore by definition means they cannot comply with Meaningful Use and are therefore subject to penalties and cannot succeed.

So, we have I think identified concerns here that while we know congress has opined that this should be the ways it's done or more emphasis on decertification and that ONC is probably reacting to that in part that we have significant concerns that while there are...that are one, already ways to decertify products for failing to perform to the certification specs and that those are probably sufficient and that two, adding enhanced emphasis to decertifying people probably will not necessarily advance the cause and could quite possibly cause significant harm to people who in good faith bought these tools that were certified at the time of purchase and tried to use them.

So, we have language there but I think we would say we would raise concern about an undo emphasis on this particular approach to addressing the concerns that people have raised about EHRs. Does anyone feel strongly to the contrary for that?

Paul Egerman – Businessman/Software Entrepreneur

Yeah, this is Paul, I agree with what is said here but I have like a different observation about it because as I read the text it talks about decertifying products that proactively block the sharing of information and this is actually a concept that was, I believe, in the SGR that was recently passed that basically says that...requires information sharing and the problem with that is that you may have one of these Apps that ONC includes certification criteria for it and you may have a vendor who is using that App inappropriately, so creating a load on the computer system or I sent out some examples to a few people, there is a situation where a vendor accidentally through their App sent false information into an EHR. So there are reasons why you might want to reasonably block information coming in and give that capability.

So to single that out as a reason for decertification is flawed unless there is some, you know, exception that clearly states that, you know, organizations can block information sharing for reasons relating to like, you know, security and privacy, and also the expense sometimes of doing that of exchanging information.

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

All right, any other inputs?

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

Yeah, our group was Group Three and we spoke about that this morning actually along the area of sensitive data. So, you may not...you have to be careful if it's blocking just to block sharing anything or it's blocking to sharing sensitive data because there is a reason to do that and I think maybe the emphasis has to be about blocking or not sharing information going out, I mean, blocking things coming in because they're going to harm your system that's one thing but I think the emphasis is on sharing out with other providers as long as it's not sensitive information then I think we want to encourage sharing and have some kind of lever, I'm not against decertifying vendors if they were purposely setting up their system so they don't share information going out.

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

This is Ellen, I would just say look at the last two bullets and see if those are supportive...

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

Right.

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

Of what you're saying.

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

Unfortunately, I'm just on the phone so I can't see them.

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

All right I'll read them, so the second to last bullet is the group strongly believes that the decertification process would need to be very well thought out in terms of violations, process, review, appeal notification and a myriad of other possible effects many of which could be more harmful in the big picture such as patients unable to retrieve data, specialists unable to share records, etcetera.

The next bullet is, there is no generally accepted definition of data blocking what objective information would be used to objectively determine an entity is blocking information.

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

Yeah, I'm actually good with both of those because that makes them do something about it and clarify it, so I'm okay with that.

Paul Egerman – Businessman/Software Entrepreneur

Yeah and my comment there is I would either add a new bullet or add to that last bullet a clarification as there may be reasonable...a provider or a vendor could have a good reason to block data going to some source. If they know a source is selling the data or involved in privacy or security violations, or is harming their system by, you know, repeatedly polling and creating a load on the system. Those are all reasonable justifications for blocking and so...

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

So, that could be stated in the positive just that there is a need to identify and permit appropriate blocking of data to protect patient privacy or something like that.

Paul Egerman – Businessman/Software Entrepreneur

Prevent privacy and security...

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

And operational load or effectiveness or something. Somebody can figure out a way to wordsmith that, but, yeah, if you added that sentence I'd be okay with it.

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

And then the top bullet which is what I said earlier was concern for end users who are using a vendor's system only to find that they are not able to comply with the CMS EHR Incentive Program because their EHR becomes newly decertified.

So, I would say the first bullet and the bottom two with the addition of what Paul said which is an acknowledgment that in fact there are appropriate reasons to do some sort of data blocking probably capture the essence of our feedback on this. Would folks agree with that?

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

This is Michelle Dougherty, not commenting to disagree, but just point out that...and this is I think part and parcel to our section, that with the expansion to Health IT certification and the moving away from the EHR Incentive Program the section we read also identify where rules, separate from the Meaningful Use Program are starting to point to the certification process.

So, I guess my only comment is not to limit itself to the CMS EHR Incentive Program because decertification could have effects on other regulations and programs, and grants as well.

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

Okay and I think we can...

Paul Egerman – Businessman/Software Entrepreneur

So this is really about decertifying products as opposed to eliminating certification criteria altogether.

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

Yeah, no and I didn't...well there is other regulations or other programs that require the use of a certified, let's say a certified technology or EHR, or a certified module in a certain way, you know, pointing to this program that is not coming from the EHR Meaningful Use Program. I will...when we debrief on May 1st we'll highlight some of that as well.

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

Okay. I would just tell you all and I've been doing these for years, these are never easy trying to lead to some clear conclusion at the end of these discussions. So...I'm going to look forward to our next leader for the Workgroup Three and the brilliance with which they're going to do a much better job than I've been able. So, let me bounce this up real quick here. I was trying to get some of the ones we might have more agreement on.

Number two the transparency and disclosure agreements, so ONC proposes to revise the principles of proper conduct to provide greater and more effective disclosure by Health IT developers of certain types of limitations and additional types of costs, I'll bridge it at that.

The Workgroup in reviewing the language proposed in the NPRM the Workgroup was generally supportive that there was a need for further clarification and that we support the general notion that there should be more transparency in the costs associated with their EHR implementations including perhaps, to the extent that it's possible to be provided, HIE fees and that this should be provided to the customer. And so we were generally supportive of this. There is additional language there that identified other facets of that but we were supportive of that.

So, I guess what I would ask is for those who may not be supportive in general of this do you have input you'd like to offer?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, I guess my question on this is, isn't this the role of the relationship between a provider and a vendor? If you're a provider you should be able to say to your vendor, you know, tell me all the fees and that would be provided as part of your, you know, contract and agreement.

I think without context this is another example where it just...the information could be taken out of context, but I think it's perfectly reasonable and expected that this would be information that would be available between a provider and a vendor as part of their relationship.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, I mean, this is Paul, I certainly agree it's perfectly reasonable and maybe this is what was just said, I just don't understand why it's part of an NPRM.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Right that's...

Paul Egerman – Businessman/Software Entrepreneur

I mean, this is like...this is a best practice but what does this have to do with the certification program?

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

Or how does a certifying body...what criteria do they assess this against?

Paul Egerman – Businessman/Software Entrepreneur

Yeah.

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

This is Mike, I don't...

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

Is it in their authority to do it?

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

Yeah I kind of...from a group of providers who probably have no technology expertise and if I'm going to...the way I was viewing this is this is something that needs to be on the CHPL and be very clear and transparent there.

So, if I'm looking for a vendor I may not have a consultant, I'm trying to do it myself and I go to the CHPL and I just...if you're viewing it...I was viewing it that way so that on the CHPL it needs to be very transparent so that I make a better choice up front.

And then I agree with, you know, once you get in negotiations with the vendor it's something that's the relationship between the vendor and the provider, but I think it needs to be very transparent at the CHPL level.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

So, just a clarifying question, are providers using the CHPL as a tool to select vendors?

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

I send people there it's a first...that's your first cut to try to get to this of what they're certified for, which clinical measures they're certified for those type of things because if you're using different measures than that's not your vendor, you use a vendor who is going to do your measures not something else. And also if it's...like ePrescribing it might be incorporated into the product or you might have to buy a separate product so what do you want to do have two products or do you want to have one it helps you make that first cut.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul, I just think you're expanding...we're expanding what certification is all about. Certification in my opinion should simply be about did the product pass a clearly described test, it should be very objective and when you put things like...when you put pricing policies in the CHPL to hope that people read it the vendor is simply going to write that in such a very general way that it's not necessarily going to be useful to anybody, because they're going to say "well, you know, this is our normal price and we charge per hour and these are the circumstances by which the charges could be impacted" and, you know, by the time you're done reading the paragraph it doesn't necessarily tell you anything and furthermore there is no teeth to that, in other words if somehow somebody prices something differently than what they wrote in the CHPL ONC has no power whatsoever to do anything about it. I mean, even the certifying bodies don't have any power to do...

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

That's right.

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

So, I have a question for the group here, because like I said I'm committed to wrapping this up in less than 9 minutes here now. So, we're not going to get through every one of these items and the general...so those of us who participated in this Workgroup I think we had a very nice discussion, we went through all this and the comments we have here, we didn't try to corral everybody and say you can or can't say this or that. We actually...everyone spoke and we added it and we captured it here and I think people generally all had agreement with the text we put in the white.

So, the benefit of this bigger group now is offering I would say a disconfirming set of perspectives or perhaps looked at the assignment a little bit differently which I think is good in saying, well is certification really even the right vehicle to address a number of these things and just because it's in the rule will it really address the problems that need to be addressed and it is appropriate to do it in this venue?

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

Yeah or is it the best way.

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

And I wouldn't dispute that, but I would...and I didn't offer those thoughts when we ran the smaller Workgroup to prep for this document we created, but I would say then I think that the NPRM is a response to the ongoing sustained frustration with an end-user community who feels they have been compelled to adopt these tools and a human end-user community who is absolutely irate with the current state of affairs and is being economically disadvantaged with penalties, you know, over half of doctors in the country are getting a penalty this year because of this program for these tools that are not working.

And so if not this program, if certification doesn't have a role to play in trying to make more publically and prominently overt the real challenges of execution in this current approach and begin to bring through that transparency and information more attention to where the true needs are for focus and effort to make it work better, because we all on this call I'm sure agree we've got to do this, we've got to do it and do it well, then where?

So, not certification then where and that's a bigger...I'm not asking for comments on the "where" because we'll go off on a tangent that we won't be able to stop, but if our feedback from this group if we are able to reach enough agreement to provide input from this Implementation, Usability, Safety Group into this NPRM process I think we've identified the high-level thing we're not really certain if certification is the right approach to address at least these three items we've talked through so far, but it's not clear to me than what levers ONC has to address some of these problems at least since it has attempted to address some of the problems through this rule.

Paul Egerman – Businessman/Software Entrepreneur

Yeah and Steve this is Paul, I'd just say in answering that question I think you put your finger on what is the real challenge here which is ONC really only has one public policy lever which is certification that's all that's left and so they're trying to use it to address a whole series of different problems but certification is not necessarily the best or even a good way to address the problem but it's the only tool that they've got and that's the fundamental challenge that we've got.

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

So, I'm going to ask this one last question and then look to Ellen and David for what you want next. My thought here is that this was a good discussion I actually think it was helpful, I think it externalized some additional challenges and some very high-level fundamental ones that address the overall rule itself.

But as far as trying to bring it to closure in this 55 minute block that we have not achieved and so do you want, David and/or Ellen, do you want to ask the larger group to take this document and not rewrite the whole thing and edit it but just offer if you have high-level points where they either agree or disagree to send that back into you and then we look and see how divergent or convergent it is and if we can encapsulate that or do you propose a different way to bring this particular part of it to closure?

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

Sure, so I think it would be useful for...if people have specific suggestions about how things should be said differently they should send those in, I mean, we do want what we present to be the reflection of the whole Workgroup and not just of the thoughts of the subgroup.

I mean, I also have been taking notes as we go along here and I'll express that there is a lot of diversity of opinion in the group amongst how for example certification should be used period. And so that's how I'd suggest proceeding so if you have specific thoughts please send those, you know, I'm making an effort to capture, you know, really the diversity opinion as Paul laid out before and I'll...when we present this I'll say, you know, look here's some things that we agreed about, here's some things about which some part of the group felt one thing and others felt something else.

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

This is Ellen, I would just ask that if folks do that they use Track Changes it will make it so much easier for me.

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

Very good so I'll just wrap...put a bow on the end of my part of this than and say, folks please take the document, use Track Changes send them directly to Ellen and she can then aggregate the stuff and get it to David and Larry who can then decide how they make use of it when they actually present out to the HIT Policy Committee.

I've enjoyed the discussion I'm sorry we didn't get to closure I just don't think it was going to be obtainable in this thing right now. And we'll just observe that I think that the fact that we've had a group of very reasonable people with differing opinions had another nice discussion which I've enjoyed on these calls. I think it does though demonstrate the challenge that we've created a very tangled web and it is very difficult now when we can even all agree on the challenges and the need to address things to even find within that tangled web where we need to go and address it because I didn't hear disagreement from vendors or consultants, or from, you know, me as a physician or the others.

I didn't hear much disagreement that there are challenges and the general nature of the challenges, and the need to address them, it's just that there is no clear path, certainly not through clear consensus, even among reasonable people how we address or get that better. I think we all agree that there is a need to get it better though. So, thank you very much everyone for participating and I'm going to hand things back over to you David and let you finish this up.

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

Great, so at this point let's just go over to Janey if that's okay. Janey are you on?

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

Yeah, I'm not sure that Janey is on, this is Bennett Lauber. Oh, am I on mute?

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

Yeah, I believe Bennett that Janey had told us that she had a conflict and that you guys had agreed that you'd present.

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

Yeah.

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

Okay that’s great, so Bennett over to you.

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

Okay, well first off I want to say that we reached the same consensus that you guys did that we reached a high-level consensus yet we had some minor levels of disagreement as you got down into the nitty-gritty of the substance of the proposed regulation and we all agree that the goals of the project and the program are all in the right direction just like the gentleman just mentioned but then when the rubber hits the road there were a couple areas where we didn’t necessarily reach a 100% consensus.

The area that we covered, I think it would be best...I’m going to just go really quickly over the areas that we covered and give a brief summary of my feeling of the general consensus and then go back in detail and cover some of the specific items, but the main part was the safety-enhanced design portion that’s the part where there was the most amount of questions and the most amount of potential non-consensus, but in general, like I said just before, that we all agreed at the high-level goals that everything was in the right direction.

The next area is the request for comment on the summative testing, in general we had a consensus that having a summative test is something that is required at the end regardless of the amount of formative testing that you have done and we used the analogy to that of like you’re taking the SAT, you know, it’s the actual test that counts not the number of practice tests that you took in order to take that test.

Regarding retesting and certification, we did not come to a consensus there as there needs to be a little bit more clarification regarding the retesting just because there is a certain dot release doesn’t necessarily mean that the entire system needs to be re-tested, however, we did reach an agreement that if there is a functional change to the user interaction associated with a particular feature or function than that feature or function should probably be re-tested and we can go into some specifics on that when we get into the depth portion.

Regarding accessibility and accessibility centered design, we were all really big fans of incorporating accessibility components into the proposed regulation but we were concerned about the ability to enforce that and which accessibility standard would we want to address or to require let’s say Section 508 or a bunch of other standards and when does the accessibility standard apply and when does it not apply?

And some of the examples we talk about there were of the aging physician who has visual problems and, you know, is trying to use an EHR that they are not very happy with, you know, so you want to make sure that you don’t disable the ability to integrate the system with screen readers or with magnifiers or all those sort of things.

So, that’s a high-level summary of the items that we covered and thanks for flipping along with that on the page, but the big whammy of our discussion was the safety-enhanced design portion starting on page 191, 105, I mean, 315(g) Section 3.

And so in general, like I said at the beginning, the consensus was that we are all for some of the regulations that are there and there are several areas where we are sort of seeking additional clarification and last week at HIMSS I was able to have some conversations with some of our previous clients and they also have some areas that I would actually like to seek some guidance and see whether that can be added into the proposed rule.

But most of the consensus, most of the issues associated with Section 315(g)(3) had to do with the participants and the number of participants and whether it's required to have 15 participants of each overall user group or is it 15 participants overall.

And one of the questions from one of my vendor clients was, you know, do all of those participants have to be current users of the system or, you know, can that be people that are not currently users of the system. So, that's one thing that I wanted to get out there. Does anyone have any comments on that so far?

Paul Egerman – Businessman/Software Entrepreneur

Yes, this is Paul I have a few comments but when you say, do we have any comments did you want comments about something specifically or just everything you said?

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

Just something specifically I don't want to have to talk for an hour. I want to be able to encourage the conversation, I want to try to accurately represent the conversations that we had the week before and then sort of open it up to comments and have everyone, you know, be able to get their feedback in. So, if you have a specific comment like around the safety-enhanced design portion that would be great and then we'll move onto the summative testing and re-testing, and accessibility.

Oh, and then I forgot to mention the quality management system portion and, you know, we had some presentations as part of this Workgroup on that and we are all, you know, really positive towards having a quality management system but we're also concerned about the ability to regulate or specify, you know, which quality management system is going to be required.

Paul Egerman – Businessman/Software Entrepreneur

So, my comment about the 15 people is to simply say first that that's an arbitrary number but it's also possibly a number that's unfair to small vendors. I mean, maybe you're a vendor and you only have five customers and it seems like then you can't get certified, you know, you can't meet this regulation.

The second comment I have is the identification of the participants is inconsistent with some of the modern approaches to testing where in some sense it's the specialty care running any kind of an ASP kind of environment you can do sort of a cloud testing approach where you tell your customers this is available for testing and comment, and you get a lot of tests and comments but you don't necessarily know like the age or the job title of the participant and so that troubles me.

And then the third thing that troubles me is the same comment I made in the previous group is there is nothing wrong with safety-enhanced design but my question is why is that certification criteria as opposed to some other vehicle. It seems to me that there's a lot of problems and risks with including that as certification and, you know, as opposed to like a best practice or some other approach.

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

Okay I understand. One of the comments that I would like to say on your comment is regarding the best practices the issue is that maybe a lot of the vendors, particularly some of the smaller vendors that you mentioned may not necessarily follow the best practices and still attempt to be certified and I like to always use the analogy of vehicles on the road and, you know, in order to sell a car in the United States you have to meet certain safety requirements otherwise, you know, you won't get the license or whatever the regulations are to be able to sell a car and be able to drive it on United States roads.

And so similarly, an electronic health record system needs to be able to meet the certain requirements for safety in order to be able to use it and...

Paul Egerman – Businessman/Software Entrepreneur

But in that response what you're basically saying is small vendors need not apply, in other words this is an approach that really locks in a small number of large vendors, small vendors, you know, if you don't have...

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

Yeah, I...

Paul Egerman – Businessman/Software Entrepreneur

If you have 15 customers and you can't put forward all of this stuff then, you know, you can't be certified and if you can't be certified you'll never get to 15 customers anyway.

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

Right I understand your concern and I agree with you that it does put a large burden onto some of the small vendors. It doesn't necessarily have to be 15 customers that's the question that some of the vendors that I spoke to were interested in. I think it's just 15 participants and they don't necessarily have to be existing customers.

We did a study a while back that used exclusively existing users of a system that had less than optimal user experience but because those existing customers had been using the system for a couple of years, you know, it passed with flying colors and, you know, does that mean that it's a usable system, no not necessarily.

Paul Egerman – Businessman/Software Entrepreneur

I just would point out though that the product a vendor might be selling is not necessarily a complete EHR system it could be a module and it could be there is only one or two users at a healthcare organization that actually uses the system. It could be that the system is sold to solo practitioners. There is...it's not necessarily the case that you can get 15 testers if you're a small company.

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

So, this is David Bates...

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

Yeah, I would agree.

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

The way around this is just not to require that they be customers. I mean, there are some scientific reasons to use 15 people.

Paul Egerman – Businessman/Software Entrepreneur

Well, maybe David, but if you say they’re not customers you also create a huge loophole in this thing. So, now a small vendor says, oh, geez I’ve got to get to the number 15 I’ll call my brother-in-law, I’ll call the person who lives downstairs, can you come in and just say that you tested and I’ll write it down so I can file this report.

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

Yeah, I would agree with the number...this is Mike Lardieri that the 15 I mean that sort of doesn’t spur innovation and if you want small vendors, especially if we’re talking about modules and once they get certified somebody can pick it up. I think it would stop some vendors from moving forward that might be great vendors for a specific module if you had to hit the 15 before someone can use it to get certified. I just guess I have a problem with that.

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

The alternative to that is some of the EHRs that have been certified for Stage 2 did studies with one or two users and that’s not enough and so I believe that the 15 was a compromise number. The industry standard for a summative usability testing is around 25 and so I think the ONC group came up with 15 as a compromise so that you don’t have to do the heavy burden of the 25 yet requiring more than the 2 that some of the vendors were doing in some of the studies that they submitted for in Stage 2.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, this is Paul, when you say it’s not enough to do one or two it depends on what you’re testing. I mean, the example that we talked about before is, you know, you’ve got...you’re going to add a new question to your admissions document...your admissions screen because you want to find out if a patient has traveled to West Africa, it’s possible you don’t necessarily need 15 people to test it and it’s possible you have some urgency around getting that deployed and it’s also possible that you have some development mechanism where you can rapidly change it if there is some feedback that says, no, instead of putting it in blue letters you put it in red letters and that’s better.

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

Yeah and I think that...the suggestion that you talked about with the blue letters versus the red letters gets into the part with the retesting and the recertification where, you know, if you don’t make a significant change to the user interface modality so, you know, you’re changing a drop down to a check box or from a check box to a shuttle applet, you know, what you’re doing is just changing the color or bolding a particular sect and in that situation then it should not be required to be retested and recertified and those are the types of A/B tests that some of the vendors would be able to do in order to enhance the user experience of the application that they’re working with.

Amazon is constantly doing A/B testing trying to generate more revenue and, you know, maybe some cloud-based EHR systems would be doing the same trying to optimize the user experience of their system.

And installed system of course is going to be different than a cloud-based EHR vendor and the cloud-based EHR vendors are the small vendors that you're probably referring to.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, just a comment on that retesting. I believe that's already covered with the existing certification processes. When vendors do an upgrade to their system they need to provide the release notes and information to the ACBs and they determine whether or not retest is required. So a change to the user interface would already be covered under that existing process. So, I think this is an example like Alisa raised earlier where nothing new is required it's already covered by existing process.

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

Okay, so I want to move onto another item within the safety-enhanced design portion and one big change is that the number of criteria that were required for the testing was significantly increased from seven or eight depending upon whether it's an inpatient or an outpatient system to 17 different items.

And so in general our group had a consensus around that, we thought that testing more things were good even though it does place a larger burden on the organization because the tests are twice as big pretty much.

And I wanted to add one comment that came from Lana regarding this list of the 17 items, she and her colleagues at NIST had recommended that we add an additional item and that is that they check the patient's history, the most recent patient history because as a safety issue that was the most likely area to find something and I sort of see that as analogous to like in Microsoft Word, you know, it remembers the most recent files that you were just opening and so it sort of provides the physician kind of a shortcut to what some of the most recent problems were with that particular patient because those are more likely to reoccur.

So, we sort of recommend adding one additional thing and making it a list of 18 items that need to be evaluated and there was pretty much consensus about those items and no one had any specific problems with any of the items that were being tested, everybody pretty much agreed, you know, it's better to test more things than less even though it did add a significant burden to the vendors.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, just...I agree with what you said with one clarification, at least in the call that I was on we talked about that right now it encompassed administrative functions so things that maybe the IT department would do that those aspects that weren't used by a clinician would not be covered and that is in the written comments so far, you know, the notes...

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

Right.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

In the paper.

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

Right and that gets back to the question regarding the participant types and the 15 participants, if it's 15 total or 15 types, because in the Stage 2 usability evaluation there are two or so tasks now that are kind of associated with the administrative functions and in the new 17 ones I don't remember the exact number but I think it's like three or four items that are more associated with an administrative user and so some clarification in the rule around whether those items should be given to every user or separate users and whether it needs to be 15 users in each user group or 15 users overall.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Because I felt in the conversation I was in we were saying this was about safety and that those things...while there was support of increasing the number of clinical items there wasn't support for having to do user centered design on administrative functions.

Paul Egerman – Businessman/Software Entrepreneur

That makes sense but what's the definition of an administrative function?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

You know master file...like set up of a, you know, rules that the IT department would do.

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

Right or changing the CPOE rules to fire more often or less often.

Paul Egerman – Businessman/Software Entrepreneur

But is like gathering demographic data is that an administrative function?

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

Sort of huh? It's kind of a gray area I'm not really sure what is and what isn't.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

That wasn't the type of examples we were talking about it was more...

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

More of the IT-related ones.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, I mean, it's like you go back to the example I gave has a patient been to West...traveled to West Africa is that an administrative question or is that a clinical question?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

That's a clinical question because a clinical user would be using that.

Paul Egerman – Businessman/Software Entrepreneur

Okay so then date-of-birth is also a clinical question right and sex is a clinical question because the physician uses that data.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, I would say it's more about is it being used at time of...with a patient there or time of care delivery as opposed to, okay, we're going to set up a new rule someone in IT in the back room is sitting down creating that it's not used during patient care or patient admission, or anything like that. It's the supportive functions maybe I'll call it.

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

Okay. I don't have any problem with carving that out I was just curious what the carve out was.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, yeah.

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

And, you know, there was a similar discussion along the lines of the accessibility portion with that as well that, you know, the accessibility may or may not apply to the back room functions or the, you know, behind the scenes function of the application where the accessibility features in the patient portals or the other portions of the eMAR, or the physician is interacting where the system should apply.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, I would say in the call I was on I think there is still a lot of questions about the accessibility functions while...

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

Yes there was.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

You know in terms of cost and value I know at least in our company we're going out to our customers to say, you know, how are you handling this now just, I mean, in many cases that would be very extensive work to do that and I'm not minimizing the importance or anything but just as compared to other things is that, does that belong here? I think it's still...lots of discussion to be had on that.

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

Yeah and that mirrors the discussion that we had during the discussions.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, yeah, agree, agree.

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

Yeah there's a lot more that needs to be done. We all agree that it's a really great feature but we're not really sure where the bang for the buck is going to be.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yes.

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

So...

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

I'm sorry, this is Lana Lowry I just joined, I apologize for being late.

Paul Egerman – Businessman/Software Entrepreneur

Okay, so one other comment...

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

Well we're glad you joined.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul, I made before, as I look at this list of 17 or 18 items is the description of participants where you're looking at for all these things, age, sex, education, occupation, rural that in a cloud-based environment you may not know that information plus you're doing a lot of stuff that just increases the cost it's not necessarily that useful information to have that about every single participant that was involved in testing.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah, I agree that came up on the Workgroup call as well. They were...they're cited as examples in the standard and shouldn't necessarily be requirements, but the standard says you should be able to describe the type of user to give the feel that it was a good valid test, but there are issues, specific issues about the list and, you know, you could identify the people that are listed in the text that we, I think, agreed to provide. That's not necessarily the right list. There just needs to be a way to articulate that the group of people that you had was a valid group.

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

Yeah and I totally agree with you on that and one of the things that I often do when I'm evaluating a study, a research study of any kind if I'm even looking at it from the NIH, you know, list, I look at the participants and I want to make sure that the people that they used as their guinea pigs in the study, you know, actually represent the type of people that the study is talking about and, you know, the criteria that's mentioned there was meant probably to help with that.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Right, I think what happened in a couple of cases is the writer of the rule took examples that were in the standard and made them requirements in the rule, which just needs to be fixed. You know what I mean that just needs to...the feedback that we wrote says we need to change this just to more accurately reflect the intent.

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

Exactly.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yeah.

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

Okay, does anyone have any additional comments on the safety-enhanced design portion that's the largest portion of the part that we were asked to discuss?

Okay, so the portion about request for comment on summative testing that was around whether a series of formative testing can be submitted, it has an alternative to a summative test, and one of the things that came up in our discussions was that formative testing is something that is required if you're going to have a user centered design process but at the end of the process you still would have to do a summative test to prove, if you will, that your user centered design process created a usable interface to the eMAR.

So, although there was a little bit of non-contention on this I thought overall we felt that you still have to have a summative test and the amount of formative testing that you do is completely up to the vendor and can be included in their description of their user centered design process.

And one of the items I remember discussing about this was that we didn't want to have the vendors have to reveal any of their trade secrets during the formative test because, you know, trade secrets need to be trade secrets, so, you know, the formative testing, the reporting of that could be more like it did happen and we found a number of issues and we're going to fix them and then in the summative test is where you would actually make a list of the areas that would still need improvement but then provide the overall usability statistics and demographics and all the information that's listed on the screen that we're all seeing right now.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Just to clarify we're not...we're recommending that we, I think we did, I think, came to consensus on this that we actually say we just...it should be summative.

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

Right.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

And we're not going to require all...here are some examples of formative because that would be assumed if you have a successful summative, right?

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

It would be assumed if you have a successful user centered design process...

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Right.

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

That you did do some formative testing.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Okay.

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

And you might not have any usability testing or any...you might just get really lucky and design something right away that is incredibly usable, you know, it's happened and then go right to summative, but it's probably not very likely, especially for something as complex as an electronic health record system.

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

Okay, this is Lana Lowry if I could please add to this statement, it would be very inappropriate if it would make any assumptions that not having formative testing is just somebody, you know, fell into luck. We do require formative testing already as the part of user centered design because the industry has to attest to user centered design it means that they must include formative testing because there is no user centered design without it. So, that was the reason why a suggestion was not to require additional reporting on formative testing because it's already a part of the rule.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yes, that's better said.

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

Yeah. Yes, she said it better than all of us could.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yes.

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

And Lana can you please reiterate the additional criteria regarding the patient history that you had discussed?

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

Is that question to me?

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

Yes it is.

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

Yes, in the course of the research that my team is conducting right now we don't have any clear data to publish or report but the analysis that we have clearly shows that practitioners consider that particular criterion extremely safety related and extremely crucial for their clinical workflow. So, therefore my team recommendation was to include this criterion into certification based on the empirical evidence that we already have.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul I don't understand so, you do or you don't have evidence that certification...

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

We do...

Paul Egerman – Businessman/Software Entrepreneur

Of that will have a positive outcome, will reduce safety defects, will save lives? Do you have data that says that yes or no?

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

First of all we have not applied that to certification to have that data. What we have...

Paul Egerman – Businessman/Software Entrepreneur

So you have no data...essentially we have no data that certifying this...

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

On certification, we don't have it in certification so how can we have data if we don't have it in certification? But we do have data that clinicians and users who we're doing all of that for they consider that to be absolutely crucial for the safety of the interaction.

Paul Egerman – Businessman/Software Entrepreneur

So, I just want to make sure, you have no data that certification will have any impact on morbidity or mortality?

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

Certification in the design process...

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

Is that correct?

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

Right, let me, yes, no, no...

Paul Egerman – Businessman/Software Entrepreneur

And then do you have any...

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

Let me...

Paul Egerman – Businessman/Software Entrepreneur

Do you have any data that says even doing this has an impact on morbidity and mortality.

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

We do not have data on any of the additional functions in certification except eight safety-related that were in Meaningful Use Stage 2. So not only this one we don't have data the nation doesn't have data on any additional that are proposed in the rule.

Paul Egerman – Businessman/Software Entrepreneur

Okay, so this is sort of a faith-based regulation.

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

Paul, you know, most regulation is based on, you know, what we know from the evidence and if, you know, if we'd had certification before, you know, and we'd done a randomized control trial of it then, you know, we might have evidence like that, but, you know, that just has not been the case. So, most policies are made, you know, in the absence of a great deal of scientific data and what you do is do evaluations like the ones that have just been described and when users repeatedly say that one issue is their number one issue it seems like a reasonable thing to address it.

Paul Egerman – Businessman/Software Entrepreneur

One of the questions I had asked in a previous call was, this data that we currently are gathering and is currently in the CHPL is anybody using it and I never got an answer to that.

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

I...

Paul Egerman – Businessman/Software Entrepreneur

We've got something that exists in Stage 2 and we're expanding it dramatically and I'm curious to know was it useful in Stage 2, did people use it, has it had an impact?

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

I apologize, I gave my name when I made a statement and I am sorry I didn't get your name, what is your name?

Paul Egerman – Businessman/Software Entrepreneur

My name is Paul, Paul Egerman.

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

Okay, thank you, Paul.

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

So, I don’t know...

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

Well, Paul...

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

Does anybody know the answer to Paul’s question, I do not.

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

Well, earlier, this is Ellen, earlier in the call we had a member talk about how they had used the CHPL information as a first step in directing customers but also there is information about the CHPL itself not being in as usable a form to the outside world. So, there are efforts to make the CHPL even easier to use than it is now and so that’s something to be factored in, that could be why some of that information might not be used as much as it could be.

Paul Egerman – Businessman/Software Entrepreneur

There’s got to be something that one could say about a situation where we have information about user centered design and the regulation is to place it in a website that is hard for users to access.

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

I agree it’s ironic.

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

Yes. Now, this is Bennett, I’m not aware of any study that has gone through all the different sites in the CHPL, all the different studies that were published in the CHPL and evaluating them and checking to see whether those have actually had an impact. If anybody has grant money available please talk to me after the call.

Paul Egerman – Businessman/Software Entrepreneur

Well, but my question was, is anybody even using it? We have like one or two, or three people who said “yeah, I use that and I used it to make a decision on choosing a vendor and it was useful information to me.”

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

I mean, if we even had like...I mean, is there even anecdotal information about, you know, a provider...

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

Yeah, this is...

Paul Egerman – Businessman/Software Entrepreneur

Going to the CHPL and finding it useful to have this data there? Because we're talking about putting a ton of information in there and I'm curious to know is it useful?

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

Yeah, this is Mike Lardieri, I had identified that earlier and for smaller providers, especially smaller providers who don't have a lot of consulting support and those types of things we direct people there as the first place to go to begin to sort out what vendor you may or may not choose. Bigger providers they just start talking to the vendors right away and sort it out and they have support to do that. But if you're a smaller provider you need some place to go to figure out "gee who should be my first group that I even begin to send RFPs to."

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

Someone had a comment there? Go ahead.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

No, I hear what you're saying, when you look at what's in there I'm just not sure that's valid. I mean, that's a good source of information for that type of decision, it's very complex and what we're talking about here is adding more complexity to it.

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

Well, I understand that.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I hear...I hear what you're saying.

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

Yeah.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I do, I do.

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

Yeah. It just...you know it gets to the level of, all right some vendors have multiple systems and, you know, ePrescribing you're going to have to get that module, the HIE you have to buy another module there is another fee for that, clinical decision support you have to buy another module would I begin to look at that vendor versus the vendor who has everything integrated as one vendor and I know I'm going to work with them and if I need to make a change I go one place that makes a difference to a smaller provider to manage that.

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

Again, this is Lana Lowry, even though it's a very valid point on the other hand the objective, in order to have the...for the information to be displayed was transparency. Because it's a safety related system and it's a safety-enhanced design one of the second goals was transparency that's why we have it reported on top of the domain.

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

Okay, so if there are no other comments regarding to that list go to the quality management system deployment. And in general when we spoke about the quality management system requirements everyone was obviously in favor of having a quality management system and we're not necessarily sure that the proposed language was exactly right but we overall supported the goals of having it.

And this was the area that was pretty much the amount of consensus. We all agreed that it's a great thing to have but not sure how this regulation will be implemented whether it would end up being the same thing that it was in Stage 2 where they just had to mention that they had one.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, I mean, I would say this is raising the bar fairly significantly from what was in the previous one because before you could say you didn't have one in place and you just had to say that so it was about transparency.

Here you have to say you have one and it has to be at least...it has to be compliant with an industry standard or have been developed from an industry standard. So, for example you might have taken an FDA regulation and adapted it to the HIT environment where every single item isn't required for HIT. So, I actually think this is a fairly significant raising of the bar and that being said, I think the team supported it, you know, that they...

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

Yeah.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

The bar should be raised and that this was a good way to do it.

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

This is Michelle Dougherty and in this way it allows flexibility for the system to pick what fits best.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yes, agree.

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

Okay, well we have consensus it seems like. So, the last section that we were discussing, which I mentioned briefly, was the accessibility and we talked about that a little bit during some of the other conversations that we had but in general everyone was supportive of accessibility. We had some conversations in and around what portions are required to be accessible and what accessibility standard would we want to use going forward and what type of mechanism would we have for enforcing accessibility or is it left to the vendor for accessibility. And...

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I...

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

Go ahead.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I was just going to say, while everyone would agree that accessibility is a good thing I'm not sure there is agreement that accessibility belongs in the certification rule. I don't think we're there yet.

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

So, accessibility as a very strong recommendation, we did talk about it being part of the user centered design process where one of the user personas that you're using is the persona of a vision impaired user or a mobility impaired user. So, you know, linking accessibility to the user centered design process is another way to go.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

It couldn't be there if it wasn't...

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

Yeah.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Right, so they would...it would be all in or all out, but I'm not...in the call I was on I don't know that there was agreement that it should be part of certification. I would say it's not...that there was no consensus there.

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

Yeah, yeah, we all wanted it but is it something that's required in the certification.

Paul Egerman – Businessman/Software Entrepreneur

And this is Paul, I mean, I agree with that last comment but I agree with it from a stand-point of saying I don't think any of this should be part of certification. I mean there needs to be some other tool. I mean if the goal is transparency there are a lot of ways you can do transparency without requiring all this stuff to be put into the CHPL.

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

When you say...

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

This Mike Lardieri, the only thing I would say with that Paul is I would want to see it in the CHPL maybe not have to be certified but if a vendor does have better accessibility for vision impaired or whatever they should be able to list that in the CHPL because then it gets to be a competitive thing if, you know, depending on what you're environment you're in and that type of thing. So, it should be able to be listed, I don't think it has to be certified though.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I think that goes...you know, why wouldn't they use their marketing material as a differentiator and publicize and promote that they have that capability as opposed to bringing it into certification. You know the whole...

Paul Egerman – Businessman/Software Entrepreneur

Yeah, I mean...

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Vendors still want, you know, see value in the market, see value in promotion and that competitively they have capabilities that other vendors don't have.

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

Yeah, I see what you're saying.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, I mean, I agree with that. I used to have a product that could be used that had a variation of it and it could be used by blind people and we publicized that and it was well received and even by providers who didn't have any blind employees, you know, they liked the idea that this was something that we had included and so it's still odd to me that you have to write regulations around it and include that in certification because I think that's taking certification in a...you're expanding it too far.

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

Yeah, I got you, okay I could retract what I said then, I could see just putting in the marketing stuff, okay.

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

This is Michelle Dougherty, I don't know that...I mean, I absolutely agree with the fact that, you know, a vendor would put something like that in marketing, but I can see where that's not always the most reliable source for some purchasers and there may be value in...some objective process that collects or validates that. I'm just going to throw it out as another thing to consider because I don't think marketing materials are always that objective.

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

They always seem to say, easy to use on them.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul, I just want to respond Michelle by saying, I certainly agree marketing materials are not at all objective but why do you think if we ask vendors to put a whole boatload of stuff like this in the CHPL and there is no ability to audit it or no penalty for putting in anything wrong how is that any different from marketing materials.

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

And you're right, absolutely, I agree, I was just, you know, the fall back that, you know, it will be handled somewhere in marketing is just felt like...we all know, we all know how it works. But you're absolutely right without any processes behind it it's just superficial.

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

Could there be, this is Mike Lardieri again, I'm wondering could there be a...if a vendor voluntarily wanted to be certified to that then they get certified and then you know it was tested and then if it's up on the CPHL you see it but not required but it's like a voluntary thing they could do on their own.

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

Sure, I mean, just like the VPATs that are required for Section 508 if they wanted to include a VPAT on their CHPL they probably could. Okay, well if there are no more comments we'll bring it back to the MC.

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

Great, all right, well thank you very much. Other overarching comments? I mean, clearly...so I think this was a really good conversation we have a lot of diversity of opinion that's good and, you know, these proposed regulations always get better when we make comments about them.

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

Hey, David?

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

Yes?

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

Yeah, this is Steve Stack, I have an overarching comment I enjoyed that discussion there. I do continue to be impressed with the high-level and also the depth of knowledge that people bring to these discussions.

I bit my tongue and didn't comment but I did enjoy particularly the discussion that Paul had earlier about what evidence we did or didn't have for the utility of CHPL and whether it was being put to constructive use and are we raising the bar in the absence of evidence and it just was not lost...and is it a faith-based activity. You know I think you could make all those very same questions apply to the entire endeavor of Meaningful Use and the path we're on.

I think we all agree intuitively that managing health information, you know, which comprises nearly 1/5 of the economy infinitely better than we currently do is an undeniable need and good. I don't think we would all disagree with that. And yet so much of the approach we've taken has at times been by very necessity other times just by judgement and decision, been quite subjective and if that is good in your view then it's a positive thing, if it's not in your view it's an arbitrary thing and I would say that many of those same questions we would do well as we continue to go forward down this path to reflect on the overall program and what really is or is not reasonable no matter whether the individual concepts themselves sound praiseworthy, if it's reasonable the way they've been proposed and the way people have been held to task for delivery of them. So, anyway I enjoyed the discussion very much and thanks for the opportunity to make that high-level remark.

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

Great, other thoughts or comments, or questions?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, just an overall comment and that is I would just kind of re-say again what Steven said, when you look at each individual requirement each one, hey that sounds like a good idea, that sounds like a good idea but then together...when you put them all together does it make sense and one of the clear points of feedback that was given I think by every stakeholder was that the program was too complex and when I look at a lot of what we talked about today and we're only talking about, you know, 10 or 12 principles in the rule, I would say this rule has become significantly...and the program itself has become significantly more complex than the program of the last version, the last version of the program.

So, I think we need to...I would like to recommend that we consider including a comment about complexity, an overarching comment, you know, outside of each individual comment we provide if the group would agree with that.

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

This is Michelle Dougherty and I just ask that we...after the third Workgroup presents that perhaps on May 1st we have time for some overarching themes like that because what we haven't discussed yet is a move to a modular approach away from the EHR, the Meaningful Use EHR Certification Program, that's expanded to more settings and how does all of that impact the discussions we had, how CHPL was used, you know, the complexities, how other regulations are referring to the certification process.

I think we still have a piece that's missing and then we'll, you know, for better or worse, I think have some overarching suggestions that bring at least a bigger picture of the rules together.

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

Yeah, so I think those are both good suggestions. We'll make sure that we do have some time after going through the Group Three's suggestions and I also think that there is a general sense of the group that less complexity would be better. We can talk some more later to make sure that everybody agrees. Other thoughts before we go to public comment? Okay, Michelle, could you get the operator to open the lines?

Public Comment

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

Caitlin can you please open the lines?

Caitlin Chastain – Junior Project Manager – Altarum Institute

If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment, please press *1 at this time. We do not have any comment at this time.

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

Okay, well thank you all, look forward to the next discussion and really appreciate everybody's thoughts and input.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Thank you.

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

Thank you everyone.

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

Bye, thank you.

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

So long everybody.

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

Bye-bye now.