



HIT Policy Committee Implementation, Usability & Safety Workgroup Final Transcript May 11, 2015

Presentation

Operator

All lines are bridged.

Kimberly Wilson – Office of the National Coordinator

Good morning, everyone. This is Kimberly Wilson at the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's 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. Please also keep your line muted if you are not speaking. 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.

Kimberly Wilson – Office of the National Coordinator

Good morning. Larry David—I'm sorry, excuse me. Larry Wolf?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Here. Thank you.

Kimberly Wilson – Office of the National Coordinator

Sorry, Larry. Alisa Ray? Bennett Lauber?

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

Hi, I'm here. Larry David is a completely different person.

Kimberly Wilson – Office of the National Coordinator

I'm sorry. Bernadette Capili?

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

Here.

Kimberly Wilson – Office of the National Coordinator

George Hernandez?

George Hernandez – Chief of Applications and Development – ICLOPS

Here.

Kimberly Wilson – Office of the National Coordinator

Good morning. Janey Barnes?

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

Hi, this is Janey Barnes, I'm here.

Kimberly Wilson – Office of the National Coordinator

Good morning. Joan Ash? John Berneike?

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

Yes, I'm here.

Kimberly Wilson – Office of the National Coordinator

Good morning. Mickey McGlynn?

Mickey McGlynn – Cerner

I'm here.

Kimberly Wilson – Office of the National Coordinator

Morning. Michelle Dougherty?

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

Here.

Kimberly Wilson – Office of the National Coordinator

Good morning. Mike Lardieri?

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

I'm here.

Kimberly Wilson – Office of the National Coordinator

Good morning. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yes, here. Good morning.

Kimberly Wilson – Office of the National Coordinator

Good morning. Robert Jarrin?

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

Jarrin, here.

Kimberly Wilson – Office of the National Coordinator

All right. Steven Stack? Tejal Gandhi?

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

Here.

Kimberly Wilson – Office of the National Coordinator

Morning. Terry Fairbanks? Betty Mims Johnson? Edwin Lomotan?

Edwin A. Lomotan , MD, FAAP – Agency for Healthcare Research and Quality-Health and Human Services

Here.

Kimberly Wilson – Office of the National Coordinator

Morning. Jeanie Scott? Lana Lowry? Megan Sawchuk?

Anne Pollock – Centers for Disease Control

Anne Pollock substituting for Megan; Megan is out of the office for three months.

Kimberly Wilson – Office of the National Coordinator

Okay, thank you very much. And I will turn it over to you, David, and Larry Wolf. Thank you.

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

Okay. Thanks very much. We have a relatively straightforward agenda for today. Basically, the goal is to try and reach consensus regarding what we'll say to the Policy Committee, and we have a summary of the comments about the NPRM from the group. We'll be going through those, and then perhaps making some edits to things.

I think what we'll use as a framework for today is the actual slides. The backdrop is that we don't have a lot of time with the Policy Committee, we have 45 minutes total, and we've been going back and forth a little bit by e-mail regarding how much of the time we should use for a presentation versus discussion, but clearly we have to allow some time for discussion. So, the longest we would talk for would be 30 minutes, and it might be less than that.

We obviously identified a lot of things during that conversation, and Larry has made a suggestion that might be helpful, for each of the workgroup members to reflect on the most important one or two things that they would like to be communicated to the Committee and the ONC. It doesn't—it doesn't have, it shouldn't be one of the overarching things, the overarching points we do plan to make, but there were enough important comments in the things that were not overarching.

So, Larry, how is that as a summary?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I think that's really good, David. Yeah, I was struck by the volume of material we have, the short time we have to present it in. I know that various of the workgroup members have some really clear thoughts about a couple of points that are really important to them, and I wanted to make sure that we got those as clearly as possible. And, you know, that there's a pretty big workgroup and we probably don't have the time to go through everybody's top points, but please reflect on those as we go through the material today to make sure that that gets highlighted, and if it doesn't, send David and I a note right after the call or during the call, because we'd like to do our best to get it into the presentation.

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

So, Larry, maybe I'll do most of the talking, because there is a fair amount of background noise for you, which is probably inevitable.

So, what I'm gonna suggest we do is that we go through the slides, and do write down the one or two things that you would like to see and emphasize that don't make it into the overarching points, and you can either send us those—we'll try to do it on the, we'll try and go around the group on this call. But let's go through the slides first, if that sounds okay. Does this sound like a reasonable process to everyone?

Male

Yes.

Female

Yes.

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

Yes, it does to me. This is Ellen Makar, and just for the record, I wanted to let you know I'm on the call and I'm gonna be making adjustments. It won't be live on your screen, but I'll be taking notes and then we'll be conferring, so that what you have to present to the Policy Committee tomorrow is complete.

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

Great, and Ellen has done a great job of putting this all together and trying to amalgamate it, which is a considerable challenge. Okay, can we have the next slide? And the next slide? I think we all know what our assignments were. Next slide. And this is just the composition of the three groups. Next slide.

So, here are the overarching points and basically, it creates a certification program that has a broader scope and applicability, which would include any stakeholder. And while the incentive program targeted specific professionals and providers, health care reform requires the broader health care community to use in exchange, electronic health information to reduce care fragmentation and improve coordination, and we see the potential for the modular approach to the certification approach described in the NPRM to engage more stakeholders and set some foundational interoperability requirements.

We designed the program, and the modular approach does provide flexibility, but it will likely be, it does carry some risk, too. It will be more complex, and this role of ONC as a coordinator to facilitate alignment is critical for mitigating complexity and cost, which a lot of people were concerned about. And some of the specific new challenges or repercussions will be that the more complex program could drive up costs for certification, especially for those who certify and test in multiple HIT modules. Second, there could be challenges to keeping the modules and the requirements at the foundational building block level and not expanding the scope unnecessarily; and then third, other parties that identify certification paths and/or compliance with the certification module critical to the foundation building blocks by requiring a module with modifications and add-ons.

So, comments about that?

Mickey McGlynn – Cerner

This is Mickey. I have a couple comments in this section. The first is about this role of ONC as a coordinator, and I think maybe—I'd like to see us ask for more clarification on what that, I mean, I think they said they see that role, but they are trying to separate themselves as well from the various programs. So they want the certification program to stand on its own, so that's a little bit of separation, yet it won't work without them really playing this coordinator role. So could we, you know, ask for clarity and understanding for the feedback on what that means so that we can see if it will actually work in execution?

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

Yeah, so that makes sense to me.

Mickey McGlynn – Cerner

Okay.

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

What was your other comment?

Mickey McGlynn – Cerner

Then at the bottom, like, where you have the bullets, I think there's kind of—what do they call it, the Christmas tree mentality? Like, the risk of kind of adding lots of ornaments onto the tree that may not be what the market really wants, because it's foundational. Well, we better get that in there, or it won't ever happen. It's kind of leaving the whole market out of the discussion, so I would recommend adding, a risk of adding many new requirements onto the developers that may not be what the market is really driving for.

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

Yeah, that makes sense to me, too.

Mickey McGlynn – Cerner

Okay, and then the last one is that, because of the fact that it's kind of a set of requirements that any program can call on at any time and say, "Okay, I'm gonna link my program to this, and I'm gonna add a few more," there is no timeline, so when it was just linked to meaningful use, you knew when the requirements were coming out, and then meaningful use didn't require those requirements until there was time for the developers to develop them.

Now that it's very loose, we can be in a situation where a program requires it in two months or three months, and there's no time for the development to get done. So I think, I'd say that consideration needs to be given to the timeline by which a program can call on certification so that there's time for the development to get done—something like that.

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

Or maybe the market would benefit from having an explicit timeline which is no longer present because of the lack of linkage to meaningful use or something like that.

Mickey McGlynn – Cerner

Yeah, or a specific program—yeah, something like that. That's great.

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul. Can I just make some comments about what was just said?

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

Sure.

Paul Egerman – Businessman/Software Entrepreneur

So, I think what was just said when people talk about market, market requirements is helpful, but what I would do is, I would link that comment to the overall sense of a broadening behind the EHR system to all of health care, and because you're broadening the certification to all of health care, you're changing what markets do need to respond to, and in particular, there's a change in what are the priorities as to what will be certified.

There's a specific example I can give, which is, in the 2015 certification criteria, if there is now a requirement to answer the question raised, there are now going to be 900 possible responses, over 900, because that's something the CDC wants. But that's not something I think emergency rooms want, or physicians want. Because that's, I think, a good example of where you've changed a definition of certification for all of health care and you changed, in effect, the definition of the market or what the priorities are for the certification program.

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

Can we look at the next slide? I think that's part of what we were trying to get at with bullet three here, but it also seems kinda different. Can you take a look at that, Paul, and see whether that—

Paul Egerman – Businessman/Software Entrepreneur

Well, it is, it is—that's correct. If you look at the third bullet, the comment there is not quite the same.

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

Right.

Paul Egerman – Businessman/Software Entrepreneur

Because you're talking about—what am I talking about? Policy concerns such as safety, business practices, and helping individuals with disabilities. Those are things that are beyond software functionalities. You're commonly given like 900 answers for race—it's actually over 900 as being the requirement. This is, like, part of an expansion of the demographic data. That just shows me a difference in priorities as to what the software is supposed to be doing, because I don't think any physician is requesting that in country, or any provider organization wants that information at that level of detail. And I think that's slightly different than what you see in bullet three which is when you're talking about business practices, which is a different variation of the expansion in the certification. It's sort of like, one is depth and one is breadth.

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

Yep. That's where I thought we would land. Okay, so why don't we make that a bullet on the main one? We may want to, I'll work with Ellen to sort of shorten some of the text, too.

Page one—okay, so should we keep going?

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

This is Mike Lardieri. I just had a question—regarding other programs implementing requirements, I thought the whole purpose was that, if we go down this road and ONC certifies the modules, the other programs wouldn't be identifying additional specifications, because they'd be using the modules that were already approved—or maybe we have to say that, because that was my understanding, is how this would work; not that states would come up with their own modules.

Mickey McGlynn – Cerner

So this is Mickey—that's not my understanding, and that, even with meaningful use, CMS, there is other requirements that are required of the software that aren't in certification that are required for meaningful use. So I'm thinking the same thing would likely happen as to what happened with meaningful use, but now you're looking at many, many other programs, so it states, it's specific programs coming out of CMS, it could be private payers who take it on. That's how we're viewing it.

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

Okay. I wasn't viewing it that way, or maybe we should tell them we don't—we don't want that to happen. [Laughter] That would be very difficult, right?

Mickey McGlynn – Cerner

Yeah, I just don't think they have the authority to say that. Like, as much as they might hope that would be try, I don't think they have the authority, and that's kind of a point about them being the coordinator as well. I don't think they are able to say what those other organizations can and can't do.

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

Okay, I gotcha. Thanks.

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

Does anybody from ONC have an opinion regarding that?

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

This is Ellen. I think, you know, there can always—you can’t control what would happen in the future. You could certainly put down what your opinion about it is, but I think, it’s interesting to me to find out how sometimes folks can find a program and then, yeah, find a way to, to add to it, right? We see that all the time when things are put together, so while this—it’s an opportunity to raise that concern, I think that’s fine. These are comments where, yeah, we might not have the ability to do anything about it, but certainly if the workgroup feels like this, just having that concern laid out on the record is a good thing.

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

Okay. Can we keep going?

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

Yeah, the other thing I wanted to mention is, maybe if we just look at the overarching comments, kind of, if the workgroup members can just kind of scan through them right now, if we just take a couple of minutes to do that, because we hit, in the conversations of the past few weeks, some key topics that members wanted to emphasize. So there is one on timeline, and so some of the comments might fit in to what’s already existing there, and then later on in the slide deck are all the detailed comments with what folks have put forward.

And yes, the devil’s in the details, and some of the most salient points are in those detailed slides. I had to make the font really small to get it in there, but we might want to see if there are specific things there that we want to carry forward and emphasize more. So I don’t want folks to be concerned that maybe some points that they had wanted to make are missing, but it just might be embedded in a different slide.

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

Right. Well, so—Ellen, what I’m planning to do is, I’m gonna go through the overarching comments first, and then ask people what things they want to underscore from the other comments. I actually think that some of the important things are in the other, other comments, and that we’ll probably want to make sure that we call some of those out.

And the things that are gonna be the most actionable are actually in the detailed comments, too, because, because some of the big picture things that we bring up, for example, here are, are—you know, and they’re important things to say, but they’re, they’re just not as easy, for example, for ONC to handle.

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

Gotcha. Super.

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

Okay. Yep, so let’s—okay, so, so, on this slide, there are, there are three things. There is, there is the Utility of CHPL, and there’s a description of what we do by there, by that. There’s also the point about other software sources, which I think Paul has made on a couple of occasions, and, and then, and then the third one is expansion of the use of certification, which we just talked about.

So, thoughts about those? No?

Mickey McGlynn – Cerner

So, this is Mickey, I have a couple just minor points.

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

Yep.

Mickey McGlynn – Cerner

On the first one, when we talked about the CHPL, I think someone described that they used the CHPL as, you know, like as a first step, almost as a buyer’s guide. I would've never thought of that, that that would be a purpose, because it’s just so complex. So I think we said the value, in our comments, and like the fourth line in our comments—I would say, I think we need to be clear on what the purpose of it is. And then there’s a value associated with the purpose, but I think there’s confusion. Like, for example, I don’t see any value in adding all this, spending 12 to 8 months redesigning it, because I think of it as just the place where providers need to go to find out the products that they need to put to a test.

So, we need to align more. I would recommend we’d say we need to align more what the purpose is before we spend that kind of time, or before they spend that kind of time and money on redoing it.

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

Okay, so, so we could reword—reword this to say that, you know, evaluation of the redesign should, should include careful consideration of the purpose—

Mickey McGlynn – Cerner

Right.

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

- evaluative, et cetera, et cetera.

Mickey McGlynn – Cerner

Yeah, just that. Okay, even if it’s as simple as I, you know, would perceive it, I think it might need a little rework. But if it has this broader purpose, it would need a lot of rework, so.

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

Mm-hmm.

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

Yeah, this is Mike Lardieri, and—because I had brought up that issue, so—and then the timeline, I think, 18 months is like way too far out there if we’re gonna use it for the purpose that I know a lot of folks use it for, before they go buy things.

Mickey McGlynn – Cerner

Mm-hmm.

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

Yeah, that would [Cross talk].

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

Yeah.

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

So we should say something about—we think that should be shorter.

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

Yeah, much shorter, yeah.

Mickey McGlynn – Cerner

Mm-hmm.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

There’s a delightful irony here, you know, guys, right—the proposed timeline that ONC feels they need to rework the CHPL, which is the time to rework software, other software?

Paul Egerman – Businessman/Software Entrepreneur

This is Paul, I was just gonna make a variation of that same comment, Larry. When I hear the timeline should be shorter, I’m thinking, well, said like a customer—“We really want the timeline to be shorter.”

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

[Laughter] There you go.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, so [Cross talk]. I don’t mean to make that as a critical comment, it’s just, like, an observation. Of course it should be shorter—let’s get it done tomorrow.

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

Yeah. I mean, here we're talking about [Cross talk]. It should be easier than [Cross talk]. Okay.

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

Hi. This is Bennett. One thing that I want to point out, if anyone has been to that site in the past two weeks or so, they did make a bunch of changes and, for me, they've helped a lot of the major usability issues that I was having, so they actually are working on this, and I want to commend the people that did it, because it really helped so far.

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

Great.

Mickey McGlynn – Cerner

And then this is Mickey, I had one other comment on this page. In the expansion of certification, we first, in line two, talk about safety and vendor business practices and then helping individuals with disabilities. So, the first two are kind of outside of the software, but in the disabilities section, there was quite a few software changes that were required. So I feel a little bit like we're mixing apples and oranges here. I think the point is more about safety and vendor practices that we're trying to make here.

Paul Egerman – Businessman/Software Entrepreneur

Should we—this is Paul. I partly agree with you. I mean, there was some things in the materials that said you have to test against, like, text to speech. And you know, that was not a specific functionality, but perhaps the—but I would be okay if you wanted to take that section that says Individuals with Disabilities out. The comment I have here is based on the previous discussion, which was expansion in the use of certification. I would add the phrase “beyond software testing.” In other words, what I was trying to comment on, and I guess _____ some of what of this is, is this is not just software testing, we're trying to do something different here to impact, like, business practices and safety.

So that was the real thrust of what this section is—expansion of use of certification beyond software testing.

Mickey McGlynn – Cerner

Okay, so Paul, so—because I had other comments on that as well. The way it’s written, it almost says, like, “We don’t like it because it’s only done by attestation,” but there’s a much broader issue. Your point is that they’re totally expanding the purpose of certification, and there’s lots of implications of that.

Paul Egerman – Businessman/Software Entrepreneur

That’s right, but it’s—and also, I just don’t want to get it confused with this argument about EHR versus HIT, which is a different expansion.

Mickey McGlynn – Cerner

Oh, great.

Paul Egerman – Businessman/Software Entrepreneur

I mean, this is, this—to me, certification is, you know, it's like a true/false examination, here. You put your software in, and it comes out into a yes or a no—yes, it passed; no, it didn't, and that's it. Plus, you know the test in advance, so it's like, from the vendor standpoint, you should never be surprised with the result. And this is a major alteration when we're talking about doing lots of other things for that. That's the expansion I was objecting to is any kind of mandatory certification that's really not objective testing.

Mickey McGlynn – Cerner

So, because—I don't think that's what this says. You said the words “objective testing,” this says, “especially if done by attestation,” which isn't really the same thing.

Paul Egerman – Businessman/Software Entrepreneur

Yeah. Well, it's the only way you can do it, I guess.

Mickey McGlynn – Cerner

But—

Paul Egerman – Businessman/Software Entrepreneur

I mean, there's other ways you can do it besides attestation. You can do, like, inspections, you can do subjective judgments. There's other ways, but you'd call that attestation.

Mickey McGlynn – Cerner

Right, but it—but it seems like we're saying, at least maybe it's me from the perspective I come from, like almost we're saying it's not the, especially if done by attestation, like, that wouldn't be good enough. But really, the point you're saying is, it's not objective, so that—you know, it's beyond the objectives of certification, which is a pass/fail.

So I, I guess I'm comfortable—I agree with the point, I'm comfortable with it, but I almost would like to see this end after, like, line five where it says “these issues, period.” The whole attestation part, I don't think, is what we're really saying.

Paul Egerman – Businessman/Software Entrepreneur

Well, I just think the attestation part is important. See, the way attestation came about was because attestation exists in the meaningful use program, and so people sort of got accustomed to it, and it's not particularly—and I don't know if you like it in the meaningful use program. Attestation, in my opinion, just does not belong in any certification program, and it's just, it's just—it's just a flaw in, in the process. I'd kind of like to leave it in. Maybe we just need to wordsmith this a little bit rather than you and I keeping everybody on the phone talking about it.

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

Yeah, how about—I have a proposal. How about if we make it a separate box and, and say something about attestation—like, certification and attestation?

Paul Egerman – Businessman/Software Entrepreneur

If that's what you want to do, fine. You're the one that's got to present it, and as long as you understand the basic concept of what we're trying to—to say.

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

It’s that, you know—

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

Well, I think it makes it easy—I hear Mickey’s point, and I think it makes it easier if we separate these.

Paul Egerman – Businessman/Software Entrepreneur

Okay. That’s fine with me.

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

You know, and the fundamental point is, you know, certification and attestation. Okay, should we go to the next one? Go down one. Thank you.

Okay, so here, there are three. One is shift from functional requirements to inoperability in privacy and security and, you know, the concerns about that. The next point is about the timeline and whether this allows people enough time to begin their reporting for stage three, and then—and then the complexity point.

George Hernandez – Chief of Applications and Development – ICLOPS

Um—George Hernandez.

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

Yeah.

George Hernandez – Chief of Applications and Development – ICLOPS

I don’t know if this complexity point is a good spot to cover where some of the certifications covering things that are covered by other regulations in terms of reducing the redundant work.

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

You broke up a little bit there—such as producing a what?

George Hernandez – Chief of Applications and Development – ICLOPS

We don’t want the certification process to cover work that already covers, like, other regulations and standards.

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

Yes, and I think we could add another phrase about that. That’s helpful. Okay. Other comments about this? Can we go to the next one? I think these are—okay, the next one was about maturity of standards and whether the standards are far enough along to be promulgated through regulations, and then there’s somebody who’s not muted, so there’s a lot of static. If you're not talking, if you could mute, that would be great.

The next—the next one is about variations among partners, and the notion that certification requirements that impact one of the segments of the market should also apply to the partners segment—do we mean should, or would?

Mickey McGlynn – Cerner

It does, the issue—I raise this issue. So, you know, in the industry today, there’s a ton of focus on the cost of interoperability and the complexity of it, but for example, in the program, the EHR, the vendor side—the EHR developer side has to do a standard public health format, but none of the public health agencies have to accept that format. They can say, “No, that one doesn’t work for me,” so a given vendor may need to do 50 different public health interfaces, even though they're certified to one, because the public health agencies aren’t certified to that same one. So that’s what this point is meant to—or at least the one I raised was meant to be about. So that adds cost, complexity, time—so if you're requiring one-half of an interface, of a transaction to be certified, the other partner organization type, I’ll call it, should need to be certified at the same time, so it’s the same standard.

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

So, that’s, that’s—that’s clear. Maybe we should shorten this and just include that example, because I have a little more trouble understanding what was here.

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

Yeah, I—this is Mike. I feel the same way. If you’d spelled it out just the way it was said, or closer, then—then that would make more sense to folks, I think.

Mickey McGlynn – Cerner

Mm-hmm.

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

Yep.

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

This is Michelle. Regarding the maturity of standards, I know, on the last meeting that we had, we discussed some mechanism of—and this, I think, was in the genomics, pharmacogenomics—that, where we know there’s important work that needs to be done, but the standards aren’t mature yet, but there’s some kind of a heads up process that this is a priority coming. And I didn't know if the group would want to include that in the maturity of standards discussion that it would be advantageous to the industry to rally around some priority areas by making that known in advance.

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

With this being one solid example—no, that makes sense to me. Okay, so Ellen, maybe you could add something to that.

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

Yep.

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

Okay. Other thoughts about this page? Okay, next one.

So, the next one focuses on requiring teams to use a user-centered design process and the intent of the regulation and integrity of a sound UCD process. And the second one just makes the point, also, about UCD that, in that safety-centered design requirement is that it doesn’t explicitly require you to include all four things that we mentioned there.

Female

Dave, I'm not sure I'm understanding this, what we meant in this second box.

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

In the second box—so I think that what we meant was that we think that the requirements should basically require a process to include all four of those things. That is to say, identification of usage errors and an analysis; second, identifying and implanting mitigations; third, tracking and auditing; and fourth, inclusion of patient history.

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

Yeah, this is Ellen. I think maybe Bennett or Janey would be best at describing this, because it really goes into the user-centered design professionals and what they would expect or want to see.

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

Yeah. I mean, so I think that in meaningful use two that, partway through, the certifiers started rejecting reports and saying, “You don’t have an error analysis.” And so there is no place in meaningful use two criteria that give specific requirements about what that error analysis is. And so I think that these four points just fill in what’s now being required, but nobody can go and point to a line number in the meaningful use two requirements to say, “This is what they’re looking for.”

And, at the higher level, the point of safety-enhanced design usability as ONC defined it as opposed to being focused on the safety aspect, this is, from a human factors point of view, this is how you address that safety level kind of overlap with usability.

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

So, Janey, do I hear you saying all four of these things are already required, you just recommend that they be called out in the rule, because it just doesn’t say what’s already required?

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

Well, it's hard for me to say what's required, because it seems like what's really—like, what could be required, and Bennett can speak to it as well, is that you need a heading in your report that says error analysis, and then I'm not even sure that they read the paragraphs underneath it, because some of the other reports that get rejected are because you're missing a heading that they expected.

But in terms—like, now that we know of reports that have been rejected, because they were missing error analysis, this is how a human factors person does an error analysis from a summative usability test. So I think that they need to have specific information in there about, about—about this.

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

To help the organizations who are certifying be better prepared?

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

And to help the vendors be better prepared, because we get calls from folks—you know, our colleagues who are carrying them out and say, “Hey, now they're asking for an error analysis; what did you guys do?” And, you know, this is what we always point to is this, which, it's really modeling off of what the FDA requires.

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

So, so really, isn't it—so, so more broadly, it's saying that, that the requirements for the organizations who are going through certification need to be clear up front and, you know—

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

Yes.

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

- we, and certainly, we've found situations where vendors got rejected because they were, they did everything that they needed to, but the list wasn't complete of what they needed to do.

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

Correct.

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

So, I think we just need that—when I read this, I didn't understand that, so I just think we need to improve the wording a little bit.

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

Yes, so let's reword the first part; that was clearer.

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

Yeah, and then one last question, Janey—this inclusion of patient history as a safety element, that sounds like a functional requirement, to me.

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

So that part, inclusion of patient history, I don't know what those words are, that we would stop with the—those words didn't come from me. I don't know what that—I don't know what that bullet is, but to identify the error and do an analysis related to the frequency and severity to identify what the mitigation is and then to be sure that there's a way to track that through post-market surveillance, those three bullets are, like I, that's what we tell all of our clients, and that's what we do. This inclusion of patient history as a safety element, I don't know what that is or where that came from.

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

That came from—this is Ellen—that came from Lana, and I know Bennett and Lana had a discussion on that. Bennett, if you can speak more to that?

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

Yeah, not a problem. So, yeah, Lana had come up with that with some of her colleagues at NIST as one of the most common safety issues, or one of the ways to address one of the most common safety issues in working with the patient is to quickly review what their most recent patient history was, because it's most likely that that's something that may reoccur. And so, based upon her experience during our conversations, she had recommended that we add that to the list of 17, turning it to a list of 18, that they examine the most recent patient history, and that's where that came from.

And then I want to quickly add to what Janey said. Janey was exactly right, and what's happening is that every one of the different testing and certification bodies has their own set of requirements. Some of them are more strict than others, and some of them will allow certain studies to get certified while others won't, and so I think the guidance that we're looking for is something that each one of those testing and certification bodies can use to help standardize the certification so that it doesn't matter which certification body you're using.

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

So, just to go back to the last point, Bennett, it seems to me like inclusion of patient history is different than the other three and we should have a, sort of a different preamble for it?

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

Yes, I would say that the fourth bullet doesn't fit into there, and that if there's gonna be a section, either in the slides or, like, in the main part or in the appendix where we talk about expanding to 18 prioritized area for safety-enhanced design, then it goes, it goes with—where, if we talk about that.

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

Yeah, exactly.

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

Okay. Ellen, you okay with that?

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

Yeah, I'll move it.

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

Okay. Good, okay. Can we, can we—other thoughts about, about this?

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

One thing, I would really like the last point that was made, that I'm not sure we covered, that said that each certifying body should be consistent in the way that they evaluate this, so it doesn't vary from one to the other.

Male

Right, and there is huge variation right now from stage two.

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

That sounds like, really, a separate point.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul. My comment about the _____ is that it's a result of doing something that's not an objective process, but you will always get variation, especially if you have this comment about reviewing patient history, because the definition of patient history can be interpreted differently, and recent patient history can be interpreted differently, and you're defining a very subjective process to evaluate a development process.

Anne Pollock – Centers for Disease Control

This is Anne Pollock. I'm listening to this, and I'm thinking that—I think what we're all saying is the same thing, that there should be standardized criteria, which would make it subjective, that is harmonized across all the certification agencies.

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

I mean, so, so I do—that's right, I agree with what was just said, and I agree with Paul, in the sense that, today, you either pass or failed the test. You know, you do the criteria and you either, if you can do it, you pass; if you can't, you fail. Today, this is not pass—it's like a review, and in a lot of cases, you know, no fault of their own, the certifying bodies aren't like many of the consultants, you know, many of the people on this call, really understand the process. So I, I think what we're trying to get to is a little more definition so it becomes a little bit more, “Yes, this is provided; yes, this is provided,” so that at least if you went to one or the other, the criteria of which you're evaluated against would be the same, but there certainly is more gray area than in the other parts of the objective test, for sure.

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

Okay, so we'll make some changes here. Okay, so—and that's the end of the overarching comments. Is there anything that somebody feels should go on the overarching list that they have a burning need to add that we did not include?

Okay. So now, let's, let's move into the, to the specific comments. And maybe we could do this most effectively by going through the groups. Let's see how it goes. But let me just ask, for the people who are in group one, are there things that we really should be emphasizing here? You know—go ahead.

Paul Egerman – Businessman/Software Entrepreneur

Hey, David. I was gonna make a comment about the de-certification process, which I think is part of group one, but it's—

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

It is.

Paul Egerman – Businessman/Software Entrepreneur

Okay, and it might already be there. I have to look, I looked at this very rapidly, because we didn't get a lot of time, but the point that I was trying to make about de-certification was that de-certification had to do with this concept of data blocking, and besides defining data blocking, it's got to be very clear that there are good reasons to do data blocking as well as the privacy, security, and things like whether or not you have a business associate agreement.

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

De-certification is on slide 15, Paul, if you want to look at that.

Paul Egerman – Businessman/Software Entrepreneur

Slide 15?

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

Yeah. Actually, it's on 16, I think.

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

Sorry.

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

It's on my 16.

Paul Egerman – Businessman/Software Entrepreneur

Okay, is that up on the screen now? Okay—there.

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

Yeah, there you go.

Paul Egerman – Businessman/Software Entrepreneur

So, I get—I didn't see the concept of _____ for privacy security. It taps on IT resources and contractual relationships, whether or not you had a business associate agreement with somebody.

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

Explain this in a little more detail, because I'm still not fully getting it.

Paul Egerman – Businessman/Software Entrepreneur

Well, my understanding of de-certification—and maybe I got this wrong—is that it was actually aimed at this concept of data blocking and _____ if you block data, your products can be de-certified, and the problems with that are there's good reasons to block data, and I tried to give some. The other problem that I tried to put in my comment is, the reasons to block data could be related to the provider's business practices as opposed to the vendor's business practices. So you could also have a situation where one vendor, I don't know, say Sutter, decides not to communicate with Kaiser. So that's an interesting issue, but the remedy for that is not de-certification, which would affect all the vendor's customers, the remedy should be perhaps some CMS payment penalty that might be applied to one or both of those vendors if they're not playing nicely with each other.

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

Yeah.

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

This is Michael. So basically, there's two comments. One is, data blocking, there's good reasons to do data blocking, and that needs to be considered; and the second comment is, data blocking could be the result of a provider's business practices as opposed to a vendor's business practices, and if it's a provider's business practices, de-certification is not the correct remedy.

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

Yeah, good point.

Mickey McGlynn – Cerner

So this is Mickey. I 100 percent agree with Paul's comments, and I could give you three or four more examples that point out a similar point, that say we're just learning all the reasons that people consider, you know, data blocking, and putting it in regulation with the only, what I would call, hammer being certification did not seem like the appropriate tool to address this very early understanding issue.

I mean, I think the first sentence we wrote here that's on the screen is that it would—what does it say, it would require further study and consideration and should not be in certification right now. It's too soon and, you know, you gotta look at, you know, the two examples that Paul gave, I could give you a few more and say, "What is the right remedy for that situation?" and I think we're trying to, you know, put it into this certification role, which may not be the appropriate place.

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

Right, so I think the examples are very, very helpful. Maybe we could just insert a couple of sentences giving those after consideration and study. We could—

Mickey McGlynn – Cerner

Mm-hmm, and we could also do the example that I just gave that you liked about the public health. So I would say somewhat—suppose you're a vendor, you have to do 50 public health interfaces. So if that, your customer is 47th on the list, right—well, they would perceive that as data, but you can't, you're not giving me this interface and you're gonna charge me for it because, you know, I have this particular public health entity. That's data blocking. I'm not sure that really, a product should be de-certified for that.

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

Sorry, John Berneike, here. I'm sure many of you have read ONC's report about data blocking, and I obviously addresses data blocking both by the vendors and by the provider organizations, and so I think, you know, whatever we say probably ought to be matched up with that ONC report. And perhaps just a, you know, semantic word choice about, there are good reasons to block data—I would kinda rephrase that and say there are acceptable reasons to block data. Because good is subjective, and you know, it may be good for the business practice of the provider or the vendor, but that doesn't mean it's acceptable.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, this might be good for the patient. You know, if the data is going to a source that is reselling their data, and I actually gave such an e-mail to ONC, there is an application currently being sold in the Apple store, and it claims to be HIPAA compliant. And in fact, the business model, I talked to the CEO, is, he takes the data and he sells it to a pharmaceutical company and gets referrals for that, and the pharmaceutical company then contacts the patients and tries to sell them stuff based on what they've been prescribed. And that kinda thing is not good for the patient, and so if it blocks that, I think it is a good thing to do.

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

This is Michelle, and along that—

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

You could just, you could say that that's an acceptable case of data blocking, but again, I think you need to be careful about how you would word that, because we all know that, you know, that's a great example of where it would be acceptable, but a lot of, you know, vendors or providers are gonna say, "Well, it's good for my business to block the data," and we obviously don't want that.

Paul Egerman – Businessman/Software Entrepreneur

It's bad for the patients if you don't block it.

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

This is Michelle. The only thing I was gonna add that I think we discussed is, recognizing with the expansion of the certification program, maybe to technologies that don't routinely work with HIPAA covered entities, and so those privacy and security aspects may not be required. And I think that goes along with the comment that Paul just made that this expansion has an impact as well on this process, and it needs to be further understood.

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

And this is Mike Lardieri—I thought part of our discussions, we identified that, we'd want ONC to begin to look at this from both sides and begin to document, you know, whether it's a provider issue or a vendor issue, so they just don't take the blocking as one sided, always being the vendor. They need to begin to get some data on what is actually happening.

Anne Pollock – Centers for Disease Control

Yeah, this is Anne. I'm just reading what's here. I think a lot of what's being said is covered in what we originally summarized. Especially, we said it three times in block that the process must be well thought out, and it isn't, and gave some specifics. So I think what I'm hearing people say is already here in one way or another, and maybe three or four use cases might be helpful in the block.

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

Yeah. Okay, well, I think we have consensus on the direction, and we'll come up with some, some—

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

David, I've got a question for the group.

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

Yeah.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

It's Larry. The discussion in the workgroup, I thought, in addition to talking about data blocking, talked broadly about the effects of de-certification. Some of that is in the summary, so I guess the question for the workgroup is, do we well reflect the discussion on the effects of de-certifying software? And also, as I understand it, while we focused a lot on data blocking as a reason to de-certify that there are other reasons why software might get de-certified that we haven't spent a lot of time discussing. You know, they may fail their testing.

Anne Pollock – Centers for Disease Control

I would agree with that, but I thought the point that that last paragraph was making really is that it's not a well-defined process that they have, and what will be the consequences of de-certification, and what would be the impact on the end user who's stuck with a de-certified module? I just think we discussed this in the workgroup that there needs to be much more thought process in what would be the consequences and impacts.

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

Okay. Well, I mean, I feel like this does a reasonably good job of carrying, of covering the overarching issues. I mean, if you have specific changes, maybe—maybe send them to, to Ellen. Recognize that what we're gonna present to the committee will be an abstraction of this, so we aren't gonna be able to get into all the details, but I do think this is a sufficiently hot button issue that we'll spend a couple of minutes on it with the committee.

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez. Can I just make a comment before we go on about the blocking?

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

Sure.

George Hernandez – Chief of Applications and Development – ICLOPS

One from the vendors' side is that some companies are very much like Facebook where the data sharing is their entire business. So they will, you will have, for example, a free vendor where the product is free, and they make their money basically through reselling the information.

And two, my second point is, as far as the blocking, I think there was a large feeling in the public that they have no control over their health data and the vendors or the hospitals or whatever are simply sharing their data with no—no _____ and no control. And I know that some patients are paranoid and would like greater ability to data block themselves.

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

So, comments regarding the other areas? So, in the field surveillance and maintenance of certification, transparency and disclosure, complaints reporting, open data in the CHPL?

Paul Eggerman – Businessman/Software Entrepreneur

This is Paul. I did have a comment about transparency which, again, I only read this quickly, I don't know, maybe it's here—but I was skeptical that this would accomplish anywhere near its intention. Because my guess is that you've got to have something written about prices or costs or potential shortcomings of the product, you're gonna end up with some document written by the vendors' attorneys that has so many qualifications on it, it's really not gonna be useful to a purchaser. And so I just am very skeptical that putting this information in CHPL has any value at all.

To me, it's a variation of, like, you think about the intended transparency for informed consent, the kind of informed consent, you know, before you have like a surgery or something. I mean, those documents are all written not to really inform the patient, they're written to limit the liability of the provider. The same would be true here—if you put in a transparency and disclosure requirement, it would be written with the intent of limiting the liability of the vendor, and as a result, it's not really gonna be useful as a transparency and disclosure statement.

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

Well, I guess the flip side of that is that some vendors might elect to use a much more transparent sort of approach and make that part of their marketing strategy. I mean, I agree that, practically speaking, what’s actually there is likely to be of limited use, but I still think it’s important to have more transparency.

Anne Pollock – Centers for Disease Control

Hi, this Anne—

Paul Egerman – Businessman/Software Entrepreneur

It may be important to have more transparency, but I also feel like, what does that have to do with certification?

Anne Pollock – Centers for Disease Control

Well, one of the things that I pointed out was, what was really irritating me in the _____ way, there was a lot of _____ did not allow us to really post our problems we were having with an instrument, and _____. It was really frustrating, because when we talked to people from other laboratories using the same product, we found out we were having the same issues, and you had to pay to have augmentation done to the IS system. It was just really a round robin, so I think that there could be things that could encourage certain areas to be more _____. Especially when they are _____ the issues.

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

Okay. Other comments about this?

Mickey McGlynn – Cerner

This is Mickey, and I think it’s in here, I think we discussed it, but a key point is this in the field surveillance, and the point that an implemented, customized system will likely be very different, or has the potential to be very different from the system that was certified, and the only bar against which the vendors can be measured is that which they are certified against. So it’s, this question of, I think it’s in here—what is the unit of measure in the field certification, that could just turn into a very complicated process, and ultimately, it’s gonna have to go back to what is certified.

I think we're in the, you know, implementation best practices learning phase as opposed to surveilling against, you know, an implementation, because there is no, there’s no certification of the implementation against which you're surveilling.

Anne Pollock – Centers for Disease Control

But a question could be, does the nondisclosure agreement encourage interoperability, or discourage? I don't think you want to discourage, but I think you could examine what is in the contracts, at least to say that it encourages transparency where it’s appropriate.

Mickey McGlynn – Cerner

I'm not sure—

Paul Egerman – Businessman/Software Entrepreneur

I don't understand—who's gonna examine these contracts? Is that the certification board, the ACD? I'm confused how certification is gonna get involved with NDAs that are individually negotiated with customers.

Anne Pollock – Centers for Disease Control

That, I'm not sure, because I'm not a legal carrying, but I've been around enough inspections of laboratories to know that you can look at certain contracts and written agreements to make sure that they don't inhibit certain activities, or don't encourage negative activities, but usually put it in a positive statement. If you don't see it as a means of looking at these contracts, I'm disappointed. Because my experience is that they still exist, these nondisclosure agreements, and I can honestly tell you that MAUD right now is the only way that I, as a federal agency, can look to see what problems might be existing with EHR and LIS systems that are of concern for patient safety. It's the only way.

So—and when I talk to people in the field, they still have nondisclosure statements that specifically impede them from making comments on poor performance in certain areas where there's a patient safety issue.

Paul Egerman – Businessman/Software Entrepreneur

So, I hear that as a plot—how does this solve this, that problem? I'm just, I'm just, I'm just curious—I, I, I don't get it. In other words, there's a difference between an outcome and a process. The process here is, that he's advocating, is this broad statement of transparency about costs and about unexpected things that might happen.

Anne Pollock – Centers for Disease Control

Right, we're—

Paul Egerman – Businessman/Software Entrepreneur

How does that relate to the nondisclosure agreement that you just talked about?

Anne Pollock – Centers for Disease Control

Well, how about performance of the EHR with respect to patient safety? Are there any patient safety issues?

Mickey McGlynn – Cerner

I guess. This is Mickey. I feel like there's a whole—I think you have a valid concern. I feel there's a whole other discussion happening on this point with ONC trying to start the safety center, there's various patient safety pilots going on with ECRI that many of the vendors are participating in. So, understanding what is causing safety issues in the HIT realm is in the study phase—lots of activity going on there to understand it and then take corrective action. On the nondisclosures, there's the EHR developer code of conduct that 22 vendors have signed as of today that specifically states all the major vendors that are in the, not—many of the major vendors have signed that says, if they sign the code, they will not have a nondisclosure agreement that precludes discussion on patient safety issues. We're trying to, you know, promote further adoption of that, and we're working with the provider groups to do it.

So I think, I think you're, it's, it's an issue that exists that we're taking a lot of action to address, and that's outside of the certification process, which I think—you know, many think that's where it belongs, including ONC, we work with them on that.

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

Could you go to slide 12? Could you go to slide 12? Because I think that we're just being asked to weigh in about the certification process and, and transparency.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and again, my comment was, I'm skeptical that using certification for this purpose with this process will be effective, because whatever document that we produce by vendors will be written by attorneys in such a general way that, to limit the liability of the vendors just won't, won't advance any of the issues that are trying to be raised. These issues should be raised with some other vehicle.

Anne Pollock – Centers for Disease Control

I understand your point. This is Anne, but I—I guess my remark would only be going back to what was just said about the objectivity. If there is guidance or documents that come out of those groups, then couldn't a subjective criteria be, in the certification process, that there's evidence that those are in place.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and I think all you do there is, you're turning this into, like, a 200 page document that people have got to put through all kinds of, of material. You can own _____ is in place, that doesn't necessarily _____ what this is all about, which is somebody's upset because they got charged a price and they figured the pricing structure doesn't work or somebody's concerned that, gee, there is some customized something that occurred in some laboratory system, but you can't find out what it is, because there's an NDA in place.

I mean, it's just—you know, those are my comments, and rather than argue that, I'm just sort of asking that my comments be somehow included in this appendix, and if people don't think that's important, that's fine; let's just move on.

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

Yeah, so I think there's a way to handle both of these, which is—what I can do is, when we talk about this, is just to underscore that, that a significant fraction of the group feels like certification is not the best way to handle this particular issue, and there was skepticism about the accuracy of any pricing information that was made available through this route.

Paul Egerman – Businessman/Software Entrepreneur

That's what I'm saying—look for the accuracy and the utility of it made available.

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

Yeah, that's a better way to frame it.

Paul Egerman – Businessman/Software Entrepreneur

I mean, I think you could write something that's completely accurate but does not really result in the kinds of disclosure or transparency that people are looking at. I mean, you just say, for example, "Oh, sometimes prices are determined by the set of circumstances that the vendor—that we face as a vendor, in which case, we'll charge market rates on a time and materials basis," and that covers everything. [Laughter] You add two or three sentences and you're out of the woods in terms of the pricing thing.

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

Okay.

George Hernandez – Chief of Applications and Development – ICLOPS

It seems like, for example, as far as, like, marketing calls—for example, someone, there should be, for example, someone could say, "I would like to be on the do not call list," and it should go all the way up the chain from everyone who has access to your name and phone number in whatever databases. And so all these entities may have a disclosure—a nondisclosure agreement, and the only transparency is needed is that, okay, this person has said, "Don't call me," and it should just propagate throughout. So, what is the effect is that that person has achieved greater privacy, and they're not—and the transparency is there just so that they can track this patient for a degree of consent through the, they don't have to—each entity involved does not actually submit all the information, it's just enough information to have an audit trail to achieve the, the greater privacy that the patient was seeking.

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

Okay. Okay, reactions to other, other chunks of this from the first workgroup?

Okay, are we ready to go on to the second workgroup with slide 17?

Mickey McGlynn – Cerner

David, this is Mickey. I just, I'm kind of having to read as I go, here. I don't see the point, on the adaptations and updates to certified health IT, I don't see the point that this is, we discussed it in the workgroup—it's already in place. Today, vendors have to report, providing updates to the ACBs of when they make changes. So it's already done.

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

Well, the first sentence is, "Some workgroup members felt this proposal was redundant and the process is already covered in the existing structures."

Mickey McGlynn – Cerner

But then—then there's all this stuff, it, so even though it's redundant—I guess, can we agree or, if it's redundant, it almost seems like we're saying we're not sure if it is, so how about all these additional things?

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

Well, so—so, some other members of the workgroup did think that this, this principle of proper conduct was a good idea, and those people did not—did not agree with you that this is redundant.

Mickey McGlynn – Cerner

Okay. I don't know, I would just ask that we, in the first say that we ask that the current, the current regulatory language be evaluated and confirmed that, you know, like that it—it's just, these things have a tendency to slip in the regulation, and I would hate to see us have to document, it's already an expensive process. It's just, like, a slightly different version of almost exactly what's required. That's all, just something that says we'd ask for a thorough review of the language to confirm whether all of this is, in fact, already covered. That way it can be done on the rules side as part of our feedback.

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

Yeah, that makes—that's fair.

Mickey McGlynn – Cerner

Okay.

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

Okay. Other things about group one?

Okay, so let's move to group two. There, we've covered safety-enhanced design, summative testing, retesting, the quality management system, accessibility, technology, compatibility, and accessibility-centered design. Things that we should emphasize there?

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

This is Janey. I thought we, like in the last hour on the previous slide, there was the two rows that had safety-enhanced design, I thought that was what you were gonna emphasize from group two.

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

Sure. We—certainly, we'll emphasize that. The question, really, is—is there anything else here that we should emphasize? I mean, it seemed to me, for example, that it might be worth, you know, emphasizing the point about user tasks that miss the rights of standard scenarios and that, that—also the point about the metrics captured at testing, which is a little bit down in the weeds, but it seems like it's an important point.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul. My question about this, on the safety-enhanced design, on page 21, at the bottom, it talks about issues of hardship and, and possible need for exceptions to the above. And that—that's just a concept I don't understand at all as it relates to certification, because that's, like, a totally new concept that the certifying bodies can give exceptions to the criteria, or provide a hardship exception. I'm, I don't—I just don't know where that comes from. I mean, that's, that's even further away than, you know, my goal of objective yes and no. I mean, that's here, which is some subjective justification of some subjective evaluation of a bunch of stuff that's submitted. Now there's, these terms seem to be raising an ability for the certifying bodies to simply waive things for some people—that seems odd.

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

Yeah, so Janey or Bennett? You want to weigh in?

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

Can we—I missed what you're pointing to. Can you tell me what you're pointing to?

Paul Egerman – Businessman/Software Entrepreneur

[Cross talk] Yeah, page 21, or slide 21, it says 21 at the bottom of the slide. There it is. So there, at the bottom, it says, "Issues of hardship and possible need for exception to the above." And so that sort of caused me to pause, because I just didn't understand how, how you can write this piece, certification regulation that we would talk about having an exception to under certain circumstances, and possibly with this thing called a hardship exception is a myth. That exists, again, in the attestation part of meaningful use, but how does that at all fit into certification?

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

Yeah, I mean, I agree that—I just, I totally missed this hardship. I don't see that there is any hardship, and it goes against, like, what Bennett was talking about earlier. We already know that we've heard of different certifying bodies today for meaningful use two holding different standards. And when you say, then trying to justify something back to them today, they said, "Well, you know, that client is bigger, so they can do those things and service different levels of standards."

So I agree that I don't see that there's any issue of hardship that you could lean back on to have things taken away.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and [Cross talk] exception. I mean, I would just rephrase that section. I would simply say, "Examples of how one size"—there's difficulty getting one size to fit everybody for safety-enhanced design regulations, and say, "These are examples as to why it is that you try to design something around a process, and it simply doesn't work for the entire software landscape."

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

But the user-centered design process does work. It doesn't matter how big or small that you are, and that you—

Paul Egerman – Businessman/Software Entrepreneur

I'm sorry, I totally disagree. I just have to tell you that I disagree with that, you know? I mean, I know that's your strong statement, but the examples are given here where not everybody has 15 people to test something, you know? And the 15 people might work [Cross talk]—

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

So, the number 15, I know that everybody keeps coming back to—

Paul Egerman – Businessman/Software Entrepreneur

Okay, okay—so let's do this. I have an opinion, rather than argue it, can my opinion be expressed here as perhaps a minority opinion? I mean, obviously, NIST just strongly believes in this. I believe that this does not work in all situations. Can I have that expressed as a minority opinion?

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

Well, this is Terry Fairbanks, if I can just interject—I would object to putting that on the record, because it's—this is not a religion or a philosophy, and user-centered design is not something that takes a major house of human factors engineers. User-centered design is a method and an approach that any sized group can take with any resources. And so I would object to the idea that, that smaller groups can't do the user-centered designs, and if you did accept that [Cross talk]—

Paul Egerman – Businessman/Software Entrepreneur

That's not what I'm saying. I'm saying smaller groups do not necessarily have to have 15 people test it, and smaller groups do not—and open source software may already be in operation, but you may not have the test data in order to get your certification. And so I'm saying there's some practical advantages to what is being written here. That's what I'm trying to say.

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

Well, I would use that analogy, I would use that analogy in the medical device domain and say that the FDA doesn't say, "Well, if you're a small startup company and you can't test 15 people in your usability studies, we'll go ahead and approve your medical device."

Paul Egerman – Businessman/Software Entrepreneur

But my argument is—

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

You have to decide whether or not this is a safety issue.

Paul Egerman – Businessman/Software Entrepreneur

But my argument is that it's not the same. The medical device is a product, whereas software is frequently a business process. It is possible for a provider to produce software that is used by a single user and has no intention to be used by anybody else.

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

Well, but that's not the case with health IT products that are being sold.

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

Yeah, but they would never need meaningful use certification, then, if there's just one user.

Paul Egerman – Businessman/Software Entrepreneur

Right, so again, I requested that I be able to have a minority position on this, but apparently that's rejected. That's fine. What I'll do is, I'll just report it at the Policy Committee that it was rejected and I'll put in my own comment directly to, you know, ONC and we'll go from there. I guess people have a religious view of safety-enhanced design and they want everybody to use it, they want everybody to record at least 15 people, and they want to record the gender and the age of the tests. I catch all of that stuff, and I catch the idea that you don't, that's the overwhelming majority. Let's move on.

Did we at least get a change that there's no hardship exception? Is that at least acceptable?

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

Yeah, there's no hardship exception. You know—yeah.

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

I think we can—Dr. Bates, you and I can try to clarify this. I think the way this came up from the different comments when I put them together was this disagreement that was there. And I think what this was, was more of an ask, or for clarification. Does that mean that there will be, does it mean that this will happen? So perhaps we can work this so that it's more reflective of what the intent was.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, but the message I got very clearly, though, is my opinion is not gonna be reflected in these notes.

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

No—no, nope. I don't think that you should feel that way at all, because I think we're trying to—

Paul Egerman – Businessman/Software Entrepreneur

Well, I thought I heard that this was a religious view, and the safety-enhanced design is, this is what NIST is saying there has to be 15 people testing it.

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

No, no, no. No, part of it is, what we're trying to do is just make sure that everybody's opinion is represented, and that's why we're going through this exercise. And certainly when you're trying not to create a 200 page document, the way things get truncated can maybe make things look one way or the other—but no, I believe that this was more a point to be raised that, could this lead to something such as this, and is that the comment that we want to make? So it can certainly get reworded.

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

Yeah, and this is Mike Lardieri. I would just like to not use the word customers and users, because a small organization might not have 15 customers, but they should be able to figure out 15 users.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, 15 potential users that meet the right criteria for the use of their product.

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

Okay.

Mickey McGlynn – Cerner

This is Mickey, a separate comment—I felt as if there was, in the discussions that I was in, there was kind of a spirit of the conversation that was saying, if you're using a user-centered design process, there's things that that assumes, such as, you'd be doing formative testing, you'd be doing summative testing, and that there was this question of, should it be formative, should it be summative? That, if you were doing a UCD process, they would all be assumed, so, as opposed to calling out, "You have to document this" or "You have to document that" or "You have to document this or one over the other," that, the fact that you have attested to the fact that you were doing it would cover some of that.

I just, I guess when I read it now, I kind of see this, "Well, they should document this, this, this, this, and this," which yeah, takes a lot of time, effort along the way to do that, and I kind of felt like we said, "Well, it's covered." So I guess I'm a little concerned, the way the language is written about "add this, add that" when, if you've already attested to the fact that you're doing it, it would be assumed that you're doing it. And I do recognize the points that were made that, when people were saying before they didn't do it, or they said they weren't doing it yet, but some of the language suggested they weren't, that there be a streamlined way to do it, but that would mean that the certifiers have to have the experience to look at those reports and know whether, in fact, it's true.

I guess I'm thinking over-documentation isn't the solution to that problem, and that's what I feel like where we landed, which isn't where I thought the conversation went.

George Hernandez – Chief of Applications and Development – ICLOPS

Well, on the issue of a minimum of 15 users, could we change it to—sorry, if the recommendation is at least 15 users, but if you don't, then you need to at least report how many users the product was tested with?

Paul Egerman – Businessman/Software Entrepreneur

No, because then you're gonna get people that are gonna use two, because there's a lot that are, that are certified now that use two vendors, so they can use two participants, and that's never enough.

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

Yeah—and this is Terry. I worry that we're getting a little focused on—user-centered design is not about how many users you test in usability, it's how you integrate information from users into the process, but it's doing it well. And I agree, I agree with what's just been said, that we don't want to encumber—remember that, we talked about early on that there are vendors who are doing this really well yet are very encumbered by the documentation requirements.

But, on the other side of the balance, we have vendors that aren't doing it at all and think that getting a complaint line is user-centered design. And so somehow we have to, to benefit both types of vendors, and that's the dilemma.

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

I mean, maybe saying something like that, because I thought that was very well said, Terry.

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

Yeah, I mean, I would advocate—I know this is late in the process, but we had talked earlier on about having two tracks, and one is that you describe your user-centered design, and if true experts—one of the problems is the HCTs don't necessarily have the expertise in what UCD is. But if true experts in UCD evaluate those and say, "Yes, this organization has a great user-centered design, they've passed the usability piece," and then the others, then they have to go through the more prescribed summative, formative, et cetera, two tracks may be able to satisfy both vendors. But I recognize that it may be late in the process to move towards that.

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

Yeah, we—

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

But I think that—Terry, I think that goes with, like, the spirit of what we were trying to achieve in the discussions that we had, in that one of the things that came out of it is, it couldn't just be to attest to it or just to describe the UCD process, but what would be the appropriate artifacts to provide if you were gonna go down the track that was the more advanced track?

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

Yeah, which would the more advanced track be? Would that be the one where you ask for an exemption or something?

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

Where you describe your UCD process—so, if you were, if you were low in usability maturity, so to speak, then the current process where you provide your summative usability test, that fits really well with someone who's just beginning with a user-centered design process. But once you are one of those groups that are more mature and have a mature process in place, you're still doing formative and summative usability activities as part of your user-centered design active process, but now what, if you were just going to, as part of meeting meaningful use, safety-enhanced design, describe your user-centered design process to provide artifact to go along with that to help the certifying body understand that you're meeting—you know, that you are meeting the process.

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

Go ahead.

Mickey McGlynn – Cerner

I was just gonna say—so, I certainly appreciate that thought behind that, but then I would have to say, you know, again, I work for someone who has an extensive process, and if now the ACBs are gonna employ someone, an expert, it's gonna add cost to the process, and I would, as a vendor, think that would be not something I would be willing to pay when I have a bunch of experts who do—you know what I mean, who already do that.

So my point is not to put the kibosh on the suggestion, it's just that that needs a lot of discussion on how to find the right solution to this real problem, where we have the, kind of what I would say early stage versus more mature.

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

Yeah, this is Terry. The only thing I'd say is, I think actually your type of vendor would benefit from this thing, because after a very brief evaluation, they would be given the stamp saying, "This group does UCD well. We don't need further documentation from them."

Mickey McGlynn – Cerner

Right, it's just talk.

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

At least that was the intent.

Mickey McGlynn – Cerner

Because the ACBs don't have the expertise, so that cause of that evaluation is going to be added to an already very expensive certification process that is now, with this complexity and modularity, is gonna come even—from our view, quite a bit more expensive.

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

Huh. The idea, the idea really is to save—that idea was generated by the vendors. That idea came out of the vendors that had a mature usability process. They said, “Why can’t they just say, you guys have a good usability process and leave us alone?” so to speak, so—

Mickey McGlynn – Cerner

Well, if we can do that, I think that we will do that, [Laughter] but I think that wouldn’t be allowed without some type of external evaluation, right?

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, that’s exactly right. It’s like when you’re taking the SAT for college, you know, it doesn’t matter what kind of preparation you do, it’s the actual score on the test at the end, and that’s what the summative evaluation is like.

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

Right, but the idea that was proposed was to not have a summative for the ones that have good use—and the cost savings would be, then they could take the tremendous resources they’re currently using to do all these summative tests, and they could transfer it back into user-centered design for new products, which—so it is a transfer of where the resources are [Cross talk].

Mickey McGlynn – Cerner

You have to—and that’s a very good point, Terry.

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

So maybe we could say that the group recommended consideration of this alternative approach and that development of it would require some work and so on. Does that—does that sound reasonable?

Mickey McGlynn – Cerner

Could you repeat that, David? I didn’t hear exactly what you said.

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

So what I said was, the group suggested considering an alternative pathway, which would have some of the characteristics that Terry had all just described, but that we recognize that making that work would require some evaluation, and it would have to be set up so that it wasn’t burdensome for vendors.

Mickey McGlynn – Cerner

That works for me.

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

Yeah, this is Terry. That reflects what I was trying to say much better.

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

Great, okay. Other comment son this section? You know, it could be safety-enhanced design, it could be, you know, summative testing, re-testing, quality management systems?

Okay. So, we move, then, into group three, and that is slide—

Mickey McGlynn – Cerner

David, this is just a minor point on group two.

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

Yeah.

Mickey McGlynn – Cerner

I think that two points got blended. One is, there’s specific language recommended for quality management systems, and I think we recommend supporting the proposed language—period, right? That narrows the last sentence in this first paragraph. We also had a lot of discussion about a risk management process that isn’t in the role, right?

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

Okay, so this is on slide 24, now?

Mickey McGlynn – Cerner

Yes.

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

I think—yeah. Can we go back to 24? Okay, so—

Mickey McGlynn – Cerner

So, you know, the four, the regulatory language is four, it’s on this slide, which basically says, “We recommend that any QMS be compliant with a standard,” and I think that the workgroup agreed, supporting the proposed language.

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

Yeah.

Mickey McGlynn – Cerner

Right?

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

Yeah.

Mickey McGlynn – Cerner

Then the first sentence is, we had some presentations early on about a risk management process, but that was not included in the rule.

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

Right, and—and what would you like to see included?

Mickey McGlynn – Cerner

Well, it can’t—it can’t be included in the rule now, because it’s not in there. Right? You can’t add anything that wasn’t in.

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

Right.

Mickey McGlynn – Cerner

So, I think what I am gathering is, someone said, you know, there’s potential in a risk management process, and I think this person is saying it’s appealing, which I have no issue with putting in, but it’s—I think we just want to make sure our point that we recommend supporting the proposed language stands on its own, because it’s unrelated to the risk management processes.

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

Okay, okay.

Mickey McGlynn – Cerner

That’s all.

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

Yeah. Okay. Any other thoughts about that?

Okay, so let’s move into group three, which is at slide 27.

Mickey McGlynn – Cerner

Oh, I’m sorry, I thought this was group three, but this is group two—the accessibility?

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

Yeah.

Mickey McGlynn – Cerner

I guess—I'm not sure, I think that some of the workgroup members supported the proposed language, but then right below it, it lists a number of points why it wasn't supported, so I guess I would just ask for a more diverse response. Some of the workgroup members support it, others have some serious concerns. And we didn't come to consensus on it, but I would say most agreed.

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

Right, and now we're on slide 26.

Mickey McGlynn – Cerner

Twenty five.

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

Twenty five.

Mickey McGlynn – Cerner

Oh, and 26, it's on—[Cross talk] yeah, I didn't see that. So, I think the change we're recommending is, change “most” to “some.” That's all.

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

Okay, okay. Yeah, I think there was a lot of diversity of opinion, I'm starting to tell.

Mickey McGlynn – Cerner

Yeah.

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

Okay, on group three, so there is, there are pharmacogenomics, so part E of certification, modifications, removal of the MU certification requirements, types of practices, types of care and practice settings by EHR definition, the CEHR definition, the ONC certification program, and then reference it, and design and performance.

So, things we should underscore here?

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

So, this is Michelle. My thoughts in looking at this, based on what's already been discussed during the overarching, we didn't address the types of care and practice settings, and there was specific callout information, so my recommendation would be that section would be an add-on, and perhaps some things in the base EHR definition—my two thoughts.

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

Okay, so the base EHR definition I got, can you explain again the first point, just so I make sure I got it?

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

Types of care and practice settings—there was, this section specifically asked for input on some questions around the behavioral health LTPAC sector and others, they wanted information or input on assessment and other priority areas, and so I think the discussion in that section was unique. We haven't seen it anywhere else in our comments.

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

Okay. Okay.

Mickey McGlynn – Cerner

The only thing I would add to that, which I have no, I'm good with that—but I think what I will call this idea of early warning, like, what might be coming, is not well defined. Because the only way that there is to show early warning is to put something in an NPRM, and that—most developers have to start working on things long before the final roll comes out. So I think if we're gonna say the early warning, we need to ask for, that they think hard about how to give an early warning, outside of an NPRM.

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

Okay.

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

True, and that's—I know we touched on it earlier, but here is a specific request for comment on the pharmacogenomics.

Mickey McGlynn – Cerner

Oh yeah, I think it's a very valid point. I'm good with the comment. It's just this, when they think early warning today, my understanding is they think, "Okay, we'll propose it in a rule," but that causes a whole lot of other things. Even though they know it's an early warning, it doesn't—it's not characterized that way. It's just their only way to show it, you know what I'm saying?

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

Yes.

Mickey McGlynn – Cerner

Okay.

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

Yeah, and this is—excuse me—Mike Lardieri. So I just wanted to echo what Michelle was identifying regarding the base EHR definition. We just—I guess it's confusing how privacy and security, is that gonna be embedded in every module, so every module needs to be able to have the privacy and security embedded, and with modules that are, that need to communicate information? Are they gonna be required to communicate by passing a C-CDA or whatever the current form is along with everything else? I think that needs to be clarified.

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

Okay. Good. Okay, and maybe now I'll just ask if there's anybody who has not been vocal on the call who has anything that they want to have underscored? Okay.

Larry, anything that you would like to bring out before we start moving towards public comments?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Uh, nope. I feel actually, in some ways, fortunate I've been in a noisy space. I got to listen to a lot of good discussion. I know there were a couple of hot points, but we can address them all in our final writeup.

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

Yeah, so—yeah, very good discussion today. I just want to thank everybody for, for all the time and effort on this. There's obviously enough things to think about and sufficiently complicated that there are really a lot of issues involved. We will do our very best to represent everybody's perspectives, and that, you know, it would be easier, for example, to represent all of the diversity of opinion in some of the written things than in the oral, but you know, we're gonna do our best to do as well as we can.

Anybody who can is encouraged to listen in tomorrow, and Ellen, anything else you want to hit before we go to public comment?

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

No, I think you guys have said it all.

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

Okay, good. Then, if we could go to public comment, that would be terrific.

Kimberly Wilson – Office of the National Coordinator

Operator, please open the lines.

Public Comment

Operator

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 comments at this time.

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

Okay, good. Well, thank you so—and after this, we'll be able to go back to some of the other issues that we were talking about before we got the NPRM and our attention was fully diverted for a bit, so I look forward to doing that.

So again—thanks. We'll do our best tomorrow, and—

Anne Pollock – Centers for Disease Control

Before you close—this is Anne Pollock—I do have one comment for you. I'm sorry, I joined this group really late, but a lot of the concerns in all three groups have an impact on the end user, the vendor, et cetera, and I went back and looked at the impact analysis for this reg, and I'm just wondering if an overarching comment could be that they need to strengthen the impact analysis itself for the reg.

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

Okay. You were breaking up a little bit at the beginning—which reg are you talking about?

Anne Pollock – Centers for Disease Control

The NPRM as addressing the certification reg—I'm talking about the certification reg and the impact analysis, which is separate from what we were looking at, the regulation statement. But you know, the reg in the beginning has an impact analysis, and I'm just saying that we had some concerns in each workgroup about the impact, so I'm just saying, I went back quickly while in the last discussion, and we're looking at the impact analysis for the regulation itself for the cert.

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

I got you. Now I'm on the right page. Okay, so we can add a statement about that.

Anne Pollock – Centers for Disease Control

I think they need to strengthen it, yeah.

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

Yeah. Okay, okay—good. Thank you, all, and we will be in touch.

Anne Pollock – Centers for Disease Control

Thank you, bye bye.

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

Bye bye.

Female

Bye bye.

Male

Bye, everybody.