

**HIT Policy Committee  
FDASIA Workgroup: Taxonomy Subgroup  
Transcript  
May 28, 2013**

**Presentation**

**MacKenzie Robertson – Office of the National Coordinator**

Thank you. Good afternoon everybody. This is MacKenzie Robertson in the Office of the National Coordinator for health IT. This is a meeting of the HIT Policy Committee's FDASIA workgroup, subgroup on taxonomy. This is a public call, and there is time for public comment on the agenda, and the call is also being recorded, so please make sure you identify yourself when speaking. I'll now go through the subgroup roll call. Patty Brennan? Meghan Dierks?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Meghan. Richard Eaton? Elisabeth George? Drew Hickerson?

**Drew Hickerson – Happtique, Inc.**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Drew. Mary Anne Leach?

**Mary Anne Leach – Children's Hospital Colorado**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Mary Anne. Meg Marshall?

**Meg Marshall – Cerner Corporation**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Meg. Mary Mastenbrook?

**Mary Mastenbrook – Consumer**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Mary. Jackie McCarthy?

**Jackie McCarthy – CTIA - The Wireless Association**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Jackie. Mike Lipinski?

**Michael Lipinski – Office of the National Coordinator**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks. Jodi Daniel or Steve Posnack?

**Jodi Daniel – Office of the National Coordinator**

Jodi's here.

**MacKenzie Robertson – Office of the National Coordinator**

Great. Thanks, Jodi. Bakul Patel?

**Bakul Patel – Food & Drug Administration**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Bakul. And Simon Choi?

**Simon Choi – FDA**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Simon. And Matthew Quinn? Okay. Any other FDASIA workgroup members on the line whose names I haven't already called?

**Richard Eaton – Medical Imaging & Technology Alliance**

Rich Eaton.

**MacKenzie Robertson – Office of the National Coordinator**

Oh, great. Thanks, Rich. Okay. With that, I will turn the agenda back to you, Meghan.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Thank you, everyone. I wanted to start by kind of restating at a high level what our goal is of this this subgroup, and that is to present to the remainder of the workgroup a taxonomy, essentially a list that helps scope out for them what the scope of their work would be, the subgroups that are going to be involved in risk – the risk-based strategy, and then recommendations on regulatory strategy. So our goal is to really give them a guide on the dimensions of the problem that we would like them to then talk about and address in their subgroups.

We – Patty Brennan took some of the notes from the last subgroup meeting that we had and then committed to sort of a tabular form, and I just want to acknowledge that this – ultimately, the format of how the information gets presented, we might come up with a slightly more consumable or readable format, so we're not committed to this tabular format. I just want to reassure folks.

But she was able to sort of put together a lot of the topics that came up in the last discussion we had. So I think for today's goals, it would be ideal if we could come up with a little bit more of what we believe is sort of the final form, the list of items that we would like to hand off to the other groups as helping them understand the scope of their work.

One recommendation that I want to sort of put out for today's discussion is that we maybe refine or touch on some of the other things that are beyond just talking about what, meaning not just creating a list of the types of health information technology that we believe that they should think about or talk about with respect to risk-based regulatory strategy, but also kind of other aspects of the problem, and specifically things like do we want them to include in their deliberation, their discussion, and the recommendations they ultimately make, issues having to do with whether they should regulate aspects of the implementation, such as the configurability, whether we want them to actually talk about and include in the scope of their discussion things that have to do with how independent components could be put together to a system – to create a system of systems. In other words, should risk analysis and regulatory strategies go beyond just the top to bottom component, and maybe address even the interface between two other independent components?

And then last, do we want to – I'd like to see if we can deliberate and get a little bit more clarity about whether we want them to consider as part of the scope of their discussion and their recommendations the process, whether they want to put regulation or risk assessment around the process of deployment and implementation. So not just the product, but actually how it is actually rolled out and implemented in a particular setting or with a particular set of providers. So that's my kind of shaping of how I'd like to – I hope that we – some of the goals that we have for this – today's discussion.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks –

**Patricia Brennan – University of Wisconsin-Madison**

This is Patty. I was able to hear some of the last couple of minutes, and I'm completely on board with you. Thank you.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So Patty, do you want to start by talking a little bit about the elements of the table that was ultimately distributed, and just talk about how that last – our last discussion made its way into this content?

**Patricia Brennan – University of Wisconsin-Madison**

I'm actually thinking I need to turn to Steve about the table. We're talking about the general subgroup philosophy for an agnostic focus of functionality table?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yeah.

**Patricia Brennan – University of Wisconsin-Madison**

Yeah. Steve, are you on the call? So I can begin this conversation, but please weigh in. And I want to also make sure that people received a message that came out today from Meg Marshall with some additional questions and some ideas. So there's a nice alignment between these two, with the idea that a way to organize the object, and not the deployment, has to do with being able to characterize who was the intended user, what setting would it be used, and what was the lifestyle, and that lifestyle – cycle stage does refer to the object as opposed – or the algorithm or the solution. I'm using the word object sort of broadly here, rather than the person themselves. I did get a little confused about whether that was persons, and then I realized, we don't have person prototypes.

Clinical and healthcare purpose, which to me is slightly different than if you look two columns over to the purpose for which it was created. So the clinical or healthcare purpose has to do with what was ... the developer's intended view of what this was supposed to do, as opposed to what's it actually used for. So – and you can see this best illustrated in what happened a few years ago with glucometers, which were – glucometers intended for home use suddenly began to be deployed in smaller hospitals, and as is well-known, the tolerance interval for glucometers for consumer use is much broader than the tolerance interval for clinical assessment in a hospital.

So this is the intended use, and these appear to me to be a little bit overlapping. We can talk about the distinctions later. The idea of who created it or developers is – has some – again, some overlap, with some idea of what appears to be maybe a mix of integrity and propriety, the purpose for which the object was created. And this has to do with – my understanding is the specificity of whether this was to be – and Meg's term for this was distribution scale, which I actually think fits it quite well. Again, not necessarily distinct and non-overlapping. These categories can be overlapping.

And then, finally, what was the distribution method? And this was intended as a way to put some structure around a large set of conversations that was occurring during our first meeting. And as I caught in Meghan's remarks today, there are other aspects we want to consider, which includes the idea of implementation and where in the life cycle of a – of an object would want to do – or what are the many places we would want to have risk assessment occur?

So let's stop for just a moment and get reactions to the table and to Meg's comments through here as a starting point to discuss the taxonomy.

**Richard Eaton – Medical Imaging & Technology Alliance**

This is Rich Eaton. I had a question, basically, and it pertains to the first bullet. Meg has – Meg Marshall has some pointed, good questions here. My understanding, and it may be wrong, but the HITECH definition of HIT is extremely broad and comprehensive, and includes hardware and software. So I am wondering whether that understanding or – is subsumed some way in this – in this graphic here, or – I don't recall any decision being made that we're going to narrow that down. Perhaps I missed it. But – so that's my – that's my question. How does – how does all this fit within a HITECH definition, or doesn't it?

**Patricia Brennan – University of Wisconsin-Madison**

I actually think it's meant to be inclusive. Do you see some exclusions in here that I might need to better understand?

**Richard Eaton – Medical Imaging & Technology Alliance**

Well, it's more a question – you know, I suppose it's possible that you could say it's subsumed in here, but I just wanted to raise that. I mean, Meghan raised that, and I think it's a very good question.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So this is Meghan Dierks. You know, my – it's one person's perspective, but I'll kind of share my perspective, that the HITECH Act came out with a very high level, very broad definition of what they saw as healthcare IT. And even, you know, prior to the history of the HITECH Act, FDA had existing, precise definitions of what they considered a medical device.

And the task that we're facing right now is providing some recommendations for further deliberation about how ONC and its partners, FDA and FCC, should think about developing a risk-based, potentially a regulatory strategy around those things that don't currently fall clearly under the FDA's definition of medical device, because they current – they have a framework for risk-based regulation. But we may also find, though, if we look at the broad definition by HITECH that there's some things that we actually don't feel probably need any special regulatory structure around them. In other words, we feel that without any additional controls that would be, you know, defined and enforced by a regulatory authority, that there are certain types of health IT that are – we deem relatively safe and don't require any special oversight or regulation.

So that's sort of my interpretation of the relationship between what we're trying to do in terms of the things – the list of things we want to have further discussion and potential regulatory strategy created, that fall under the definition of HITECH Act, but we feel pose some special considerations and require some kind of additional special controls, but don't go and fall clearly under the medical device definition. I don't know if that helps.

**Richard Eaton – Medical Imaging & Technology Alliance**

And I think it is – it is helpful. I think it would be helpful to the other groups if we say something to that effect, then. Here – the devices are here, the products that we feel are already sufficiently regulated, that don't need additional regulation, and they're appropriately regulated. I think that helps draw boundaries on something that's hard to draw boundaries around. I think it would be very helpful to the other groups if we ...

**Patricia Brennan – University of Wisconsin-Madison**

Do you – this is Patty. Do you have a suggestion for some boundaries, even if they're – just as a starting point?

**Richard Eaton – Medical Imaging & Technology Alliance**

Well, I think following up on what Meghan was saying, if we specify certain types of products and/or devices which we believe are already appropriately regulated and don't need added consideration, I think that's a good starting point.

**Patricia Brennan – University of Wisconsin-Madison**

Okay.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

And so if I can elaborate a little bit, let me just see if this is where you're thinking. So the FDA currently already regulates software that's embedded in a traditional device, and they regulate it as it's essentially a component of a product that falls within their standard definition of medical devices. So it would, in my – from my perspective, that would be out of the scope of anything that we would recommend, because that's already falling within the regulatory framework of the FDA. Is that – that's sort of one of the boundaries, right?

**Richard Eaton – Medical Imaging & Technology Alliance**

I think so. I think so.

**Patricia Brennan – University of Wisconsin-Madison**

So Meghan, another exemplar I'd like to push up to see if we could figure out which side of the boundary it might be on is social robots. So there's been a couple of news briefs in the last couple of weeks about robotic assistance for the home that are intended to interact with individuals and remind them of medication times. Some have very fanciful views of – these may go as far as guiding a person in passive range of motion, maybe assisting a person in ambulation. But there's a – there is a component of scheduling, maybe even decision logics, that would be presented not through any familiar software or computer screen, but rather through an inanimate but engaging object. So –

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So –

[Crosstalk]

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

– using that as an example, maybe we could talk through some of the – some of the issues. So using that as an example, first, you know, as you described it, you're right, it would not fall within the traditional definition of FDA medical device, because it doesn't directly treat or diagnose. It handles maybe processes, some health information. For example, might process medication – a prescribed medication schedule, and prevent – and present a user with alerts or updates or recommendations on what they should themselves – what actions they themselves should take. Is that – is that a fair description of what you used as your example?

**Patricia Brennan – University of Wisconsin-Madison**

Yeah. That's fair.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yep.

**Patricia Brennan – University of Wisconsin-Madison**

Yep.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So it is an example. It doesn't fall within the traditional definition of medical device, might fall within the definition of the HITECH HIT.

**Richard Eaton – Medical Imaging & Technology Alliance**

Right.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

And we would talk a little bit about – so then the next question comes, without any oversight or any special design controls, do we believe that, you know, that a malfunction or a poorly designed functionality could potentially lead to harm to a – to an individual user? So in other words, are there some risks, potential, theoretical risks associated with the misuse – foreseeable misuse or the malfunction of this type of product?

**Richard Eaton – Medical Imaging & Technology Alliance**

Right.

**Patricia Brennan – University of Wisconsin-Madison**

And so I could envision small risk of – if a battery ran down or a power failure occurred, that the clock would be off, and a person's medication schedule would be put off the cycle, say by two hours or something like that. So that's to me a small risk. I could imagine a large risk where a passive range of motion engagement – well, that would put out of a device issue anyway, right?

**Elisabeth George – Philips Healthcare**

Isn't one of the challenges – this is Elisabeth. Isn't one of the challenges that you have with specifically identifying device is what I always call the creep factor?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Right.

**Elisabeth George – Philips Healthcare**

You identify a device, and people have a tendency to gradually creep with what it does. So it goes back to the Congressional hearing, when they were asked the question of is a scale a medical device. The answer is, it depends. It depends on how it's being used. It depends on what its claim is. It depends on the risk. So there is no one device that you could say the device is not – and I think that's why it's more how it's used, and I think you – you know, the matrix that you have here where you talked about intended use and how it's being used, that description of that robot, you know, I think if you walked across this device, is that, you know, it's a consumer only. It's personal home. It could probably fall in any one of the life cycle. It potentially could fall in any of the clinical care areas, depending how it's being used. It could be created by any of the people in the – in that box. It could be a single use, so it's custom, or it could be broad use. So I think that's where –

**Meg Marshall – Cerner Corporation**

This is Meg Marshall. I want to get something clear about the chart that's being used. Just from my understanding, that was the intent of one of the bullets. I don't think it's intended to be a walk through where the rows, the horizontal rows, are dependent on the columns. Am I correct in that? So that –

**Patricia Brennan – University of Wisconsin-Madison**

Yes. That is true.

**Meg Marshall – Cerner Corporation**

So perhaps – yeah. So perhaps the outcome that we're actually looking for is more like a decision tree, where we can have more of those –

**Patricia Brennan – University of Wisconsin-Madison**

Right.

**Meg Marshall – Cerner Corporation**

– independent variables.

**Patricia Brennan – University of Wisconsin-Madison**

Exactly.

**Meg Marshall – Cerner Corporation**

So if we were to start with a very high or very broad definition, and I'm not sure of the protocol of the group, if a consensus is required, but let's assume that we're all operating under the HITECH definition and the FDA medical device definition. It seems like that would be the start of our decision tree, the delineations between those two. And then our value is to help provide these components or the – you know, the independent variables that are here that would make up the decision tree. So, you know, are you – are you a medical device? If no, then you're over here. What is your intended use?

And then perhaps ultimately we hand off that decision tree to the risk group, and the risk assessment group takes it on and says, okay, so now we've – we've gone this far with our decision, and your risk is high. So what ultimately does that mean? Does that mean that now you are required to do pre-market notification? That you're required for good business – but, you know, what exactly does that mean, if your – if your risk is at that level?

So I think that that might be a little bit helpful, if we turn the visual a bit and maybe started approaching it as a decision tree.

**Patricia Brennan – University of Wisconsin-Madison**

Very nicely said.

### **Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So I think it's a great suggestion. I think it's the most pragmatic from, you know, helping them sort of frame their discussion. One thing that I would kind of maybe suggest is that – in terms of as you work your way through the – so the decision tree is nice, because it first starts out very high and says, okay, if it meets these criteria, you know what? It's a medical device, and just go with that.

I think that, you know, as I imagine this decision tree moving down, the caution would be to not – for our group, our subgroup, which is really charged with creating what's the scope, is not to actually give a specific recommendation, but just say at this branch point, you know, perform some type of a formal risk assessment, and then how is that risk assessment – you know, what are – what should be the scope of thinking around the way you do the risk assessment? And then, you know, apply some controls based on, you know, the risk stratification, and the controls that you should think about would include – potentially include all of the following, but please consider these on the list of things to deliberate.

Because I think we're not going – our group I think isn't tasked with giving specific recommendations, but instead helping the next two groups make sure that they address at a minimum the following, you know, aspects or dimensions of the problem.

### **Meg Marshall – Cerner Corporation**

Yeah. This is Meg again. I absolutely agree with all that, and I would continue to add and say that we need to make sure that the decision tree, even if the group thinks that it's a low risk or a low level of oversight needed, that the decision tree allows that to happen. So within that broad definition of health information technology, it is possible that there are some – that there's a component of software that, you know, ultimately will end up without any oversight, and I just want to make sure that that tree recognizes that.

### **Patricia Brennan – University of Wisconsin-Madison**

And I think that's actually important in any graphical representation we develop. And Meghan, if you want me to give a try to put this into a tree model, I can. The important point is that we have the various next level, if you will, alternatives coming out from each option. But there needs to be a and it doesn't fit here space, and maybe even during our discussions next week – or this week, sorry. We are in DC. A statement that says who's going to make that decision that it doesn't fit here. But I think these are really very help – this is going to lead to a very helpful conversation.

### **Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

This is Meghan Dierks again. A couple of things that – I don't want to go off on a tangent and truncate this conversation, but I just want to make sure that I mention a couple of things that we haven't really talked about. You know, one of the things that I kind of want to have on a list of in scope, meaning that we're not going to solve it, but we want the next two groups to explicitly address it, is, you know, how exactly – what specific type of risk assessment will they propose? And I think the easiest way of kind of explaining my thinking here is that when it comes to traditional products, it's easier – it's not universally easy, but it is easier for that – for you to sort of count the number of products out there and estimate the number of times that it's used in a given life of that product, and then count the number of times that it malfunctions.

So it becomes relatively easier to kind of quantify the probability of failure, and even quantify the failure mode. Software is really difficult. It's difficult in so many ways, because you may be able to count how many licenses you have, but it's very difficult to know how many times the product's actually being used. It's very difficult to count even, if you think about one specific functionality within a piece of software, how often that's being used, and under one – what conditions.

So I've struggled with this for many years, trying to figure out how do you actually quantify the probability of a – of a particular failure, all the modes of failure, given the diversity of implementation. So let's say for the sake of discussion that we were to, you know, come up with a list of things that we wanted them to discuss and think about. One of the fundamental challenges that the next two groups will have is developing some reproducible way of quantifying probabilities of failure, the severity of harm, sort of the traditional ways in which you assess risk with other types of products.

So I don't know if we want to spend a couple of minutes talking about how we want to describe to them or talk about the scope or how we want them to think about it. But that's going to be a big challenge.

**Patricia Brennan – University of Wisconsin-Madison**

Meghan, I'm not exactly clear on what the – what you're asking, but I – if I can say it back to you, you can tell me how much of it I actually understood.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay. Sure.

**Patricia Brennan – University of Wisconsin-Madison**

It's Patty. When we present this taxonomy to our colleagues for their deliberation, we are anticipating that they will attend to certain other features in its use. One aspect that's very important that we hadn't brought up yet was the idea of tracing – tracking failures, or at least tracking near misses of failures, so we can actually generate an evidence base for the risk – future risk assessment.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Mm-hmm.

**Patricia Brennan – University of Wisconsin-Madison**

A second one is some guidance to the committees, and this is where I'm now getting a little bit confused, some guidance to the committees about what aspects of risk management and what strategies for risk appraisal we would like them to consider. Did I hear that right?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So not exactly, although those are all valid points. So typically – now I'm going to talk – I'm going to step back a little bit outside of the specific problem we're facing. Typically, if you want to use a risk-based approach to either regulation or design or risk management, you basically have to have some defensible and reproducible way in which you measure the probability of harm, probability of failure, and then the probability of harm, given the failure.

So we talked I think in our last session about it's important that we figure out a way of tracking failures, but, you know, ten failures, which might sound like a lot just in raw count, is really a low probability, if it's ten out of ten million uses, right?

**Patricia Brennan – University of Wisconsin-Madison**

Yep.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So the standard – you know, when one thinks, whether you're talking about the other regulatory bodies, EPA, the NRC, FDA, all of the bodies that sort of regulate public health and think about a risk-based strategy to formulate their recommendations and their regulation and their enforcement, you know, most of them try in some way to come up with a – hopefully, ideally, a quantifiable way, how to quantitate the probability, and try to shy away from sort of ponderous or overly burdensome controls when the probability is very, very small.

Now there are two things. You have to consider how to measure the probability, but also how to measure the severity of the harm. So those are two really important dimensions, when you're thinking about a risk-based strategy for making regulation or controlling how a product is manufactured or distributed or used. It's really going to be difficult. It's very difficult for software, because you never know what the denominator is, right?

So it may be that they may have to err a little bit more towards what the severity of harm is, what other mitigating strat – mitigations exist outside of the product itself. But I don't know if from our perspective, from our subgroup's perspective, we want to just explicitly put that on the list, so it's, again, the taxonomy goes beyond just these are the products we want you to consider, to also these are the other dimensions of the problem that we want you guys to deliberate when you think about it. So the taxonomy isn't just product, but it's also the other aspects of risk assessment and regulatory strategy.

**Meg Marshall – Cerner Corporation**

And this is Meg Marshall. I like that approach, and I don't know if you had an opportunity to sit in with the risk assessment group last week, but maybe one of the things that we can do to avoid duplication of work is to just do a simple categorization. So the risk is high, medium, or low. And if we have any thoughts around that would look like or what distinguishes, we could certainly forward that one. But it seemed like Paul had a pretty good grasp of the components that they were looking at for the risk assessment.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay. I'm glad that you were on. I wasn't on the call. So if you – if you're sort of reassuring us that they really are thinking about this, then I think that's good, and we wouldn't have to duplicate that.

**Meg Marshall – Cerner Corporation**

Oh, yeah, yeah. Absolutely.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay. Great.

**Patricia Brennan – University of Wisconsin-Madison**

Let me interrupt for just a moment, because Steve has come on the line – actually, came on quite a while ago, 20 minutes ago. And so I wanted to see if he has something that he wants to contribute at this point.

**Steven Posnack – Office of the National Coordinator**

No, no, no. Sorry. I'm sorry about being a few minutes late. I don't have anything to contribute at this point.

**Patricia Brennan – University of Wisconsin-Madison**

Okay. That's fine.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So –

**Mary Anne Leach – Children's Hospital Colorado**

This is Mary Anne. Going back – kind of going back to the decision tree, I think that would be a great explanatory format. And start at the very top with what's – you know, what's carved out either under HITECH or medical devices, you mentioned. And as we go down the tree, it would be great if we could annotate it with examples of what we're talking about, so people can relate to the different levels.

And I also sat in on the risk call, and I think they're absolutely working on a lot of the same things in terms of the risk stratification, so –

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Right.

**Mary Anne Leach – Children's Hospital Colorado**

– I think our groups are pretty tightly aligned.

**Patricia Brennan – University of Wisconsin-Madison**

I have heard – this is Patty. I have heard, though, a caution about exemplars.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yes.

**Patricia Brennan – University of Wisconsin-Madison**

And I tend to be an example kind of girl, but maybe – maybe if we can just take a few minutes to see how we can use examples without making them become anchor points.

**Mary Anne Leach – Children's Hospital Colorado**

Right.

**Patricia Brennan – University of Wisconsin-Madison**

And anyone who can solve that –

**Mary Anne Leach – Children's Hospital Colorado**

Well, no, again, the problem is it's all the stuff we haven't thought of yet, right?

**Patricia Brennan – University of Wisconsin-Madison**

Right.

**Mary Anne Leach – Children's Hospital Colorado**

That we're trying to regulate.

**Meg Marshall – Cerner Corporation**

May I ask – this is Meg Marshall again. What are the expectations for the in-person meeting? Realizing that we're kind of short on time, will there be additional opportunity for discussion, or how would you like – what would be the best format to kind of group this together and make it make sense, at least for our first pass at a presentation.

**Patricia Brennan – University of Wisconsin-Madison**

Well, Meghan's going to go first.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So yeah. I have to go first. So I can tell you the – what the – the expectations are that we have a very brief sort of presentation, I think, you know, one or two slides, and a discussion of our – the process by which we came to that. But I think that we're going to open it up to the group, and there'll be a little bit more discussion, so that what we – what we present, what we come up with in the next 24 hours to present, won't be set in stone. I would anticipate there's value in hearing some feedback from the larger group, and then finalizing something to hand off by the end of the second day. Patty, did you have a different set of expectations?

**Patricia Brennan – University of Wisconsin-Madison**

Yeah, that's my understanding. For some reason, and Steve, you might be able to clarify this, or I think MacKenzie's also on the call, it appears that there actually is a plan to have the taxonomy group make a presentation, and the other two groups react to the presentation, and then have workgroups in the afternoon. Is that – is that structure familiar to other people? Or did I dream that?

**Steven Posnack – Office of the National Coordinator**

Yes. This is – this is Steve. I'm just trying to pull up the agenda. Everyone should have gotten an email from the ONC **SACA** email around at least noon eastern time today, 12:30. The other two subgroups are going to go for about a ten minute stint in the beginning, and then the taxonomy group has roughly a full two hours to have discussion with the broader group. So happy in the next, you know, 24 to 36 hours to help you all pull together whatever show and tell type of thought processes, etcetera, that you want to put into a PowerPoint or whatever other type of medium that you'd like to use.

And then, you know, we can – I think part of it would be to key up for the workgroup to say like, does this direction make sense to everyone else? It does to us. Get feedback. It'll be informative to the other groups, probably, to help them as they consider their charges as well. Does that help?

**Patricia Brennan – University of Wisconsin-Madison**

Yeah.

**Jodi Daniel – Office of the National Coordinator**

Yeah. And this is Jodi Daniel. Just to add to that, I think the rationale in having you guys have time first thing in the morning with the whole – the whole workgroup was that the tax – this workgroup sort of sets the tone and thinking for the others, who are kind of diving in deeper, based on – based on sort of the thinking that comes out of this workgroup, this subgroup. So the thought was to have enough to tee up for a conversation and discussion, try to get some rough consensus of the workgroup, at least enough so that the risk and innovation group and the regulations group have a construct to work with in thinking about their charges, and that would be – my recollection is that would be in the afternoon. The other workgroups kind of – the workgroup breakout sessions. But hopefully based on a great discussion that we will kick off in the morning, and hopefully some general agreement about the direction.

**Patricia Brennan – University of Wisconsin-Madison**

I think that's very clearly my understanding of it also. So someone asked about what we were trying to accomplish. Did that give you enough of an answer, or do you want to go into some more depth about this?

**Meg Marshall – Cerner Corporation**

If you're referring to my question – this is Meg again –

**Patricia Brennan – University of Wisconsin-Madison**

Yeah.

**Meg Marshall – Cerner Corporation**

– I was – I was more specifically questioning how we could facilitate that within the next couple of days. So are we looking to perhaps have some email feedback on the components here in the chart, and then maybe the subgroup gets to a rough consensus as far as what components belong in the chart or the decision tree or whatever it turns out?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yeah. I – this is Meghan. I am – I'm going to hope that – I will actually volunteer tonight to put together a – unless someone else wants to do it first – sort of a, you know, straw man first pass at the decision tree –

**Patricia Brennan – University of Wisconsin-Madison**

Oh, Meghan, I've got one. I've got one that I'm going to send you when we're done with the call to get started.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay. All right. Great. But I'm going to ask everyone – certainly everyone who's on the call right now, and then we'll also – we'll certainly include everyone else, to see if you can take a little time to look at it, provide some feedback, add notes, and over the next 24 hours, which is really all the time we have before we're on site, is to try to synthesize that all together into one, you know, sort of one coherent presentation, and then that'll be enough to stimulate the discussion amongst the larger group.

**Meg Marshall – Cerner Corporation**

Okay. Perfect. Thank you.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So we're – we have about maybe 15 more minutes I think of real time. I wanted to see if there's – you know, thinking about all that we've talked about in the last session that we had, and then what discussion we've had today, are there any other things, any other dimensions or aspects of this problem that we aren't certain have been raised by the other groups, and that we think we want to have on this list? And I'll start by just naming one additional thing that I don't recall has come up in discussion, and that is whether there's been any thought or thinking about recommendations we want to make on talking about the need for evidence or data prior to the broad sale, marketing, or distribution of health IT, some evidence, either, you know, through simulation, through controlled investigation, or anything like that, that demonstrates some basic level of safety or efficacy.

**Patricia Brennan – University of Wisconsin-Madison**

I think it's a great question, and certainly open to a lot of conversation. How will we decide what the risk is?

[Crosstalk]

**Mary Anne Leach – Children's Hospital Colorado**

I think that'll be the heart of the conversation, I think, with the innovation group. And I would agree we need – we need evidence to prove efficacy and value. I mean, that was another dimension that I've been thinking about here with the model, is, you know, what's the value proposition? Obviously, patient safety and efficacy, but, you know, I think we want to think about the cost burden as well. This is probably not the group to think about that, though. I guess that's the regulations group.

**Patricia Brennan – University of Wisconsin-Madison**

When you said the cost burden, you mean the cost of generating evidence, or the cost of purchasing and using the device and the object?

**Mary Anne Leach – Children's Hospital Colorado**

I think the cost burden of the regulatory – as I was thinking about it, it's the value of – the value proposition of the regulatory framework.

**Patricia Brennan – University of Wisconsin-Madison**

Yep. Got it. Thank you.

**Mary Anne Leach – Children's Hospital Colorado**

So that we are not stifling innovation, we're protecting patient safety, and we're not overburdening the health system with additional costs.

**Matt Quinn – Federal Communications Commission**

This is Matt Quinn. Just to maybe put things in a little bit – a different context, one of the other things I work on is Interagency Committee for Disability Research, the assistive technology subcommittee. And one of the big questions is so what assistive technology should the government support? Not, you know, allow to market, but should pay for or support? And trying to generate, you know, evidence with enough power and enough time availability to support decision making in that marketplace or even support is impossible. No matter if you had \$100 billion, you couldn't do it.

And that's one of the real challenges here, is that there are unlimited permutations of disability and assistive technology to potentially support, you know, that, just as there are unlimited permutations of context of use and health IT. And trying to require in some way that there be evidence of a traditional nature to support that is a challenge. Just to provide a little context from a different world.

**Patricia Brennan – University of Wisconsin-Madison**

But you've got the problem characterized exactly as I think it was intended, which is to go beyond the burden of creating the evidence to then what one does with the consequence once the evidence and the risk are created.

**Matt Quinn – Federal Communications Commission**

Exactly. I mean, policy decisions are made on that, but it's impossible for the research as we've done it in the past to keep up with the marketplace.

**Patricia Brennan – University of Wisconsin-Madison**

Yep.

**Matt Quinn – Federal Communications Commission**

And you're risking stifling, for example, an assistive technology that could help people, or excluding it from government support, just because it takes, you know, however many years to do an RCT and costs \$1 million. And ... limitations.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yes. So this is Meghan. That – I agree when you think about the method of generating evidence or data being, you know, a randomized clinical trial. There are other ways, particularly with software, where you can do – you can generate data and evidence for performance as designed through, again, sort of simulation, and through, you know, very – and I don't mean simulation as – I mean a very specific sort of computer-generated simulation. There are other ways of doing – doing it.

**Patricia Brennan – University of Wisconsin-Madison**

I agree with you, Meghan. What I was hearing – Meghan. I'm sorry. I keep saying your name wrong. What I was hearing was that there's multiple ways to generate the evidence, although RCTs are considered still to be the, quote/unquote, best. There are other best ways, or good ways. And then the second thing that I'm hearing, from what Matt is saying, is there will be a downstream policy consequence that we need to at least foreshadow in our conversations, that objects that are considered at a certain level of risk, may above a certain threshold never be paid for by state or federal funds, or will always be covered by state or federal funds. So there is a – a consequence of the risk-based framework will be other health activities about the object.

**Matt Quinn – Federal Communications Commission**

Yeah. I was just trying to provide a little context on – in that – you know, by – don't be too constraining. In that other context, you know, trying to require levels of evidence that just are not possible, given, you know, the – a million different kinds of disabilities, a million different assistive technology solutions that are potentially on the market, a million different contexts of use and situation, it's just, you know, each one needs proof, then we'll never get there.

**Patricia Brennan – University of Wisconsin-Madison**

And I think that's the intention of the framework, is to – is to allow for some robustness, as opposed to a one-of approach to regulation.

**Matt Quinn – Federal Communications Commission**

Yeah. Yeah, yeah.

**Meg Marshall – Cerner Corporation**

So this is Meg Marshall. I realize that we're, again, sensitive, back to the time. So I'll volunteer to help out. My question was, so I know that the components were from the straw man that we discussed last meeting as well as the materials that you had created beforehand, but I do have some specific comments on the components itself, and the actual terms within here. So I – it sounds like the best way to get that back is through email. And I also have some additional suggestions for, you know, other types of considerations. So is that the preferred format? I should just email these back to you?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Meg, this is a good time to at least give us an introduction to them.

**Meg Marshall – Cerner Corporation**

Well, so some of them are very specific. So for example, under the developer column, we have private company. I would probably change that to a different term, and then I would add government entity or what have you. So there's some nuances here as well. But as we look at whether this looks like a decision tree or whether this looks – you know, how – what the visual looks like, you know, we've identified risk as one component that we want to be considered, albeit not by our subgroup. And I think that it's important that we understand the differences between the levels of oversight.

So for example, if all logic points to a high risk component that has, you know, quite a bit of possibilities for patient safety issues, then it might lead to a high oversight, and just understanding what that could potentially mean, versus a clinical application or a patient registration application, for example, that has very little impact to patient safety, possibly, and that would be low oversight. So what – a low oversight may not require pre-market notification, or may not require the labeling. So it's just – I'm kind of speaking out loud. I don't have it prepared right now. But that was – I'd assume that we would get to that type of discussion within the workgroup today, but it sounds – you know, we're running out of time. So if email works best, I could certainly do that.

**Patricia Brennan – University of Wisconsin-Madison**

I think that's a good start, though. I think I got down – the key issue that you just mentioned was the level of risk of – to the – linking the level of risk to the actions that will follow, or to the decision rules that will follow, as one starting point.

**Meg Marshall – Cerner Corporation**

Yeah. And I do think it's important, also, as we're – we've got our components in here. They aren't ranked right now, but if we have any thoughts around ranking of them, so if it's urgently critical that the first question you ask is who is the intended user, then that should be higher up in the ranking, and certainly higher up within that decision matrix. So –

**Patricia Brennan – University of Wisconsin-Madison**

Excellent point. So is there a desirable ordering of assessment? Excellent. Other things?

**Mary Anne Leach – Children's Hospital Colorado**

This is Mary Anne again. Is there another element here – we sort of hinted at it with diagnosis or diagnostics, but clinical judgment, is that a – is that an element of the model that needs to be considered?

**Patricia Brennan – University of Wisconsin-Madison**

If I can say that back to you, it's a question of should we have, as we look across the list of taxonomy, whether it's – the object is intended to be free standing versus mediated by clinical judgment?

**Mary Anne Leach – Children's Hospital Colorado**

Or substitute for clinical judgment.

**Patricia Brennan – University of Wisconsin-Madison**

Okay. Let me put that as a – as a – I have a other considerations page on my slide, and I think it's a really good one. It's a can this replace, augment, or supplant clinical judgment.

**Mary Anne Leach – Children's Hospital Colorado**

Yes.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

So this is – oh, I'm sorry. Go ahead.

**Mary Anne Leach – Children's Hospital Colorado**

Oh, I'm done. Thanks.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay. This is Meghan Dierks. One other – so another maybe way of thinking about this, we can put both, if they're sufficiently different, is this the sole source of information leading to a decision? I've found just in clinical practice and in thinking about, you know, assess – independently assessing the risk of something like decision support, that, you know, risk increases or decreases if it's a sole source or the sole reliant source of information, versus if there is confirmatory – some – a source of information that can confirm or bring to the attention of the user a possible discrepancy in the information that's being presented, prior to the decision or the intervention or the action that's taken.

And that's true whether one's talking about something in the hand of a consumer, a patient sort of consumer, versus something in the hand of a clinician, a trained, licensed clinician.

**Patricia Brennan – University of Wisconsin-Madison**

I like that very much.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Then – yeah. So – and then another sort of aspect that doesn't appear on what we've currently distributed is whether we should consider whether the piece of software or the information technology is a slave versus a master, meaning does it – is it actually going to reshape or change the way something else that's consumed or subsumed by it? So it's going to be the master versus the slave. And one could think about this in terms of a piece of software that might actually become a master to a conventional medical device, or a piece of software or piece of health information technology that would be a master to another piece of software.

So an example of that would be if a – I'm just making this up off the top of my head, but if you had a piece of software that tried to sort of triage patients based on a description of a presenting complaint, you know, neither of those products are conventional medical devices, but you can imagine that the algorithm that kind of ranks or reshuffles the order of the patient who needs to be next seen could have health implications, and is really – it's now a master that's working off of just say triage intake registration piece of software.

**Patricia Brennan – University of Wisconsin-Madison**

I don't –

[Crosstalk]

**Patricia Brennan – University of Wisconsin-Madison**

Great.

**Mary Anne Leach – Children's Hospital Colorado**

I would also add in that, is there any translation? Are we in any way translating analog to digital? Is there any way the data is being manipulated or changed as a result of the operation of the object?

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

In that the change itself would fundamentally impact or shape the – either the probability of an adverse event occurring, or the severity of an adverse event, if it was misinterpreted? I think that's a – that's a second key aspect of it.

**Mary Anne Leach – Children's Hospital Colorado**

Or pose risk. Right.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yeah. And I just – kind of just a gentle reminder to the group that sometimes I think there's a tendency when one thinks about regulation as sort of being an all or none or very onerous, but there are kind of – again, if it's risk-based, you know, regulation could be as simple as in the design of this, you must demonstrate that you followed, you know, standard – industry standards, and that you've done sufficient testing of, you know, reliability, or that you have done, you know, a formal design review prior to really – I mean, it can be as simple as that, with, again, much more significant regulation, more prescriptive as the risk goes up.

But, you know, even in, you know, moderate risk situations, that type of a kind of regulatory strategy can be highly effective in mitigating risk, without being, in my opinion, overly burdensome.

**Patricia Brennan – University of Wisconsin-Madison**

Meghan, I don't quite know how to translate that. So in my notes I wrote how will the developer demonstrate that the regulation was followed, and that's not – I know that's not what you're saying, but if you'll –

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

No.

**Patricia Brennan – University of Wisconsin-Madison**

– look at that part on the slide and fix it, that would be great.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yeah. This – that was more just an offhand kind of reminder to the group that, you know, and it's beyond the scope of our subgroup here, but, you know, regulation can take on a variety of sort of flavors and be quite effective without being overly prescriptive.

So I think we have six minutes left, and I want to first ask our moderator if – when we have to open up for public comment, and just – that gives us maybe one more minute in our group just amongst ourselves to make any additional comments. But I really want to encourage everyone to use email, review material – review everything that may come your way in the next 24 hours, and that Patty and I will try to put something together for review by everyone before Thursday morning.

**MacKenzie Robertson – Office of the National Coordinator**

So this is MacKenzie. We are scheduled for public comment now. If you do want to take another minute or two just to finalize any other discussions, that's fine. And then I can go ahead and open it for public comment.

**Patricia Brennan – University of Wisconsin-Madison**

MacKenzie, can I just clarify? It's Patty. Do you have to send out this draft of slides to the group, or can – after Meghan sees them, can she send them out? Or should I just send them out to everybody right away?

**MacKenzie Robertson – Office of the National Coordinator**

You guys can feel free to send the email around directly to yourselves.

**Patricia Brennan – University of Wisconsin-Madison**

Okay.

**MacKenzie Robertson – Office of the National Coordinator**

Once the slide deck is final, if you can send that to me, that's fine.

**Patricia Brennan – University of Wisconsin-Madison**

Okay.

**MacKenzie Robertson – Office of the National Coordinator**

And then I'll have it ready to post for the in-person workgroup meeting.

**Patricia Brennan – University of Wisconsin-Madison**

So I'm going to ask if the members on and off the call will look at the slide deck and give your feedback back to Meghan, and if you want to copy the whole group, fine, but Meghan, you'll have the last touch on these.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Well, that's a big responsibility.

[Crosstalk]

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

I will try – you know, I will try not to do anything crazy, people.

**Patricia Brennan – University of Wisconsin-Madison**

You can send them to – I mean, we can certainly look at them if you want feedback. But I think –

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Yeah. Sure.

**Patricia Brennan – University of Wisconsin-Madison**

– that really it's a straw – to start to have a discussion.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay.

**Patricia Brennan – University of Wisconsin-Madison**

And I would tell y'all right now, the tree doesn't work. I got another model, but the tree – maybe you can make the tree work. I couldn't make the tree work.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

Okay.

**Patricia Brennan – University of Wisconsin-Madison**

Okay.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

All right. I'll give it a try.

**MacKenzie Robertson – Office of the National Coordinator**

Are we ready for public comment, then?

**Patricia Brennan – University of Wisconsin-Madison**

Yep.

**Public Comment**

**MacKenzie Robertson – Office of the National Coordinator**

Okay. Operator, if you'd please open the lines for public comment.

**Rebecca Armendariz – Altarum Institute**

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press star 1. Or if you're listening via your telephone, you may press star 1 at this time to be entered into the queue. We have no comment at this time.

**MacKenzie Robertson – Office of the National Coordinator**

Okay. Thanks. And I just want to remind everyone again, we do – the agenda for the May 30, 31st meeting did go out to the workgroup members today, and there's also the online FACA portal that has some resources posted that were specific to this workgroup. So please check that periodically as well.

**Patricia Brennan – University of Wisconsin-Madison**

MacKenzie, can I ask, will we have this material – the slides duplicated for the meeting on Thursday?

**MacKenzie Robertson – Office of the National Coordinator**

Yep. There'll be handouts at the table.

**Patricia Brennan – University of Wisconsin-Madison**

Excellent.

[Crosstalk]

**MacKenzie Robertson – Office of the National Coordinator**

So if you guys can get a slide deck to me – let me think – by – if possible, on I guess tomorrow, tomorrow night? But we can still have them printed the morning of, if you send it to me first thing in the morning.

**Patricia Brennan – University of Wisconsin-Madison**

I think that's going to be helpful.

**MacKenzie Robertson – Office of the National Coordinator**

Okay. If that's all, we can call the workgroup meeting adjourned.

**Patricia Brennan – University of Wisconsin-Madison**

Well, this is Patty. And let me thank everybody, and particularly Meghan, for your contributions and work. And Meghan, you can have the last word.

**Meghan Dierks – Harvard Medical Faculty – Division of Clinical Informatics**

No, thank you, everyone, but I am relying on everyone to take a look at what does go out in the next 24 hours, and let's try to use that time really well.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, everybody. See you in a few days.

**Steven Posnack – Office of the National Coordinator**

Thank you. Bye.

**Patricia Brennan – University of Wisconsin-Madison**

Thanks.