

**HIT Policy Committee
FDASIA Workgroup
Transcript
July 26, 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. Please remember that this meeting is being transcribed, so when speaking, please announce your name. I'll now go through the 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

AnnaMcCollister-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?

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare

Here.

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

Esther Dyson? Geoff Clapp? Jackie McCarthy? Jared Quoyeser? Jeffrey Jacques? Jonathan Potter? Joseph Smith?

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health

Hi.

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

Julian Goldman?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian Goldman's here.

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

Keith Larsen?

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

Here.

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

Lauren Fifield?

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

Lauren's 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

Sepulveda, here.

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

Sorry. 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?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Good morning.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Here.

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

Michael Swiernik?

Michael Swiernik, MD – Chief Executive Officer and Founder – MobileHealthRx, Inc.

Here.

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

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 – National Program Director, Project Health Design – University of Wisconsin at 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?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Good morning.

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

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

Hi Paul. Bradley Thompson?

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

Here.

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

Jodi Daniel?

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Here.

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

Matthew Quinn?

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

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
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 other ONC staff members on the line?

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

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
There are the other FDA members also on the line.

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you. Any other FDA members?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Okay. With that, I'll hand it over to you David.

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

Thanks very much Michelle. And thanks so much to everyone for all their hard work in putting together these recommendations. The workgroups have really put in a lot of time and effort and obviously this is coming out of everybody's summer. The plan for today is to spend the bulk of the time discussing people's reaction to the overall report and then we're going to reserve some time at the end to go through the public commentary that we've received. I'll very briefly summarize a few of the comments when we do that, but we'll spend most of the time discussing the comments, and it's a really good set of public comments.

I want to note that these recommendations should be considered preliminary, we're very much looking for feedback and refinement and can't really make major additions at this point, but we could make lots of corrections, subtractions and clarifications. I've tried hard to put forward things which the whole group or nearly the whole group agreed about, and as you'll see, the bulk of this really comes from the subgroup's work, which has been intended to reflect a consensus process. Going forward it will be really usable to have your specific suggestions around changes in language. Many of you have a lot of experience in the regulatory and legal world, and it's important in these worlds to use the right words. If you have changes like that, please just send them to me and I'll try and work them in.

Now going forward, the plan is that I'll present these to the HIT Policy Committee on the 7th. The Policy Committee has previously been briefed about FDASIA; it includes multiple stakeholders, as does this group, representing a broad range of perspectives. We now know what the schedule is, I'll have about 45 minutes to present and 45 minutes of discussion, so the current length of the deck is about right although we could, if we need to, fit in a few more slides. Obviously it's been a huge challenge to condense all the work that we've done into this timeframe, both from the perspective of presenting what all our thoughts are, but also it's just been hard getting the work done as fast as we needed to do it. And a number of you individually and some groups have expressed concerns about that. And I apologize for the speed with which we've had to do this, but this is the task that we were given and we've had – we just had to accomplish it.

We can include some slides as background material, and we'll almost certainly do that. After August 7th, the Policy Committee will give us feedback, which we'll then address before the final report. We do have another discussion of the full committee meeting, which is scheduled on August 1st, which we will follow much the same sort of process that we have today. But I think people will have had a chance to digest things even further, we'll make as many refinements as we can between now and then, to try and get it as close to where we want it as possible. I do want to note again that we've not been asked to produce a full framework ourselves, that is going to be done by the agencies, but we've been asked to identify the key issues that a framework should address. And I think we've done really a nice job on reflecting on things and identifying what some of the key issues are.

Now, the way that I structured our report was to provide a brief introduction, which I think is reasonably self-explanatory, led with the suggestions of the Taxonomy Subgroup regarding what should be considered in and out. Some of the material that the taxonomy group put together will probably end up in the background area, just because of space reasons. Then we'll go through the recommendations of the Risk Subgroup and some of their material also will go in the background area. Then the Regulation Group and then the Innovation part of the Risk Subgroup, as they proposed some outlines of a potential new framework, and it seemed like that was just the place that this fit best. And then we'll wrap up. So that's sort of a short summary. Let me just stop there and take some questions before we start to go through the report itself.

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

David, this is Patty. I just want to commend you on putting together a very concise document from lots of input, and I know we'll have lots of conversation today, but it was very, very nice to read through it.

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

Well thanks so much. Well, why don't we jump in to the actual report? Lots of people have – I know have thoughts about specific parts of this. Let me just start with the introduction, which is I think goes through slide 7. Any comments or concerns about that? One that Elisabeth George already shared with me is that on slide 7, we just give examples of problems, and I think I'll start the slide by just making a qualifying statement that we believe that HIT is beneficial in the aggregate. That really comes through on the slide before, but this slide is examples of problems that have been found with HIT.

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

David, this is Meg Marshall. So for example, your – we look like there are specific use cases and examples and maybe – a little bit closer, this would be apparent, but do you cite the references for these?

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

I do not and that would be a reasonable thing to add.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian Goldman here. David, there are – I did find a few references from the document that was posted on the website that you had posted on exemplars. And I have a document that I can send you with a few links to published standards. It isn't for all of those that you have, but I did find a few.

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

Great. So – yeah, so that's a good example of something that we can put in.

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

David, this is Brad Thompson. I have a process question; I should have asked this at the outset. I was scanning through the document and I didn't see the notes in the note section of the PowerPoint. In the Regulatory Group we used notes, I thought they did in the Innovation Group as well, are you going to include those notes and make them part of the final document?

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

They – both your group and the Innovation's Group did include notes, and I elected to take those out. In some places they – there were issues just in terms of matching them with the – with what's in the text itself. And it seemed like it would be less complicated not to include all the notes. That being said, there's a lot of useful material in the notes and – but in the interest of time, I elected to take those out. The sort of thing that I'd like to include in the notes would be references or website citations, that kind of thing, so that someone can get to.

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

Well here's my concern, and we had quite a bit of discussion in the Regulatory Subgroup about this. We didn't quite know how to write the PowerPoint to make it meaningful. Normally when you create PowerPoint, you put words on the slide and then that's meant to just sort of augment what you say orally. And so we were struggling because we didn't want to write full sentences and everything on the slides so much, so we thought we'd put the descriptive full sentences into the notes. And then that way, whoever's reading this report, even if they don't have you in the room giving the oral report, they can get a sense of what it means. And so as I look through a lot of the document, people used proper PowerPoint, the problem is, without the accompanying oral words, it's not very meaningful. So, I'm – when you put all of the work together that difference in writing style comes out. There are some places where we use full sentences and explain things, other places where we use traditional PowerPoint style and just a few words. So it makes it very difficult to read or to understand what the report is without having a person or live human being to ask.

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

When we present the report, I will be there as a personal live human being and that will be – it'll be recorded and all the – all that will be available and transcribed, as is our conversation today.

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

Well I understand, but the document is going to sort of live on beyond that day and it would be nice for the document to be as meaningful on its own as it can be. And since the notes were already written, it seems to me it would be valuable to cut and paste and drop them in.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

So for example, this is Todd. I know there's one slide, I forget which one of these that had a bullet that said, there's a need for more standards or more something like that. And it was just a statement that if you – just as you said Brad, if you just pick this up and you go through it, you're saying, so what's exactly – which exactly do you mean. And in the prior content, that might have a lot of meaning, but whenever you just take the slide set as it is, you really lose that content.

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

– for including footnotes, but Brad I got feedback from several people that there were many instances in which what was written in the notes they felt needed to be changed or conflicted and was –

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

Well we can improve that.

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

Yeah.

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

I mean, this is Keith – .yeah we – Keith Larsen. We did the same thing; well I did the same thing. I put notes in with the slides because again, even if I took this – well, I'll take an example from the Regulatory Group where they were putting in "Bs" and "As," ambiguous versus broken. Really even to get that definition you had to go to the notes to – I mean, the notes will help you kind of understand those notations.

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

I'm comfortable going through and putting in things that are explanations that are footnotes and so on. I don't know that we have time to go through and write notes for everything.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

David, is there a thing that either folks feel strongly about putting back in or including in notes or if there are things that you would want to send around, we could also probably send things around and maybe have somebody at ONC try to accept comments and reconcile them and then shoot them back to the group. Or something like that; we may be able to do some stuff behind the scenes if there things that folks feel are important and that you're comfortable with. Just let us know how we can be helpful in addressing some of the details that folks want and that you want in there. There may be a way – we're willing to help in any way we can.

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

Sure, thank you.

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

David, this is Meg Marshall and I sat in on the – there was quite a bit of value in some of the notes in the Regulation Workgroup and I appreciate that. I'm wondering if perhaps, an accompanying document, and we talked about augmenting with appendices or things like that. Perhaps it would be appropriate for a separate document that may not enable – or may not assist you during the presentation, but something that is at least on record and accessible to the Policy Committee, if they need to go back through and look at the slides, to get the additional content.

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

The – we talked about producing additional text reports, we don't even have a – I think that the most important thing is really to agree on kind of what the main points and the high level concepts are and I'm not confident at this point that we really have consensus around that. And time is reasonably short, so I guess I'd prefer to focus on the high-level points.

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

Well I'll give you an example of where the lower level notes actually helped to get consensus. For example in the regulatory report we have this comment about ONC and one of the gaps was that it was not mandatory. And on one level, that made people want to figure out what that meant, did that mean, for example, that ONC's requirements should become mandatory, and no, that wasn't that view of the group. So on the one hand we put on the slide mandatory, on the other hand, we then explained what we meant by that. So, that's an incidence I thought of where the text actually helped create the consensus when the actual slide by itself didn't reflect it.

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

Um hmm, um hmm. Okay. Could we – so can we move on and talk about content related points? And what I'll do is I'll go back through the notes that we have and extract things that think are used, so I'll get them out from ONC around that. Can we move on to Taxonomy? Are there other comments about the background?

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

Yeah, this is Martin Sepulveda. It seems to me that the background is imbalanced with respect to the proven benefits of HIT versus the risks, that they've been demonstrated in published literature and that it would be worthwhile to try to provide some of the evidence on the value of – the benefit that has been delivered by the rapid development and implementation of HIT.

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health

Yeah, this is Joe Smith I support that completely. I think we do run a risk – by highlighting the risks we're trying to abrogate; we run the risk of unnecessarily focusing on those in the absence of the background of the huge benefit.

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

I can certainly make the initial statement stronger. I mean, I agree that – I think that we have consensus that overall, HIT improves safety a great deal, but that being said, it can also create some new risks. And we don't really know how big the risks are, we actually have a better sense of what the benefits are.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

David, this is Jodi Daniel. Are folks just suggesting that we have something talking about the benefits and something talking about the risks?

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

I think – this is Keith Larsen. I think the issue is that we're leading off with risk rather than putting it in the background of here's the benefits that we've seen and then saying, but it hasn't all been positive. That's a different message than starting off with that mortality rate has increased and we're prescribing on the wrong patient and we're overdosing. I mean, it just – it gives you a whole different kind of feel for it.

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

The first point, I'll just note is that it's exactly the same as the IOM's first point, which is that HIT does – can improve safety overall, but that there are multiple anecdotes about new risk. But we can certainly expand the benefits part of things, that's easy to do.

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

Yeah, this is Lauren Fifield. I have a document I can send over that sort of highlights some technostics of Health IT the rates occurs in the real world setting. And I think that's really what it is, it's not to say that Health IT can't pose risk, it's that the only reason, one of the reasons that Health IT has been introduced to healthcare is to help kind of in the bigger picture, the bigger setting of healthcare. So sort of not so narrowly in the focus of is it safe, isn't it safe. And that the healthcare setting in general already has inherent risks and so I think shifting the – away from how is Health IT either helping or hurting to, this is a place where there is – that patient safety is something that is at risk. And that Health IT can of course be a part of the problem, but that more than ever we're looking for it to be part of the solution moving us forward, not just on patient safety, but in general. So, I think it's just a paradigm shift and it's just definitely one that I felt that the IOM report had sort of...I think the intention was good, but when it was read, I think it didn't necessarily indicate that there's just already a game plan of things that needs to be corrected and improved.

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

Even like the first – Keith Larsen – even the first statement, mortality rate increase. I mean, you really want to know the scope of that, if that's from the one study I'm thinking about or something else, I mean it sounds like a general impact to patient care across the nation. Is that really the scope of it?

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

That was for children who were transferred in for special care –

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

So it went back to that study. Again, it just – I think the idea of having what are – what happened the – benefits, what is the – and the other suggestion about what is the background risk. Because we had a lot of discussion in all the groups about relative risk, in other words there's the risk of HIT, there's also risk of the status quo, and try to put these in context is all.

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

Um hmm. Okay. Let's –

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

David, this is Patty Brennan.

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

Yup.

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

I would like to ask that a bullet be added that illustrated something other than EHR CPOE type issues with HIT, because quite a bit of the taxonomy was set up to think about other kinds of IT that might be in use, whether we considered in-scope or out of scope. And this slide is a place where we could say something to the effect and the title examples of issues is really examples of problematic issues and if we needed problematic issue with say a smartphone based app for a patient or a Fitbit and the lack of data standards, we could certainly work one in there.

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

Sure. So go ahead and suggest one and I'll add it.

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

All righty, thank you.

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

Okay. Let's move on to taxonomy. And this obviously got truncated a good bit, although the remainder of the work of this group will go in the auxiliary material, but these are slides 8-11. And basically here I thought it was most important to include the defining characteristics, because that was very helpful, then gave one example, which includes – which was, I happened to choose product types. Primarily because there are a number of examples, which are both in-scope, and out of scope, and it was useful to have some that are out of scope and then one example of the decision tree approach.

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

This is Brad. So on slide 8, up at the top it says in quotations "in-scope for risk-based regulation" or again in quotations "exception from risk-based regulation." I'm just not clear on what that means, can you explain what that's intended to say?

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

David, do you want me to try this?

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

Sure.

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

It's Patty. Keith, what we were trying to do is to distinguish the two categories that a particular product or entity or algorithm could be put into. One category was that this should be considered for risk-based regulation and the second category was to say this should not be considered for regulatory – risk-based regulation. And so it may be more appropriate to change exempt, which is a language piece that I had suggested, back to out of scope.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

And this is Meghan Die –

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

So I'm – if I can just tease apart my question a little bit more. So on the first one, in-scope for risk-based regulation. The way I heard you just say it is that this is what should be considered for regulation and in fact, I think when you did the work, it was considered by the – to be considered by the working group. Do I understand that right? In other words, this part of the report doesn't say, for example, here's what should be regulated and here's what should not be regulated. Am I tracking?

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

I don't want to confuse the conversation, but Meghan?

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

Yeah, that's a ver – so this is Meg Marshall. That's a really good point, because that's the hand-off between the Taxonomy Group and the other group was – the Taxonomy's scoping task was, and I'm reading this from a previous session, was not to define HIT or its regulation, but to define the scope of what the other groups should be discussing. And so the terminology, to use the term, in-scope for risk-based regulation or exempt from risk-based regulation really gives the appearance that that's what the discussions were, and these weren't. We – the Taxonomy Group was intended to guide the discussion of the other subgroups, not the eventual outcome of what's in regulation and what's not.

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

I'd say let me ask Meghan Dierks to weigh in on this also, please.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So we – its Meghan Dierks speaking. We had tried hard to frame it as what should be subjected to deliberation and – discussion and not say – .not create a list of what we thought needed to be regulated. So it's a fine line, I think – I sense David you're looking for something that's practical here that would communicate to the Policy Committee a little bit more crispness around the problem they're trying to solve. But we did try hard not to actually declare what we thought should be regulated and not regulated but what should be considered – I know it's not –

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

This is Jodi Daniel, let me try to see if I hear what folks are saying. I think that the way – it's just a language problem, I don't think anybody's disagreeing that its in-scope for risk-based regulation sounds like it should be regulated. And maybe if we added the word framework, like in-scope for –

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Yeah, I think that's exactly –

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
– framework –

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center
– Yeah, that's fantastic

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
– may or may not be regulation, but that it should be discussed as a part of the framework, and maybe that –

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology
– that captures it? Okay.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Yeah, this is Meghan. I think that's fair because I think what we had intended was that this would hand off to the other groups and the other groups would say, okay, what the framework will incorporate is everything from the most minimal level of oversight to something that's got heavier levels or oversight. But we wanted to actually declare what we thought would belong somewhere on that continuum.

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

So could we say something like recommendation for what other subgroups consider in deciding – in recommending what to regulate? I said that horribly, but there's got to be ways that we could relatively succinctly say what I hear everybody saying, which is that this was designed to guide the other subgroups.

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

Sure. I – yeah, I – so I think we – I think I have some language that will satisfy people around this and why don't we move on, and I'll circulate that and if you don't think we're there, then we can make some more changes.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

David, Julian Goldman here. I have another comment on the same slide, slide 8. I wonder, as part of the conversation, the word functionality is in bold on the second bullet point. I wonder if the word should be risk, if that's where the word risk should apply in this slide, and I'll pose that question to the folks who composed this and have thought about it.

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

Yeah, which slide were you referring to Julian?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

The same slide that we're on, slide 8 – so – the number.

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

The risk-based regulation is the consequence. This is Patty. And what we wanted to guide people with the taxonomy was not to make the endpoint of the taxonomy a determination of the risk of the entity, because I could envision an entity that was risky, but really was regulated under some other form, so it didn't say in the decision tree. So the taxo – the decision tree was designed to go through some steps that looked at how the entity as a whole functioned and was intended to function, which incorporated everything from who developed it to how was it distributed. And there are risk components in each of those, but this was meant to be a synthetic or a multi-faceted decision.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

One comment – this is Meghan Dierks, one other, maybe just elaboration. I think the reason why we frequently cited the term functionality was that we – it was more precautionary. We did not want to frame the thinking or what would be in scope for the consideration of the new framework in terms of a specific product, because products have lots of functionality and the risk is around a particular function that maybe part of the system – so – I'm sorry?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Yeah, as the intended use or the application of that –

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Right. And so we thought we really wanted to shy away from declaring maybe at the product level something might be out of scope for the new risk-based framework because it was just an oversight that one tiny functionality hadn't been considered and that was in fact where all of the risk was involved.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

So thank you for that clarification. In the interest of time, let me just explain my concern and then maybe it isn't an issue. When I see the work functionality in this slide and I think about one of the later slides, for example, the matrix in slide 16, that is actually showing a relationship between technical functionality and assumption of the risk or a definition of risk, where we have the columns of risk, low, medium and high. And in there, in that matrix, we're looking at functionality and we're saying that that is identified with risk when ultimately risk of course depends on other factors, the intended use, the hazardous situations that might arise, and the likelihood of those arising. So I'm concerned that by using functionality in this slide that we're on now, slide 8, it is leading us down the pathway of confuse – and confusing the issue. I don't have a specific solution other than using the word risk here, but you've explained why you didn't use the word risk here, so –

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Yeah, so again – this is Meghan Dierks. I think – I'm averse to interchanging that word. I can work offline with David and others to figure out another word to put in. But I think that we're not intending to have risk there. Because you want to decide whether you think a product or some entity or something should be evaluated using a new framework, based on what its intended use is and the types of patients it's used on. Not – and then that applying that framework, you sort of stratify the risk and then make a decision about what controls you put in place. So, this was purely we wanted to just say, okay, we're not going to go down a list of existing finished products and say that should be – the new framework should be applied to this or not. We wanted instead to think in a forward thinking way to say, okay, what are the kinds of things that health IT is capable of doing and given what they're designed to do, do we believe they should be evaluated and assessed using this new framework. That was purely the goal there was not to be – to paint it into a corner in describing an existing, finished product.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

I certainly wasn't proposing describing existing products. I think that emphasizing the word – using the word risk as a scoping criterion doesn't refer to a product at all, it just refers to the risk – the patient.

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

So, this is Bakul, can I sort of suggest something? I think that functionality, I can see Julian's point, functionality is to think about specific products, but I think the intention here is more about the purpose of the technology, it's not the technology itself or the type of product itself. I think maybe a word issue here as well, as we had in the previous slide. So, maybe think about including the intended purpose or just the purpose or something like that, if that's what makes it.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Well just to clarify, I'm not advocating – I'm not saying that we have to have or I feel strongly that we have to have the risk there instead of functionality. My concern is that by using the word functionality and not explaining, we have actually introduced something that I was specifically concerned about, which is in Table 16 we're using functionality to define risk. That's exactly what's – that's depicted in that table, which would be – the only real outcome I'm concerned about is that confusion between functionality and risk and somehow we've let it happen. I'm not saying changing the word – is the only solution, it's just that I'm raising this issue because I realize, reading through this deck that that is a way – in a way is helping to cause that confusion. So, I don't have a specific solution, I don't want to slow down things David, but I – there is a problem here in the way these concepts are being interrelated.

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

So, I think it's important to look back and forth and we want to try and be consistent. And one of the challenges when you're working in multiple groups is to achieve that. And why don't I work with Meghan and Patty offline and we'll come up with a different way to frame it. Let's move on to the risk part of things, if we can.

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

David, sorry, Anura Fernando here, if I could raise one more point here that I think will carry over into the subsequent slides. If we're looking for a mechanism to distinguish the current regulatory path for the task that this project is essentially establishing, is the current regulatory path not also risk-based? So saying that this is a risk-based framework versus an existing one that's not, is that fundamentally correct?

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

I think the current framework is risk-based.

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

So is this in fact serving to actually distinguish the output of this group relative to the current processes?

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

Uhh –

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

This is Meghan Dierks. I think I'm interpreting – I think one way of interpreting it, the output of this workgroup is to provide input on a new framework. And the purpose of using risk-based as an adjective or a qualifier is just to say, we wouldn't propose a framework that was devoid of using risk as a driving principle, I think that's the only goal. It's not – I don't believe it's being used to compare the current framework that's used for say conventional devices as not being risk-based.

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

Thanks.

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

Okay, so, good point. Comments on slides 12 to 16, which are the ones that –

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

David, this is Meg Marshall. I'm sorry, before we move on, and I have – I realize that you're – pressing on – for the second time, but I do have some other worrying comments, I'll just – for the group. But I do think it's important on slide number 10 that we talk about how the information exchanges. I think that the intent here is to have it be the verb and not the noun, that the – we're not looking at regulating information exchanges, such as one would expect on a state-based exchange or etcetera, but it's really just that the features that provide the health information exchange functionality. And I think that's important to make sure we're all in agreement on that.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

This is Meghan, I agree and I think that would show you the reason why we emphasized the word functionality, but I agree, yeah.

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

So Meg, what kind of a change are you recommending for slide 10?

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

On slide 10, where it says health information exchanges, on the left-hand side, just make that health information exchange. Because when you use the plural, you're implying the noun, and that's I think where we're definitely trying to stay away from.

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

I understand what you're saying and I think –

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare

Meg, this is Elisabeth, but it might be better if you had "l" and the "E" as small letters, so it doesn't look like it's that HIE.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

I can send that change to David, thank you.

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

And Dave, it's Paul Tang, I've been trying to get in, but they had me off the line.

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

Okay.

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

Anura Fernando here. One more comment on slide 10 is –

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

Can you hear me?

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

We can hear you, yeah.

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

Okay, just want to get in the queue, because the operator had me deactivated.

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

Sure. Okay, Anura.

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

Yes. On slide 10 we have general purpose, communication tools, and I have some concerns about that being in the out of scope – because it covers a variety of different things and it's fairly broad. So for example, if you had a distributed alarm system that relied on page in for alarm escalation for remote clinicians, would that in fact be out of scope and the infrastructure and supports that?

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

I think this is another example where we're talking about the difference between a product and a function, and so to me the function is certainly in – would be in-scope, not to reopen that conversation and confusion, but that the substrate that it runs under the general-purpose communication, cell phone or pager system, to me is not in-scope. So we're not going to regulate Qualcomm, we might regulate a functionality that runs on top of Qualcomm.

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

But aren't we also talking about defining a new – help to support things like mobile medical apps, for instance, where you can abstract potentially the platform away from the app itself. And so to have something as broad as general communication equipment out of scope is to move us away from those types of spaces.

(Two people speaking over one another)

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Patty, this is Meghan, I was just going to suggest, we could make a specific list to help disambiguate that.

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

That sounds good, that's great. Thanks.

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

Thanks.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian Goldman here, just want to interject briefly. This is an example of the challenge we run into if we start to separate risk from the discussion. Once you apply consideration of risk, if it was alarm data being sent by a pager, then that would be in-scope, because probably, because of the risk, in-scope of the regulatory framework and of course paging of old, non-time sensitive, non-critical data probably wouldn't be. So this is part of why I worry about that issue. Anyway, that's it.

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

Okay. So, thoughts or comments about 12 through 16.

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

So David, this is Paul, can I follow up on the –

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

Sure. Yeah.

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

So, I couldn't get into because the operator had deactivated my line, but I wanted to speak strongly in support of what Meghan and Patty did in terms of declaring this as functionality or function, rather than risk or rather than product. I see the value of what they did. I thought part of the logic in the three subgroups was to essentially do context independent work so that we then later apply judgment or ONC's – the tri-agencies apply judgment to combine the scope of the taxonomy, the risk, the innovation and the regulatory options to form a framework. So I really like the way that the Taxonomy Group spoke of it, absent of a risk discussion.

I also am not seeing the word functionality on the matrix on slide 16 at all, so I'm not seeing where that function – where that confusion is coming in, but I think the risk matrix is also developed context-free of what you would apply it to, and independent of what regulatory options you would have. I see value in doing it the way it was done, I believe, the three subgroups. So, I just wanted to speak in support of the way they've laid it out, for those reasons I just said.

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

Julian, do you want to respond? I wasn't able to find it either, the word functionality, but I understand your point.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

I'm sorry, the word – this is Julian, were you referring to me or Paul?

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

Yes, as he suggests to you, I can't see the word functionality on slide 16.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

No, no, it's not on slide 16. What I was saying was, by using the word functionality as a scoping criterion we introduced the pathway that functionality starts to get aligned with risk. And what I was saying is that we see the result of that kind of intermingling of functionality and risk in the way information is depicted in slide 16, in the matrix. And an example is, we have functionality such as something being close-loop, which is a function over the in column for high risk, and it may be that that closed-loop control system is a very low risk system, such as a thermostat on the wall. Or it could be a high-risk system, and it may be part of an intra-aortic balloon pump or it may be part of a closed-loop insulin glucose administration system that's using the EHR, an infusion pump and other components. And that's the problem with – again, the word functionality is not inherently bad, it's just that we can see that we're on a slippery slope and we're using functionality to apply risk, when you get to slide 16, and that was my concern.

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

This is Lauren. I think the sort of point of confusion here that on slide 8, I do think it's sort of a wording issue in that on that particular slide...sorry, I'm trying to pull it up on my – okay. Where it says the decision tree approach that emphasizes functionality as a primary scoping criterion, I think that that wording in that second big bullet indicates that functionality would be the first sort of criterion that would be looked at to then establish where that particular piece of health IT falls in a regulatory or a risk- based approach framework. And I think Meghan and Patty meant to say that it shouldn't be that we're categorizing at the product level that we're categorizing even just at the level of functionality, and I am in support of that. Rather than saying all of an EHR fits a functionality that may be involved in a high-risk activity. But I think the wording there is just misleading in that it's almost putting functionality at the top of the hierarchy for kind of bucketing into a risk category, and it seems like it's more – approach that emphasizes risk of the use of certain functionality or something like that. So, I think everyone might be saying the same thing, but that wording is very misleading. And if that's not the case, then the wording is misleading –

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

I think we have consensus at this point that we'll – we need to come up with some wording. I find that a little confusing, too. But, I have also struggled with what to do instead. But let's figure that out offline and keep going on the risk part of things.

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

David, just –

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

Yeah.

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

This is Keith. Again, I think what would strengthen it as you're doing it is – I agree with the approach that taxonomy took towards functionality, but then we followed up with slide 10 which then – because slide 8 says we're going to emphasize functionality, not products and then we go right to product types rather than functionality types. Having the list of what was meant by functionality might clear it. Because even when Julian was talking about closed-loop systems as a functionality, I didn't make that connection. But when we're hearing the word functionality without examples, I think that's where we get into problems.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So David, I can help you with that offline.

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

Great, I do want to keep us going because I'd like to get close to the end if possible today. So comments about the risk part of things.

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

So David, Anura Fernando here again. On slide 12, did we consider the ISO 14971, 2007 definition that goes beyond just the health of people and includes damage to the property or the environment. And the reason that I ask that is because if you consider a device connecting to another device, and the provenance of potentially harmful data originating from one device and impacting another device in a broader system, having those additional pieces there could allow for the additional risk considerations.

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

Actually this is Brad, I would further state that why don't we use something that's also aligned with 80001, would start there and then add to that a reduction in effectiveness or a functionality or a breach in the data or system security, all of which is really tied to how these things get used in a deployed environment.

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

This is Paul Tang, just to resp – I think we did mean – so this is the risk to patient safety, so we did mean harm to a human. I can see how the environment can contribute to harm arising, but I don't know that we are speaking about harm to the environment as an end outcome.

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

It's not specifically – sorry, Anura here, not specifically harm to the environment, but rather data originating from one source, let's say an EHR that would then enter another regulated device, like a medical device, being itself a source of "damage" to the second device, in that it's corrupted or malicious in some way. And then that's – that – is this part of the causal chain for the harm to the patient. So, I mean look at the current risk management standards, they look not only at the direct patient contact implications of harm, but also the indirect sources of harm, including things like in vitro devices, laboratory equipment, that type of thing. And so having that extension of the definition, allows for consideration of harmful data provenance.

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

So I guess the short answer to that is that the indirect harm – the harm that arises to the direct mechanism would be incorporated in the cells of the matrix, but no, the matrix wasn't designed to capture harm – the harm in the environment that you spoke of. So data corruption occurring as – is transmitted through the environment can lead to risk to an individual, i.e. a patient, but the matrix covers the end result of harm to the indivi – to the human. I think it would really expand the matrix a lot to be incorporating all the other harms that you speak of, yet I believe they're incorporated in the – how they manage that stuff that's harming to the human. Does that help?

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

I think so, maybe as we go through subsequent slides that might help.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian Goldman here, I just want to mention maybe offline we could perhaps consider more about what Anura just said. It's a class or type of hazard that is at the heart of many future applications for health IT and if it isn't seen easily by anyone to be within scope of what we've produced and presented, then I would consider that to be a gap that we don't want to continue to have. That's just my thought on that.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

And then as I said, a reduction in effectiveness or degradation in security are two additional aspects beyond just patient safety and the standard ones, that should be considered, so we can discuss that offline.

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

I'm wondering if we can handle that with some – maybe a little additional text or –

Brad Smith, PhD – Research Director, Innovative Care Delivery, Co-Director, Altarum Center for Consumer Choice in Health Care

Yeah.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

We have complexity on there with no text, is there any intent to add to that or –

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

Sorry what, which part do you have a question on?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

You have complexity in the bottom bullet with nothing associated with it.

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

Oh, okay, we could include it there or it could be under the last row, the network connectivity, standards and security.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

No, I was making a separate point.

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

Okay, so, yeah I'm open to comments on that definition that would help.

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

So, Anura Fernando again, a general comment on complexity. If we're using complexity as a metric for risk assessment, then I think we'll need to be cautious in stepping forward in that direction, based on the nature of safety. If you have, for example, a failsafe or a fail stop that can be achieved from a fairly simple design perspective, you can de-energize a product and it'll failsafe or fail stop or whatever the term is that you want to use. But if safety is predicated on the system continuing to operate, then we may need a fail operational system, in which case it may be necessary to increase complexity to maintain safety. And so you sort of have this concept of active safe versus passive safe or active safety with a higher level of complexity actually provides for a safer system rather than the assumption that a simpler system is de facto safer.

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

I think the – this is Keith. I think the question on this slide though is that it says its basic definition and there's no definition. It doesn't say how –

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

(Indiscernible)

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

– yeah, it just says here's a list of definitions and you don't have a defined term.

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

Right, no, there's something that's missing.

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

So, open to suggestions, please.

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

Well there may be a definition from the IEC that just got cut off here.

(Indiscernible)

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

Sorry, the – I think that perhaps the definition just didn't get pasted in or got cut off, but the other definitions are from the International Electrotechnical Commission.

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

So if somebody has that verbiage, if they can send it to me that would be a start anyway.

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

Right.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Also, Julian Goldman here, I'd like to propose that we add another definition there for hazardous situation. Hazardous situation is the situation in which that hazard exists, it's not something that's used. So, that's a defined term and if we could add that, I think it would help _eek_58:53 out the issues in the future.

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

Anura here again, and Julian's last comment, I think one of the next slides had a comment about that very fact. We used the term risky and it may be more advantageous to use hazardous situation there, but I'll wait until we get to that slide.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

So if it would be helpful, I'd be happy to provide a definition for hazardous situation with a reference, or if someone already has that, perhaps Todd or someone else or Jarrin.

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

I'm just doing a time check, what I would like to do, actually at this point, unless anybody has big picture comments on the risk slides, is to have you send suggestions to Paul and let's move on to the regulation slides, if that's okay.

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

Sorry David, just one more comment in the risks, I think this is the risk section, so this is slide 15. There's a comment that software may be complex, but can be tested comprehensively. I think there's a significant school of thought out there to be considered, that software possibly cannot be tested comprehensively or at least proven exhaustively. And therefore it should be taken into consideration whether there are systematic faults and random faults that need to be addressed. And that may be useful for consistency with other IEC standards like 6304. Just wanted to put that out there for the record for consideration.

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

Just send me the language, at first glance, it seems to contradict the other point that you made, but let's see if we can't reconcile that.

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

Sure.

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

So let's move on to 17 to 26.

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

This is Brad Thompson. You're covering a lot of ground there and I know you took a lot of it from the subcommittee's work. Can you tell me, it might help everyone if you could just explain where you changed things?

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

I changed really almost nothing. Let's see, possible I dropped a slide or two, just to get to the appropriate number of slides, I can't remember. I believe that perhaps the most – one thing I did do was to make 25 and 26 slightly more summarized. Let's see, on slide 25, you had suggested re-examining things every three to five years, I changed that to periodically and those are really the major changes.

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

So on that slide, the second bullet point where it says to improve post-market surveillance, which needs improvement, all of that appears to be new, I'm just wondering where that came from?

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

Let's see, I can't remember, possible I changed that bullet point.

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

Because all of those words are new and I'm just trying to figure out how the process – did that come up through a different committee or where did that come from?

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

This is Meghan Dierks, I recall in the last subgroup meeting there was quite a bit of discussion around that concept, towards the end of that call, but that's the only comment I can make.

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

Right, so actually these are – those are – so those are words that I added, I added it after our last – after the last call, and your report didn't basically include anything about post-market surveillance in the final summary things. And you didn't want to have these be summary points, but I felt that these did come across as summary slides, and they're sort of specific recommendations. So the three points there are taken from slide I think 24.

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

So this is just meant to capture the slide before, these points under the second one.

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

These are meant to be the recommendation points from a slide before, yeah.

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

Julian, that's an area that you spent a lot of time thinking about, are you comfortable? I don't know the area as well as you do, are you comfortable with these points?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

I am trying to follow –

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

We're looking at slide 25, the second bullet, the first point is that vendors should be required to register products which are considered to represent at least some risk, if a non-burdensome approach can be identified to doing so, we probably talked about that for 25 minutes on the last call. The second is better post-marketing surveillance of HIT is needed, including post-implementation testing. And the third is approaches are needed to allow aggregation of safety issues at the national level including federal support for doing that. Actually all those points were made by a large number of people in the public comment period, too.

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

So you use the word register in the first of those bullet points, vendors should be required to register products, that's a term of art at FDA, it has a very clear statutory meaning. Are you invoking that meaning?

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

So, I'm open to different terms.

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare

This is Elisabeth. Just one of the other things that popped into my mind when I saw register under the word, the larger bullet of post-market surveillance is, it almost sounds like registry, which is a very – which is a part of post-market surveillance. And I guess I was thinking what we had talked about was more or less a listing where you might list our products annually with the FDA, so what you're doing is registering that product, not filing for a post-market registry. So you probably need to pull that bullet out from under post-market surveillance.

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

Or you could – wouldn't – so wouldn't – gotcha, okay.

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare

The registration process is not a part of the post-market process.

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

Gotcha, that's a good point.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian here, in answer to the question, this generally looks okay. In addition to the comments that are being discussed, but I do see something that is of some concern, and it's the point that says, higher risk software use cases per the Safety Working Group report, including those where the intended use makes the software risky. And again I go back to the matrix in slide 16, if that's the definition of higher risk, that does not include the intended use, some of those are purely based upon the technology and whereas in the sentence in slide 25, it appropriately says, it invokes the intended use, which is the right way to do this. But again, applying that to slide 16 shows the problem with identifying risk based purely on technology.

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health

This is Joe Smith. I'd argue that the term risky is – it's almost _too cool_ 1:07:31 to sort of to have meaning here. I mean, I think what we're searching for is some notion of wanting to see some threshold risk but we've been quite hesitant to describe what that threshold risk is. So I think there's this notion of linking it to intended use that makes sense and has a durable history, but the notion of saying that that use makes the software inherently risky, I think that has less meaning.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

I'm certainly not proposing that, is that – are you taking that from my comments or –

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health

No, I'm taking that directly from slide 25.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Okay, got it.

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

So why don't you suggest some different language for that.

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

I see in this slide 25, that where we had medical accessories and there was a parenthetical, the same parenthetical exists behind high risk CDS, that that parenthetical's been removed, could you describe the thought process there?

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

Um, I think – I do not recall why I took that out, I think my thought process was that medical device accessories are already pretty well clearly defined by FDA.

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

We spent an awful lot of time talking about the fact that that's not true and in fact the above recommendations, one of the first regulatory slides says FDA needs to step in and define accessories. That was a big discussion point throughout our deliberation. I don't think that's right, I don't think it is clearly defined.

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

Well, we can add it back then.

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

David, can I make a general observation on slide 25?

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

Sure.

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

I think just listening to some of the discussion, it sort of feels that difference between what is health IT and what is medical devices is still ambiguous. Just walking through the taxonomy and I think that in general the principles are good, but I think that because we don't have a box around what is health IT is maybe causing some of the issues and it may lead to some ambiguous or unclear directions for medical devices in general. Hello?

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

Hi, okay. So, other thoughts about, I'd particularly like to hear from some people who are not on the regulations group.

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

Could I – this is Paul Tang, could I get a definition of what "C" existing mechanism for immediate relief –

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

Oh, perfect segue, and I'm on the Regulatory Working Group. I was about to say something, but since Keith said, no, or rather David said not to, this is Robert Jarrin with Qualcomm. We had a slide in there that spoke about program mechanisms that could enable innovation. And that slide goes towards that "C" column, which basically explains six or so mechanisms that are available to the agencies to be able to clarify some of their current thinking, to be able to ease restrictions on those lowest risk or lower risk HIT products that could get to market much more easily, if the agency actually came out and did some of these things. That slide has disappeared and I have a problem with that because I feel that that slide describes what is currently in slide 18 and 19 I believe, those slides that speak about FDA.

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

I think that the reason that I dropped it was just for length purposes and because we have a whole bunch of other slides later about innovation.

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

But I think one of the problems that I have with this is that this is almost like a fundamental aspect of whatever it is that we as a FDASIA Group are going to be recommending. I took the 618 language to say that we were supposed to work on a regulatory framework, and that can be taken to mean an existing framework or one to be created as a result of this group, and I think we should have both. I think our first recommendations should be to talk about those existing mechanisms that promote innovation and protect patient safety and avoid regulatory duplication. That slide goes to that.

And our second recommendation may be a framework to be developed, and keeping in mind that whatever it is that we're going to develop will potentially require a lot of time, it will potentially require legislative action, obviously taxpayer dollars, rulemaking and then subsequent implementation. All the while, in my opinion, innovation suffers as all of that is being played out, which is why the first recommendation is so vital.

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

Okay. We'll note that slides 26 through 37 – 38 talk about a potential new framework.

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

Again, I would like to see that slide re-incorporated, the one that was taken out.

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

We can certainly – I can do that.

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

And I realize that some of that wording may be very prescriptive, we can also work on that wording to make it less prescriptive, but I just want to make sure that those concepts are in there.

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

Yeah. Okay.

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

Thanks.

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

David to help you – this is Brad Thompson again, to help your audience, are you going to maybe break this into parts and say kind of these slides relate to improvements to the existing regulatory structure that could be done more immediately. And then we have these slides that relate to more fundamental changes that would need to be addressed over time?

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

I think that's a good way to frame it. Yeah. Okay. So, we want to keep this moving. If you could look at 27 through 38.

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

This is Brad Thompson. This isn't a substantive comment, but it is a comprehensive – or comprehension comment. It feels like we go over the train then we go over the train again and so some of these things like comparing medical device regulation, you've got slide 28, the pros and the cons. To some extent that whole slide could be moved up to go right after the description of the FDA process, and then would sort of naturally lead in to this pros and cons slide. It just feels to me a bit disjointed. But the other comment here, and this goes to what Keith has described as his writing process, some of these slides, the actual text is kind of cryptic. And again, the notes were meant to explain what these words meant. So, I do have concerns about the slides, either we can incorporate some of that up into the slides, or we can add it back into the notes, but some of these are written in traditional PowerPoint, which is very few words.

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

Right. So we've talked about how we're going to handle things with the notes, and I'll be going through those. I think it's a good point about slide 28, slide 29 is really – and 30, and 31 even could be moved up.

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

Yeah, they could. This is Keith. I think that would – it would help the continuity so you're not, like Brad said, is that you're not addressing a subject and then addressing it again, when – I go with that.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian Goldman here, a comment on slide 28, I'm not clear on what's meant on the left under the pros, process control, not outcomes. Process is an important part. The product evaluation is also a key part of assessing the safety of a medical device, so process alone is insufficient. I don't know if that was the intent here or not.

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

It was so much richer, Julian, in those notes. No, I'm just kidding. I mean, again, it was the emphasis on – that the focus is really looking at maybe outcomes is not the right word, but specific functionality versus the process to develop the functionality. But it actually was – I tried to have the explanation in the notes section.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Oh, okay. Just a point I want to capture here is that part of the medical device regulation or part of our design with medical devices that should be considered here is its process and product evaluation of being very important to help support the safety of the device at use.

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

But it doesn't define what the device has to accomplish, is what I'm saying there. I mean, it says how it should be created and how we evaluate it, but it doesn't try to define, for instance, all the devices and their specific functionality. It's just the approach is a little bit different.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

So you're saying it's a positive attribute of current medical device regulation is that it doesn't define what the device should do or how it should be built, but it helps support a process that will – for quality, and –

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

Well, it doesn't define what the end product is, it defines how you create the process and – I mean, how you create the product and how you evaluate it, but then it leaves what the product is, the definition of the product open so that it accommodates all medical devices and new medical devices that come out. You're not precisely saying, I need a Smartpump and a Smartpump shall have these specific requirements within the Smartpump. I mean the contrast here was – is that in the certification process what we end up doing is defining – have definitions for specific functionalities and how those functionalities, in some cases, are actually implemented. So it's a – approach.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

I think I don't want to speak instead of an expert like Bakul or someone else from the FDA, but I think there are quite a few products that do have a mixture, in a sense it's a mixture. But there are specific performance requirements in guidance documents that describe – based upon experience and history, where there's more – greater requirements around the devices themselves. And there are the more general requirements that apply to all devices and the processes that apply. So sometimes those things are considered, and that may be relevant when you use that example. I don't think that's a significant point for this slide deck, but it – since this may live on, as was pointed out before by Brad, it may be worth kind of refining that a little bit and somebody at the FDA can help us with that. That's just a suggestion.

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

Okay.

Michael Swiernik, MD – Chief Executive Officer and Founder – MobileHealthRx, Inc.

Hi, this is Mike Swiernik. I had a – I'm sorry on the prior discussion, I was only looking up through slide 25, so I actually had some comments on slide 26, which is the second page of the recommendations. And this may have to do with what Brad was saying about additional info that's not captured in the slides that might be relevant. So the first two points the creation and adoption of needed standards, on that one, I have an opinion about the standards, but I think what the "what's needed" means is probably really important there in clarifying that what we think is needed and where we think things aren't needed. And then in the second one, that private certification, I have strong feelings about whether or not private certification would be helpful here, but it may depend on what exactly is meant by interoperable products to be used in networks. I'm not really sure if that's – I think that's narrowing the scope substantially, in which case I may agree with that, but I'm not – it's unclear from the slide what's actually meant there.

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

So this is Brad. I don't mean to sound like a broken record, but it was – that was really exported in the notes and so if there's some of that note content that can be moved up. The interpretation of it being, I don't know if it's narrow, but it's certainly not wide open, was referencing work of groups like the Continua Health Alliance and some others that are developing private certification of just as the slide said, interoperable products.

Michael Swiernik, MD – Chief Executive Officer and Founder – MobileHealthRx, Inc.

Oh, okay. That was really interoperability certification in which case, that I agree with, I was concerned that it's talking about like private certification of EMRs or something like that, which I wouldn't necessarily –

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

Yeah. No, this is – right.

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare

This is Elisabeth and I can mention that when I looked at that I actually was thinking, because I know it came up during one of the meetings, the self-certification process as well that we used the analogy of the European Union process that we have. So, I agree that there's another point where the notes would have been very valuable to make sure we knew what was being communicated.

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

David, this is Bakul. Can I ask a slightly different question?

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

Sure.

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

In the May meeting, in-person meeting, there was a lot of discussion about the process of implementing health IT and the big systems and how those are some of the sources of issues people were concerned about. I didn't see a reference in the recommendations for that particular part of the process or issues to be addressed. Can that group comment on that?

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

Yeah, I think we decided it was largely out of scope.

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

Oh. Sorry, I must have missed that, but I didn't think that was the case. Okay, Patty, Meghan, you guys thought that was out of the scope?

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

I think it was in scope, but I can say that I'm not sure we created an artifact. I do recall, Bakul, that there was a fair amount of discussion around that, where there's sort of a void in current risk management. Where there's a lack of clarity when you begin to put systems together and create these much more complex systems of systems that there's no framework for either assessing the risk independently or adjudicating who's ultimately responsible for system failures or high risk scenarios that are created or hazards that are created around that. But at this late stage, I don't know how the work – feels about declaring it formally in-scope or if you feel like at this late state we could include that in the published artifacts that that'll create problems.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

So this is Todd, I thought it was in-scope and that's why I think at the face-to-face I set a couple of use cases on the table that specifically looked at these kinds of conversion networks.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Is there a particular point on this slide that you're concerned about? I mean, I'm trying to figure out if there's a way we can finesse this. So Bakul, which slide were you worried about?

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

I'm just wor – I'm looking – I've patiently waited through the regulations slide and –

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Right.

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

– trying to see if the point about implementing health IT has risks, especially in the larger systems – or the bigger concern from the group that I heard in the May discussion. And I felt like that is sort of somehow captured in your taxonomy group and I'm going back and seeing if it's captured or not. But I thought it was captured.

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

I don't think it – I actually think it fits, Meghan, within the – when we talked about modification and life cycle issues about systems.

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

Right.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

We can make it a little bit more explicit, it's literally adding it to that – a little bit and see if it has –

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

It's not – so when David was explaining what he included in the slide deck from our slides, if I can dare drag you back to slide 10 for a moment. We do explicitly say under the product type category, in-scope hospital information systems of systems.

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

Right.

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

So does it need to be more explicit than that?

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

So if that means that the processes and the issues that arise from creating the systems of systems are addressed somewhere, I was looking for either in the risk group or in the regulations group or innovation group, that point to be addressed and I'm not finding that.

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

I see. And I would agree that that's something we thought might be difficult to carry through and it may be, as I'm looking – I'm sorry, this is Patty. As I'm looking at slide 16, there's something – there is a line about four up from the bottom called complexity of implementation and upgrades –

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

Right.

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

– which is where I think that – that's where I would put this. Now I've been thinking about this with you all for three months, so maybe a person naïve to the framework might not, but I think it's not explicitly excluded I guess is what I might suggest.

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

Okay.

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

Actually Patty it's on the blue row at the bottom, part of a more comprehensive software or hardware system.

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

Right.

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

So can I ask Bakul how you would define a large system? When is it a system versus a system of systems? I mean, what's the smallest or the largest system that you cons – so that's – I think that's where David's coming from, and what Patty just said, is how do you decide when it's too big for this framework? How do you define system versus system of systems?

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

I don't think I have a definition for what a system of systems is, because if I take any system, it is a system of systems, right?

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

Yeah.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

It's getting hard now.

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

Yeah, so I actually don't prefer the word system of systems, because it's non-meaningful for me. But I was not actually thinking of systems of systems – but specifically what I was thinking about Paul was, implementation of EHRs in a big hospital. There are a lot of issues people brought up saying that that's where there's lack of process or inconsistencies in process, issues that arise and there is, I think people talked earlier about responsibilities of – transition of respons – etcetera, etcetera. And I felt that was something that was not touched by many people, or when I say many people, either by regulatory bodies today or even thinking about doing that. And I thought that was an important topic that most people brought up that should have been addressed somehow in the recommendations. And so on walking through the regulatory recommendations, I didn't see that and maybe for the risk part, I think you may have captured it sufficiently or maybe implicitly captured it here. But I guess the question is more for Brad and the regulations group, or even maybe for innovations group, is that something that you guys talked through and is that something you guys feel the regulat – the flavor of that the feds will come out with should capture.

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

Can I just make one comment directed to? I agree with you Bakul about its missing from the recommendations. The way it shows up in the matrix is the blue, the next to the bottom line of blue talks of being part of a comprehensive software and hardware systems, that captures the technical component of system integration and the risks that would be introduced.

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

Right.

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

The middle part of the green above that, complexity of implementation and upgrades, that's the complexity of the implementation process –

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

I see.

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

– which you also referred to. So, both those concepts are in here, but I do agree with you that – and it's not necessarily used in the recommendations about what should be considered in the regulatory framework. So I think you picked that – picked it, yeah.

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

So, Brad or Julian or Keith, anybody want to respond.

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

I just –

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

Yeah –

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Julian here, I'll just wait until after you Keith.

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

Okay. It was regula – I mean was addressed a little bit in the slides from innovation. I'm looking at the slides that were sent out yesterday and so the numbers may not line up, but it was talking about the accountability model and what do we do about local configuration. So in that deck it was slide 36. And we tried to talk about it as did – but we're talking about it from an innovation type deal of – but in here is who's accountable for that, the local configuration and extension of the software and in this case we said that it's really a framework where there's local control and local accountability. But there was some addressing of that. Go ahead Julian, I think it was.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Yeah, thanks. Yeah, I'd like to say that I think Bakul has raised a good and important point. And I'm not – I agree it needs to be brought out in the deck and in the re – in some way, to point out that in the real world, there are hazards and challenges associated with implementation, due to the very nature of health IT and what we're trying to accomplish today. And I'm not sure that we really addressed the parts of that that we need to, or let me change that, I'm not sure that we need to address it in great depth. Because it isn't really something hard to understand and it's probably well understood, but it just should be captured clearly in one line somewhere so that it's part of our work. But I think that the discussion also – and the point Bakul brought up pointed to something else, and I think perhaps a way to think about the data and – in slide 16 was the risk, both medium to high –

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

I think we may have lost Julian. I – just cognizant of the time and I want to spend some time on the Request for Comments hopefully people can access these. We requested them June 30th and we have a summary of these. Let me just run through that summary very, very quickly.

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

David, before you do that, this is Brad. We didn't really get to the end of this discussion, are you going to pick this up again in the next call or when –

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

So I think what we'll do about this last point is we will, as Julian suggested, and add comment someplace to say that there are important hazards associated with implementation. This is not an easy thing to regulate and I don't know that it's especially amenable to that. If you disagree –

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

I mean that's the direction I was going to it, that it's really – it's a local accountability and local control. And it doesn't really lend itself to national regulation of –

(Several participants speaking at once)

M

I think that's right.

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

– process or documentation.

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

All of that is fine, I was just asking there are other slides left that we hadn't talked about.

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

Sure.

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

There are, I think we're not going to get to those –

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Hello.

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

– because I really want to get to the public comments today and we'll go through the other slides the next time.

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

Okay.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

By the way, I was disconnected, Julian here. I think I made the point that I – the call was dropped, I don't know.

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

Yeah.

M

All good.

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

David?

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

Yes.

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

Just because it's relevant to our goal of – from the risk and innovation framework. I think that this concept of how to address implementation or upgrades or how systems interact kind of calls out an important thing about the risk dimensions framework, and maybe it's just that we haven't really had enough time as a workgroup to address it. But, I think of course the risk dimensions framework does a good job of characterizing the various kinds of risk that could be introduced to the health system by health IT. But I think that becomes very difficult because if you look across even if the row of sort of complexity of implementation and upgrades, lower, medium and higher risk, it defines well what you might – what is reasonable to say it could introduce lower, medium and higher levels of risk. But I don't think that we've really gotten to a point of characterizing what that means in the actual real world clinical setting and how we would measure it, what support requirement we expect might come out of that. I don't think we actually even know that. And so I think all in all, we can add as many lines as we want about needing to address this, but I think that it's one, important to acknowledge that there are still many unknowns. Two, a need to characterize what all of these things mean in the real world setting before we can even set out to try and regulate anything to mitigate those sort of real world outcomes that we're looking to avoid. And three, I'm really hoping that at least next week we can start to move things along, kind of translating some of those risk categories to – and those real world items that we're either looking to mitigate or looking to improve, really defining them and making them measurable.

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

Yeah, that makes sense. So, let's move on. I hope people have had a chance to take a look at the Request for Comments; a lot of very thoughtful comments. Several organizations suggested that we review the full range of health IT products carefully to judge the extent to which they pose risk to patients and that that does not mean that all types need to be regulated. Clearly we – I think we supported that. A number of people supported the BPC report.

Around risk and innovation, one point that seemed especially relevant to me was that a number of people commented that a significant contributing factor to patient safety is system configuration and use, which goes along with what we were just talking about and there were a number of examples presented around that. Just, does it fit? It would be helpful to add something to the report about that. In terms of which factors or approaches could be included in a framework, a number of people also mentioned the BPC report. There was a lot of support for using existing voluntary safety reporting systems. Also for leveraging dark network – databases. There was support for using standards. There was support for security testing from several organizations.

On the regulatory front we were asked to conduct an environmental scan of existing regulatory efforts, which obviously was done quite thoroughly. We were asked to clarify some of the agency roles and avoid overlap, which again we've identified a number of places where overlap exists. So that's an ultra-high level, very brief summary and I'd just be interested in anyone's thoughts about other points that were made that they think we should include. There are obviously lots that were made that are very helpful.

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

This is Paul Tang. I'd just like to support what you're saying. I think in general the work that's been done through this workgroup with the diverse representation, has certainly brought up a number of these topics that have been reflected in most comments. I think we have certainly done a considerable amount of work to address them, so I think they're pretty well covered.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System

Dave, Julian here. I think it may be worth noting, for the public, that the various meetings have all been recorded on line and even though there's content that hasn't been incorporated in the slide deck, there's extensive discussion and broad-ranging discussion of topics, I should say, that are part of the record. And I think that – I've been impressed by the range of topics covered and the depth of topics covered.

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

Actually David, this is Robert Jarrin again from Qualcomm. In one of the slides at the beginning of your deck, I think it's slide number 5, it talks about committee process and it mentions multiple conference calls, but there were actually dozens of conference calls, it may be more applicable to say something like that. But you also mention much of the prior work done in this area, including IOM Committee recommendations, the report of the BPC, among many others. Instead of mentioning any one group out there, if we're going to mention them, you may want to add as an appendix just a list of those organizations that commented and those that we've been considering. Because we have considered Continua, for example, there's the Mobile Health Regulatory Coalition and others. I don't think it's fair to list one out, IOM I understand because of the prestige of the institution, but –

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

I'd be fine with dropping the BPC one, it did get a lot of mention in this set of comments, but I was ambivalent about how to handle that myself.

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

David, this is Patty. I'm struck by the absence of consumer group commentary in the public comment, and I recognize that the comment period is over, but I would like to – I don't know if it's been reflected somewhere in our final report. But that we did seek and incorporate, to the extent possible both in the membership of the committee as well as in the conversations, issues germane to lay users of technology, it's not just the professionals.

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

If I could just clarify, this is Jodi Daniel. The commentary – is still open, we have told people to respond by a certain date if they wanted it to be included in the Committee’s deliberation, because of the limited time you all had. But if there are folks that you think would benefit from commenting on this, then you want to call their attention to the Federal Register Notice, they can still submit comments and the agencies can still consider them.

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

Oh excellent. Okay, so I – because I think I would reach out to – a little bit to some of the usual people that we see in the consumer field, and I have had some conversations with some people from AARP. I was a little bit surprised there wasn’t a mention in the commentary from them.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Patty, this is Mike Lipinski with ONC. I just wanted mention that we only heard from Community Health Initiative, but the comment period runs through August 31st, so they have up until then to make comments for consideration by the agencies.

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

Excellent. That’s helpful, thank you.

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

This is Meg Marshall and perhaps Jodi this is a question that you may be able to answer. The RFC specifically asks about the types of HIT that should be addressed by the report, and so there’s a little bit of disconnect with the output of the taxonomy group in that it directed the discussions of the subgroups. And I’m not sure that we actually, as a workgroup, came up with a definition or endorsed a definition, and I see here from the RFC submissions and summary that there are actually several possibilities or several submissions there. I’m just curious around what happened to kind of close that gap. Obviously you, Bakul, Matt and the other agencies involved will have this discussion and kind of come up with this on your own, based on our discussions or how do you see that playing out?

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

Meg, sure, I mean we can obviously take all of the input on our own and considerate it. That said, there’s also – you all are providing initial comments and input to the Policy Committee in the beginning of August, which is this presentation that David walked through. The final presentation to the Policy Committee, hopefully for their approval and submission to ONC is in September, so you’ll still have some time, if there are particular things that came up in the comments that you want to discuss, you can do that. Or you can point us to them, if there are particular things you want to make sure that we consider, you can do that. So you also have some time and yes, we will consider all of the comments that we’ve received, whether or not you all take them into account, we’ll look at them as valid for developing the framework. So, specifically those that came in after the first deadline, which was the one that we said was for committee consideration. Does that help?

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

Yes, definitely. I think that I hear you say more time and theoretically I know that it’s on the calendar, like today’s session, I know that there’s a lot of concern around expanding the slides or introducing topics that may be at this late stage in the game. So what I hear you saying is that as the work – even as the workgroup continues to work over the next month or so, we may not be able to influence the slides themselves, but can continue the discussions. And to continue submitting either to the full workgroup forum or perhaps to the agency heads, some additional thoughts that we have, is that a fair assessment?

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Um, not exactly, because I would say that we can only consider the input that we get from the Policy Committee, so it has to be something that's been presented to the Policy Committee and then submitted to us. It's just the Advisory – the Federal Advisory Committee Act rules. We're supposed to consider recommendations from the commit – the full committee. What I'm saying is, and this is up to David as the chair, as far as what gets discussed between now and September, I'm saying there are still meetings on the calendar in August, if there's something that David wants to have a discussion on and if you all agree with having a discussion on, you can. We will consider all the comments that we receive from the public, whether or not you all have time to consider them. But if you just have a discussion in the workgroup and it's not something that you get consensus on and bring up to the committee, we're not supposed to use that to make our decision. So, of course we're listening to the conversation and it's part of our thinking, but technically we're supposed to focus on what comes through the whole process.

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

Okay. Thank you that does make sense. And my last question, before David says that we don't have any more time, is directed toward David. So, I understand that the presentation to the Policy Committee you'll have 45 minutes and much of that will be your commentary. And today we did have a chance to review the slides, very briefly, but I'm very curious as to whether we'll have an opportunity to hear a little bit of your commentary or how you plan on presenting the content of the workgroup. And not necessarily a dry run, per se, that would take up an entire 45 minutes, but do you see that as potentially happening during our Thursday call, is that you take the opportunity to kind of feedback to us as a workgroup how you interpret the slides and what you intend on presenting and maybe receive some feedback there?

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

I had felt that it would be more valuable to actually to get more people's input and hear from you. I could certainly run through the slides if people feel that would be the best use of the time, although I'm kind of – I wouldn't favor doing that personally.

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

I understand and I was referring that to group. I just recognize the importance of the actual presentation and the commentary being part of the public record, in addition to the slides. I just thought it might be an opportunity to do that.

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

David, this is Brad, just a process question. You're obviously going to present the slides, but are other people going to be on the line as well and if they want to add a particular point of emphasis or respond to maybe a question that someone on the Policy Committee asks, will there be other voices heard or not.

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

The usual is for the person who represents the group to do the presentation. Jodi, do you want to comment?

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Um, yeah, that's typically how it's done. It's usually the chair of if we have co-chairs, the co-chairs that make the presentation. Often we'll have somebody on the committee, if there's somebody on the Policy Committee who is also on the workgroup, they might jump in, that sort of thing. But that's usually how it's been done.

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

I mean, what if it's a scenario where David isn't comfortable answering the question if maybe it was work done in a subcommittee and he wasn't present when the discussion was had?

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

(Indiscernible).

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

I will defer to David.

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

Yeah, what I would do in that instance is take a note and then talk to someone from the subgroup.

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

That's if it's apparent that that's what's happening. I mean, the question is, if somebody asks you and there was discussion about it that you weren't present during that discussion, you wouldn't know about that discussion.

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

Of course Brad, you understand that representations by the chair of any organization or committee are done this way all the time, right.

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

Well I understand that usually the work proceeds in the presence of the chairman, because it's work among the whole committee. Here we've broken down into 3 and that's made it a bit different.

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

So that's common in companies, organizations and committees, it's a representative process and the chair is presenting our combined work. So I don't think there's – it doesn't sound like there's any difference, I guess is my point.

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

How about – it usually works, well, we won't get – we've talked about whether there ought to be a written report that is, in fact, a consensus and we're stuck with a PowerPoint approach, that at times is very cryptic and that crypticness is a cause for concern.

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

I'd say you've made clear your perspective about that. We're at the end of the hour and I do want to leave time for public comment. Michelle, could you – I'm going to make one more comment and then could you get ready to open the lines. So between now and next week, the Risk and Innovation Group has another call, we'll get some input from them. In the next meeting we'll go through this again and we will get to the last few slides, I'm really sorry we didn't get to talk about those. If you have comments about those between now and next week, please feel free to just email me suggestions. It is important that they match with the rest of the recommendations and so, have a careful look at those. And with that, let me ask Michelle to open it up for public comment.

Public Comment

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

Operator, can you please open the lines for public comment?

Caitlin Collins – Project Coordinator – 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 do have a public comment. Please proceed with your comment.

Nandan Kenkeremath, JD – Vice President Government Relations and Public Policy - QSI/NextGen Healthcare

Hi, this is Nandan Kenkeremath with QSI/NextGen Healthcare Information System. My comment goes to the risk factors and that the nature of health information system risk is very different than the type of risks of traditional medical devices. So, when you're going to your sort of framework and looking at sort of level of risk, the distinction between how you would approach the program looking at system risk is very, very different and needs a different kind of model. And that element or distinction of risk, to me, is a big piece of how you would do the architecture different – and so, I'm just wondering if people could consider that in how their articulating the framework.

Caitlin Collins – Project Coordinator – Altarum Institute

We have no more comments at this time.

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

Okay. I want to just thank everyone. I feel like this was a really productive call, we made a lot of progress. There's clearly more to do. There are clearly a few rough edges I think this will be better the next round, so, not be perfect, but we'll do the best we can. If you have specific suggestions, please feel free to just email them to me, I have a whole list of things that we'll do, based on what already came up today or if they're better oriented to separate chairs you could send them to those individuals. I think we've talked about who has done what, but you can send things to either of us. And then I will work on trying to assimilate everything. I just want to thank everybody again for all their hard work.

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

Thanks David.

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The next meeting is Thursday morning, August 5th.

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

The next meeting is Thursday morning.