

**HIT Policy Committee
FDASIA Workgroup
Transcript
August 1, 2013**

Presentation

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thank you. Good afternoon everybody, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy FDASIA Workgroup. This is a public call and there will be time for public comment. The meeting is being transcribed, so please remember to state your name when speaking. I'll now take roll. David Bates?

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

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Anna McCollister-Slipp? Anura Fernando?

Anura S. Fernando. MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Elisabeth George? Esther Dyson? Geoff Clapp? Jackie McCarthy?

Jackie McCarthy – Director of Wireless Internet Development – CTIA: The Wireless Association

Good morning.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Jared Quoyeser? Jeffrey Jacques? Jonathan Potter? Joseph Smith? Julian Goldman?

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Keith Larsen? Lauren Fifield?

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

Morning, here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thank you Lauren. Martin Sepulveda?

Martin J. Sepulveda, MD, MPH, FACP – Fellow & Vice President of Research – IBM Corporation
(Indiscernible)

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Can you say it again for me?

Martin J. Sepulveda, MD, MPH, FACP – Fellow & Vice President of Research – IBM Corporation
It's Sepulveda.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thank you. Mary Anne Leach? Mary Mastenbrook? Meg Marshall?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Meghan Dierks? Michael Swiernik? Mike Flis?

Michael Flis – Regulatory Affairs Director – Roche Diagnostics
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Patty Brennan?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Richard Eaton?

Richard M. Eaton, JD – Director, Industry Programs – Medical Imaging & Technology Alliance
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Robert Jarrin?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Drew Hickerson?

T. Drew Hickerson, JD – Assistant General Counsel & Senior Director, Business Development – Happtique, Inc.

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Todd Cooper? Mohit Kaushal?

Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association
Good morning.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Paul Tang?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Bradley Thompson? Jodi Daniel? Matt Quinn? Bakul Patel?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Are there any FDA staff members on the line? Are there any other ONC staff members on the line?

Simon Choi, PhD – Senior Science Health Advisor – Food and Drug Administration

This is Simon Choi, FDA.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

And this is Anna McCollister-Slipp I just joined as well.

Martin J. Sepulveda, MD, MPH, FACP – Fellow & Vice President of Research – IBM Corporation

Hi, Martin Sepulveda, I just joined as well.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thank you. Are there any ONC staff members on the line?

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator

Mike Lipinski.

Elise Anthony – Senior Policy Advisor, Meaningful Use – Office of the National Coordinator

Elise Anthony.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Anyone else that we missed?

Esther Dyson – Founder – Edventure Holdings, Inc.

Esther Dyson.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

All right, thank you. With that, I'll turn it over to you David.

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

Great. Well thank you. Lots of work has been done since we went over this – these last, and I think the slide set is greatly improved, although it's still not perfect. So things that have been done since last time, I went through and added many, but not all, of the notes back, tried to include in particular ones that were clarifying. Sometimes the notes were quite lengthy and it was clear that they will not all get presented, so those are many of the – that I have truncated. To help with clarification, I've asked the subgroup chairs to write up two pagers to supplement this work, and that will be done over the next couple of weeks, it won't be done by the Policy Committee meeting time and the aim will be to expand or clarify issues that would benefit from clarification. We've gotten the feedback around a number of things that some of the references are a bit telegraphic and some expansion might be helpful. Some of this could include some of the notes that people generated already, but were not included in the presentation. And the aim is with these two pagers, to share them first within the workgroups and then with the entire group.

In addition, since I sent out the initial draft of slides, a number of materials from the Risk Subgroup have been added in, and you'll note that the size of the presentation has changed from fairly small to now 10 megabits, so it got substantially larger. I'll note that suggestions, which are really specific about how to make the slides better, will be easiest to implement. I made a big effort to try and include all the suggestions, but I got a lot of suggestions after last round, and if I have missed someone's suggestion, I apologize, I did my level best to go through them all, but I got enough that I'm not confident that I got every last one. If I didn't, it was not intentional. And additional – we can make additional minor additions.

Furthermore, I got a set of additional specific suggestions and corrections from our federal colleagues late yesterday. Some of those are big picture, which we will talk about today, others I'll just implement as they either correct errors or inaccuracies. Please do note that the slides have been renumbered because we moved some, as were suggested, we added some and there was one duplicate. The plan today – my plan today is to start with the conclusion section, because we didn't get a chance to go through those on the last call because we ran out of time. And I do want to just note again that this will not be the last chance to refine these, we're going to be getting feedback from the Policy Committee, we'll have the opportunity to make additional refinements. Bakul, is there anything else that you would like to note about the overall process and where we are?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

No, I think you covered it all, David. Patty was asking me before everybody joined, the clarification on two-pager and I was basically saying that this is an opportunity for folks who are not on the sub-working groups to either provide input into the other working groups work material. Or if there are things that are missed in the overall big presentation, or if people have other thoughts and ideas, this is a way to capture them, so, everybody's heard and everything is – most everything relevant is documented.

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

Great. Okay. Other general questions before we start in? Okay. So if we could, could we go to slide 47, which is the overall summary.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

David this is Brad Thompson, a word of approach. You've got, I don't know, 50 slides or so and you have I think 45 minutes. How are you going to calibrate your oral presentation to the written one, because it would appear that we have far more here than you can get through in the time allotted?

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

Yeah. Well I talk reasonably rapidly, but I will be focusing on the materials that are written on the slides. There are several of the slides that we're probably going to end up hiding, or moving to a subsidiary deck, because a number of them came in last night. There are some from the risk area that we probably won't show. So, I may end up truncating things, but I will work it out so that I hit the 45-minute mark on the nose. Okay. So, thoughts or comments about 47, 48 or 49.

Richard M. Eaton, JD – Director, Industry Programs – Medical Imaging & Technology Alliance

This is Rich. Maybe this is just semantical, but on the second bullet, it says have proposed a risk framework, which may be useful in considering whether or not regulation is needed. I thought what we're really doing is providing recommendations with respect to develop –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

– also not just whether it's needed, but what kind of regulation would be relevant.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories

This is Anura Fernando. On bullet four, would it be useful to add and maintain patient safety?

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

Sorry, I couldn't hear the last bit.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories

Would it be helpful to add there, and maintain patient safety?

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

Yeah, I think that would be reasonable. Okay.

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

On slide – on the same slide, bullet four, I'd really like it if you can put the word current in somewhere. Have described what we believe will be helpful to promote innovation currently or current in there somewhere.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Why currently?

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

At least for the slides that we have for FDA, we have mechanisms that can provide immediate relief to innovation and that's not really factored in the overall summary and I think it should be.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Forgive me, I still don't understand the point you're making.

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

So in other words, if you go to one of the slides towards the beginning, which is under the FDA portion, its slide number 33, we talk about current FDA program mechanisms that could enable innovation. And these are recommendations of what the agency can do currently, presently to be able to enable innovators to get their products out to market quicker, especially for lowest risk and lower risk HIT.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

But don't we also want to consider the long-term?

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

We do want to consider long-term, but there's nothing in there about current mechanisms or current ways to enable innovation. It's almost as if that we're only talking about the longer term processes.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Maybe –

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

Should we say something like maybe in both the short and long-term or something like that?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Yes, exactly. Thank you.

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

Sure, that would be great.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Because current – if you add currently, it limits it and I think what you're trying to do is make sure it considers both.

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

Correct. Correct. Both is very important, I just – the way that it reads it reads as though we're only talking about the longer term regulatory solutions and I think it really needs to be both. Thanks.

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

Okay.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I have – Julian Goldman here. I have two comments on slide 49.

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

Great.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

The first comment is, in the first bullet, the fourth check mark that says higher risk software use cases including those where the intended use makes the software risky. I think that needs to be reworded a little bit because the software isn't risky as much as the use of the software is risky. And I don't think that needs to be wordsmithed right now, I'm sure there are folks who can do an excellent job, but I propose that that be reworded so that it's technically more accurate.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul Tang, I'm not sure I – I think we've just – we've mentioned that there are two risks, risk can be introduced by the way the software's designed or written, and it can also be – risk can be introduced by the way it's implemented and used. So I get your point about its more than just the software itself, but clearly, the software has a role in it – in the design of the software.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Yes, yes, yes. But ultimately, it's the use of the software in a given setting that makes the – that introduces the risk.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Well, let me just give a boundary case. So let's pretend software was written right-left reversed from the way that people normally write it, everything's in the lower right corner instead of the upper left, where people typically look when you read. That would be a design that would highly encourage risky behavior, would you agree.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

It would be – so.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

This is Lauren Fifield. I think this was just, I remember this from last week. I think it was a wording issue that the word risky didn't feel like it had been anything that we'd used and it felt a little bit odd. I think we were suggesting things like including where those were the intended use introduces higher risk or increases the risk profile to high risk or something like that.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Now were you focused on "intended use" or were you – I guess the point I'm making is, clearly software design has a – is a significant component in its – in introducing risk to patient safety.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Paul, this is Bakul. Can I – I think you're saying that not only the situation where the software is used and the intended use of the software, but also the making of the software –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Correct.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

– and I'm using very colloquial – so if I were to wordsmith this, I would just leave it at high-risk software use cases and then not use the word software risky, because I think that may be the trip point.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Yup.

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

So if we – would that be okay with everybody?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

This is Patty; I think that's a great solution.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Having brought up the point, I'm certainly satisfied with that.

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

Okay.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

And the second point I wanted to make is in the first part of the second bullet where it says, "vendors should be required to list products which are considered to represent at least some risk, if a non-burdensome approach can be identified for doing so." So in reading this it implies that vendors would not have to list products, which represent a risk, if a non-burdensome approach cannot be identified. So if we're unable to find a non-burdensome approach and burdensome and non-burdensome are open to interpretation, then vendors would not have to be required to list products. And I don't think that's the intent here, I think the intent we want is that we want a non-burdensome approach to make it easier for vendors to list products, which represent at least some risk.

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

So would you feel more comfortable with saying something like vendors should be required to list products which – let's see –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Or maybe list products in a non-burdensome way.

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

Can you just do "and," and a non-burdensome approach can be identified to doing so?

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I would say that the other way around, I think, which is that, what we're recommending is that a non-burdensome approach needs to be available –

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

Yeah.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– to make it easier for vendors to list products which represent only some risk, because that's our recommendation.

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

Make it two sentences?

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I think it could be one, the recommendation of our group is that a non-burdensome approach needs to be developed, so it's a non-burdensome approach needs to be available so that vendors will be – such that vendors – it will be easier for vendors to list products which are considered to represent at least some risk.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Maybe it's just the "if," that – the vendors should be listed using a non- – employing a non-burdensome approach.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Exactly.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

A non-burdensome – yes.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

It's the "if" that is the problem, the if –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Yeah.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Yeah, so the onus is on us – the administration, to come up with a non-burdensome approach but the recommendation is that everybody's listed so we know who's doing what.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Exactly. The conditional "if" is the problem and I agree with what you said.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

And also, – this is Lauren Fifield. It might be worth, in the commentary, I don't know if it's worth introduction into the actual slide, but commenting that as expenses for this things grow, you risk shutting out entrepreneurs, so non-burdensome I hope also includes cost.

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

Yes, definitely.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program n Medical Device Interoperability, CIMIT, Massachusetts General Hospital

It's – I agree with the point you're making, but it's, I think, a different point that the fact that the sentence has a conditional "if" which undermines the strength of the recommendation.

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

Gotcha.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

Oh definitely, I agree with you on the conditional. I was just adding.

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

Yup.

Richard M. Eaton, JD – Director, Industry Programs – Medical Imaging & Technology Alliance

A few questions, this is Rich Eaton. Under the check marks, that one bullet for the regulated software, it would be important for the FDA to improve the regulatory system, I know these are overall recommendations, but that sounds extremely open-ended. I don't know what that statement really means or could mean. And a similar type of question with regard to the second dash, better post-market surveillance of HIT is needed, including post-implementation testing. Again, extremely open ended and while conceptually I'm not opposed necessarily to that concept, it's just so open ended that it really depends – it could be extremely burdensome or not burdensome very much, or, it's just so wide open it's kind of hard to understand what we're asking them to consider.

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

So those are both good instances in which we can provide specific examples. There already are specific examples for the first one, but there are not for the second one, but those can be added. We probably don't want to add them right here, because these are our overall recommendations, but –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Right, I think to David's point, this is Bakul, I think this may be a perfect item to clarify either in the companion document or –

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

Yeah, but that's a good suggestion Rich.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

This is Lauren Fifield. I guess I just want to say, as we were going through all this David, thank you for incorporating all the feedback. This is a monster of a PowerPoint, so, I appreciate it and I am really glad to hear that we are now working on a companion document for exactly the two bullet points on this slide that have been pointed out. And a lot of other areas where it's just nearly impossible to fit in the complexity of thought, the difference of opinions, the range of ideas and sort of clarifying things like this that can be so open-ended. I know there's a large group of us that are equally supportive, so I just wanted to say, for the record, that for a group of us that have been sort of concerned about not really being able to represent well all of our ideas in a PowerPoint, I'm really supportive of any sort of supplementary material.

And then on the second bullet, better post-market surveillance, I also wonder if there's something to be put for better post-market surveillance and something along the lines of aggregation and analysis of data. Because I think that's one of the key things that may be part of post-market surveillance but is the one that matters the most in terms of yielding results from such surveillance and also could have the biggest cost impact on any or many agencies. Since the standardization and creation of formats needs to be created for reporting health IT events, that that data needs to be analyzed after it's been aggregated, feedback needs to be given. So, I don't know if there is any way to characterize that as well, or if that's just for the supplement.

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

Take a look at the next bullet, which is intended to relate to that.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

Sorry, then maybe there putting something about standard formatting –

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

Yeah.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

– health IT specific standard formatting. Sorry, you'll have to forgive me for – it's early.

Richard M. Eaton, JD – Director, Industry Programs – Medical Imaging & Technology Alliance

David, Rich Eaton again, with regard to the points I just mentioned, is there going to be any mention made, either on the slides, either a notation on the slides or in the presentation or both, that qualifying those two statements in examples in a companion document or something? I was just wondering if – it wouldn't have to be extremely wordy in this document, but probably should be recognized that these statements are going to be – need to be qualified.

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

Yeah, I mean for the first one, we do have – we have a lot of details already, and we'll add an example for the second one.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

David, this is Paul Tang. I wonder if we mi – if we agree, and it does sound like these bullets echo what the IOM Committee came up with, if we do agree with it, certainly there's a lot more detail there and they had the benefit of working for 18 months on something that we're trying to do in a very short period of time. But to the extent we agree, that could actually be both reinforcing and clarifying, to refer to something else that's been described more thoroughly.

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

Yeah, that's a good comment. I think we can and should do that. Okay, are we ready to go back to the taxonomy area? If people have other comments about this later – actually, before we go to tax – so let's go to slide 6, if that's okay. So slide 6 is – it relates to the backdrop and as per people's feedback here, I strengthened the statement here and tried to make it clear. I think we have a pretty strong consensus that HIT is clearly beneficial; we have these anecdotes though about new risk. And then in the next slide – go to the next one – these are examples of problems, and as was requested, added references for each of these, added more specifics. I swapped one out for one that was – the one that has a very specific reference. So, how do people feel about this at this point?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

David its Patty, I continue to be concerned that this slide really speaks to clinical information systems only.

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

I think you sent me another example and I just forgot to include it.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

I mean, if the intent is to restrict that way, I can be in support of that, but it was my –

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

No, I think we should...I think you’re correct and I just forgot to do it –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Okay.

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

– and we should have another example.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Yeah, it was a – I forget whether it was a blood glucometer or something, but it was just to make sure that the committee doesn’t see HIT as EHR.

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

Right.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Julian Goldman here. I agree, I think we had some other examples that really strengthened the understanding that health IT includes the communication between medical devices and EHRs. And a kind of functionality is essential, but unavailable today in part because of the problems we’re trying to address through this regulatory framework.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Paul, this is Patty. Could I ask you to comment whether there’s a way we could make sure the committee gets that we’re speaking about something broader than EHRs?

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

Yup, so Julian, if you want to send me another example, that would be good to include.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Okay. I think some of the – I think you had more examples, I’m trying to remember the small ones, but the document that you had posted Dave, to the website on – the one pager –

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

Yeah.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– also had a few very good examples and they were –

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

Yeah. So last time people asked me to only include things here that had references, and –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Ah, okay.

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

– so that’s what I did. So I would need one that has a reference –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Got it, I’ll have some for you during this phone call, some more, and then you can decide how to use that.

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

Great.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul Tang. One, I think the backdrop does a really nice job of saying, hey look, here's things that are benefitted by HIT, here's the possible – so anyway, I think that was a very nice framing. I'm a little concerned that on slide 7 that it leads off with something where it certainly was in the published literature, it's been critical of that particular study. It does show a lot of what's done – what can be done that's not the software itself – well actually – at any rate, it may be a ta – it may be easy to take that study out of context and that's my only concern. And I agree with Patty about its nicer to have a broad representation of HIT. But I wonder if there are ways to point out how there's literature that talks about the different areas in the software development, implementation and use, where problems can arise, and that's why it's a complex issue actually.

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

Sure. So it was almost certainly in that first instance an implementation issue –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Yeah.

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

– and the same system was implemented in a couple of other institutions and there were no such increases. And what I'll do in the presentation is say that, actually all these issues have been addressed. But the issue is, they often are addressed only in a few places, and there's the risk that people repeat these same mistakes. So the first one was an implementation issue. In the second one, hospitals which got these – did the flight simulator, then did better subsequently, but if you don't do something like the flight simulator, probably many places will continue to let orders like that sneak through. For the third one, there's a very clear strategy to – , which has been demonstrated to work, to help prevent that problem. Again, it may or may not be that widely implemented. So, that's part of the reason for picking these examples.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Um hmm. One comment on the first one, which a lot has to do with implementation, but one could also argue that after that – after hearing about the experience of that one hospital, people developed work around to software-induced risk to make it safer to use. So interestingly, it is an interaction, even that one example. But at any rate, it's just to illustrate the complexity of all this.

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

Okay. Can we move on to slide – the taxonomy slides, to slide 8. And let me just note here, I have so many different documents open – okay, so the – our federal colleagues asked about this, they found it confusing to say what's in scope or out of scope. Does the group mean for the workgroup consideration or that regulatory oversight is not needed at all. Patty, do you want to comment about that?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

This is a tough one to get clear on, so be patient with me. This is Patty. Our use of in scope versus out of scope was a way of designating whether a particular entity, a software package, a decision support tool, a device, was subject to the risk-based regulation. And there could be devices, software applications, that had exceptionally low risk, but they were still subject to the risk-based regulations and the designation would put them in the low risk category. There was no attempt to say, in scope – I'm sorry, to say out of scope meant low risk, out of scope meant should not be considered under the risk-based regulatory structure. That's it.

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

So is that –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Is that – and so, it's open for discussion, but I just wanted to make sure I was clear about what we were thinking. If Meghan's on the phone now, she may want to add into that.

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

Right, or –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

So this is Brad Thompson, maybe I can just ask a couple of questions, it'll help me understand. I mean, first we have to figure it out, then we have to express it in the best way. So if something was in scope, does that automatically mean that it should be somehow subjected to A), I'm not saying whether it's FDA, ONC or whatever, but a regulatory requirement? If it's in scope, is it – does that necessarily mean that it would be regulated in some manner?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

That is consistent, yes.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul. Interesting, I didn't interpret what you said meant that – I thought it was in scope for us to be covered by the framework, you could apply the framework that we're recommending to that and come up with an answer to the question you raised Brad. That is, is it useful to regulate this or not; but that it did not say, all things that are being discussed should be regulated one way or another. I had always assumed Patty that's what you meant, but –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Well, I guess I'm getting a little bit confused again. I think – what are you hearing I'm saying different from that because I guess I thought both of you said the same thing.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay, I think what we're sayin – what you guys said was this is the scope of the discussion. We would try to recommend – provide input to developing a framework that would help you decide the answer to Brad's question, what should I do from a regulatory point of view for everything that is within scope? It does not mean that everything within scope should be regulated. Did I catch the nuance of what you asked Brad?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Um, so I – I mean, this goes back to the example Paul. I can clearly see that we don't want to regulate Verizon's networks, but we may place in scope a direct – for the sake of argument, I hope this doesn't confuse it, a Direct Message Center of a Verizon network, guiding a decision action. And it may be, because it's advising on a – it's a very clear statement going to a known user, no difficulty in interpretation, it might not require regulation, but the clinical application is in scope, the Verizon network is not in scope, the clinical application is deemed did not require regulation, but it still went through the consideration process.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I think that's consistent with my interpretation. Yeah.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

So – this is Brad. So up until this point, and I'm having to rethink my understanding, but up until this point, I thought we all were sort of holding hands saying that what the Taxonomy Group was doing was helping the rest of the working group describe or define what the working group should consider for purposes of making recommendations. So, it was the front-end of the funnel that – it was that group guiding the rest of us on what we should analyze for making regulatory recommendations. Not that, if it was in scope that necessarily meant that it should ultimately be regulated by someone, somehow. Because those are two different things, right, I mean one is an internal process, one is defining so that the committee can function, what the committee should consider over the course of the last two months. The other being a recommendation to say, look, all of this has to get regulated somehow, now we need to talk about a tiered, risk-based regulatory approach that places high regulation on high risk and low regulation on low risk. Those are very different things, and I'm just trying to understand, A) what the taxonomy committee or working group intended. But then obviously we all have to ultimately agree on what's recommended by the whole group.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Yes, I concur with the last statement. I, and speaking for the Taxonomy Group, if there are members on board that have a different understanding, please speak up. It was always my understanding that our work extended far beyond the scope of this 90 days of activity, but in fact was designed to recommend a structure that would allow a regulatory group to figure out whether a particular entity should be considered – should be evaluated under a risk-based framework. And it's possible that regulatory body would deem the entity, the software or the decision tool, as being exempt or not needing any further regulation, but that the consideration of that would happen. And so I think it's a question of where we're drawing the line.

And the two things that you said that are different than mine, one was that I believe we were doing more than simply explaining to the other two workgroups what they should be thinking. But rather we were actually adding our guidance regarding a set of indicators that would help a developer, a vendor or a regulatory body know whether an entity should be subject to consideration under the risk-based framework. And second, I believe that it's possible that you could evaluate something under the risk-based regulatory framework and deem it not needing any further evidence or being of low risk or whatever the phrase is that the risk group was using. So just because it was considered by the risk-based framework didn't mean it was risky.

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

Right. So that's correct. Meg, you were on the group, any other thoughts?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yeah, thank you David. So it's interesting that we're at this stage of the game and still confused about the scope of the Taxonomy Workgroup. And I have to admit that it was my interpretation that we were guiding, as Brad had mentioned and I sat in on some of the regulatory sub-workgroups where Meghan sat in and kind of clarified and defined that point that while – from an overall perspective, I mean obviously we captured defining characteristics of what should be included in HIT. The primary purpose of that was to hand that off to the Risk and Innovation Subgroup and the Regulatory Workgroup to try to have them clarify their individual pieces within that. So –

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

This is Steve from ONC and perhaps myself and Bakul might be able to help straighten this out a little bit. I mean I think from our perspective, ultimately the work that you all are doing now will tee up the work that we need to do in drafting a report, which includes a proposed strategy and risk-based regulatory – recommendations for a risk-based regulatory framework. So the output, at least I think from my perspective of what I would be looking for that would help us would be what the agencies report should focus on, from a scope perspective, relative to health IT and not on what or how or whether something should be regulated.

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

Right. And so what the Taxonomy Group has proposed is a framework for kind of – for getting to that process.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

This is Lauren Fifield. I think there's some confusion, because in our first, I guess and only, in-person meeting, we had a lengthy discussion about the Taxonomy Workgroup and what was meant by in versus out of scope. And at that time, in scope wasn't that it should, in fact – whatever was in scope should be regulated, it was rather that it was something that we should consider. And it sounds a little bit like that that sort of – that paradigm remains the same, but the who should consider has expanded beyond our workgroup to the agencies or whomever else. Is that a fair characterization, because Brad isn't crazy, I remember having a discussion about very specifically that in and out didn't mean in regulation, out of regulation.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

It's Paul. Just sort of trying to act as an observer, I think we are all widely in agreement, including Patty, and it's only one of our initial responses to the question that was confusing. But I think we truly are widely in agreement and that it hasn't changed from the beginning.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

I agree Paul, and this is Bakul.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

I agree with that too Paul.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

And maybe it's just the words and what each person is using, and I know it sinks in much better for me in what Steve just mentioned is, is it in consideration, and I think Lauren used this word, too. Is it in consideration for other groups? So, I'll give you a little other – a slightly different perspective. So further down the slides, in the summary of recommendations, a word is used, health IT should be handled this way. I think, at least from the federal perspective, we're looking for, what does that mean when the recommendation says health IT should be considered this way. We're trying to find a link for what does that mean, does that mean that – so I'll give you a very concrete example. On slide 10, it makes a lot more sense to say, you guys have considered all this stuff in scope as part of this discussion. And it sort of makes low – a little odd for me, at least from my thinking perspective is the third bullet from the bottom it says, disease severity scoring algorithms are not considered – were not considered as part of the discussion.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Which slide are you speaking from Bakul, please? It's not on the screen – oh, there we go.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Slide 10, out of scope. Yeah, so there are things that – there are some inconsistencies that make me think we need to be very clear, either it was part of the consideration of the whole workgroup, that's what we call in scope and maybe that's the word we should use, either workgroup charge or workgroup consideration.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Well Bakul, this is Meg Marshall. I think that the confusion lies is that there was never really an official handoff. So the Taxonomy Group didn't hand this over to the Risk and Innovation Group and the Risk and Innovation Group took this and said, okay, now how are we going to apply this to our matrix and how is this going to guide our discussions. It's kind of the same issue with the Regulatory Group. So, I'm not sure that that is a true statement that these weren't considered as part of the discussion within the other subgroups. So, if there's a way that we could kind of express that this was not necessarily – that – I think that the greatest value from the work that the Taxonomy Group did was to define the boundaries of HIT. And maybe not necessarily to highlight this out of scope type – these out of scope examples, because as you clearly mention there, some of these were actually discussed in the other workgroups and may, based on those discussions, actually fall within scope, based on the risk scoring mechanism.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yes.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So I'm not sure if it would be valuable to maybe take that entire right hand side of the column out and then just change in scope to possible examples or something like that. But I agree that there wasn't – this wasn't exactly a process that you could see was followed in the subsequent workgroup discussions.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Ah, I see.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And this is Paul. To follow on a little bit, when we did have that discussion, I think Meg was presenting it or Meghan was presenting it, for example, population management tools was one that was acknowledged as to hey, we had some difficulty classifying this. But I think Meg might actually be having a good suggestion to – because we didn't come to closure on that.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

So here's a list from my thought process. I'm seeing the Taxonomy Group drew a box around what is health IT and we can discuss whether it was – or not, and in parallel, because we are short of time, in parallel the Risk and Innovation Group and the Regulations Group took that initial step from Taxonomy Group from the May meeting. And further discussed how things should work or the risk and innovation and regulation, and they may have found a few things that the initial box may need to be changed, and I think that's really what Meg is pointing out, or were considered as part of sort of the discussion. We have two options, we can flag those things that were not initially part of the initial box that the Taxonomy Group had created. Or adjust the box to include the things that the Risk and Innovation Group and the Regulations Group thought about to include as part of scope of the workgroup and thought – or otherwise thought they should not be included in the scope.

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

To further that thought, from my notes from the face-to-face meeting, this is Jarrin from Qualcomm. One of the things that I think was discussed was the idea of creating two concentric circles, the first circle being what is within scope and then the next smaller circle being what should be regulated that's within the scope.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yeah.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

The concentric circles make sense to me. I do think that we're – it would be helpful for someone to try to identify where there's really disagreement, because I'm really hearing more agreement and some concern about a small boundary condition, but maybe I'm misunderstanding this discussion still.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

I think the challenge is how to represent the output of the workgroup and how it influenced the other groups. And I think the natural tendency, based on the wording of these slides, is to apply that to the overall regulatory framework. And so I do agree that I think we're all in agreement that we need to make sure that that does not come across. So whether we use the term in scope, out of scope or however that should be changed, that that really reflects the taxonomy's value in directing the subgroups and that it was not intended to influence what may or may not be ultimately part of the framework itself. And I think once we kind of take that – put that lens on as we view these, and make the appropriate changes, I think the rest of this will fall into place.

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

Okay. So why don't I work with Patty and Meghan to do that, and we – there have been significant changes in some of the other parts and I want to spend some time on those. How about if we move on to –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Sounds like a good idea.

Anura S. Fernando, MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories

This is Anura Fernando, could I raise one more concern that crosses between slide 8 and slide 10? So on slide 8, we use the term functionality, and then on slide 10, in the out of scope area, we still have – many of the things that are described there are applications, with the exception of the out of scope bullet 4, where we talk about general purpose communication tools. The last time I brought up an example of a paging system, for example, being used to convey medical device alarms. So the term functionality, if you look at it from the perspective of general-purpose communication tools, functionality could be paging capability or email functionality; however, it's the intended use of that application to convey a medical device alarm that could make it in scope. And so, I think the use of the term functionality as opposed to something like intended use, could lead to some level of confusion there. And then also, mixing general-purpose communication tools that could be used for multiple applications as out of scope among many other specific applications could also pose future problems.

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

So how would you suggest resolving that?

Anura S. Fernando, MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories

So one option might be to replace the term functionality in slide 8 with intended use and then in slide 10, replacing general purpose communication tools with general purpose communication applications, maybe specifying that there may be applications using those tools that would still fall under the in scope heading.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

This is Patty. I'm a little bit concerned about the first recommendation because we have intended use as one of the defining characteristics.

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

Yeah I think that would make it circular.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Yeah.

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

I think we could do the second thing.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

I think the second one makes a lot of sense and if you can think of a – if the word functionality is causing more problems, then we should come up with a different word there. But in the Taxonomy Group's discussion, and again, others on the phone please weigh in, the intended use was what the developer or designer of the entity expressly stated as the use plan, as opposed to what somebody actually did with it. We saw functionality as being an integration of these different characteristics, what can the end user do with this rather than – rather what did the designer believe it was established for.

Anura S. Fernando, MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories

So would application then work in lieu of functionality, or something related to application?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

I think that it might, if I can ask to have that discussion with Meghan and Dave as we prepare our two-pager, I would be willing to take that forward.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Well Patty I think it's important, I think it does raise a good point, because we use the term innovation, functionality, use, application, tool. So I agree that there's some work that needs to be done, and it would probably affect the rest of the slides throughout. So maybe if there's a caveat or a definition that we've used to justify the selection of a particular word, perhaps we could designate that as such, an asterisk or footnote or something just so that we understand the distinction between the intended use of each word.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Sure. I think that makes sense and it certainly seems that this, as we were thinking – as I was thinking about putting our two-pager together, that this is a hot, hot, hot word and it may, in the end, end up in a different expression, the word functionality. And I think that we could probably find a better word. We may find challenges with each word. Are you suggesting we select a – try to put a vocabulary together right now or just work on the two-pager and get it back out to the group?

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

Let's do it offline because there's a lot more that we want to go through. Let's move on to slide 12. Paul, do you want to say a few words about what's changed since last time?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Sure. In this one, the only addition – so last time you might recall that there was a complexity – dangling complexity word, I could not find and didn't get anybody suggest what the IEC might have as a definition. So I left that off because actually complexity of different kinds were defined later on in the document and appear later on in the slides. What I did add, and I made a mistake because it's not in IEC thing, is added a definition, so just a basic definition of transparency, because that is something that's described as one of the dimensions for risk, and this definition came out as a summary of our discussion we just had yesterday. So it's just to make clear what are things we're expecting developers to be transparent about, and it will appear later on in the risk framework. So that's the only thing that changed on this slide. And if you want to advance then to slide 16, or at least whatever comes after 15, the first colored matrix...

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

If I – Julian Goldman, let me just interject that we were also missing – we discussed the term for hazardous situation, I did email a definition for that this morning so that that could be added if desired. I think it's an important definition.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay, so I'll look at that, I didn't get anything this morning.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

No, not yet, right.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

So that came from IEC?

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Yeah, it's an ISO IEC definition.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay, let me look at that. So the thing that's changed in this colored matrix are a couple of things. One is, and this is in response to Julian's suggestion about risk, so in the second blue row, instead of likelihood of risky situation, it's likelihood of hazardous situation, and the same appears in the medium risk. And the other thing I changed, based on Anna's comment yesterday, was 100,000 patient year, now these are still fairly arbitrary, but it did seem like when I said 100,000 patient years, that might have been at least one order of magnitude off, so I just adjusted that one order of magnitude.

The next series of slides, of which David may just choose one or a couple, but show what we discussed yesterday – if you just move to the next slide please. And that is to go through a series of six use cases that try to span the gamut of kinds of things. One showing it's not just EHR, it's more broadly HIT and showing the gamut between something that people widely agree are low risk – lower risk and chances are should not be regulated, to things that are pretty hard to think about and deserve more attention. So as one exemplar, this one is for mHealth nutritional application, as a standalone kind of an application. You basically enter, it may be UPC code, the food item you're describing, it spits out what's the nutritional content in the way that's described by USDA. And it could, when you configure it to say, I have diabetes, provide you with some information that says, oh, what's this food item – how would you assess the value of this food item considering your health condition.

So if you go through and you go, what's the purpose of the software, well, it's information only. It's clear, they describe exactly how you would use this. The intended user is someone – either consumer or someone with diabetes, but they are knowledgeable about the implications of food items to their diabetes. The severity of injury, very low probability of harm, it's just informational. Likelihood of hazardous situation arising, very rare, less than 1 per 10,000 patient years. The transparency, the software output is easy to understand, it's calculation, what is it doing with what database, it could be the USDA database, is clear. The ability to mitigate is clear because it's not forcing food down your throat, it's basically giving information to the human intermediary that decides whether or not to use it and how to use it.

The complexity's pretty low, the application's fairly mature, the USDA guidelines have been around for a long time. The complexity of the build, like saying I have diabetes or I have hypertension or heart failure, is straightforward. The complexity of the training is very, very low, way less than an hour. It's not – it's a standalone product, not interfaced to other things and its network connectivity is – it's actually not even – it uses cell technology to access the USDA database. And by the way, I made that application up, just as a way to think through this. So, let's go to the next –

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

Paul?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Yes.

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

Hi, this is Jarrin. I hate to bring this up, and I can bring this up offline if you'd like to, but the last line on network connectivity standards and security, I've been kind of battling with this for a while, because I realize that we're trying to make it fit to what's more a medical framework –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Right.

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

– as opposed to you know where we're coming from a communications framework. But it's really not accurate to say that it's tightly controlled wireless spectrum compliant with standards are either less risky or more risky than other types. For example, you have unregulated spectrum, all spectrum is actually regulated in this country, so right off the bat that's inaccurate. So there are things that I could – I'd like to propose to you, –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I see.

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

– but we don't need to get into a conversation about this now.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Somebody told me Blue Tooth was in an unregulated spectrum –

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

It's unlicensed, it's unlicensed but that doesn't mean it's not regulated.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

So, yeah, please help me offline. Please. I can use all the help I can on that one.

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

No problem.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

And, I need to add – I would like to add something to that, Julian Goldman here. I've also asked some of our experts within our hospital system, networking and wireless experts, and their eyes were drawn to this line as well with the statement that, Wi-Fi compliant with standards can have issues, especially in dense environments. WMTS licensed spectrum can be interfered with and "there was an example recently of a cellular system in Australia being disrupted by a beer cooler." And this message to me concluded with, "risk of wireless networks need to be assessed based upon the criticality of the medical device or system, not the characteristics of the wireless protocol. Interference can occur with anything."

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

So just ple – yeah, I'm very open to this, I took this – somebody gave me this, but I'm completely educable.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

All right, I think the point that we discussed on some of the previous meetings applies to this, which is, the labeling of the columns as low, medium and high risk I don't think is really the intent, even though those are the words. What these are really describing is the ability to assess risk, that the things all the way on the right, it can be more difficult to assess the risk. Black box might be hard to assess, the closed loop might be hard to assess. All of those things might be harder to assess, but they still may be very low risk. So –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Julian –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– that would be, I think, the way it's being described. Go ahead.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

What I did in response to your comments before, is if you look in the upper right hand corner, the column's labeled higher risk/greater attention, and I think that captures what you just said. In some cases –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

(Indiscernible)

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

– it is higher risk, it certainly has the potential for higher risk and maybe the – a way to think of it is that you'd want to spend greater attention.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

This is Todd Cooper, I just want to say, I agree with Julian's point there a hundred percent. And as I said many times before, using the word risk, which has a very precise definition, part of which you've included in the materials, as opposed to the ability to assess, I think it just – those of us who look at the word risk and then try to understand these columns, it always sends us off into the weeds.

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

The word is – for the wireless world, our word is usually reliability, and I'm not sure if that's something that could be factored into this.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

And Paul, just to continue with your comment about the right most column saying greater attention, but it applies to all the columns, because the things that say lower risk, may not be low risk, it may just be easy to assess the risk. They may be very high risk.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Absolutely.

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

I think perhaps the best way to assess this is – to address this is in some other slide by making a couple of these points.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I would agree with that. I also think that it's really important, this has come up so frequently that this slide is – to folks who are used to thinking about risk, as Todd said, and especially people familiar with submitting things to the FDA, doing a hazard analysis. This is a new use of the words and an imprecise one that is very difficult to apply and understand. But I would recommend some additional subtle modifications to this table, as well as some type of supporting or explanatory slide.

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

So let's keep going.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay. Could you go to the next slide please, and one more please. So here's an example, again, I made up this product, this is an implantable insulin pump attached to an implanted continuous glucose monitor from which it gets signals and you program the pump using an external command module to react to the glucose sensed output and generate a baseline insulin dose that's being continuously infused into this person with diabetes. With that kind – it is – it's this combination of the glucose sensor, the pump and the external command module, which obviously communicates in a wireless fashion, and submits the data up to an EHR and PHR is the system.

So if I go through this same logic going through the left column dimensions, I had this draft thought with these yellows where I'd indicate some of these – where I'd classify some of these dimensions. And you can see, it looks a lot different from that nutritional mHealth app. And all it does now, this is how you use the tool to think about this application or whatever word we're coming up with, and what its potential risk or hazard is from a public safety point of view. Go to the next slide please. And here's an EHR, and what you see right away is the right hand – in the lower half yellow is in the area – that green area, is where the user has a lot of customization or configuration or build. And that illustrates the point that it's not only the product, but it's the way that it is built or customized and used that does contribute to the risk of potential harm to an individual, in this case a patient.

As I went through this process, as I said, I did this for six different exemplars of different types, what became clear is that there are types of applications that are easy to fill this out in, and there's a lot less of it depends. Actually, go to the next slide, and there are two more slides to advance, too. One more, and one more. So I covered CDS, I covered PHR, so the observations – sometimes it's quite easy to classify these applications as lower risk, and by the way, it's not an absolute low or absolute high, it's lower and higher. Those apply to the standalone, they're very narrowly defined functions, less variability in context of use, and that's an important attribute that we discussed in our call yesterday. So that sort of typifies a class of applications.

On the other hand, you find that software that's more complex, it's harder to classify in a precise way. There are so many times when you'd use the phrase "it depends." What does it depend on? A lot – it depends on the context of use. There's more complex – the more complex software is harder to develop, it's harder to QA, there's greater effort and expertise required to implement it, the build function. There are more interfaces to other systems and you'd have to rely – there's a greater reliance on the process of developing it, managing it and controlling for predictable failure rates with risk controls. So you can see how it's almost impossible to prospectively prescribe a way – an algorithm for saying, oh this does cross this bright line or does not. Next slide please.

So in a sense, going through the exercise revealed for me one, it's useful to go through and make sure you methodically go through, in a sense, a checklist of things to consider as you look at this application. And see is there a way to define a bright line or at least clear criteria for software that really shouldn't be regulated in the sense that we know now, but may need to have transparent labeling so that one, it's clear to everybody what's the intent, who should use it, with what qualifications, for what purpose. And, by the way that it would be then bound by FTC regulatory authority about what your declaration of its use is and how you are accountable for that. There's a defined – you'd want to – could you define a bright line or at least clear criteria for software that warrants regulation on the other extreme, or at least greater attention, if you're going to do anything on a case by case.

And is there this big middle ground where, as we've talked before certainly in the context of the Regulation Subgroup discussions, that there should be a learning situation, have a robust surveillance mechanism where you track adverse events and near misses. Again, like the airline industry for the majority of the software that lie in between where we could potentially draw a bright line, probably easier to draw a bright line for things that should not be regulated. And less easy, but still probably necessary to say, hey, when you fulfill – when you cross one of these thresholds in this set of criteria, then you do need – you will face some regulatory oversight. But in the large majority, we've got to – we're in a learning situation yet, and there's some regulatory discretion. That's – I'm trying to describe for you the experience I had in using the risk attributes to go through different exemplars and trying to come up with some findings, if not some draft recommendations. Open for other members of the subgroup to discuss or the full committee workgroup.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin, Madison

Paul, I found this very helpful as an illustration. Is your assessment that we've got something that is workable?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I think so in the ways that are listed in this slide. Probably – we can probably draw a bright line and that would provide regulatory clarity, which is one of the things that’s been asked – vendors ask and asked of us. For the left side, the lower risk, let’s just – let’s have a clear label and maybe the “regulation” is labeling, because I think that’s so important, it’ll be so important to our surveillance function, for example. And we probably can, it’s a little harder to do, but can define things that are clearly “should be looked at by regulatory agencies,” but our main message, and as I say, this is consistent with the Regulatory Subgroup, is we need to put in place something where we can learn. Right now we don’t face a learning situation, we have the obstacles to sharing and we don’t have the central repository, we don’t have the central investigation and we don’t have this mechanism for sharing lessons learned broadly. Because everybody’s relearning, and unfortunately, going through the same exposure to harm. There are a number of things that could come out of this exercise, actually.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Hi, this is Anna. I’ve been more silent probably than usual this morning, but I wanted to say I think this is really helpful. And I think this kind of robust surveillance mechanism where you have the ability for people to either, and I keep saying, doing a rating system or some sort of online feedback mechanism where the community is contributing information would be very helpful for patients as well. Because it would give – nobody expects a device to be absolutely perfect, but we do want to know where the bugs are and the more people that are creating clear – are providing clear feedback into what bugs they find and when, would be very helpful in helping to shape expectations about technology and what to be aware of.

Esther Dyson – Founder – Edventure Holdings, Inc.

Yeah, this is Esther. It’s sort of like lightweight post-market surveillance, if that’s a possible concept.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

It’s sort of crowd-sourcing post-market surveillance, which I think is – I mean that’s what’s worked so brilliantly in things like iTunes and with the App Store or some of the other places. We can’t just say, here’s all this data FDA, go analyze it, but we’re only going to give you a budget of \$25 a year. This gives everybody who’s invested in a process the ability to provide feedback, not – these are people who will be using the product and –

W

Here, here.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

What’s interesting is we do not have any of these three currently, and that’s I think the problem to solve.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, exactly.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

So, we can’t do good or har – watch out for harm.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Right.

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

Okay –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

This is Bakul. I – just a request. Esther, you mentioned lightweight post-market. So when, I'm just thinking forward now, when we see this in the report and we are starting to work on implement – designing a framework, the question would automatically come to me, what does that mean? I mean, what were you thinking when you said lightweight, is reporting just too burdensome, or just making it easy physically or stuff like that. So, I guess my point is, we don't need to answer that here, but in the two-pager or the companion document, when people use terms like that, it would be useful for us as the feds to sort of understand the thinking that went into it.

Esther Dyson – Founder – Edventure Holdings, Inc.

Okay. Well, if I can build on what Anna just said, something more like a transparent, publically acceptable place where people can report their experiences. And you can obviously provide some kind of gateway so that they need to have a product registration number or something, so that you don't have all kinds of crazy people just making stuff up and posting it. They need to be in some form or another, a registered user of the software, that's the vendor providing that gateway. But then they need to make the data, not the identity of the users, publically available so that other people can see it, and then if there's a safety issue, obviously the feds would have the ability to communicate directly with that consumer. And of course, I hope the company would be doing that already.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yeah.

Esther Dyson – Founder – Edventure Holdings, Inc.

But something like – where it's public, but protected and vetted and open for comments and open for other people to see.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

And that's exactly what I was looking for.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission

This is Matt from FCC. One of the – I think one of the differentiators is that this is consumer sourced rather than healthcare sourced, and so a mechanism that requires somebody to submit an AHRQ format to a PSO isn't relevant for consumers, and so thinking about the full array of health IT, including consumer products.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I don't think this necessarily – I don't necessarily think this needs to be limited to consumers or outpatient uses. I mean, I could see this being helpful for user forum. I mean user forums are incredibly helpful, regardless – within the technology industry. So, I mean, have something analogous in the EHR world, all doctors like to complain about their EHR, so maybe there are certain tweaks that could be helpful that hospital CIOs could use, and I don't run hospital technology groups. But, I think it would be helpful regardless of the application, to have it public and have it available for people, to Esther's point, have some sort of registration so that you have to be a real user, not just somebody dissing somebody's product.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

It's helpful to have Lauren speak this way, because this goes back to the IOM Committee report as well. Probably one of the things that has gotten most in the way of this are some vendor contractual requirements that you not share screen shots. And it has gotten in the way of everything from training, it's interesting, we're going through an upgrade now, and we can't actually publish little videos to help people learn to use the software, because of that restriction. And clearly gets in the way of either improving the design or improving patient safety. And as I say, this is something that –

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

Just to clarify, Lauren wasn't speaking, I don't know who that was.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

That was me that was Anna.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Oh, sorry. Okay.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I think people confuse the two of us.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.

Yeah, and I'm Practice Fusion and Lauren is very supportive of posting as many training materials as possible, in support of good implementation and use of health IT for the record.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Good, although misattributed, it's supported. But anyway, that was on one of David's summary slides, it was an IOM recommendation and it goes directly to this and it makes it lower cost. But right now there's a real inhibition.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Let me remind – Julian Goldman here. Let me remind everyone that on July 3, we had a session on event reporting paradigms, and that recording and the slide deck are on Health IT Policy Committee website, the FDASIA subgroup website. And I know a lot of folks were not on that call because it was right before a holiday weekend, but a lot of these – some of the folks who just talked were on the call and a lot of these ideas are recorded and documented in the slide set. So Bakul, when you're looking for other information about this, I would recommend that you look at that presentation and the recording to catch some of the discussion of things that weren't mentioned during this phone call.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Great. Thanks.

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

Great. So, terrific discussion. Let's move on to 25 to 39, if that's okay. These are the Regulations slides.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

David, this is Brad Thompson, I wonder if you might be willing to just sort of highlight any changes you made. I went through them and didn't see a whole lot of change, but if there are ones you could flag for us, it might facilitate discussion.

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

Sure. So I have not made any changes either. I did get a couple of minor suggestions to make some changes about – from our federal colleagues, but they're mostly clarifications about things. So there's really nothing of major substance.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I have a que – this is Paul Tang. I just have a question on this use of the word risk again. So this – it has Class I-III and it goes risk, low, medium, high. To me it's understandable, does the same objection that people had about the term risk apply to this too?

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

This is what the FDA is doing right now.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Right, but it seems like the way we've used risk is the same – it's in the same spirit. Yes of course a Class III item could still be – could still perform well and do better than the human, but it does have the risk potential. I mean, that's how I'm reading this and I would say that the use of the word risk in the matrix is similar.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

This is – Paul, this is Bakul.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Yeah.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

I think I would say the risk is similar, I think the thinking is there, but you have to also put in the context that the current framework addresses everything, implantables and software, right.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Right.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

So, keep that in mind, because that – I mean this slide only specifically says this is our current paradigm and this is a framework that exists today, and I think what you have done in your group and the presentation that you have, is sort of taken software as a special subset and sort of stratified that.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Right. I'm just thinking that the word risk is used in the same way, and it's not – it's actually not judgmental.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I think the difference here is we're talking about the risk of the totality of the device and its use.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And in the matrix, how's it different?

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Because in this case you could have something with – that has complex software, things that fall into the rightmost column in the matrix could still fall here into low risk, it depends upon how they're being used, the use environment and a number of other factors. You could also have something that in the matrix is in the left-most column, which ends up here being a Class II at a much higher risk, because of the nature of how it's used. So the use environments and other characteristics ultimately determine the risk. So the frequency or likelihood of occurrence of the problem, the use environment and essentially the intended use go into the recipe that determines ultimately this risk.

So it's not inherently whether the software is complex or not, or closed loop or black box or any of those things that drops it into any of these categories. That's why we were focusing on separating the hazard, the hazardous situation, the likelihood of occurrence and including those in ultimately determining the risk, because that's how it's done in the standard approach used by the FDA and other risk assessment methodologies. Todd is very experienced in this, and I know others are on the call too, and if I misspoke or if you'd like to add anything that answers the question.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Bakul, is that consistent with the way the FDA does this? So, the intended use would change it from one class to another versus risk of the device.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Ah, it does, yes. So some of it does depend on the intended use and the functionality of a device, so that's why when you were trying to correlate the low, medium, high for health IT to here, I don't think it's a 1:1 correlation –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

– for low, medium, high, and that's something that we should keep in mind is all I was saying.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Because high, when you say high, it does not relate – because we – one other clause that the software does not do is body structure function modification, which is part of our law as well, that becomes a greater risk, compared to something that does not do a body structure function modification, if that makes any sense.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

But you can have a calculator that almost has the same –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yes.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– algorithms that is used to calculate say something like body mass index. We may have something that's not terribly more complicated that's used to calculate radiation dose –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Right.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– and the calculating program, the algorithms and almost everything else is vir – could be identical –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yeah.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– but one of them if there's an error will kill someone, and the other is probab – may or may not, or you could calculate BMI and other numbers and use that for chemotherapy or you could use it for a weight loss program. Those are intended use differences –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yeah.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– and use environment differences, and also the training of the personnel, and again, not to – what Bakul is –

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

That's right Julian. So Paul, you have captured that nuance that Julian just mentioned in your scenarios –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I think it's captured and I'm beginning to understand it's more how its labeled.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Yeah, the intended use essentially.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yes. Yeah – you can't –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I'm sorry, what my – I didn't mean the FDA label, I meant the labels in the column – the column label. That's what I mean. Yeah. Sorry, yeah.

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

Let me –

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

– and other loaded words –

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

Let me just bring up a specific thing about slide 38. There was a question as to – on this slide, what was the intent around computer-aided diagnostics. Slide 38 right now says that – says FDA shouldn't subject – HIT shouldn't be subject to FDA premarket requirements and what it – what do you – where does CAD fit in, because that's been regulated for a long time.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

CAD – right, CAD would normally be considered a form of CDS, it's clinical decision support, it's computer aided diagnosis, which should typically be considered in that second column, high risk CDS.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Why is CDS in fact called out separately versus any other kind of soft – yeah? What's special about CDS?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

I'm not sure anything's special about it. What we were doing was sort of turning the definition upside down and saying, rather than trying to say what all should be regulated, we were trying to say, what shouldn't be regulated and the only way to do that was by subtraction. So we just went through the FDA categories of existing regulation and subtracted them out from what – from the scope of this section. So it's just listed one among four of things that needed to be taken out of the definition.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

So I guess I'm trying to figure out what is special about something labeled clinical decision support. So is Julian's calculator for radiation doses, is that a CDS?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

Yeah, so that's a great question and that is precisely, if we go back several slides, I lost track of what the number is, but one of the early slides in this regulatory section is that FDA needs to answer that question of defining what CDS is. And they, in September of 2011, started on an initiative in that regard, they had a hearing on it and have had discussions on it and so forth, so that needs to come to conclusion at some point in order to answer that question.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

The one example, if I were to map this question over to the matrix, in the high risk/more attention cell we listed provides diagnosis or treatment advice. Would that be something approaching what you mean by CDS or high risk CDS?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

It would, it's not very specific –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Right, but that's the – what you meant.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

– it's in the right ballpark.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

David, I was just going to raise an issue I think we talked about on our last call, which is, somehow organizing this regulatory content, which is really the second half of the presentation. And I think what I had suggested earlier was putting it maybe into two buckets, near term improvements and longer term improvements, but whatever the two buckets or whatever the structure, I think the second half of the presentation would benefit from some structure. Just somehow giving the audience a better understanding of how each of these recommendations relates to the others. I think the work of the Innovation Workgroup really focused more on longer-term objectives, I don't want to put words in their mouth, but that was how I read it, where a lot of what the Regulations Group came up with were more specific and immediate things, like eliminating specific duplication or ambiguity. So, I don't know if there's some way you can do that, but somehow I think the organization needs to be improved.

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

Okay. Yeah, I think – I agree and I can certainly say that, but I'll add something to – just to make it clearer.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

David, this is Keith Larsen. Just to another organizational issue. Last time what we talked about, and what you did in here is, we said that rather than go through each one of the three – each of the regulations with a regulatory view and then do it again with innovation impact view, we were going to try to mix them up. And I see the innovation slides have been moved up, but we're going from FDA to ONC down and then repeating – going through it with the regulatory slides. Did we want to mix those up and essentially say here's the regulatory view, here's the innovation view on each one of those and just integrate the slides a little differently. Just a suggestion.

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

Um, we could do that. I can see pros and cons of doing that. I'm inclined maybe – maybe not to just for – because it may make things complicated down the road. But, so let's just keep moving if that's okay.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Okay.

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

And move on to the next set of slides, which I think are 42 – starts with 40 anyway, 40 and the next several. Keith, do you want to describe – you made a few changes, do you want to just describe what's different?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Yeah. Actually, the discussions yesterday made changes to slides 26 and 27, 28 up above, when we're talking about the different regulatory frameworks and their impact on innovation. And then I added that subtitle, the Innovation Impact Review to distinguish it from the Regulator Review. When we get down to slide 40, nothing was changed there or that – where we got the other change was really in slide 44 now, which had to do with again, like Brad was saying, these longer term issues. There was – 43 talks about the national accountability, what we expect the national – to do at a national level, but one of the holes that we had in our discussion last time with the full group was brought up yesterday in our small group, which is, so what about all the implementation? And because again, even as you look at Paul's slides, one – and what we've talked about is that the context of use and how the software's set up is in many cases almost as important as the development of the software tool itself. And so where the national focus is really on regulation of manufacturing. We also talked about what do you do with implementation.

And so slide 44 was really talking about – I mean it does have some content change in that what we're talking about is what do you do with this configuration and implementation of software. And the suggestion there was to do more of a locally owned process with local accountability, but with some oversight. And in this case it was the idea that you accredit a process and one of the discussions was about using like JCAHO that accredits different processes already in healthcare settings, but that you're not really making this – you're not sending the reports nationally, up to a national center, you're really designing, documenting and proving a local control system. Thoughts?

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

Yeah. So I guess I might – I find it personally a little hard to think about how the Joint Commission would do this, and I might make it just a little more conditional, like perhaps like an entity – through an entity like the Joint Commission. I don't know what others who have to do implementations think.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

I don't think it's necessary – we weren't saying that Joint Commission had to do it, it was the idea – I think the principle is that, and I was giving an experience of what we've been doing internally. When the FDA started talking about regulation of medical software as a medical device, one of the things that we were trying to set up was...or to show is that you could regulate it or manage it locally with a local accountability. In other words, set up a process of review and a process of just a process of how you, in our case, develop and implement software. But if it was a different medical center that is consuming vended software, how do you set up a process in order to review and test and prove your implementation. Because as we looked at the early on slide, many of the reported problems had been in the realm of implementation and so how do you do that without creating – how do you create the oversight without creating a burden of national regulation, and that's what we were trying to approach here.

And so it was really this idea that you have a review of the process, that it's a locally developed process with local control and accountability. And then the other part is, how do you give oversight to that, and one of the suggestions was using an organization like JCAHO, but that's not a firm recommendation, just said that you have to have some accountability that this is taking place.

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

Okay. And one other thing that's not mentioned here is some post-implementation testing, an example would be doing a test at the end to make – to see whether or not you have the right – the key decision support elements in place.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

It's a little bit on – you mean before you implement or after you implement?

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

No, after you implement.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Yeah, that was that last bullet, the feedback and results collection and analysis –

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

Okay.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

– probably could be wordsmithed a little bit, but that's – since we're using the word surveillance, it might be best to repeat it there, rather than feedback.

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

Okay.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And what about national learning though, how – should we include some kind of reporting so that information can be aggregated shared more broadly?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Yeah, I think that that would add to it, too. Because again, you would want these – you want to encourage that there is a sharing of lessons learned and even implementation stories that help other people and that's – so I think those two changes could be made.

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

Okay.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison’

Can you clarify a little bit about what was just recommended, the idea of sharing stories? Is this as part of a larger, sort of set of examples of post-implementation reports that could be made?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Yeah. Again, as we talked about and what Bakul asked, what do we mean by lightweight. I think part of what was the discussion in the session that Julian referred to is the idea that the reporting system now is more for patient safety incidences and it's more of – it's a big deal to file one of those. Where what we're saying with the national surveillance is that we talked about having it lightweight in the sense that the impedance to file a report is less, because the use of the report is not only to define incidences of patient safety risk, but also share information. And so in this case, it's really saying that we're generating a lot of information at the user level and that the information should be shared up in a repository so that people can get the benefit of those experiences.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Okay. Thank you. I just wanted the – it sounded a bit unwieldy and a different kind of a reporting structure, but you're not suggesting that would be the only post-market kind of reporting.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

No.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Okay, that's great.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And Keith, would that recommendation then go into the national accountability versus just local?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Well, I think a local part of the process should be to report experiences to the national, but the national is – the local, again, everyone has some kind of local information. And we've talked about how vendors have a tremendous amount of information about how their products are used and what are the experiences of their users and what their users expect for enhancements and everything else. And what we're asking the national – to do on the national level was really to organize – have a way first to lower the barrier to assuring that information by expanding the use of the information, the transparency of information, but really to organize that, because that can only be done at a national level. But then the local accountability is to contribute to that.

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

Okay. And it seems to me like slide 43 then should include something about aggregation of national – the safety issues at a national level.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Yeah. Yeah, okay, I can add that.

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

I can – yeah, I can do that.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Okay.

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

Okay. Other thoughts or comments about these slides?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

David, the only – the comment I have – this is Patty, is a little more of a Meta comment. But I think we need to be encouraged to be careful about the titles, because we're talking about taxonomies and frameworks and structures and I think that – and we want to try to limit the vocabulary, so that in the report to the HIT Policy Committee, that they see, as I see these are three components of a framework. That there may be a different kind of a wording, but somehow we want to make sure that they're understanding these three components are linked together.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

That may be a follow on to that, so –

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

Well, somebody just – you're saying three, so there's national and local, I –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Oh no, no, I'm sorry. I meant taxonomy, risk, regulation and –

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

All right, got you, got you, okay.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And maybe sort of related to that, it's not clear to me, because this is an amalgam of multiple slide decks, that there's clear recommendations from the FDASIA Workgroup per se. So not quite sure how to interpret the difference in the overall summary, the – what was just called summary of recommendations for a new framework, etcetera. I'm sure that's –

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

Um, so, I mean, the last three slides are intended to summarize what the FDASIA Workgroup overall is suggesting.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay.

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

So, the first slide says what we did, and I think it does that reasonably succinctly, and then the next two are intended to summarize what we're actually suggesting. And if you think that there are other things that should be there or if there are things that should not be there, we should talk about them.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Maybe re-label slides, what Keith just went over, because it says summary of recommendations, so that's where some of the confusion is.

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

Well the – it says summary of recommendations for a new framework, and that's the recommendations about the new framework.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

So is that in your overall summary though?

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

No. But part of – in the overall summary, one of the things that we did was to suggest a new framework, and that is in there.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

That's on slide 48.

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

Yeah.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

You mean the last bullet?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Yeah.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I see. So the second bullet says risk and frameworks, is that what –

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

Which slide are you on?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Slide 48, bullet two.

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

It looks to me like something got –

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

Yeah, something –

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

– corrupted here. I'll reword that one.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Yeah, okay.

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

Okay. Any other thoughts? So, over the next week, I'll be making the additional changes that we've identified today, which will basically be refinements. We'll then get some feedback from the Policy Committee, the subgroups can be working on the text, which will hopefully provide some additional detail and kind of fill out the – fill in the blanks and then help the agencies down the road in figuring out what we meant by our recommendations.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

David, this is Meg Marshall. Could you just talk a little about that process? So it sounded initially like the chairs were going to draft the two-pager –

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

Yes.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

– what's the time frame and so on?

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

Yeah, so the – we've asked to get them back by I believe it's August 12, I don't have that document open. And so what that means is they'll need to work on drafting those in the near term. I haven't heard back from everybody to sort out what their vacation schedules are and so forth, I know Brad is on vacation now, so I really appreciate his being on the call. So they will develop the initial draft that'll be shared then with the subgroup and then the intent is for us to be able to review each of these as a larger group, because things that come out from this group have to be products of the overall group. So that will happen over the next couple of weeks. Any of the subgroup heads, do you have questions or things you want to ask about this?

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

David, I haven't gotten a chance to talk to Meghan yet, but I think we should be able to get the draft to you in time.

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

Okay. Great.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

This is Patty.

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

Paul or Keith, any comments?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

So the August 12 then, that's when we start sharing with the full group, so we need to do the draft and then share it with the subgroup before August 12?

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

Yes.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And I can do that for my section.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

I'm good with that, too.

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

Yup. Brad and Julian?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So this is Meg again. Just a general comment, some of us have been sitting in on other subgroups, so perhaps it might be beneficial to expand that to outside of the membership. I, for one, would be interested in participating in reviewing other workgroups, as well as Taxonomy. So my general request is just that, and I again am appreciative of everyone's vacation time, etcetera, but if we could have more than a day before August 12 as a subgroup to review, that would be hugely beneficial, maybe three or four days would be great, if it's possible.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Okay.

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

Sure. Brad and Julian, any comments?

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

I don't see any inherent problem, but Brad and I haven't had a chance to chat about it, given the fact that he's traveling, but I think sharing it – I don't see any barrier to sharing the information, as needed. More input is better.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC

This is Brad, I'll just need to figure out some evening time when I can try and help.

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

Great. Okay. Well, once again, thank you all. I think at this point what we'll do is open up – open things up to public comment.

Public Comment

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Operator, can you please open the lines?

Ashley Griffin – Management Assistant – Altarum Institute

If you are on the phone and would like to make a public comment, please press *1 at this time. 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. We have no public comment at this time.

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

Okay. Well I just, once again, want to thank everybody. We are now into August, which does end up being a busy vacation time, and appreciate all the input. I feel like the product continues to get better and we will be in touch. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare

Thank you David.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison

Thanks David.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital

Thank you. Bye.

Public Comment Submitted During the Meeting

1. Regarding the bullet point on 'Vendors should be required to list products which are considered to represent at least some risk, will the aspects of the software that confer the risk be specified?