

**HIT Policy Committee
FDASIA Workgroup
Risk Assessment & Innovation Subgroup
Transcript
June 13, 2013**

Presentation

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good afternoon everybody this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's FDASIA Workgroup the Subgroup on Risk Assessment and Innovation. This is a public call and there is time for public comment built into the agenda and the call is also being recorded so please make sure you identify yourself for the audio and transcript that's being prepared. I'll now go through the roll call. Keith Larsen?

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

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Keith. Paul Tang?

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

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Paul. Geoff Clapp? Esther Dyson? Mike Flis? Jeff Jacques?

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Present, MacKenzie.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jeff. Anna McCollister-Slipp? Jonathan Potter? Jared Quoyeser? Mike Swiernik? And Mike I know you're on I think that was you. Jodi Daniel or Steve Posnack?

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

Steve is here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Steve. Bakul Patel? I think we have Simon Choi.

Simon Choi, PhD – Senior Science Health Advisor, Center for Devices & Radiologic Health – Food and Drug Administration

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Simon. Is that you Bakul or is that Simon? I think it's Simon. Matt Quinn? And if there are any other FDASIA Workgroup members on the line if you could please identify yourself.

Anura S. Fernando, MD, MS – Principal Engineer, eHealth – Underwriters Laboratories

Anura Fernando is here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Anura.

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

Joe Smith.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Joe.

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

Hi it's Jackie McCarthy.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jackie. With that I will turn the agenda back to over to you Paul.

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

Thanks, MacKenzie and thank you everyone for joining the call. I think they're trying to sort out some of the problems and I don't think it affected this particular meeting but we had some cancellations go out for some Workgroups and I don't know that any of those calls have been cancelled, but we're trying to figure out what's going on because every once in a while an admission goes out without canceling it.

But at any rate, we have a couple of agenda items, a couple of major agenda items, we're going to continue our iteration of both the framework for patient safety risk as well as risk to innovation, we've divided it as we have in the past, Keith is going to cover the innovation, risk to innovation and I'm going to cover the patient safety risk. This is an update of both frameworks based on the discussion that we had at the face-to-face as well as some e-mails that we've had in between.

In addition, I'll go ahead and start out with the patient safety risk framework. I've done a couple of things one is update from some of the discussion based on the face-to-face meeting. Also, added the medium risk that's something David Bates had mentioned in our face-to-face thinking it would be helpful and going through an exercise, as it certainly was, and of course this is just getting words onto paper so that it's easier to critique rather than come up de novo in a setting like this.

The other thing that came up during the face-to-face was the usefulness about decision tree and someone on this call, the last call mentioned this as well, isn't the intended user and the purpose really a big determinate in this – not in the sense that it gets the most weight but if you're going for an information only to patients for example maybe that opts you out of going through the rest of the criteria so that we may consider and in fact if you look at the matrix with the different colors it's approximately ordered in a consider this first, then consider that, then consider the next group and certainly open to discussion on that, maybe we'll do that after we go through the matrix itself.

And finally, want to look at exemplars and I don't know how we left it with the full group in terms of every – I think every group wanted to have some exemplars to at least test our different – each framework for taxonomy, for risk and for regulation. So, we'll find out a little bit more about how – do we each develop them or is there going to be a central core, remember that we went around, did a bit of a round robin I'm not sure everybody gave exemplars, but there probably hopefully will be some pool for us to draw upon. Any comments about that before we sort of delve into the framework itself?

Okay, so on your – hopefully you also all have it in front of you, or it's on the screen, but of course this is much smaller print. Why don't we start from the first one, which is the purpose of the software and intended user and some of the changes? So, the purpose of software could be solely for information or it could be making decisions on its own and the in between might be it makes recommendations but doesn't necessarily carry them out as in the higher risk.

With the intended user there was a comment about, previously I think I said licensed professional but another helpful word is credentialed, in other words there is some third-party that says "hey, here's what this person should be able to do" and if it's within the scope of the practice of that credentialed professional than of course that would be lower risk.

The other side would be that it provides, and I've added some modifiers to help clarify as someone requested, that it's advice, it's particularly diagnosis and treatment, and the reason I chose those words are those are things within the license or the scope of practice of let's say a clinician, particularly a physician for diagnosis and treatment and that the system gives that advice directly to the patient and you can appreciate how that would be a high risk.

And in the middle is making recommendations to patients and not necessarily diagnosis or treatment, it could make recommendations for follow-up or things like that, but that might be a medium risk. So, let me open that up for people's comments and proposals.

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 & Technology Officer – Palo Alto Medical Foundation

Yes?

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

Hi, just a clarification and maybe you already have – the intended users is expressed by the vendor is that the intention here?

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

Yes and then that's a really good point because remember we talked about you had the tri-agencies but there are other agencies that actually could come into play and FTC is one of those. So, if – so when a vendor declares "hey, this is for professionals only" or "this is for patients" then you need to be held accountable for all the responsibilities that go along with that and FTC can help us enforce that part, but excellent point.

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

Hi, this is Mike Swiernik.

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

Yes?

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

The intended user piece I think maybe – there are probably some other edge cases we want to figure out how to include so two of them I can think of are that a lot more systems now a days are shooting for multiple different types of users so they may act as a bridge between the licensed professional and the patients for instance and so they'd have multiple users and then the other case might be where I think it was your issue Paul with the interface between two systems who would the user be in that case if both sides of it are just systems.

And so I don't know if this is – I guess what I'm saying is – and also in this I don't know that just because it's to a professional it's necessarily lower risk. To me almost the intended user is almost informational and looking at all other pieces but maybe not necessarily risky although I do agree with the ones you have here being for the most part how risky it is. I just think there may be other ways to – you might be able to flip these around or something.

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

Sure, good point. Let me try to give an answer to the first two questions and see if it's satisfactory and if so I can add that kind of wording. So, one of your questions is, if it's going to intended – the intended users are multiple kinds then my guess is that you would have to apply these criteria to each user.

So, for example if it's for the licensed professional to do something within their scope of practice you might say "hmm that seems appropriate" and it's information only low risk, but if you're also saying "oh, and patients should be able to use this too" then you'd have to get the more strict criteria, the higher threshold in terms of not having regulation apply, but in other words it would be an "or" so you'd have to meet the criteria for both intended users. In the interface between –

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

–

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

Yeah, okay, the interface between two systems it's interesting, let me try that. The system – if all you do – let's say you're a conduit and you connect information from one place to another then the two "users" are the systems you are connecting between and they would be responsible for having their own users but you aren't directly the patient for example or even the doctor is not a direct user, consumer of the data flowing between those two systems if your role is to connect the two and I'm just throwing that out as a straw-man way of handling the question to see if that makes sense.

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

And yeah I think another example in that would be say a decision support system where the user was only ever another system but the people it was effecting were the professionals and then – and I'm not sure if you're saying with the conduit maybe that gets it out of this framework because it's not intentional, but I think with the decision supports we want to include them. So, I think, yeah, somehow hooking that into whatever the intended use of the calling system might be. I don't know.

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

That's an excellent question. So, in that case there is some transformation going on in this box and it is to take in and puts then it spits out a recommendation and yes it does go through somebody else's interface to get to the user, so I think we'd have to find some way to make it clear that the person is causing this information to – that develops that information in this case the decision support recommendation is the one that's being evaluated. So, if that's acceptable then we need to find ways to make that clear.

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

Yeah, and the only concern I have in saying that is I think we talked about last time too how there are a lot of third-party systems that you might use for very basic services that have nothing to do with healthcare and I wouldn't want this to unintentionally bring them in scope just because they happen to be

–

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

Correct.

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

Like say, I don't know why you'd do it but you might use a third-party service to do basic math functions for instance and you know, that doesn't necessarily mean it should be regulated. I'm not sure how to do –

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

No, these are good exemplars to test it against. So, that latest example you gave is intended to be the first kind but I think that warrants clarification. Other people's thought about the answers, the proposed answers to that question?

Anura S. Fernando, MD, MS – Principal Engineer, eHealth – Underwriters Laboratories

This is Anura Fernando, would it be potentially workable to include that type of third-party software so for example Metalware, operating systems, libraries things like that, if their targeted for healthcare application into these same buckets, so for example if there is a real-time operating system that is developed with medical applications in mind and let's say it's a real-time operating system using an IV pump then having it in that high risk bucket along with the application software that actually controls the pump.

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

So, you would be proposing – you’re proposing that since this real-time operating system for IV pumps was for a health App that their software would be included in this and whoever submits for approval whether it’s the IV pump manufacturer or the OS developer they would be subject to these criteria.

Anura S. Fernando, MD, MS – Principal Engineer, eHealth – Underwriters Laboratories

Specifically if they’re making claims to support risk management for healthcare applications. So if it’s a general purpose then no but as their making specific claims then yes.

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

Okay. Other thoughts, reactions?

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

I think with that, although I like that I think the – this is Mike Swiernik again – the challenges for application – like we have again I mentioned at the meeting that’s health – the difference between health and wellness even though a lot of it is the same. So, if I were to say “yeah I run a service that does BMI calculations” I wouldn’t want it to be something where – or I don’t think it would be good if there was a situation where someone could say “well I do it for health applications” and suddenly I’m regulated and someone else says “well I only do it for wellness ones” and therefore I’m not regulated. So, you have to be careful about that although I agree with you, with the last speaker.

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

Okay, so let me try to incorporate some of this feedback into a revision and pass that around. I’m just going to watch the time. I have until 7:15 my time, 10:15 East Coast before turning it over to Keith. Let me go to the next cluster, so after we’ve settled who it’s for and what is the purpose then we’re diving into the risk profile, risk to patient harm.

The severity of risk that’s a change from magnitude of the risk and the addition is the medium risk, so we have something very low probability of harm to life-threatening so the middle is potential for non-life threatening adverse event. The number of people exposed, people asked for some quantification so I tried to – I just threw out something for people to react to. Few people being less than 100; a lot of people being greater than 1000 and moderate-sized being in between.

The likelihood of risky situation arising, if it’s sort of once in a blue moon less than once in 100 years or it’s common there is another kind of situation though I thought I’d put in the medium risk which is it’s unpredictable but it’s going to come up like every year. So, trying to say something in between common like happening, you know, fairly frequently.

Transparency, it’s either really easy to understand what it’s output is, the blood pressure for example and how it’s calculating it to it’s a black box and you just get the output and something in the middle, yeah it’s operating transparently but you’ve got to be a software geek to understand this, well, so that sort of halfway fulfills that.

And finally, the ability to mitigate harm, there is a human intermediary that is knowledgeable and expected to know how to interpret this and interpret the implications, and can intervene, and that happens all the time versus a closed loop and the human is clueless, the medium might be there is a human intermediary, yeah, something can happen you can observe if you pay attention but it’s not built into the flow from information into action. So, it is neither required that the human be involved as in the left column and it doesn’t happen on its own completely like in the right column. So, open it up for comments on this sort of patient safety risk characterization.

Anura S. Fernando, MD, MS – Principal Engineer, eHealth – Underwriters Laboratories

Hi this is Anura Fernando again.

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

Yes?

Anura S. Fernando, MD, MS – Principal Engineer, eHealth – Underwriters Laboratories

I just had a question or needed some clarification around the exposure. So, would it be anticipated that the developer of the software App whatever would be able to predict the exposure or would it be up to system integrators who may actually be incorporating that into a broader specific clinical system or would it be up to regulators to make that determination.

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

I think, to – let me try and answer, I think it would be the developer and they obviously know because they had to do the whole marketing analysis to even figure out what's the business plan and business model. So, my guess is they do have a target so it's both intended user and how many of those are there out there anyway. Certainly the regulator has its opinion but my guess is it may be based somewhat on what the product developer says.

Anura S. Fernando, MD, MS – Principal Engineer, eHealth – Underwriters Laboratories

Thanks.

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

This is Keith Larsen, I mean, we saw this a little bit with the taxonomy group also about what is intended scope of use and how does that work when again we're talking about some mobile App where the intended use, I mean, could really just skyrocket because of its availability for distribution.

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

One would guess that was predicted and predictable by the developer and my guess is the regulating agency would also appreciate that if this is going viral this would apply to large populations and you'd have to think of the risk in those terms how does that sound?

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

I mean, the only thing I – I mean, again as we talked about these things it kind of gets into – there is the criteria for inclusion and then there is the avoidance response where you're trying again like, I think Mike brings up, do I call it wellness so I don't get regulated versus healthcare where I do.

Do I call it wellness in order to – and this was brought up I think by the representative Mike from Roche, you know, do you – it is what I call it and how I define it, can I do that to avoid regulation. And then if I become – if I pop up above radar what does that mean? For instance if the intended use was a few people and now it's gone viral do I respectively apply the – for instance the good manufacturing processes criteria to that software?

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

Well, let me try and answer and maybe Bakul can also help. Let me see if you're going to – if you're going to do this, i.e., try to hide under the wellness banner then using it for healthcare would be "off label" and is there an analogy Bakul between the vendor can't promote the off label use, I believe that's true, then similarly this vendor of wellness uses can't promote it for care side, would that be a useful analogy?

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

We won't – I mean, people – a healthcare provider using it for health, for off label use is a totally different situation as opposed to, you know, some vendor trying to purposefully trying to promote it for off label.

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

Right.

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

I think that's something that we're very sensitive towards, yes.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

But, this is Anna McCollister-Slipp, I mean what would that mean in terms of like simple software designed to tell you, you know, carbohydrate counting for insulin dosage? I mean, some of the stuff I don't think is particularly useful but all it does is basically site all of the nutritional information from the label of packaged processed foods. So, would that suddenly become regulated because it's designed specifically – it has something in the name that says diabetes or for, you know, something – or heart disease of whatever the case may be.

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

Let me try to –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

But if we say "stay healthy" it's not.

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

Right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I mean that doesn't really make any sense.

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

So, let me try to approach that by something that maybe a little easier to certify. So, let's say you have a home blood pressure device and there is some kind of certification criteria that says "oh, they have gone through this certification criteria and it is made to be used in a professional setting" that's a threshold where you can – where the vendor could say I either have this certification that allows it to be used in professional settings or I don't and that should be made clear to whoever purchases it. It will be a little harder to test but potentially there could be a way of saying cost counting, but what do people think about that?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Well, I have a home blood pressure monitor and I have kidney disease from my diabetes and I use my blood pressure monitor sometimes to make decisions about how much diuretic I should use.

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

So, is it –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

You know, if my blood pressure is a low does that change the risk factor because I choose to use it that way, it's not marketed that way but that's the way I choose to use it, but, I mean –

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

Let's pretend it does have a seal of approval or does not and you know about it, you say, this is certified to be complied with these professional criteria or it doesn't and you knew that would it change your mind?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Absolutely, I only get ones that have been certified.

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

Well, then that seems to be part of the answer, right?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

But that's a patient's machinery as opposed to an application that tells me what carbohydrate count I have as in a cracker. I mean, and if somebody comes up with a great App and a hospital nutritionist decides to use it when they're calculating doses for, you know, a diabetic, and an inpatient diabetic meal does that make that App not useable because the person happens to work in the hospital?

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

I think – so let me – I'm just throwing out answers to see if I can test.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Sure and I'm just throwing...

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

Right, right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I'm doing the same thing, so I'm not trying to be argumentative just for kicks.

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

So, my guess is both of those rely on a database and what should be clear whether you're a consumer or a nurse in the hospital is what database did that come from maybe that's something that doesn't happen now and it should and we know what the reliability and of course every database can have its mistakes, but let's say it does come from the US Food and Agriculture, USDA, well whatever it stands for.

M

Yeah, whatever.

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

Wherever it comes from we know that, you know that and everybody knows that and everybody knows yes it's fallible, but it's very reliable and that's the information you have to make decisions based on that. That would be part of the reason why you'd have to – those would be some of the meta rules that apply if you were – if these things are to be labeled.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I guess I wouldn't necessarily have a problem with that, if it were part of the App software or, you know, in the iTunes Store or whatever. I think it would get a little complicated if all that stuff had to go through Bakul and FDA. I mean, and I don't want to speak for Bakul, but I think that would be a huge – and I know we're not talking about innovation right now but I think that would just be a huge barrier that would just make people take their talents elsewhere.

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

Well –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I mean, once it's all of the – you know, as part of the Affordable Care Act all the different food restaurants have to start putting calorie counts for their stuff so if somebody puts all of that into an App that doesn't come from USDA it comes directly from the manufacturer, they then have to certify that that particular fast food chain did an appropriate calculation of the calories before they could market that or make that software available?

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

So, Paul, let me –

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

Sure.

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

Try to attempt to address Anna's comments here. I think it's going back to your point of transparency, right, and also a counter question could be is, what would we want that users of whatever App and it could range from the calorie counting to anything and we may – and to be something that does provide clinicians with the radiation therapy parameters that gets into a – so a big range right?

What is it that you expect when you're looking at the calorie counter what are the expectations that we can agree on that needs to be there? I think that's the transparency part the way I read it and I don't know if Paul that's exactly what you were thinking?

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

Yes.

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

So, we should think about either it should be looked over by, you know, entity A or not or certified or not but maybe think about are you expecting it to have something that it uses data from either the manufacturer who has tested what those calories are or it comes from USDA whatever. I mean, that's the level I think we need to think about and not about, you know, whether it needs to be looked over by somebody. Certification was just an example I think Paul was trying to get to.

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

Hey Bakul this is Matt maybe to add onto what you're saying a little bit, transparency could also refer to datasets/mechanisms by which –

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

Right.

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

We collect information about what, you know, what we think or potential risks and what's actually going on in the field and so, you know, the way that people could use something could be unanticipated and to have those learning systems in place would be really helpful separate from regulation.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I think if everybody was as transparent about where it came from, you know, whether it came from the USDA or the product's manufacturer or I hired this 16-year-old to go around to all fast food restaurants and write down on calorie count. I mean, as a consumer who uses things like this, you know, from time to time to make decisions about things that affect my health that would be fine with me as long as I had a sense of where it comes from.

You know, I've got fitness tracker Apps that have pretty clever interfaces for food counting that are a lot better than some of the diabetes ones, you know, I'm guessing, I could be wrong, I'm guessing that those did not go through FDA but it's certainly helpful when I go back and look at my glucose levels and my blood pressure levels and my food tracking to be able, you know, if I take the time to put all these different data sets together to be able to get a sense of how things are working in terms of my insulin dosage.

So, I would hate for somebody to be discouraged from developing some, you know, similarly clever applications because they happen to market to a diabetes audience as opposed to somebody who is just trying to lose weight.

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

So, Anna, let me go back and I think you brought up some good points. Let me go back and try to expand on the transparency because I think that is truly, and you even said it yourself, that's truly one of the things that the most useful and would help at least give consumers and other users the ability to understand, you know, how this information was derived. So, let me go back and add to that and try to address those issues. Other comments on this blue section?

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

This is Keith, I think the interesting part on transparency is it's – I mean, we're using transparency in this case as a parameter or a method to categorize and select devices and software for regulation. What we've talked about in the last couple of minutes though is a different type of transparency that is transparency to the consumer whether that's an individual patient or a clinic, or hospital that is purchasing something about, you know, where did this information come from and has there been any certification, which it really kind of goes beyond what we're talking about here, you know, I just introduce as a comment for later, for instance when Anna was talking about if she looks at two things how does she know that one went through an FDA process versus the other one didn't and what did that FDA process mean? Did it mean that just went through good manufacturing processes or that they endorsed the calculation and the database?

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

That's a great point and I think, you know, this is Matt; there are two sides to this. Think of that as potentially a mitigating factor for different – for certain kinds of risks whereas there is a broader transparency around just knowing what those risks are and understanding them pre and post market.

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

So, I think the way I was going to incorporate this discussion is to add something up in the purpose really, it's really a declaration by the developer, by the vendor of what's the purpose of this and where did I get information. So, I'll try to add that and then you can all provide feedback, but I agree one that it's an important thing. Two, with Keith's note that it's not the same transparency software operation that's in the blue, I think it's more transparency of what is this, why is it made, and how did I put this together which is up in the first green area. So, these are good comments and good additions.

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

This is Mike Swiernik, two minor comments I think one the likelihood of risky situation arising I think the denominator in that probably needs to be something like patient life years or something rather than years.

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

Yeah.

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

And then the other, the severity of risk, a few people mentioned that there is risk with existing care and that we should somehow incorporate that into this, so I was going to propose that we make these severities relative to whatever the affected populations existing risk is.

So, a life-threatening potential to someone who has, you know, perhaps 50 years statistically remaining in their life versus someone who has 3 months statistically remaining in their life is very different. The only problem that I know of although others will probably have other problems is that it really opens it up to risks associated with off label use in that case, but that maybe one way to incorporate that.

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

Yeah, I'm nervous too about that. You wouldn't want people to prey on folks who have a desperate condition.

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

Right.

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

So, one of the stand outs, at least for those of you who are a little on the older side, Laetrile, you know, a pill to people who didn't have other traditional means and of course the only people who could claim success are the people who survived the Laetrile. So, you know, you could get into all of this work in the areas where they don't have any hope and let me just provide anything and if we adjusted it by that we could get into trouble.

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

I agree.

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

I think that – this is Keith, I think that's an interesting discussion of balancing particular patient risk, again, the example that we used quite often in the meetings was oncology drugs and the Laetrile again gets into that category. But the idea that that's how I balance change in innovation but maybe not on inclusion or exclusion of software, you know, because again you couldn't say, well this is only for people to have one month left to live, first it's kind of a small demographic.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, but if you told – if you were told that you were going to die in two months and there was nothing you could do I don't know –

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

Right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I might give Laetrile a chance.

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

No, but what I'm saying is –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I mean, I know we're talking about –

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

It's a personal balance; I mean in that case you're applying the software that divides to a particular situation. What Paul's matrix is about though is inclusion/exclusion of devices and software for regulation, which is a different calculation.

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

So, let me just modify that a little bit, so this has no determined, pre-determined use, it is a way to assess, to think about risk for a piece of whatever it is in this case it's software so it's not predicting that it be regulated.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Sure –

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

Now, I have 8 minutes left –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

–

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

I have eight minutes left let me try to get through some more of this. So, the next area is complexity and what I added here, the middle group is – so the complexity of the software and it's maintenance, added that too, and the medium complexity is you could be fairly complex but we have a really good deterministic testing procedure that can assess how safe is this versus it's really complex and boy all kinds of things can happen some of which could really affect patient safety as in the right column.

In the complexity of the implementation and I added upgrade, the build could be very straightforward and it really doesn't change materially the integrity of the output or it's very complex and sort of all that – that's limited or no guardrails. In the middle you have a build and configuration that's moderately complex but the guardrails that have been built in significantly limit your ability to cross it at least without warning into things that may induce a life-threatening risk.

And the complexity of training and use, it's either really easy to use and you understand what's the – this is a blood pressure, I understand the blood pressure, etcetera and there is minimal training to know or you may take days and that's certainly true of comprehensive EHR systems to train people and you can understand how none of us are going to get all of this right the first time or it's moderate and I just gave some arbitrary thresholds and time, less than an hour of training is required versus multiple hours or multiple days.

So, that's my first discussion attempt at throwing out how do we characterize the complexity of software and its maintenance, the complexity of the implementation and upgrades and the complexity of training and use? Comments?

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

This is Mike Swiernik, I like the use of the term application of mature technologies and that first box says a possible way to lower risk and I think we talked too about how complex does a piece of software that relies on 10 different APIs look in this framework and maybe that's a way to capture that if all the APIs are very mature and stable sort of applications then maybe that's less risky than someone who is using 10 of them but all of them are beta and have never been used in production before and that kind of stuff.

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

Thank you. Okay and the blue one uses part of a comprehensive that's the appreciation that, you know, everybody can do their best job but when it gets all connected it can introduce a lot of risk and that's just true.

So, either it is standalone and everybody understand what it does and you can certify it on specific hardware or it always uses part of everything and all the output from this in between piece of software is subject to interpretation and possible misinterpretation that could induce harm or something that interacts with a few systems in the middle but the interfaces are well described and perhaps Mike would like adding mature in here as well, it's well used, a broad adoption.

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

Hey, Paul, this is Joe Smith.

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

Yes?

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

How do we marry this with what is really kind of an opposing set of concerns around single point of failure or unique or solitary points of data. So, you know, we had this discussion about when a particular software module provides a unique answer for which there is no other context, a single point of failure there can cause, you know, can cause harm because there is no way to understand if, you know, if that is or isn't in context, unlike something like weight where you know a patient's weight, you know by history and you can look at them and you can realize that, you know, what I get it that's wrong because I have lots of context.

There are some pieces of information that are solitary and in standalone systems that's more likely where you get a solitary piece of information whereas in connected systems you've the likelihood of more contacts that would kind of obviate the concern around a single point of failure. How does that play against this row of your matrix?

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

Great point, Joe and that is one of the things I couldn't fit in before, but as you talked it seems like there is a way to describe – we talked about the standalone product but maybe we can characterize both the single point of failure and the redundancy and/or the redundancy that's built in and maybe there's a way to stick that into either here or the green above but thanks for reminding me and does that seem reasonable that I could try to find a way to stick it into the blue or the green above?

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

I think so, but it's the notion that connected systems can provide context which has some adherent safety features.

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

Right.

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

So, there ought to be some positive attribute associated with, you know, kind of complex, you know, parallel systems where you get lots of information that is good for checking as opposed to being, you know, having it appear as though standalone systems are uniquely somehow more safe.

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

Yes.

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

I think we would be missing the point.

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

Good point. Other comments on that? Network connectivity, the only thing I added was in the middle to say, hey, if it's either wired or tightly controlled spectrum versus completely unregulated there maybe something in the middle where, gosh it's unregulated but we've got lots of experience, it goes into the maturity concept again and we just haven't seen any problem with interference.

So, in the one minute remaining let me – so what I'm going to do and thank you for this excellent feedback, I'm going to go back and revise the matrix with the feedback. I also think it's helpful for me to throw out some straw-man definition of the left most column, i.e., these attributes and I think that's one of ways we can work in some of these questions and answer some of the questions in that description as well as for example adding transparency up to the first screen and give that a whorl.

And let me ask whether people thought that this sort of step-by-step sort of decision tree approach using the purpose and intended users one of the – at the top branch to say, hey look if it's really information only for patients then you don't – it's a no in terms of working down through the rest of the tree.

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

This is Keith, just a comment, I mean, it's a little bit going to Joe's comment too, which even if I look at that first one purpose of the software, make a recommendation to the user it almost – the nature of the information itself, you know, and how much context is around it is pretty interesting, because if I have a calorie count for instance whose purpose is just to count up, you know, what calories I got from eating and the purpose of the calculation is just weight gain or weight loss it has a different connotation than if what it is, is a calculation for let's say radiation exposure used in the decision of whether to do another x-ray. So, almost the subject of it and how much – well maybe it's covered in your transparency in that, but the subject itself seems to be accounted for or needs to be accounted for.

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

I think that's true. I think I can work it into the definition of purpose of software.

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

Okay.

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

And then you would be accountable, you would be held accountable for example by both the FDC and FDA saying, hey you said this was something that the radiation oncologist can rely on or you didn't, or you just claimed that, that would be transparently projecting your purpose.

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

The other comment is as we look at our interaction with other groups – I mean, what we're trying to do is define patient risk so the regulation group can make some kind of recommendation of a regulatory response. How do you see this consumed by that group?

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

So, if each of these, so for – if a product was low risk in all of these, just as an example, then there is some algorithm that would predict the intensity let me just for lack of a better, the intensity of regulation that may or may not apply. So, if they were all low risk, lowest risk for example you'd say, I'm not sure we should be regulating, issuing any regulations for things in that cell. Likewise for something that is triggering the higher risk for all of these things you would go, gosh this might apply as something where we need to have regulation, have certification, etcetera.

But I'd imagine the calculus to be such that once you add up these risks then you would be looking in a certain cell and saying, of all the regulations I could have is it just labeling, i.e., is it just transparency or is it something that a product has to be tested and potentially even go through a clinical trial. I would know about ballpark what I should be considering. I don't think it would be completely – it's certainly not deterministic, but it would say here's where I should, I as a regulatory agency should focus most of my attention.

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

All right, just a follow-up comment, and, I mean, right now we're kind of thinking about the regulation as it is now, you know, I have my manufacturing type regulation, you know, what was the process that created the thing and was it a good process, you know, did it account for things. We have a certification-type approach which ONC is using that really gets to agendas of best practice.

If we take a specific patient risk for instance the risk that – one of the risks that we talk about is that I'm operating on the – I'm using the software where the – I either don't know who the patient – the subject matter, the patient or the patient that I'm looking at or the identifier of the patient is different than the data that I'm looking at, I'm looking, you know, it's a mislabeled chart. How does this address specific patient risk in that case?

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

I'm guessing that would fall under the complexity, the green complexity area.

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

Okay.

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

Let me take that as an exemplar. I wonder if any – whoever is taking notes could we capture these scenarios that have been raised during this conversation so at least I can test it against those and feel free everyone to submit more, but so for example Anna’s case with the carb counting, the radiation exposure that Keith mentioned and this how do we try to avoid things that are bad stuff, it’s almost a usability. So, we’ll try to –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I could provide lots of other hypotheticals as well.

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

I’m sure you can.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I mean, I don’t want to take up all of our time, but I mean some stuff that have actually been discussed among –

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

Yeah.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Diabetes interventions.

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

Yeah, so send that into me Anna and let me test them.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Sure.

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

Okay, I want to turn it back over to Keith. Thank you so much for this discussion. I’ll turn this around and try to reflect the discussion. I’ll add some definitions as a way of addressing some of the questions and open for your comments.

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

Okay.

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

Thank you.

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

This is Keith –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Thank you Paul for doing that, sorry Keith, go ahead.

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

No problem. I don’t see the – and I was trying to get a hold of MacKenzie about the slides that I sent last night.

MacKenzie Robertson – Office of the National Coordinator

It’s already uploaded.

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

Is it?

MacKenzie Robertson – Office of the National Coordinator

Yes.

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

Oh, there it is, terrific, thank you. All right that takes care of one panic button. All right, why don't we go to the next slide? Okay, some of these – and I don't know if you had a chance to review them, I did them – I mean, I finished them late last night and I should have gotten them out earlier, but some of this is just a review of what we talked about in the meetings in Washington and I just wanted to refresh a couple of things but then I wanted to get down – the core of what I wanted to discuss today is really again, what is our work product and our approach.

Just a couple of slides though is I'm running from the assumption that everyone is interested in patient safety, in other words it's just not the FDA that is interested in patient safety, but ultimately the hospitals and the patient that are consuming these devices and software have a vital interest in inpatient safety and everyone is trying to promote that.

At the same time is that we need innovation, we just have to have it, because we don't have all the answers yet and the answer really – I mean, even as we promote best practice sometimes it's premature because a lot of best practice is consensus, it isn't proven best practice and so we need space to be able to innovate and in fact innovation itself is sought to improve patient safety and that anytime that we talk about solving problems in healthcare IT has a central role.

The third thing is that we need to encourage more not less participation in this innovation sector and that's come out a couple of times as that if the regulation is such that it discourages companies or individuals to participate in this sector then we, you know, we discourage innovation just by that and there was an exemplar of the HIPAA rule and the opaqueness of that that caused people to shy away or shun this type of sector. So, those are the kind of sections I'm going into. Next slide.

Well, first were there any comments on that first one on assumption? Are there any other assumptions or does that really cover or do people have other assumptions as we go into this?

Okay, I think that was really mainly summing up the other things. This thing, as we look as source of innovation risk, and this maybe goes back to a risk discussion too, is that the easiest thing is to regulate the parts, the hardest thing is to regulate the assembly of the parts into working system as consumed by either the final consumer being a patient or a physician or a hospital that are using these things in their system and I'm not sure we've addressed it all the way, but, you know, each of these things also contribute to innovation. Let's just go to the next couple of slides.

Okay, we had talked about in our meeting in Washington the standard approach is to identify risk, respond with regulation and try to mitigate innovative harm. The reverse is trying to promote innovation and address patient risk will address promoting innovation and then adding, you know, addressing then those things in regulation. Next slide.

Let's go back, well, no let's go on this one, we talked about a learning framework that is predicated on transparency and acceptance of relative risk and again going back to everyone is interested in risk but they need information in order to make their viable decisions. I mean, even the decision Laetrile that we talked about came down to individual patients looking at risk and data and making individual choices.

And then in the learning framework is really to – an effort to prevent only the out of bounds errors like losing track of patient focus things that again misdirect me. Next slide.

This really isn't – I know that – a little bit we thought we were breaking new ground, but, you know, going back and reading the IOM report – I mean, this is a quote straight out of it, it's saying to encourage innovation in a shared learning environment. Then it made recommendations focus on shared learning, maximize transparency, be non-punitive, identify appropriate levels of accountability and minimize burden.

And this – as we look at this I think that as we look at these patient risks and innovation we could get into a new level of regulation addressing specific patient risk. In the end what we're trying to do though is I believe trying to get these shared learning environments and these things were also echoed in that bipartisan report as the recommendation to create a learning environment for safety of Health IT. Again, this transparency. Let's go to the next slide.

So, as we look at this in the government's role, again going back to the IOM report is to provide policy guidance and direction to compliment, bolster and support private-sector efforts and then to correct misaligned market forces and the transparency was really – because as we look at regulation, risk and innovation they're not mutually exclusive is what I'm trying to say and so we're trying to produce an enticing, innovative environment for more people to join and to help participate to solve problems and what we're looking for the government to do is to referee that and to correct misaligned market forces not to for instance to find the solution of the software.

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

I think this is great.

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

Because, I mean, again, so we're looking for a different type of regulatory framework on this. Let's go to the next slide and then I want to open it up. So, as we looked at the different approaches and this is what it really comes down to, because again, what we end up with is what we're tasked to do is provide recommendations to FDA, ONC and FCC. And so what is the form of those recommendations and there have been a couple approaches and these are not totally mutually exclusive, but what I wanted to present today or get feedback on is what are, excuse me, what are people's feeling about the approach or how – what's the structure of our work product.

One of the options would be to emphasize a general framework for analysis of proposed regulation and that really goes to the Appendix D in the IMO report, it goes to the article that Joe Smith suggested, which was a full article the Appendix D was really that abstract.

The second one, approach could be the critique of current regulation with exemplars. I was trying to stimulate some conversation on that with my e-mail earlier this week as saying, okay we've all had varying degrees of experience directly with the current regulation, and do we have examples where these things worked or didn't work on their impact of innovation.

The third kind of approach would be to regulation development process recommendations. This is more like how do we insert consideration of innovation in the development of regulation. Third option would be specific regulatory implementations. Okay, this – it's a little bit like number two the critique but it's really taking them as a class. So, things like certification. How does certification – what are the dos and don'ts of the certification process, what is the impact of the certification process?

And then the innovation requirements, this was one that we got some direction from Bakul is saying, okay, we talk about requirements for patient safety what are the requirements for innovation so that those requirements as much like we design software what we do is we put out all the requirements out on the table and then we're going to make some kind of value judgment prioritization but at least we see all the requirements at once before we develop software.

So the next slides were just examples of those different things. Maybe we could just touch them, the next slides real lightly, again it was things like Appendix D where it addresses the policy uncertainty, compliance burden, and you know, these terms and these abstracts from different industries. Next slide.

Okay, the exemplars, you know, critique current regulation through use of exemplars, we have the FDA development standards, the ARRA certification, HIPAA, I put Surescripts in there because that's a supported certification process, you know, making some comment on incentive motivation programs, penalties. Next slide.

Then you have generally more of a process type approach, you know, where do you insert these considerations, do you have a formal innovation impact report type thing. Next slide. So, this is a little bit like number two but really trying to take these different interventions and profiling them against – regulatory interventions and profiling them against innovation. And then the last slide.

These were ones that we talked about with Bakul during Washington and, you know, what are important, you know, we can approach it as a requirements document. So, let me open it up to discussion of which one of those approaches or combination should we really be pursuing as we put together our work product? Maybe we can go back to slide eight, which lists all of them. Okay, thank you, comments?

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

So, hi, this is Joe Smith again. Are you suggesting and I don't mean to say you are but that we choose one or that we highlight a couple that are, you know, kind of essential parts of the paradigm for going forward.

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

In the end what we have to say is, you know, what we going to present and it can be a combination, but what do we want our work product to be, because what we're going to do is give a report out to the FDA, ONC and FCC and we want them to do something in this area. So, how are we going to make our suggestion? What's the form of our suggestions? So, yeah, I guess I am saying choose one or choose a combination of approaches so that we can then focus a little bit better on defining those.

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

So, there were two that resonated with me but others feel free to comment in. I like the idea of their being recommended things that can, you know, kind of encourage innovation and then to the extent we can get alignment requirements for, you know, a meaningful innovation pathway forward.

And I think the latter might give some people some hesitation, but I think one of the things we talked about is, you know, in this software space the notion that non-interoperable systems should be non-tolerated and so one could imagine requirements for innovation being, you know, adherent to standards-based interoperability, communication standards.

And where recommendations can be around, you know, the way we imagine the regulatory framework treating innovative products with the notion of, you know, as we've talked about the notion of adopting more of a CD mark standards where, you know, we approve a process by which you're making stuff but we don't so much task the final product ad nauseam but instead do kind of post market surveillance.

So, that could be a recommended path where a requirement could be, if we could get alignment, the notion that at the end of the day you have to adhere to those standards for interoperable communication. Those are the kind of things I could see being impactful.

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

Okay.

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

So, Keith, this is Paul, I think our overall approach is to say only when regulation is needed and we're trying to have a framework for how would the regulatory agencies approach this question for any given product class, how can you do that without undue negative impact on innovation.

It seems to me that your fourth, 1, 2, 3, 4th bullet, which says there are a number of regulatory approaches and they go from labels to certification, to thou shalt not and you might imagine some end dimensional matrix where you could just look at each cell and take the cross parts and say, hey in this particular case, let's say this really high risk situation, we've got to make sure we cover these and we might use multiple regulatory approaches and in the other ones you could be very hands off. It seems like that's what you're saying in bullet four.

I'm a little nervous about bullet five being in the regulatory domain, that sounded more like design principles and would we really want to regulate what people do in order to innovate? We might want to consider that we wouldn't want to interfere with some of those things but I don't know that we would require them as a public policy.

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

Well, which one was that the innovation requirement?

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

That's the innovation requirement. So, I think those are design principles but I'm not – I'm having trouble seeing how regulation would be – why would you want to require those of people?

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

Well, not it's a requirement on the regulation itself; it's not a requirement to the developers. It's saying that as you – because I'm looking at regulation as a product in this case and what I have is requirements on the – the requirements for the product include things like patient safety and they include things like promotion of best practice, but then they also include requirements of the regulatory product itself, requirements of protecting innovation and specific requirements that need to be addressed in the development of the regulation products. So, it's not a requirement of the software development, it's using software development as a metaphor for or an analogy to create a regulatory product.

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

I see. I guess I'd be nervous of being prescriptive with that as well, but at any rate I liked you bullet in four because there are different levels that you can see applying, you know, judiciously to each risk profile.

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

Right, okay.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna, I'm wondering if – I really like this and I think this is a really helpful way of looking at it, so thanks very much Keith for doing this. I really like the notion of the principles for preserving innovation and sort of laying that out, you know, I think there's a lot of room, you know, we might even – and I'm not going to get into designing regulation, because God knows there are people who can actually do that and do that for a living like Bakul.

But maybe have principles for preserving innovation things such as, you know, required transparency or maybe you'd even have different tiers sort of like, okay so if you want a little bit more room to innovate, you know, manufacture A here are the rules, you have to have open APIs, you have to make all of your data completely transparent and useable in standard format, you have to release it on a weekly basis or quarterly basis, or whatever the right timeframe might be so that.

You know, it helps manufacturers kind of get their head around it by saying, okay, yes we want a different level of regulation that we consider less stifling but in exchange for that we get, you know, we are going to have open APIs so that anyone can access data and be able to download data from whatever device, and we're going to make all of our data not just the data that we want to make available but all of the data generated from these devices available for other people to mine and use, and critique.

Because one of the biggest issues that we're having, you know, again with – and some of these other initiatives just in the patient world is nobody can access any of the data so we have no way of really assessing, you know, how well is this product working or how accurate is this. So, as a patient I was involved in, you know, HIT innovation I would find that very exciting because I would feel like more people could go in and critique it, you know, above and beyond FDA. I mean, we could sort of have, you know –

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

Right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Sourcing monitoring.

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

I mean, one of the site conversations that we had there is we're talking about the class system and I think everyone is familiar with class, you know, where they do a kind of consumer reports on different vendors and products, and it's a pretty simple approach, but this sector is so starved for information that it's made class a king because there isn't the data out there.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

There's none.

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

Yeah, that's right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Some of this has tried to – I mean, if you tried to get information on which insulin pump is more stable you can't get it.

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

Right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I mean, you –

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

And so –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

And again, I don't mean to pick to on the insulin pump manufacturers it's just one that I use.

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

Yeah, because it's vital to you.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, 24/7, yes.

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

But, I mean, again it kind of goes back to this idea if we're all interested in risk do we have the data to assess risk which may – I mean, if you look even – you can't separate out innovation, regulation and risk into three spheres they do interact and the gist of the IOM report and of the bipartisan report is the first and foremost is transparency, you know, let some sunshine in on this stuff.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Right.

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

So, that people can assess it. I mean, we go through assessments of products all the time here in the hospital, I mean, we don't do all of our own development, we assess products all the time trying to get information about those products is almost impossible, you know, non-biased information.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, it is practically impossible and all of the information is collected it's just not made available and, you know, like there's a variety of different reasons for that, but, you know, from different manufacturers and – but I just don't think that's acceptable.

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

No, I don't either.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I mean we're making products upon which people's life depends and, you know, and mistakes or small instabilities can make a difference on whether you live or die. So, if you're going to have this product on the market, especially if you want more regulatory leeway to be able to innovate, you know, software interfaces or more customized user audience, you know, interfaces or whatever, which is great and I think needs to happen, then you need to make all of your data transparent and available, and useable so that more people can access it.

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

This is a great discussion, this is Matt, and one of the things I think that would be really helpful for us Feds is, you know, to provide recommendations or thoughts on how we could – what data would be useful and how through, you know, regulation or rulemaking, or whatever that or not that we could facilitate the transparency of this and, you know, some – there have been ideas proposed for PSOs and other things but there are potentially others that the group could come up with and so how do we actually do it, what would you recommend and what data would be really useful, kind of useful, not that useful.

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

Okay, thanks Matt.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I think I would be happy to brainstorm with you on that and sort to think that through, because this is something I do a lot of speaking in the diabetes world.

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

Okay.

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

This is Matt, I have this mental picture of, you know, the taxonomy and I've been promising to send this to the group, but the taxonomy has under it, you know, for each of these categories dimensions of risk and then, you know, what data sets could we potentially use for measuring that risk and then what policies or levers could you use to facilitate it's – you know, the development of data sets where they don't exist or the expansion of data sets where they do across the spectrum and it's going to be potentially different for consumer products versus professional use ones.

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

Okay. Other comments? So, what I'm kind of summarizing, okay, so – well maybe I'll have to do a little bit of this afterwards, but again, the idea that we're trying to put together a full structure, thoughts on a full structure not just a reactive, well this is what will hurt innovation, but really a full structure of how to promote innovation and also the – it gets into an accountability model to a certain extent because you want to promote innovation, you want more work in this sector, you want more good minds thinking about this and not to be turned off by getting into this area but then you want them through transparency to be accountable for what they do and that their results are perfectly available for people, the consumer and then again the consumer in this case can be a hospital system that's selecting a system or selecting devices or software to incorporate into the hospital, a physician whose trying to look for software supports in their clinic or a patient who is trying to look at all these different things and really be able to have accountability through transparency. Does that model work?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I think that would be – I think that would be a very helpful, helpful approach because, you know, I may not do or maybe I would, you know, use my companies tools to analyze some of this aggregated data, but, you know, working with some of my diabetes patient friends where, you know, maybe we hire somebody whose actually a data analyst who can go through the data to say "huh, well this is really interesting" and then put it up so that other patients can see it or, you know, whatever the case may be or maybe the American Diabetes Association could access the data and be able to do their own analysis that way you sort of crowd source surveillance so that not all of it is thrust upon, you know, the people at FDA who are all, you know, very overworked and also trying to get access to some of this information.

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

Sure, I mean, the whole thought of post marketing surveillance and making it available is really saying that it's not all up front. I mean, I take Julian's example on the sampling rate that we talked a little bit in the closing minutes, what I – do I need a regulation that specifies the sampling rate of a monitor or do I need to have the particular vendors solution for sampling rate commented on and transparent, you know, the reaction against those things or the judgment on those things be transparent, because I think that if you put transparency in there and you see those things that again the vendors interested in public safety, the vendors interested having an accepted product in the marketplace and so using regulation to – as was stated in the IOM report, to channel or to facilitate market forces through transparency in this case.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Exactly, exactly.

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

Make a self-correcting system.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Right, it's – I mean, and I don't know if this is the right term or not but the whole, you know – when I was talking at the meeting in DC, you know, the notion of kind of a learning regulatory environment that goes hand and hand with a learning health system and I don't necessarily know what that means or if that's the right way of thinking about it, but, you know, we can't – you know, if we want to have a learning health system we can't have a regulatory system that has to evaluate everything before it happens.

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

Okay.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

So, you know, how can you have a learning health system where innovation is happening on a daily basis but also have regulatory oversight and I would think that if everything were transparent but, you know, there would be entire markets forming around, uk2 evaluation and assessment of the safety of various devices or systems, or modules that would be complimentary to the regulatory approach and then FDA could choose where they need to get involved as opposed to try to do it from, you know, a – stop it from happening before they get a chance to look at it, because that would just keep things from happening and none of us will benefit.

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

Kind of like Consumer Reports doing their own tests on cars and publishing them.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Exactly, but you've got to have the data before you can do that.

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

Yeah, yeah.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

So, but, it doesn't stop people from innovating on the car front and I know nothing about cars so I'm not going to –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

But, yes, so the – you know, you could have entire ecosystems of people who do surveillance and then put the results up there on the web and then other people could critique them but the necessary raw materials for all of that is transparency both in terms of methods as well as data and, you know, we want people to protect their intellectual property, but there's got to be a way to do that, but the raw data needs to be accessible, but the market look at it, let FDA look at it and, you know, but let people be free to innovate and to sort of improvise as saying "go."

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

Right.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

– of an individual patient – who might want to put something up on the App Store or whether it's Intermountain finding really cool things that they can do with their own internal data system.

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

Right. I want to be respectful for time I think do we have – should be opening up for public comment?

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

MacKenzie?

MacKenzie Robertson – Office of the National Coordinator

Yes, this is MacKenzie. Operator can you please open the lines for public comment?

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

Keith were you ready?

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

Well, I'm just looking at – we have what 5 minutes? So, we probably should open it up for public comment so that we – I appreciate everyone's comments by the way.

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.

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

Okay, I appreciate everyone's comments, I would encourage you to keep sending e-mails and maybe have your thoughts on this thing. I appreciate the feedback and will try to formulate it into more of a framework and for critique. Thank you.

MacKenzie Robertson – Office of the National Coordinator

And this is MacKenzie just to remind everyone the next appointment of this Subgroup on the calendar is on Tuesday, June 18th at 11:00 a.m.

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

Okay.

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

And then when is the next full Workgroup call?

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

Tomorrow morning isn't it?

MacKenzie Robertson – Office of the National Coordinator

Yes.

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

Or tomorrow afternoon.

MacKenzie Robertson – Office of the National Coordinator

Tomorrow afternoon from 2:00 to 5:00 p.m. Eastern Time.

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

Okay, are we supposed to present something?

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

I saw – there was an e-mail from David this morning with a draft agenda; I haven't opened it up yet.

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

Okay. Okay, thank you everyone, really appreciate the discussion.

MacKenzie Robertson – Office of the National Coordinator

All right, thanks everybody.

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

Thank you.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Thank you.

Woman

Bye.