

**HIT Policy Committee  
FDASIA Workgroup  
Subgroup #1: Taxonomy  
Transcript  
June 10, 2013**

**Presentation**

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you. Good afternoon everybody this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. Welcome to the HIT Policy Committee's FDASIA's Workgroup Subgroup on taxonomy meeting. This is a public call and there is time for public comment on the agenda and the call is also being recorded so please sure you identify yourself for the transcript and audio. I'll now go through the roll call. Patty Brennan? Meghan Dierks?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Meghan. Richard Eaton?

**Richard M. Eaton, JD – Industry Manager – Medical Imaging & Technology Alliance**

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Rich.

**Richard M. Eaton, JD – Industry Manager – Medical Imaging & Technology Alliance**

Hi.

**MacKenzie Robertson – 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.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Elisabeth. Drew Hickerson?

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

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Drew. Mary Anne Leach? Meg Marshall?

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

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Meg. Mary Mastenbrook?

**Mary Mastenbrook – Consumer**

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Mary. Jackie McCarthy?

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

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Jackie. Jodi Daniel for Steve Posnack?

**Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator**

Steve is here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Steve. Bakul Patel?

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

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks Bakul and Matt Quinn?

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

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Okay and the ONC lead, Mike Lipinski?

**Mike Lipinski, JD – Policy Analyst – Office of the National Coordinator**

Here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks, Mike. Okay, are there any other FDASIA Workgroup members on the line whose names I haven't called? Okay, with that I will turn the agenda back over to you Meghan, we'll just hope that Patty joins in.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay. Hi, everyone thank you for joining on this follow-up call. I wanted to – just to set the agenda, I wanted to spend just a minute re-capping what the subgroup charge is then really spend the – maybe about half – about half of the time talking about the May 30<sup>th</sup> presentation highlights focusing on what we thought were the reactions by the group and the areas, not so much the areas where there was sort of maybe a sense of consensus but the areas that people drew out and said, you know, I'm not so sure I agree with that. So, we'll talk about those. And then move towards the final agenda item which is trying to come up with a refinement and propose our final in and out-of-scope recommendation.

So, I'm just going to start with a 30-second restatement and again, just really so that we keep our discussion really focused, just a reminder that the in and out wasn't what's in and out for regulation but what was in and out for consideration, the items that we really wanted the other groups to consider or include in their deliberation and so for that reason I felt like if we were going to err maybe erring on the side of being – having too much in the in scope would probably work for us versus excluding something and then the other groups not talking about it at all.

And then the other groups their goal is to come up with some recommendations and strategies which they will then hand off to our federal representatives. So, that is the recap. We sent out the slide presentation from the May 30<sup>th</sup>/31<sup>st</sup> meeting and I had – I apologize for the lateness of it but what I did – what I tried to do is I went back to my notes from the – that came out of the discussion after the presentation and went back to the slides and tried to put a kind of yellow highlighter over those topics that I thought stimulated the most discussion and I may have missed some so I want to ask the group to also, you know, bring attention to things that we thought there was a lot of debate on or a lot of discussion or there were additions that we had not included at all in our slide and that might be a good guideline for what we try to talk about in the next, maybe over the next 20-30 minutes.

So, first let me ask is there anyone who is on the call currently who did not receive the slides in today's e-mail? Okay, all right so I thought I'd just quickly mention a few of the things that I thought were raised, you know, stimulated the most debate and then we can start there and then branch off as the rest of our group sees fit.

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

This is Patty; I just want to let you know I'm on.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Oh, great, hey Patty before I start – before I start anything did you want to have any sort of overarching or –

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

Oh, no, no we chatted about the agenda earlier and I'm fine.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah, okay, all right.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

And Meghan this is Mary Anne Leach I'm also on from Colorado.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Oh, great, hi Mary Anne.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

Thank you.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, I'm going to quickly state them, we could go to the slides when we start talking about them, but let me just mention the ones that I thought had raised a little bit more discussion, the first was, you know, we had actually started out by talking about our organizing principles and made a statement that we thought it was appropriate to be platform agnostic.

So, the first item that drew a little bit of discussion was whether or not it was appropriate to be platform agnostic or have them divided explicitly and a good point was made I think by our FCC counterpart that there are separate sets of risks, if you think about a particular type of health IT, if it's delivered in a wireless mode versus a fixed, sort of connected mode there are additional sets of risks and so I think it was an appropriate point that as the other two groups deliberate either functionality or capabilities of a particular type of health IT that it might actually be perceived as being low risk when wired but, you know, much more higher risk then maybe come into scope for a particular regulation if it was wireless. So, I think that's one issue.

And then the other question, we had felt that it was – we were indifferent to whether something was installed versus software as a service, but again, there is always the possibility that something might have been perceived as not having a particularly significant risk profile when installed and then different set of profiles when software as a service or vice versa. So, the first item was the platform agnostic approach.

The second, and I'm not doing this in descending order I'm just literally going through slides, the second item that I think drew a little bit of discussion was –

**W**

Are you having – are you going to have the slides changing on the screen?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

We can go to them, I'm just listing the –

**W**

Okay, I didn't know if you were going to do that?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

No, let's see, I don't think it's necessary, we can go to a specific slide on request when we talk a little bit more about it. So, the second item was that on the – when we were talking about aspects of the product lifecycle that we wanted to be explicitly in scope, potentially out-of-scope was – or in scope was training but potentially out-of-scope was the specific methods or modes of energies or training and the original thinking had been, you know, we wouldn't want them to spend time talking about risks or regulatory approaches about whether something could be a web-based training modality versus stimulation-based training etcetera, just that we thought it was relevant that training be a part of this whole thinking around risk and risk mitigation.

The third item was and this probably stimulated quite a bit of debate right at the outset was if a device or a product was currently recognized by FDA as falling within the medical device definition and already had clear regulatory oversight in place using an FDA framework whether it was in scope to revisit the nature of that regulation. I'm not explaining that very carefully, but this would be if there is a product out there that the manufacturer has registered and listed list that product as for example MDDS would we believe it was in scope for those products that are clearly identified as being regulated by FDA, would we consider in scope re-thinking the whole regulatory strategy around that.

**W**

And Meghan, I don't know if you want comments now or do want us to hold them?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Well, let me just – I'll just list – let me just – there are two more.

**W**

Okay.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

I was going to list and then we can decide let's forget the first two and then focus right in okay? So, then the next one was in the specific product types potentially out of scope had been – were two that I think it was – Farzad may have made – Farzad may have made the comment, population management tools and cost-effective in analytic software and the argument about being out-of-scope is they aren't – there are several steps before that might actually get to decision making around treating of an individual patient, instead it was those were sort of uses primarily to think about models of care delivery for a whole population or the type of management of particular diseases within a large population.

And then the last was around health information exchange, it was considered – we had it on the in scope side, I think some people felt it sort of depends on whether we're thinking about health information exchange as a repository versus thinking about some of the future thinking advanced functionality that health information exchanges may be able to do so they don't just deliver information or serve as a – but might actually put into the hands of the user some additional functionality such as calculations or risk stratification or something like that.

All right, so those were the items. So, let me stop here and ask the group if we want to move to one in particular and start out discussion and resolve whether in scope or out-of-scope around any one of those particular topics.

**W**

So, Meghan I think what you're saying is that – shall we start with the in scope out-of-scope list?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Well, so, I think you missed – my introductory comment was that I went back and took the notes from the 30<sup>th</sup> and 31<sup>st</sup>.

**W**

Right.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And I focused on – I went and highlighted those that generated discussion or debate or had some counter points made in particular. So, and that's what I've just finished listing were the ones that generated the most, platform agnostic approach, methods and modes of training being out-of-scope, whether an existing well-defined FDA-regulated product we should put back into scope, whether the regulatory framework should be changed, population management tools and cost-effectiveness analysis tools and then last is health information exchange.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

Meghan, this is Mary Anne, I'm actually okay I think with the changes as they've been proposed except for the medical device, which I think the regulatory group is also considering out-of-scope but the use cases we're hearing are absolutely focused on medical device integration, so maybe we narrow the scope of that to not revisit medical device FDA authority but to identify and escalate medical device integration and potentially propose a standard API between the medical devices and EMRs, that's the piece I think that's really missing here. HL7 isn't great but at least we have something on the other side, but I think that would be an interesting way to take that feedback and maybe focus it more specifically.

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

Well, and I guess, you know, this is Elisabeth George, I guess one of the questions that has come up a number of times and the gentleman, I believe it was Michael Flis, that was sitting next to me and myself, I think what we were trying to voice as a concern is that there are companies today that are medical device companies that were forced into having their products handled as 510(k) that we do not believe maybe should be once we go through this whole taxonomy and all of that other process.

So, I guess that's why we were trying to say things should be revisited, there shouldn't be an assumption that just because something has already been classified and has a 510(k) that it by default is a medical device.

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

Could I try a slight clarification to that and it maybe that there are certain medical devices that also have an IT component to them and I think increasingly medical devices will, this is Patty speaking, sorry, whether it's a medical device that provides information about a senses physiologic state like expired O2 or the PO2 monitors or if it's a device like an implantable cardioverter and defibrillator that keeps cardiac rhythm, so there is an IT component and there is also an IT, if you will, system maintenance component if a device can say whether it's battery is drying up for example.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, traditionally – hi, it's Meghan Dierks, traditionally FDA's approach has been that the embedded software, the software that's embedded within the product is considered a component of it and that the risk profile and the regulatory approach rises to the level of the finished device so that if the finished device is a regulated device the software embedded within it is as well, is as well, you know, a regulated component. So, but –

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

Are you saying this is okay because we're covered? Because, I think the difference now Meghan is that some of the software is creating things that become part of a clinical record whereas in the past they did not necessarily. So, the cardiac rhythm component of an implantable defibrillator really never went into the clinical record.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah, so – so some of what I think you might be alluding to is the other class that the final rule on MDDS applied to which is products that are independent of the medical device but configure closely with it and pass the – essential serve as a transit of information. So, a medical device sends data to this MDDS product, which then displays it or stores it in some way whether storing it in an EHR or storing it, or displaying it on a screen, or some other handheld device or something like that.

And I think Elisabeth, if I – I don't want to read too much into your comment, but your concern is that, you know, software, standalone software whether, you know, solidly MDDS or MDDS-like or other types of products if manufactured by a company or an entity that already makes traditional medical devices felt as though they sort of automatically had to default to that regulatory framework.

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

Correct.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And that has led to an unevenness, so to speak, in the playing field.

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

Yes, that's exactly right.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And, you know – so, I think this is a point maybe we can get Bakul to weigh in on this about whether it should be in scope or out-of-scope is maybe fundamentally re-suggesting that the other groups consider in scope standalone or software only products that yes are currently regulated under the traditional Class 1, 2, 3 regulatory framework and whether those should come into scope for revisiting maybe alternative ways.

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

And I guess I, you know, maybe I want it clarified, I'm not even saying that they should have alternative ways necessarily I'm saying that the output of this group should be how do we handle all of those things that fall into the definition of Health IT because I think the concern we have is, is that if we don't discuss it because we assume that it's already been classified all those companies that are making it as an application on their phone are going to say "well, it's not addressed so can continue doing what we're doing."

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Sure.

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

So, that's kind of where mindset is. So, again, I'm not necessarily saying to change it I'm saying –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes, but you want it on the table –

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

Yes.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And clearly –

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

Yes, don't forget it so that we can make sure it's communicated to everyone.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, what we could do – since the statement, you know, when we got to the decision three and right at the top devices that currently meet the definition of medical device we were going to advocate for potentially – for out-of-scope, defer to existing framework and there was a lot of debate, maybe we could just label the issue a little bit differently and instead say within scope is this question of whether additional or alternate regulatory strategies should be developed within FDA for standalone software, is that – so instead we're saying – we're not going to say devices are in scope instead say the question about possible alternative regulatory controls might be in scope. Would that be acceptable to people?

**W**

I think it's device integration or device integration standards that – and it may not be a regulatory it maybe more of a, you know, voluntary private, you know, development, a standards development but I think, you know, the issues of data coming incorrectly or sampling incorrectly from medical devices into the EMRs, I mean, that's been the use case we discussed in Washington. I think it probably needs to stay out there for discussion.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay. Any other thoughts or comments on the existing standalone software that's considered a medical device?

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

This is Meg Marshall again, I do like the risk statement and certainly encourage and support, but my question is so you mentioned looping Bakul in, I'm not sure if Bakul is on this call now, but would this topic then go to the regulation subgroup in enough time for them to consider that as well? It seems like a huge part of their work, if they're focused on avoiding duplication, is going to land right in the middle of this so probably the early they know the better.

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

This is Bakul I'm on the line. I would say another approach would be is using sort of examples or types of products that we definitely know or the group definitely feels is not Health IT that FDA already regulates and then we can look at those fringe areas where, you know, I think you brought up – people brought up software and sort of maybe tease that out a little bit and just leave that on the table as Patty suggested.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay.

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

Obviously, we're not talking implantables, we're not talking –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

No, but are you – so Bakul let me throw out one example and see if this is what you're getting at. So, and I think you and I had talked a little bit about this. So, the PAC system, Picture Archiving Systems, that really serve more or less as a repository or storage is sent to a display of historical images or images that have been taken already from a primary image capturing or imaging modality device.

**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 Faculty**

Would that be an example or is that too solidly in, because that's been regulated for a very long time.

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

Correct. I would be willing to say if that group decides that that's an area where there are parallels in other parts of Health IT that are not and then this is – that is solidly a – I feel that's in the gray area not solidly one way or the other, especially when you talk about storage, it's been regulated for a very long time, but that's not the question here. The question is if you throw that example as a topic for discussion does that mean that in similar functionality the risk control needs to be in place in other areas which have not been regulated and then we can – then you can talk about whether that needs to be changed or not changed.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Right, okay, because I think you're right that there are, you know, real corollaries between the functionality of a PAC system.

**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 Faculty**

And let's say, I'll even throw this out at the other far extreme, a health information exchange meaning you want to make sure that you always do correct data patient matching and you put the appropriate controls in place to lower the probability of patient data mismatch.

**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 Faculty**

You have, you know, certain control, design controls in place to assure that one doesn't overwrite existing data unintended and, you know, that when the data are retrieved and then displayed or retrieved and sent to some other product that they aren't adulterated or modified in any way and then the last is sort of around this whole issue of modification through compression and it's less of an issue when you're dealing with non-imaged-based data but, you know, it's the same thing do you alter in the effort to compress and store more efficiently or transmit more efficiently what controls are in place so that you don't inadvertently transform or change the data.

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

Right, right, so data integrity, availability and confidentiality is important and the data can be anything, so it can be image, it can be numbered, it can be database, what else, anything else. So, yeah, I'm fine with leaving it on the table but, you know, with notes or whatever you want to say it has been dealt with in a long time in the sort of like known things and people are going to take that from there.

**W**

Yeah, I agree with Meghan I think was just talking about the HIE issue. So, I would see that as definitely in scope correct? Health information exchanges?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

I think it is but I don't maybe I'm recalling, maybe I'm not recalling it correctly I thought there was a little bit of – I wouldn't – maybe it's too harsh to characterize it as pushback but there were some questions raised about whether that belongs in or out and I think the problem is we have one mental model of HIE using that label today, but I think in the future it may be very different and it may have a lot more functionality that we currently only see with installed type of, you know, installed software or installed products.

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

This is Bakul and I think Patty mentioned this, I think relinquishing the fact that whether it should be regulated lightly or heavily, or moderately is a different question and maybe if we are having the discussion I would like to see it on the table so we can at least discuss and then decide to either discount it or not discount it.

**W**

I think that's the right way for our group to proceed, Bakul, I think that we have – we're talking about keeping this in versus out is not saying regulated versus not regulated.

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

Right.

**W**

It's saying on the table for the discussion in the taxonomy and there are other aspects of our – other teams working on the light versus heavy and while we are interrelated I think our charge is to provide some guidance around the target for the regulations.

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

Right and Steve, this is Bakul again, I'm sorry, Steve and I we were talking after the meeting and I was personally envisioning in a one sheet of paper which has two columns inside scope versus outside scope and, you know, we can define what inside scope means is it on the table up for discussion not necessarily – so we need to define what in scope means and what out scope means.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay.

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

This is Meg Marshall I'd like to make a comment and I'm really pleased to see the conversation around the – I think this ties in really well with some of the topics that the innovation group is trying to tackle as well and so if you look at how health information technology has evolved and what may have been classically defined as medical device many years ago under today's current standards may or may not fall within that same definition.

I'm curious as to whether it would be appropriate for this Subgroup to perhaps recommend an ongoing process that helps with this review, if you will, of emerging technology or maybe it's just a periodic review that the current regulation is or oversight is appropriate.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, Bakul has that come up in the – you're in all – I think you sit in on all of the Subgroups, has that been talked about or are the Subgroups all thinking only in terms of the immediate, you know, recommendations that are handed off to you and your other federal partners?

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

I've heard some discussions about, you know, ongoing maintenance of either, you know, the taxonomy or approach as we learn more so that's the – you know, I tie that – in my mental model it ties into that learning system people talked about.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

There's another category that sort of came up in our community here in Colorado, one of our community hospitals had a 10 day downtime, it was a MEDITECH site, one of the issues was MEDITECH's capability for high availability disaster recovery and I think they have since patched their product, is that existent today within the EHR certification, this is Mary Anne Leach by the way, is that existent today in the EHR certification process or would that fit under kind of general conditions of use or, you know, business continuity. Now we are so dependent on these systems that ... is there a business continuity element that needs to be included somewhere in the process?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, that's a great question, this is Meghan Dierks, that's a great question and I can, I think this is accurate that – I can tell you that it's not an element of the certification and I think everyone on the group appreciates that certification really is talking about a product meeting certain functions, demonstrating it has certain functionalities to render it eligible for incentive payments, etcetera.

Now that being said, if you thought about the traditional FDA device specific regulatory framework it would identify downtime or unavailability as potentially a risk if you could identify or map it to potential for patient injury and the regulations would call for the use of some design control or some management by design that would reduce, as low as possible, the risk of that unavailability or downtime, because unavailability is in fact – presents a patient risk.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

You bet.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, I think that's – yeah, I think that's a very good point and, you know, it could be another one of those things where that's actually one of the hazards posed by information technology and we could just explicitly indicate we want that topic or that concept just like we wanted maintenance in lifecycle to be in scope.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children’s Hospital Colorado**

Right.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

We could explicitly state we would like to have the issue around availability and continuity of function to be explicitly in scope.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children’s Hospital Colorado**

Yeah, I mean, at least for a discussion topic and, you know, it doesn’t have to be heavily structured I think in terms of regulatory process.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children’s Hospital Colorado**

But maybe there are guidelines the vendors can follow as a part of certification, because I think some vendors have the capability to build a high availability environment and some vendors don’t and yet they’re certified.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children’s Hospital Colorado**

So, I think it’s a good topic for discussion, thank you.

**W**

So, I’m hearing that we’ve moved the taxonomy to now have another dimension of the lifecycle or maybe another dimension in addition to the lifecycle, which is disaster, recovery –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Sort of like redundancy and availability.

**W**

I think it’s fine.

**W**

You could put it in like general conditions of use or –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah.

**W**

You know, what I mean, it doesn’t have to be a standalone.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

**W**

I think it’s kind of a condition of use, which is availability.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes, yes, so we can – I’ll squeeze that into a logic thing so we don’t – I’m trying to avoid maybe creating yet another dimension, but –

**W**

Yeah, I don’t think we should.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And Bakul is I think suggesting to us that we even simplify it more and just have a two column in an out.

**W**

Right.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

But under – we could put a heading under it.

**W**

Well, I think the idea as I'm hearing it is that, in our notes or our preamble we need to say – I do like the in and out model, but I think we need to say one of the caveats is that there is a variability in risk and evidence across the lifecycle.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Any other comments about the availability issue? And then I was going to ask a quick question that hopefully we can resolve. Any other comments about availability? Because I think that's a very good point.

All right, so I just want to quick resolve, because I had listed – in the slides I had listed these two items as being potentially out of scope, but again there was debate, one is population management tools, and again that – and cost-effectiveness tools and I think the counter argument – so we had proposed those as potentially out of scope and I believe that the counter argument revolved around, well they could shape, they could potentially shape coverage, benefits, insurance benefits coverage, availability, you know, ability to access specific types of treatment and, you know, I think it can be a slippery slope moving into health policy and, you know, we're not proposing that what's up for debate is aspects of health policy and access to care. So, that was my strong inclination of sort of moving those to the out of scope, but is there – can we talk a little bit about that and see if we might be overlooking anything?

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital**

**Colorado**

You know, some of the – this is Mary Anne, some of the population health products that are out there are creating clinical guidelines or using clinical guidelines, it kind of depends how you define population health, you know, if it's retrospective analytics I think that could be out, if it's sort of prospective evidence-based guidelines and predictive modeling maybe that's in.

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

This is Matt Quinn, just a thought here is that that's probably not the best way to describe it, maybe you guys could get a little bit descriptive, you know, more specific about what aspect. I could see on one hand how, you know, for example relational databases as a technology would probably not be in Health IT but it's the health intelligence that would come with for example, you know, querying a private – a physician practice querying the functionality of an EHR that aggregates all of the patient data and saying, you know, just pick out the ones that have these indicators of diabetes, it sounds like Health IT to me, whereas the database technology itself they can be used for, you know, querying anything would not be. Is that what you're thinking about or something different?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Well, this is Meghan Dierks, so on the – let me give a concrete example of cost-effectiveness. So, there are tools out there that one can purchase which look historically – which do a retrospective look back at utilization and sometimes under a specific disease and given the same outcome will inform the end-user which was a more, a lower cost approach to the management of the patient. So, again, with, you know, the same – and same clinical outcome, which is the least expensive or there is also software that will, you know, indicate when generic equivalents are available things like that.

So, really primarily revolving around the cost function might have a calculation in there around cost, but start at baseline assuming it's either the same outcome or, you know, an accepted guideline. So, that's an example of cost-effectiveness analysis, it's often done at a – I would say it's often done at a population level meaning they don't compare Patient A to Patient B they compare a statistically – they tend to compare a statistically powered Cohort A against Cohort B, same outcomes at a group level and one sort of mode of healthcare service or health delivery, or choice of therapeutics was less costly and achieved the same outcome.

**W**

So, we're – just to regroup what we're saying is that software that assists in making clinical recommendations about a specific patient even if drawn from HIEs or broad population assessments would be considered in scope.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

That might be the case, maybe I should re-explain, because that wasn't what I was trying to explain. I was trying to explain if one was looking at what is the least costly way of managing, you know, decubitus ulcers and trying to achieve the same, I'm sort of making up this clinical scenario, and the software will look at historical claims that look at – basically stratify the population they have the same outcome and it will tell you which one was less costly and achieved the same outcome.

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

This is Bakul, if I were to guess I think Patty maybe onto something there in terms of describing what we mean by the population outcomes studies. Another way to maybe – I'll just throw this out and I know you guys are thinking – if a topic could potentially raise patient safety issues or required a push in the innovation area it could be any number of things. You may want to leave it on the table for, you know, identification of the risk, patient safety risk –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, should – and Patty and Bakul let me just try to refine it a little so that it doesn't come back up, you know, come back up for, you know, a heated debate, should we add, you know, we don't really care exactly what it is but if it ultimately shapes decision making around treatment of an individual patient or is that even too – is that getting into too much detail?

**W**

No, I think that's exactly – I mean if we're going to split hairs over individual patient versus the clinical management decision for 10 patients I think that we don't want to go too far down that track. If the use of the tool or the algorithm guides clinical interventions then it should be in scope.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay, all right, so that's a great way of –

**W**

So, then that takes us everything from Epocrates to –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

**W**

To the Apache scoring system.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

**W**

And I know that we're still going to have somebody who is going to say yes, but that wasn't intended and so maybe we need to modify this to say if the intended use.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Intended use, yes.

**W**

Because I don't want those Epocrates – those Apache people in my back.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Right. Well, the good news is I don't believe, and I'm hoping – I don't believe I've ever seen anyone inappropriately using that to decide, oh, they have such a bad score we're not even going to treat them, I've never seen that which is the good news. So, I've not even seen the foreseeable misuse of Apache scoring and disease various scoring, but, okay.

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

It only means the risk is really low.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah, the risk of, you know, unintended misuse or –

**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 Faculty**

Right, right, okay, so I've got some notes there on if the intended use informs –

**Matthew Quinn - Director of Health Care Initiatives - Federal Communications Commission**

So, this is Matt, just to go back to the definition again of what – just trying to interpret what you guys are saying, one flavor of tools are things that are used for underwriting so there is a whole series of algorithms and other things that are –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

**Matthew Quinn - Director of Health Care Initiatives - Federal Communications Commission**

You know, used for underwriting either financial risk or clinical risk and then there is another set of things that are used for population health management and, I mean, you were talking about the former rather than the later there, does anybody – could you say a couple more sentence about what you were thinking about in terms of population health management tools and why they would not be involved?

**W**

Actually, I wasn't trying to exclude them.

**Matthew Quinn - Director of Health Care Initiatives - Federal Communications Commission**

Okay.

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

I was trying not to split hairs around if I'm Patty Brennan and taking care of Jane Doe versus I'm taking care of Jane Doe and 10 other people who have the same diagnosis and profile as Jane Doe I would see both of those being in scope.

**Matthew Quinn - Director of Health Care Initiatives - Federal Communications Commission**

Yes.

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

And there will be point where we'll say, so is that everybody in the world like recommendations for cholesterol screening or something like that and I think there will – we won't resolve that today, but what I wanted to avoid was restricting it to a specific client in front of me decision.

**Matthew Quinn - Director of Health Care Initiatives - Federal Communications Commission**

I agree, I agree, I was just trying to understand what you guys were talking about rather than –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And Patty let me just throw one more example out to make sure that – because I think we're erring on the side of putting more in with this notion of it is informing treatment of one or a few patients. What about and I'm not saying for or against, but what about there are software tools out there that look back at an individual patient's two year or one year historical utilization and based on, you know, some cost function or some threshold function will then put the patient on a list for outreach for care management, that's a sort of a classic set of software tools used by, you know, insurers and by health entities. And so there the patient continues to have access to the traditional forms of care but might not – if the system malfunctioned they may not, for example, be offered additional care management by a social worker for example.

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

Right.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

To me, I would say, you know, we could put it in scope but I feel like, you know, it's nice to have something to go out of scope and I might make the case or make an argument that we could say that's out of scope, but I think someone could make a cogent argument, you know, it does change and it's just low risk, but it would change access to care or potentially change the way in which someone is treated in a certain, you know, a certain way.

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

It seems to me that we're coming down to putting into scope anything that can affect the care process or access of an individual patient.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

Or Patty as you said, this is Mary Anne, as you said intervention, care intervention.

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

And what I think Meghan just brought forward was that I've been on the other side of this so my managed care group sent me an e-mail saying we've noticed your on this medication and that medication therefore you are in our hypertensive management program and what would happen if I wasn't on those medications, the 85,000 who aren't on them never got into that care management program even if they actually did have hypertension.

So, it maybe if we want to use the word intervention colloquially that's fine with me, if we say that what's in scope are information tools, software that guides the determination of interventions afforded to or delivered to an individual patient. And then that kind of draws a huge circle around almost everything.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

Yeah.

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

And what I want to then – when we get down with thinking that circle is all right in our last couple of minutes I want to propose two things that I actually think are outside of that circle.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay, well, I think that's a good, I think that's a good suggestion.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

And I think that would be a good discussion topic.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, let me just do a quick time check, we have 12 minutes and we do want to open it up to the public comment at the end. So, I'm going to make one last sort of statement about, you know, the next step after this call, because this should be our last sort of planned convening of this Subgroup and Patty maybe you want to make your comment. So, the – expect – I had a conversation – I think Patty and I had a conversation with the Chair, Dave Bates, and he recommended that the final output of our group is essentially a one page summary of recommendations and ultimately I think it's something on the order of two slides that go into a slide deck. So, that's what ultimately putting everything together, all of the deliberations our Subgroup has had and the comments and the feedback we got and then today's discussion that's will ultimately put this together as.

So, we'll circulate, our goal will be to circulate it to everyone and have you, you know, give us feedback but we'll have some artifact out the one pager and a couple of slides in short order sometime this week hopefully by the end of the week. So, I just want to get that so we didn't run out of time. Patty do you want to throw in your last two questions about out of scope or do we want to see if there are any questions about our concrete deliverable?

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

Let me – forward from the group first, I can pull the chairs prerogative at the end and add one in but let's open it to the group first.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay, so quick questions about the concrete deliverables? It ends up being, you know, a very small thing you have to compress all of the thinking around into, but –

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

This is Meg Marshall, so I think that Meghan and Patty were included in some conversations by the bipartisan policy where they attempted to look at what is considered HIT as far as software, so there is a Subgroup or a small group that it looks like may have actually provided, as Bakul mentioned, a column list of what's considered in or what's considered out and I think they based it off of three different types of software and then they moved to categorize and provide some examples. I just – I offer that as perhaps something that could be referenced by the Subgroup or even just leveraged as a review to make sure that, you know, that as your definition, as your artifacts are being delivered for the meeting perhaps – Workgroup.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Meg?

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

Yes?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah, Meg, I just – I'm sorry I missed the first statement, were you talking about the bipartisan policy center document?

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

Yes.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Okay, all right.

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

That maybe valuable to share with the Workgroup.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yeah, I to wait until I got permission from them like 5 minutes before this call started to distribute it I just wanted to make sure I got their permission before we redistribute it, so we can send it out. I would say we should read it and we can virtually via e-mail talk about what elements we think align with our framework. There are things in it I don't personally on my own agree with necessarily, but there are some parts of it that I think are useful.

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

I would agree that we should circulate it and refer to it by reference without endorsement.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Yes.

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

The last piece of – this is Patty, my last two cents rather than two sentences have to do with the fact that we've really largely talked about regulation and what's in and out of our taxonomy based on things that are employed in the clinical professionally delivered care environment and I would like to make sure that we have if nothing else at least a caveat that identifies the enormous amount of self-management and self-management tools that are emerging and the importance of considering a regulatory strategy for them and maybe out-of-scope of FDASIA completely I don't know, but I –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Oh, so Patty?

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

Yes?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

If we were to include on the column that's in scope user, you know, we had four elements that we said were in scope for user type one was just the general public consumer under their own health management.

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

Right.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

And let me see if there was another area where it kind of – and we also considered in scope developer type, any independent entity who might develop it independent of whether they actually sell it for commercial interest so that would be sort of the garage developer, so that covers two sides of that.

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

Right, I guess –

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

If we include the user there that would then put everything into scope who, you know, all of the individual patients or individuals using it for their own use not under direction of a clinician, right?

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

Yes and in ours – our current, I think it's our current slide 19 which shows distinguishes between patients under care by provider from the general public user, consumer use management that distinction is correct in my thinking and I'd like to see that stay, but when we threw the big circle a few minutes ago and talked about information technology's intended for driving interventions with individual patients that sounded to me like it – there maybe things that would be restricted from that.

For example, I mean, I hate, everyone goes to the vitamin issue and nutraceuticals immediately, but that's where I'd have to go is that, we would say there maybe things that I as a person want to monitor for example my menstrual cycle or my fertility period so I can have another baby, which I might not be doing under the care or an intervention of a specific clinician but the device that helps me assess my vaginal mucosa should be – and gives me a printout, should be a printout that reads something that's trustful eventually to a clinician.

So, there needs – we shouldn't just dismiss stuff if there is no clinical oversight on the care, I'm sorry, I'm making good for the last minute. So, take it in your hearts and we'll continue it in the discussion.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

Any other comments? So, I think that's a point well taken we'll make sure we have that clearly outlined. So, are there any other comments? It's your last chance before we open to public comment. Last chance at least in the context of this call, we do have I think the remainder of this week to try to put something together and exchange it via e-mail. So, MacKenzie, do we want to open it up to public comment?

**Public Comment**

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Sure, operator can you 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 \*1 or if you're listening via your telephone you may press \*1 at this time to be entered into the queue. We have no comment at this time.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

All right, Patty do you want to make the last sort of thanks and I would say congratulations to the Subgroup for the work we've been able to achieve?

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

Yes and I wanted to specifically thank Meghan who has been great to work with. I appreciate people's willingness to try to meet on short time horizons and remember that we are going to be meeting on Friday the 14<sup>th</sup> and if you have comments that you want to be sure get introduced in a systematic way, if you want to send them directly to David that would be acceptable, but it would be helpful to copy me or Meghan on them so we can work them into our comments also.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

Quick question, this is Mary Anne, is there another in person meeting anticipated before like August?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

So, my understanding is that not for the group. I think, I might be wrong, but I think David Bates will be going on site and meeting with the federal stakeholders but I don't believe that there is a larger in person meeting scheduled.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

This is MacKenzie and there isn't, there was only the one in-person workgroup meeting.

**Mary Anne Leach – Senior Vice President & Chief Information Officer – Children's Hospital Colorado**

Okay, thank you.

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

MacKenzie, could you clarify for us what the meeting the first week of August is then? Is that –

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

So, the timeline for this workgroup and the subgroups is there will be an initial or draft set of recommendations ready for the August Policy Committee meeting and that will be in person so that's where David and whoever else is identified to present will present to the Policy Committee in person, the initial or draft recommendations whichever they are at that point and then there will be at the next meeting in September the Policy Committee meeting again is going to be in person and that's where the either additional or final set of recommendations would be presented to the Policy Committee. So, the August and September meetings are meetings of the full HIT Policy Committee where the Workgroup will be presenting to the Policy Committee. I'm just not sure who exactly will be presenting yet.

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

Could you send us the dates of those because I know that we can dial into those.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

I believe, I'll double check, but I believe they might have already been sent after the Workgroup meeting, but I'll just –

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

Okay, thanks.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

– to everybody.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

All right, well thank you everyone I really appreciated meeting with and working with everyone and thank you again.

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

Thank you to everyone and thank you to MacKenzie and your group for facilitating this and for Bakul you've been really helpful to have on these calls. Thanks everyone.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical Faculty**

All right bye-bye.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thanks everybody.