

**HIT Policy Committee
FDASIA Workgroup
Risk Assessment and Innovation Subgroup
Transcript
June 18, 2013**

Presentation

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

Thank you. Good morning 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, the subgroup on Risk Assessment and Innovation. This is a public call and there is time for public comment on the agenda. The call is also being recorded and transcribed, so please make sure you identify yourself. I'll now go through the roll call for the subgroup first. Keith Larsen? I know Keith is here. Paul Tang?

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

Here, thank you.

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

Thanks Paul. Geoff Clapp?

Geoffrey Clapp – Co-Founder – Better

Here.

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

Thanks Geoff. Esther Dyson? Mike Flis?

Michael Flis – Regulatory Manager – Roche Diagnostics

Here.

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

Thanks Mike. Jeffrey Jacques?

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Good morning.

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

Thanks Jeffrey. Anna McCollister-Slipp?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I'm here.

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

Thanks Anna. Jonathan Potter? Jared Quoyeser?

Jared S. Quoyeser, MHA – Director of Vertical Segments for North and South America – Intel Corporation

Here.

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

Thanks Jared. Mike Swiernik?

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

Here.

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

Thanks Mike. Jodi Daniel?

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

Here.

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

Thanks Jodi. 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. Matt Quinn? And for the full FDASIA Workgroup members on the line, I have 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. Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Hola.

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

Thanks Todd. Lauren Fifield?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Here.

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

Thanks Lauren. Are there any other FDASIA Workgroup members on the line who I haven't called? Okay, with that, I will turn the agenda over to you Keith, so you can do the innovation discussion first, and I think Keith got disconnected. Paul, are you set up yet?

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

Yes I am.

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

Okay, so we'll have Paul go first. Thanks Paul.

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

Great, thank you. Thanks everyone for joining. What we're going to do is play the tag-team as we have been doing in the past for the subgroup and Keith's going cover the innovation framework and I'm going to cover the patient safety risk framework. And, hang on one second; I'm sorry about that, I'm just getting kicked out of the room. Okay. So this is about the patient safety risk framework, and were all of you on the full workgroup call?

M
Yes.

W
Yes.

W
Yes.

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

Okay, so then you've heard me go through the matrix as updated, based on our call and the full face-to-face workgroup meeting. What I've done since then is put together as I promised to you last time, put together a very first draft of definitions of the dimensions in the first left-hand column, and maybe it would be useful to go through that and then maybe go back to the matrix and see if there are any updated comments. So that would appear it was distributed hopefully this morning, as page 2 and 3. Do people have that handout?

W
Um hmm.

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

Okay, great. So in the purpose of software, here's where I tried to point out, it's really – you can't have a purpose without intended users, so it has intended purpose and somewhat goes into users. And we had mentioned on the first call, as declared by the developer. So the developer is responsible for announcing what is the purpose of the software we've developed and who is intending to use it. In a sense, that becomes sort of the labeling in sort of a drug term. So it says, this is what we intend the software to do and on one hand it says, well this is limiting the scope of the system. So if this is a radiation planning software for use by radiation oncologists only, then they have a very restricted scope and certification, if it comes to certification for example, and you wouldn't have to be responsible for saying explaining to any person off the street. Another way you could handle it is, if it's information only without any recommendations for patients and consumers, well that might, according to our decision tree, get you a bye in terms of having any regulatory – regulation applied to it. And so you would be held accountable to that and potentially this could invoke the FTCs jurisdiction saying, this is what I'm advertising my software to do and who's to use it. If you try to push it for other things, then that would be sort of a no-no and it would be comparable or analogous to the off-label use.

Intended users, and we pointed out that can be different kinds of users, it could be a human user, as we commonly perceive it, but it also, based on previous discussions, could be another system consuming the information or the output coming out from the system. And the risk assessment, as we discussed last time, would then be applied to each class of intended users that you, the developer, declare. And clearly you could disclaim saying, well, it's not to be used by someone not qualified, and you just say who is qualified to use it.

Severity of risk is really the seriousness of potential patient harm that might arise from appropriate use of the software. So this would be everything from virtually no risk or very low risk, to an adverse event resulting from the use of software that could vary from being a non-life-threatening to a life-threatening adverse event. Now one of the interesting concepts that the taxonomy group raised in our face-to-face was that risk could be from anticipated or designed applications, but they were anticipating the possible foreseeable inappropriate use. It's interesting, but I can understand what that means is well, you can't actually – yeah, you want them to go down this path, but yeah, they could use this other path and that might be something foreseeable inappropriate use.

Number of people exposed is the number of patients whose care's likely to be exposed to the potential risk measured in someone's suggested in patient-years. So this is formed by a combination of the people with this potent – relevant condition, it could be diabetes, it could be people hospitalized, for example or people with a specific cancer, and the number who could be exposed to the situation under which the software could be used. So it's sort of the multiplication of those take the number of people that are potentially exposed to this risk. The next attribute is the likelihood of the risky situation arising. So if there is – the software's applied to these kinds of folks, there are certain combination of factors that could produce this risk situation. What's the likelihood, what's the probability of that arising?

The next case is the software operation, and we included data from the full workgroup, not exactly sure how to include that, but here's my attempt at doing that, and that's to say that this describes the visibility of the data, how it's calculated, the algorithm, and the knowledge source that's being used, we had that discussion before, in generating the system's output. If the user of the system knows all those things, then he or she can have a better chance at sort of establishing the credibility of this systems output. The consumer, not the patient consumer, but the system that consumes this output could be a human directly or it could be another system. And on one end of the spectrum, then the recipient output can be all the data and all the calculations and just really know what's going on, and this is just a fast way of calculating, in a sense. On the other end of the spectrum, it could just simply be a black box and the user has no knowledge of that, and that's of course the more risky situation, for there's no way to intervene.

Speaking of interventions, the next attribute is the ability to mitigate harmful conditions. And that's the ability of a human detect and take action to mitigate any potential for harm. So one way is a human intermediary could be mandatory, so the software system provides certain information, a human must act on that and carry out any intervention. It could be optional, that is, there's a potential so the system would feed into something else, but there's a potential for the human to observe it and could take action if they choose, that might be a medium risk situation. Or the human could be completely excluded, as in a closed-loop operation.

The next cluster of attributes is really – deals with complexity, the first one being the complexity of the software and its maintenance. I didn't have another synonym for how to describe complexity of the software, so that I sort of almost restated that, it's being complex is not tantamount to saying, well this must be regulated, for example or that this is risky, it's just a statement of fact, it can be complex. But one way that it could be complex but yet not – but still be safe is there are test procedures that you can test very comprehensively on getting the right output from this software. Another condition that makes it safer is you can operate it reliably. So this is just to say, this attribute or this dimension of patient safety risk is something you'd have to take into account when you decide whether it warrants regulation or not.

The next one is complexity of implementation and upgrade. I think we're all familiar with the very complex, comprehensive EHR systems where there is a lot of build that's required for implementation, and that's a chance to introduce risk, at least. On the other hand, something where you just plug a device in and it measures your blood pressure, you understand what the blood pressure is, that's a much, much lower complexity and the implementation is almost none. The next part is the complexity of training and use. The more complex the output is, the longer it takes to train someone. So one proxy for complexity of this all is the number of hours that's required for training. It could be days, like it is in some EHR situations or it could be almost instantaneous, like a consumer grade device.

The next dimension was its use in a more comprehensive software/hardware system, and the kinds of considerations that go into this attribute are how many interfaces are used to connect the system, either input or output? Are the interfaces mature, they're using broadly adopted content and messaging standards? What's the level of redundancy to avoid single point of failure? And how clear is it or how unambiguous is the system output when it is consumed either by a human or by another system? And network connectivity I really didn't know how to further characterize, it's pretty clear in the framework itself. Let me pause there and see what questions people might have or comments or additions to this.

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

This is Meg Marshall –

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

Paul, this is Bakul – go ahead please.

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

This is Meg Marshall. Hi Paul, thank you very much. I think this is really developing into a very easily understood, comprehensible table. The question that I have, and perhaps I've just missed something, I'm sure that it's been covered, broadly when an IT developer thinks of risk mitigation factors, we look at the processes and the activities that we go through in building a safer system and that would be things like the user-centered design, internal testing, quality management systems and certainly the concept of the post-market surveillance and the recording of the patient safety issues after the software has been deployed. And I'm curious, you mentioned testing as a risk attribute. I guess how would you characterize those elements and those activities as risk mitigators?

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

Thanks Meg for your question. So I tried to – this is a risk framework for assessing a product, not necessarily the processes that you described. So I think, and let's see how this tests out, this describes the output, the product, and its implementation and use. So like the user-center design and the quality management system, etcetera are processes that are used in the design and development of a system and that could be one of the avenues that's used in order to assure the safety of it. So I would imagine like the regulatory subgroup or FDA and ONC and FCC, when it receives our input and develops its framework, would be able to decide which lever to pull in order to best accomplish a certain objective. And this risk framework is how to you consider the possible sources of risk in the product itself, its functionality, its implementation and its use, but not necessarily the process of getting to the product. Does that make any sense and how does that – is that consistent with how people are interpreting this?

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

Well, I guess that my question is, is there an opportunity for this discussion and it sounds like you might – like you are perhaps recommending that it would be for the regulations group. And I think that the question is, as far as building the safer system, how many of these activities are going to be pieced – you're absolutely right pieced together as levers that need to be pulled and if you have a – if you designed this and if you used a user-centered design processes and if you've implemented the post-market surveillance then we're assuming that you have a safe product. So, I guess maybe I'm just looking for where the appropriate place is for that discussion.

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

I think it would be a combination of those are the kinds of things hopefully that the Regulation Subgroup is elaborating on, like what are the different ways you can "regulate," which include certification of these – processes. And I think Keith is going to talk about that some in terms of how you can mitigate some of the risk in innovation.

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

Okay, thank you.

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

Hopefully that helps and certainly bring it up if it's not covered in one of those two areas, but I think Keith's going to touch on it and then I think it's most appropriate in the Regulation Subgroup.

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

Hey Paul, this is Mary Anne Leach; sorry I joined a little late and kind of an audit member of your group. I wonder under network connectivity if it would make sense to add something like ability to receive pushed updates. We have some safety issues now with devices that are network connected, but they're not able to accept an SMS pushed patch or fix, that also poses risk because we can't fix it unless you touch every device. So it has – I guess it would fit with network connectivity, but it's the dimension of being able to accommodate a pushed update for upgrade.

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

Very interesting thought. Would you – what do you think about putting it under the complexity of implementation and upgrade that row?

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

I think it fits there too, and it's about having all of our vendors be compliant with technologies like SMS, for instance, so we can quickly push a patch if we need to. So, yeah, it probably could fit there, that would be great. Thank you.

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

I'm a little reluctant to say – to describe how things are done –

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

Right.

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

– but certainly that concept of ho – whether it's a virus or some critical updates how is that done and how is that managed and how easy is that, that's a good – concept.

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

Right, exactly, which is can we electronically touch all the devices.

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

Right, so let me include that in the next iteration.

Geoffrey Clapp – Co-Founder – Better

Yeah I just wanted to – this is Geoff, of course a train's going by right now. I just wanted to reiterate, like I don't think we should talk about how but I think the idea of remotely updating should be under the update category. It should be – there should be some things that don't need to be remotely updated, but I think that whole ability to update should include the complexity of the update and we can probably have that update category broadened a little bit to be both update and then the complexity of the updating, and then that would have its own matrix – but updating on its own is a category.

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

Yeah, that makes sense. Let me add that.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Hey Paul, this is Anna McCollister-Slipp.

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

Hi Anna.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

And one thing that I've sort of been thinking about that sort of instinctively feels sort of like it's missing is the aspect of choice. Do I as a patient or would I as a healthcare provider have a choice of whether or not I used this particular software or something else? So in the case of an insulin pump, at this point I have no choice, if I want my data, I have to use their data download platform or obviously you don't have a choice of the specific interface on the pump itself. Or same thing with the majority of the blood glucose monitors or blood pressure monitors. Is there only one choice in terms of the software that it takes to run this product? Or even when you get to like a large healthcare organization or hospital, do individual providers have a choice?

And my reason for saying that is because if you have a choice amongst different software, you can choose the one that's best for the way you work or the way you think. And I think that only having one source of software doesn't necessarily add an element of risk, but it certainly changes the attitude towards the software, if that makes sense or changes your relationship towards the software.

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

So would that be something that the individual developer would have control over or that could change over time?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yes, the individual developer would have control over it, but the way that it currently works is if the medical, and again I don't mean to pick on the poor diabetes device companies, they just happen to be the ones that I'm familiar with. But if the CGM manufacturer wants to make an adjustment in their software that you use to download your data, it has to go through FDA approval, so that slows down the rate of innovation and it makes it a lot less usable. So, it creates a greater risk in the sense that people don't use it because the software isn't particularly helpful or user friendly or it doesn't work on an Apple platform or whatever the case may be. And maybe it doesn't fit into this paradigm, but I just feel like –

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

Yeah, is that a risk of the software or is that a risk again of the regulation?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, I don't know. I just wanted to throw it out there because I think part of what would be helpful is if we could have more choice amongst different platforms, like if you could have access to data and then different people could develop different platforms that meet different individual user needs. But, right now, the way that it works is you've only got one choice and you either use it or you don't use it, so some people just choose not to use it, which creates a risk of not really getting the most out of their devices. And similar to EHRs, my company does EHR data analytics, a lot of physicians choose not to do coded data input and they put everything in the note, which makes it harder to transfer, it's more difficult to transfer notes securely than it is to transfer coded data. So, as we start looking at hospitals are going to share data and make it available for other hospitals across the country to access the patient-level data, that's an issue that people are grappling with, to some degree.

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

It sounds like what you're describing is some market dynamics or the ecosystem, I'm not sure it's something we can apply to an individual developer or its product.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, maybe.

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

Paul, this is Bakul.

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

Yes Bakul.

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

I was just going to ask maybe a clarifying question. On the table you have, third row says severity of risk and you have the probability of harm. I'm trying to go through my head, the columns are labeled low risk and high risk, can you clarify what was – how do those two columns and rows sort of reflect each other or reconcile?

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

So maybe a different order might help. So let's say I am developing a software for diabetes, well that's a very common condition, versus I'm developing it for melanoma, let's say, something uncommon. Now, so first I'd get the number of people that could potentially be exposed, then I'd say, well what's the chance of the situation I'm worried about arising? So let's say it's, let's see, it's a little harder to make diabetes and melanoma, let me choose a cancer that has radiation therapy as one of its options. Well, there's "X" amount of people who have this condition, "X" amount of people who would get radiation therapy and radiation therapy could have life-threatening potential. So from the severity of risk, let's say it's calculating the dose, it could be pretty life threatening, so that's how – I've gone through three rows. The number of people with this rare cancer is small, the number of folks who could be exposed to this way of the calculation occurring in an adverse way is smaller still, but the severity of the risk in that calculation is overdosing radiation could be life threatening. So you have this calculus that would go across these five rows and say, okay, so let me say, very few people could be harmed, it could be life-threatening and it does make very clear to the user, the radiation oncologist, what's going on so they could – that's one way of them intervening and saying, no, no, no, this is way off, there must be something going on with the calcula – you see what I'm saying?

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

Yeah.

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

You go through that thought process to say, well, on balance we have a good tool, which affects few people, rare that this bad situation would come up, could be life-threatening, but there are human intermediaries in the middle, and that's the thought process you go through of saying, what's – how is the patient safety risk profile for this category. Does that make sense?

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

Yeah.

Geoffrey Clapp – Co-Founder at Better

This is Geoff. This is one of the areas I wanted to bring up, so I'm happy Bakul did. Which is, so if they're equal, if two things are of equal severity, but this one's lower probability, then by mathematical definition, because it affects fewer people, even if they're – risk, it's lower risk? And I think that creates this unintended consequence. I'm not sure the number of people is a real metric that we want to use only because then when two things are of equal other risk, just saying, well, it affects less people so therefore it's lower risk, but if I'm one of those people, not really happy to hear that. And I'm not sure what it really means from the patient standpoint, so –

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

I understand the comment, and it's not – so these five rows, you just don't multiply them all and you get some number and you use that number. It's just the things, dimensions that a regulatory agency, like the FDA would use in order to try to characterize it. So they can make an independent judge – whatever their philosophy is, their regulatory philosophy is of saying, hey look, if it – even if there's only a hundred people in the country that have this condition, but this thing could kill them with this probability, then we want to put it through a very stringent regulatory cycle. Do you see what I'm saying; they can decide that, that this is what you would – these are the factors you'd look at?

Geoffrey Clapp – Co-Founder – Better

No, I understand that, I don't understand why we're saying these are important metrics, why we're suggesting to the FDA that this is one of those things you might want to look at.

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

Why are we sugg – ?

Geoffrey Clapp – Co-Founder at Better

I don't understand why we're suggesting that the number of people that could be affected is something that they might want to regulate. Because do we really feel like that's an important method?

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

Yeah, if something is applied to all people of senior age, that – I mean even small tweaks, even small possibilities create huge potential harm to the population, that's – I mean in my mind, that's why that's an important figure of merit.

Geoffrey Clapp – Co-Founder at Better

I agree with that side, it's the other side that I have a challenge with, that fewer people, the fact that it affects fewer people, therefore is something – so if we took the fact of the number of people out, the small tweaks and severity would still – all the other factors would still kick in. What I'm saying is that the same idea could be used in reverse and therefore it doesn't – the absence of that factor doesn't mean that the case that you just described wouldn't still be true.

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

Umm, I think – well, I mean, I think people would just like transparency in everything else, I think people would like to know how much of the population is affected, and that does affect how you view, I think it does.

Geoffrey Clapp – Co-Founder at Better

I mean, it's not part of – it's not like – being a 510(k) it wouldn't be used. So, I mean, it's fine, I don't – I personally don't think it's a good metric, as far as how many – I don't think that that transparency, I mean, it's not like that's going to be – I don't think that us even putting in this thing guarantees – transparency either. I think it just sets up the reverse, it sets up the well, it's only a hundred people. So, I don't know, I just don't see in the end how it's actually used to get what we want to get out of it.

Michael Flis – Regulatory Manager – Roche Diagnostics

Well there – this is Mike Flis. There is a regulatory precedent for considering the number of people who might have need for access to the device and then relating that to the regulatory control. I think it's referred to as the humanitarian device exemption, that if there's fewer than a certain number of people that will benefit, FDA will help bring that product to the market fast track.

Geoffrey Clapp – Co-Founder at Better

I completely agree with fast track, completely agree with fast track, I just meant as a risk, a safety risk. So I don't disagree that the number of people is meaningful, I'm just saying, in this metric about whether it helps in the safety framework. Completely agree with you on fast track, absolutely. – I mean, we don't have to keep debating it, I mean, it's one I have trouble wrapping my head around.

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

Well I think we can use the precedent that Mike was quoting saying this is something that enters in regulatory – regulators minds and we just want to make it transparent.

Geoffrey Clapp – Co-Founder at Better

Sure, sure, just – purpose – we think to the fast track how stuff gets approved and how stuff gets looked at should move into the safety context. I think that we should at least describe how we think that is and make sure why we think it should be used.

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

This is Mike Swiernik. On this point, I think the number of people was meant to be part of a broader calculation that included the likelihood of risky situation arising. So a rare event if it effected – even if it's rare but the total number is 6 billion people that might be more common than something that's common, but affects less than a hundred people. So I'm not sure that number was meant to be completely in its own – on its own, it's part of the larger group. I may be wrong, but that's my interpret –

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

No, that's –

W

What if it's rare but it's severe, right? I think that would –

M

Yeah, that's what I'm trying to –

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

There's no calculus here, this is just one of the dimensions, what should you fact – it's like a check list, think about how many people have the conditions, how many people would be subject to this software, what's the likelihood of a risky situation arising and what's the potential harm. And it's the thought process.

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

Hey Paul, I have another one, this is Mary Anne again, that kind of maybe sits under network connectivity and that is, compliance with security standards. And again, we don't have to name any particular standards like NIST, but I think there are generally accepted security standards that protect against malware and antivirus, all of which can compromise safety, I think if it compromises data integrity. So – and there's also methods of training developers on security standards, so just that whole concept of security, perhaps.

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

No thank you, that gives me something to write about networking and is part of the definition, so thanks, I'll put that down. Other comments about anything –

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

Paul, this is Meg Marshall, I'm not sure that this – any change whatsoever but perhaps it's an example to use as well, when talking especially about large population that any given error could affect, especially as HIT and EHRs advance and become much more intelligent. I'm thinking specifically of some of the clinical decision support mechanisms that ACOs will be using that perhaps could – a very specific example: recommend that a patient is at high risk for readmission. Some of the errors, if you will, in the algorithms or the calculations may not become known for quite some time and may impact quite a few patients in the meantime. So, for example, if a condition or if a weight or if some indicator perhaps is incorrectly calculated in an algorithm, but it only affects a negative – it only provides a negative recommendation that affects maybe 1 out of every 1000 patients, that might be something that takes some time before it actually elevates as an issue. So I think that it's accounted for in here, but it might be a good example to talk about some of the challenges, it's not always something that breaks and is immediate, it might – the impact might actually have a much larger population.

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

Okay, thank you. That's something I'll try to put in maybe a preamble. I think a lot of these issues maybe we have to deal as a preamble – let me think about how to do that and if you have a suggestion, I'm certainly open to that.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Hey Paul, this is Todd Cooper.

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

Hey Todd.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

One of the definitions that I would be interested in seeing added to the bottom is just your definition of risk, to make sure there's clarity on what that is, since it gets used extensively in here. One of the issues around that, and I've voiced this before, is the challenge, given the formal definition of risk, and the lack of knowledge about, for example, the use context which is integral to being able to assess risk, how you can actually come up with an idea of low, medium or high. In fact, I think Joe Smith mentioned before that for many of these, as you change the use context for this, you could easily flip the low and the high, just by saying – just by changing those factors. I'm wondering if perhaps instead of looking at low, medium, high risk, you might instead focus on concern, low, medium or high concern that might then inform the regulatory process as to a level of concern about the potential for a given application to impact safety or have its effectiveness be reduced. And in that sense also the dimensions, I think it might be nice to put a definition of dimensions for that left-hand column; I am assuming it is something around – something like factors contributing to harm, potential factors that might result or contribute to some sort of an unintended consequences, should be considered.

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

Yeah, I think I've sort of at various times used dimensions or attributes or factors, but that's sort of the concept. I also agree that we need to have a definition of risk.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Yeah, defined risk in definitions that way would help. And, like I said, for the labeling of the columns instead of levels of risk, I think something that takes people like those who have been in risk management for a long time, it's kind of like, okay, how exactly do you assess that. If you said look at levels of concern, that would help immensely.

Michael Flis – Regulatory Manager – Roche Diagnostics

Todd, would you – I'm sorry, this is Mike Flis. Would you recommend that Paul simply refer to published standards for definitions of some key terms, such as harm, hazard, risk, risk control, safety, those types of things, because they're already defined in ISO and –

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Absolutely.

Michael Flis – Regulatory Manager – Roche Diagnostics

– IAC standards.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

I think that would be helpful, and to include those, because that would then help inform those who aren't familiar with those definitions about that language. And how that's – especially when this is handed off to those who are currently in the regulatory – regulated world, it'll make sense to them and it'll also help inform the workgroup who's not necessarily in that world yet.

Michael Flis – Regulatory Manager – Roche Diagnostics

And it also reduces the amount of work we have to put in; we don't have to create definitions where they already exist.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Absolutely.

Geoffrey Clapp – Co-Founder at Better

This is Geoff, I just want to double down on that comment, I think it should also be true, again we don't have to suggest the specifics, but I think the preamble has to say that any of these things, whether it's user – some things that have standards, like software complexity, and some that don't like user-centered design. That what we'd be asking the FDA and ONC and FCC to do is make sure that when they implement a framework like this, that it does drive to either existing or new standards or expectation. Because one of the biggest complaints about the regulatory landscape in general right now is ambiguity and so we want to make sure that as we introduce things, there are standards for a lot of the things that Paul mentioned, there also are not for many of the things.

And so, we want to make sure that that should be our suggestion, if not specific things like the NIST standards for software – and things like that, at least we're driving saying, yeah, we do want these to have examples or the common definitions or things like that, versus creating a whole new world just because it's software. Software has existed with MDDS for a while and a lot of terms have been figured out and are quite usable, actually. So, we should make sure that we make it clear that we want to be careful about the ambiguities.

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

Good points and thanks some of you who have sent in some of the language that I'll fix this up and put them in the last round. Any last minute comments before we turn the second half over to Keith?

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

Hey Paul, this is Mary Anne again. This has come up in discussions with some of our children's groups which is, clinical decision support and all those elements around that, it may fit under the complexity of software, but everything from dependence upon clinical decision support to alert fatigue to the interoperability of clinical decision support between devices and EHRs. And maybe it doesn't fit, maybe it's too specific of an application, but I don't know, something to noodle on.

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

Okay, thank you. Well thank you for everybody's comments and I'll try to wrap this set of comments into the next round. And I think we're getting closer, hopefully people feel that way. Okay Keith.

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

All right. Okay, let's take the next slide. I sent these out last night, there are many slides, but I really just wanted to concentrate on the first twelve slides and again, with our full group that we had last week, there are a couple of things that I took away from it. One is that that what we're working on is really a regulatory framework for the regulation of HIT, it's not a specific or added response to individual patient risk that seems to be the motivator or why the law – out, but we're really trying to talk about the regulation of HIT itself. The Regulation Group, in their presentation, really are doing a process where they're reviewing existing laws and regulation in regards to HIT, and so they went through the FDA labeling and then also the medical device regulation, with the goal now to go through what ONC is doing and FCC. And then, the consistent request from that group was trying to get, and this was again brought up as one of our approaches to this, is the setting of innovation requirements so that those requirements could be on the table at the same time that we're discussing patient risk or fit for use of the software or any of the motivators to do regulation. That part of it would be also consideration of the innovation requirements. Any comments on these takeaways from the last meeting? Okay. Am I still connected?

M

Yes.

Geoffrey Clapp – Co-Founder at Better

I hear you.

M

We can hear you.

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

Okay. I was just trying to get the next slide. Okay, thank you. So one of the things that Brad went through in the Regulation Group was differences between medical devices and software, that although the scope of the medical device regulation itself is broad enough to encompass HIT software, it was largely applied to physical devices. And so some of the questions that came up, and then what he was going through was what regulation – which of the regulation within the medical device seemed applicable to software and which did not. I think that's useful from the standpoint of trying to understand the differences between those things, so as we talk about risk patterns or innovation patterns, that we understand some core differences between them. The other question I wanted to do then is to look at what are the innovation requirements, and I put some slides in here to start the conversation, they're not comprehensive at this point. And then stratifying by levels of innovation or opportunity for innovation.

So next slide. Okay, medical device versus HIT. Some of the differences that I put on here, and maybe we can – because what we're saying is that if we apply the medical device rule directly, I mean that approach, where does it not fit and why doesn't it fit. And so one of the things that I listed here is turnaround time that software has a shorter lifecycle. It's expected to be customized and configured to varying degrees. It contains tools to extend the product function many times, especially when we talk about EHRs with decision support and you measure it against practice impact, not absolutes. In other words, the effect of the software isn't just is it safe or isn't it safe, the context really does make a large bit of difference. Are there other differences that we should highlight as we're talking about a physical device versus software?

Geoffrey Clapp – Co-Founder – Better

So first of all, Keith, this is a good thought, I think it really sets the context of you know why it feels like some of this we may have figured before and some we haven't. Sorry, this is Geoff again, I – to say that. Maybe, and I'm only leveraging what someone said earlier, and I want to highlight that they were the source or the inspiration for it, but I think that the updatibility and kind of the network connectivity. I think that difference you could – it's a specific instance of the first version or the first thing you have here in the lifecycle, but maybe that connectivity, and especially data connectivity, both affects upgrades, security and privacy very differen – maybe in the 70's when the Medical Device Law came out, it was like all the devi – the data on the device, how you would bring it in or sitting in the hospital, maybe that connectivity with HIT maybe we should highlight both upgrade and data privacy and security.

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

Okay. Thank you. Other comments?

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

Keith, this is Bakul. I was just wondering, in the previous slide you mentioned batch analysis, talked about differentiating medical devices and software. I guess my question is, and I have to refresh myself on the Taxonomy Group, did the Taxonomy Group or to your understanding, Health IT is limited to software only or is it more than just software that's considered Health IT?

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

Well, that's an interesting question because there's no physical device that I know of now that doesn't have some software in it, and you could go the other way that said that although software is more virtual, it still controls or at least sets up communication between physical devices. So it's very hard to be very clean on that boundary. I think by doing this exercise, it's not so much to say that there's – we can consider software completely divorced from physical devices or physical devices completely divorced from software, but there's a certain amount of – I mean those two kind of extremes at least let us look at the differences between the two things is we're approaching. So it's more of a kind of mental exercise to say, can we consider this independent and see how we're going to – what are the attributes that are different, so that we can account for them.

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

Right. Sure. Yeah.

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

This is Mary Anne. Maybe we need some criteria that qualifies a medical device for consideration in – because I think the Taxonomy Group did struggle with this and I think they're in in one scenario and out in others and I think we probably need some criteria under which medical devices are in. Because a lot of the issues we're talking about are integration of medical devices, so to what extent does that interface need compliance with certain standards, for instance?

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

I think that what I'm trying to do here is a little bit different and it was spawned by the discussion with – that the Regulatory Group was having, is that what we have is the existing regulations, which we're starting to apply to HIT, were written for a different – a slightly different world, where the idea was really to – I mean the proximal use case was a physical device. And now we're doing this, we're applying some of those regulations to software. And so it's trying to look at – to say if we did that, okay, what would be the consequence and which things in software are different and need a different approach? If I'm manufacturing a device then, for instance, in approval process, because my time – my turnaround time is longer, as soon as I have a good design, what I want to do is manufacture millions of these things and recoup my expenses. Where with software there's an expectation of constant improvement, with fast turnaround time, which is a different type of attribute, so mainly this is just trying to get at attributes that we need to account for as we go through. Why is it different and what are those attributes do we want to keep, because they are different and they lend themselves to innovation? Does that make sense?

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

Keith, this is Meg. I think that makes perfect sense and perhaps it's in the terminology, the semantics of the slide itself – of course understanding that – the questions and the title make sense, so maybe it's just the impression left with the wording and it can just be played with a little bit.

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

Okay. Also I'm just trying to do this to get at these items, because what we're saying is, and we could say for instance that the medical – I mean we could take the stand that the medical device regulation has worked perfectly well for creating medical devices and keeping them safe for patient use. And there's really no difference between a medical device that software is just another medical device and so the regulations that work in one place should work directly in the second place. If we don't believe that, if we think that there are some unique things that would both – well, unique things that would cause us to regulate software differently than a physical device, that's really the point of this exercise, mainly to get these things. Not necessarily that this is part of the final report, it's mainly what things should we think about as we talk, because then we get back to then, what are these attributes that are different that we really want to enhance? Or, which one of these things that are different that we really want to suppress.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna. I think this is really helpful because there are important differences and using the same standards to evaluate an insulin pump versus something that will take the data from that and display it in something that's more user friendly. I don't think that makes any sense, so, I think this is really a helpful construct.

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

You're – for your data to different platforms. If I have a physical device that I don't assume that I can move the logic from one physical device to another manufacturer's physical device, but I do have the expectation that I can move patient data from one device to another. So I have different expectations.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Correct. Yes.

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

And that I can connect different platforms and be able to deal with the data on the other platform, the other device platform in this case, and I can do that safely.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Exactly.

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

Okay. Other comments on this?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

This is Lauren Fifield. You all just forgive me for the background; I am walking in New York. But I just wanted to try and reiterate what Keith was saying that being on the Regulation Subgroup, the point of going through existing regulatory processes and regimes is to say kind of, imagine if we were to apply this health IT, what would be great? What wouldn't work? What do we want fixed? It certainly isn't to say that we would use all those rules and I think that – I'm glad that Keith is highlighting these points, because there is not just the technical, should we regulate, should we not, does health IT fit in the definition of medical devices. But it's really philosophical differences between device development and software development that I think everyone would really do themselves well to internalize, because it makes a huge difference in how I think we think about our recommendations.

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

You guys still there?

Michael Flis – Regulatory Manager – Roche Diagnostics

Keith, this is Mike Flis. I don't understand the third line well enough to comment, the tools to extend the products function. Historically regulatory decisions are driven primarily on the intended use of the product. If you put software in the market, which is prepared to have its intended use extended, how does that fit into innovation risk regulatory framework? Is that what you're suggesting here?

W

Keith, are you still with us?

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

Yes.

(Extended silence)

Lauren Fifield – Senior Policy Advisor – Practice Fusion

This is Lauren again. I don't want to speak for Keith, but I think one of the – this may fall into the category of integration, but I think a medical device is treated by the manufacturer to help a provider or a patient or an end-user to measure something to get some sort of result. And I think an EHR or some other interface could be used to enhance the use of that product, certainly manufacturers of devices could all create their own EHRs, but one of the things that we've heard from providers in particular, and I think patients, is they don't want to have to log into a thousand different portals. And so, I think one example that would be most prominent of that line would be sort of enhancing the sort of use of the data that's generated by that device as an example. Keith is that what you were thinking?

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

Sure. Sorry, I got knocked out for whatever reason, service just stopped on my cell phone, even though I'm not moving, so I guess holes just move around. So I didn't get the comment altogether, but the – could you just give the essence of it again, sorry.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna. I don't want to speak for Lauren, but I think she was basically saying there's a difference between a medical device that's used for a particular clinical purpose versus software that's used to make – sort of extend the value of that. So, I think she was just kind of echoing the gist of where you're going with this, and Lauren, correct me if I'm wrong.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, that's right. And Keith I was trying to respond to someone else, who's name I didn't catch, but just sort of clarifying kind of why it is that software would exist to a – device, why not just have the device to serve it's intended use, and I think it's because we'd have a proliferation of kind of user interfaces, as an example, that doctors don't want to deal with, they want to just deal with one or two interfaces, again, as an example.

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

Okay.

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

The question was around that third bullet, it would be interesting to hear your thoughts on an example of the tools to extend the product function and what the intention of that was.

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

Well again, if I look at the tools that are put into software because what we're trying to do is really adapt software or negotiate between our software and our clinical practices. It's a little bit different in a medical device, medical device have a specific task I'm doing, I'm taking a blood pressure or I'm monitoring vital signs or I'm delivering ventilation, and it's a task within a process, Where with software, what we really have is we're trying to – we're more engaged in a longer piece of the process. And so in order to adopt to or adapt to many of those processes, the manufacturers put in things like decision support tools, so that we can add decision support to the process. Where if I have a physical device, I'm rarely going to go in there and change its algorithm, I input parameters, but I don't change the algorithm.

Another example is that I give you tools to do – to create new forms and create new data collection tools. So the idea that I regulate, for instance, a presentation is very difficult when locally I'm creating different presentations, and I have the ability to do such. So I think that's a difference of software that needs to be noted, that is different than a physical device where the manufacturer has more control. Other comments?

Why don't I go to the next slides then, again, I think that the purpose of this slide is mainly to think about the purpose for which some of the regulation was created versus the use cases that we have now in software. But let's go ahead and go to the next slides. Okay, so as we talk about innovation again, or risk. We've talked about this a couple of times and it comes up in our meetings is that we have the top level or developed software, the creation of the product itself. And of all the – probably of all the steps in the regulation and that, this is closer to a medical device, because they have to do with the manufacturing process. But then what we have is software setup and customization and extensions, so at a minimum we're configuring the software, but then we can also customize workflows, we can customize forms, we can extend it and collect data that was not initially anticipated by the manufacturer.

We have the whole integration with our medical processes, which is really driving this customization, of how is this really going to work in my clinic or how is it going to work in my hospital. And applying those processes because again, the software is engaged in more than just one task within the process, it really is managing a process. And then we have the communication devices that we connect to the software, and then we have how we combine technologies, which is either in a predictable way, meaning that the entity, the clinic or the hospital are predictably connecting devices through interfaces and through services. And then non-predictable ways that the user is combining other available technologies into their process.

So if we look at those things, next slide, and we take the idea that what are the innovation requirements, and the innovation requirements may be different, based on which level of innovation that we're talking about. And by collecting the data there, then we can talk about these different things and how regulation affects these different levels of innovation. So let's take the next slide. Okay, for example, for the vended software, some of the innovation requirements and these are very sparse slides because they're mainly to get other people to chime in on this thing. One is – but looking at these different levels, what are the innovation requirements and then, what kind of model or accountability model are we trying to set up that serves both having good, safe tested software and meeting the needs of innovation. So comments on that? I mean I just put two things here, one is policy clarity, another one is it's standards and standards help innovation by increasing opportunity for small-scale products. Other ideas on innovation requirements at this level.

Geoffrey Clapp – Co-Founder – Better

So, if you combine the previous slide – this is Geoff again, isn't this – a recommendation then coming out of this or at least something that you want the group to consider about limits on regulations or what you've called here the locally created and locally configured. So, is that – because they're kind of driving towards a recommendation or something, you've got a trend there that's kind of written into those two slides I think suggested, but at least maybe that's a conversation we could have right now about those points, so they drive towards a recommendation.

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

Yeah. And let's go back to the previous slide just for a minute. What we're saying is that, I mean, as we've talked about regulation and the risk pattern from Paul and that, we've talked largely about creating a software entity, if you will, either extended or its created locally, but we're creating software, but then we have these other things about configuring and extending it. For an example, if every time I write a rule and my decision support system that was provided by the vendor, so I'm given the tools, that do you apply for instance, the whole manufacturing process to the creation of a single rule. Where you can see that creating the tool itself that has the regulation – if it has a different risk and innovation pattern or needs, then writing a rule using the tools that were provided by the vendor.

So this is really again trying to stratify on each of these levels, whether the innovation – whether the parameters of innovation that we're trying to preserve are the requirements, going back to what the Regulatory Group was talking about. I mean, to kind of put the conversations together, they're saying, they're looking at the existing regulation, does it fit with IT, does it fit then and if they were trying to change it or propose a new set of regulations, what are the things that they want to preserve that are unique to information systems and promote innovation? So this is again just a way to look at that issue and to start to enumerate those requirements of innovation. Sorry, that went on a long time. Comments?

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

Hey Keith – this is Meg. Is this an appropriate place to talk about, I suppose it would be the actual deployment of the product that we're trying to use as an example that requires innovation. And one thing that I think of is, in addition to rapid deployment, the ability for the user to assume a higher level of risk. So is this an appropriate place, I suppose, for that discussion?

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

Yeah, I think it is because again, and that's why I put accountability model on those – I mean, looking at these different levels. What is the type of innovation that we want to preserve at that level and then what does the accountability model look like? I mean, to take it to the extreme, if what we got was software from vendors where no changes could be made in the software, no configuration, no customization, no extension, then the accountability model is really centered on the vendor themselves, because they control the full function of the software, much like again, a physical device. But where you have this local configuration and customization and extension, what does the accountability model look like for that, and how do you regulate that accountability model without destroying innovation? We've talked about not discouraging new manufacturers to get into this space, but we could also discourage the use of the tools within an institution to better serve their processes, if we put too much of a regulatory burden on that – or oversight on that.

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

Absolutely and I do think that there's a lot of value in having the ability to field test products, if you will. So without calling it a clinical trial or a clinical study, but having that ability to interact with the user, with the user having the understanding that they're assuming a little bit more risk because this is an early or rapidly developed product in its early stages. So I'm not quite too sure how to articulate that, I mean you're absolutely – you hit it on with the locally created and the locally configured being part of that user dynamic that is outside of the manufacturer control, but also part of the assumed risk – the understood assumed and inherent risk.

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

Okay. Other –

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

Keith, this is Bakul.

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

Yes.

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

I was just wondering, on one hand, I mean to your comment, you were saying that we want to make sure – I mean, what I'm hearing is that innovation is required where you can and maybe Meg said this, being able to field test changes and to get the feedback so we can be innovated to meet the user needs. So how does that concept and the concept that you talked about before in the innovation subgroup, how does that match up with Paul's risk dimensions? And is there – and maybe this is not an answer for now, but is there a plan to think about that, to come up with some alignment or some way of teasing out where things need to be balanced?

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

(Indiscernible)

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

Well I think, yeah, go ahead –

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

No, go ahead Keith.

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

I think it's interesting, because much of the risk profile that we've done is really to give tools to a regulator going back I think to the idea of regulatory discernment.

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

Um hmm.

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

Do I apply to this or that? Where I think that these start to overlap is to say that in this case, and I hesitate on this a little bit, is that – well, it goes back to the comment that context matters, that we talked about this morning. I mean, the easy example was if I have a drug-dosing calculator and I'm calculating a dose of Penicillin, the context says it's not very risky.

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

Right.

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

If I apply that same calculation or capability to oncology medications, where I have a narrow therapeutic window, then it matters tremendously. And yet when I put the calculation together, I think that I have the same obligation to make it correct, because I don't know – I mean part of the deal is I don't know how the calculation is going to be applied. But the context, what we're talking about here, is a context of use; one of the big differences again between a physical medical device and software is that the context of use has a lot more variation with software. And that it will be applied to a lot of different contexts that will be more varied, and so how do you make that application both something that you want to promote and at the same time, is a safe application.

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

And this is Paul. Let me just extend and compliment that. So in a sense I think all of the attributes of innovation that Keith has been discussing are covered on the matrix. So in a sense, the matrix describes a risk profiling, innovation is a special perspective that we want to and called out by the statute, the special perspective we want to make sure is certainly not restricted and potentially even promoted. And so context is another good way of describing it as well, but the context of innovation in applying – protecting innovation in the context of patient safety maybe and then actually could work the other way around, protecting patient safety in the context of innovation. But I think innovation is a special perspective on patient safety risk. Does that make sense, does that sound right?

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

It does, yeah. I think it's covered; I just wanted to make sure that we are not missing some parts.

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

No –

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

But the issue really is, as you look at this particular slide, at the top two levels where I'm manufacturing something, it's easier to do the risk profile. As soon as I start getting into these things, which is actually what we want to promote, I mean, why we have decision making tools is that we expect and that we hope the hospitals and clinics will look at their own set of issues and problems and insert decision support as a solution to those problems. And that we want them to be innovative in using the software more as what the IOM envisioned, was a consultant and a guarantor of safety rather than a threat to safety or to alter processes in an unsustainable way. So it requires a different regulatory approach to that because I'm not just dealing with a supplier in this case, a supplier with the labeling and the device laws, but I'm dealing with a physician who's using the tools to make something unique.

We didn't get very far in this and I'm looking at the time. Are we doing okay on time or do we need to go to public comment?

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

We are going to have to go to public comment before the call closes, but if you want another minute or two to wrap things up, we can do that.

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

I think that where I'd like to go with this, because it – I mean, where we were last time is we said how do we approach it and how do we get a work product. I think that it is, what I'm proposing is that the idea of putting out requirements, innovation requirements is – was one of our options and it seems to come up now in multiple meetings. And so, but then stratifying it based on these levels of use and context, I think, is a way I propose to structure this. What I propose then is to put out more of a like Paul has, I think it was very useful, because Paul's now extended his document beyond the matrix into written definitions of these things. So I'd like to do the same thing is start to circulate this as more of a written document and have people comment on it and add to it, so that we can iterate on these plans. Anyway, thank you for your time.

Geoffrey Clapp – Co-Founder – Better

Keith, thanks for the work you put into this, this is clearly – we have the easy job of commenting on it, so thank you for that.

W

Yeah, than – again, thanks for – you and Paul are doing all the hard work, so thank you very much. I think this is really helpful and shaping up really nicely.

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

So are you ready to open up for public comment or do Paul or Kevin or you guys have any other comments?

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

I think we need to go to public comment, given the hour.

Public Comment

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

Okay, sorry Keith. Operator, can you please open the lines for public comment?

Caitlin Collins – Altarum Institute

If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We do not have any comment at this time.

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

Well thank you, on behalf of Keith and myself, thank you for joining the call and thanks for your vigorous participation and hopefully we're making progress on both of these fronts as we move towards our deadline in delivering some output to the whole group.

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

So Paul, this is MacKenzie. I'm not showing any other upcoming subgroup meetings on the calendar right now.

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

I think this is useful to meet together, does everyone agree?

Various participants

Oh yes, very much.

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

– to email, okay. So could we go ahead and try to schedule some more time please MacKenzie.

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

Sure, so I'll send an email to both you and Keith just to figure out the timing for that.

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

Sounds good.

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

Thank you everyone.

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

Thanks everybody.