

**HIT Policy Committee
FDASIA Workgroup
Risk Assessment & Innovation Subgroup
Transcript
May 20, 2013**

Presentation

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

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, subgroup on Risk Assessment & Innovation. This is a public call and there is time for public comment built into the agenda. The call is also being recorded so for the recording, please make sure you identify yourself when speaking. And also, since there will be quite a few members on the line, if you could also remember to mute your line when you are not talking. I'll now go through the roll call for the subgroup members. Paul Tang?

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

Here.

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

Thanks Paul. Keith Larsen?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

I'm here.

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

Thanks Keith. I'm hearing that there's an echo, so if someone has their computer speakers on, if you could please mute them. Geoff Clapp?

Geoffrey Clapp – Better – Co-Founder

Here.

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

Thanks Geoff. Esther Dyson? Mike Flis?

Michael Flis – Roche Diagnostics – Regulatory Manager

Here.

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

Thanks Mike. Jeff Jacques?

Jeffrey Jacques, MD – Aetna – President, Neonatal Solutions

Present.

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

Thanks Jeff. Anna McCollister-Slipp? Jared Quoyeser?

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

Here.

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

Thanks Jared. Jonathan Potter?

Jonathan Potter, JD – President – Application Developers Alliance

Here.

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

Thanks Jonathan. Mike Swiernik?

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

Here.

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

Thanks Mike. And for workgroup members who I know are on the line, I have Todd Cooper.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Good morning.

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

Thanks Todd. Anura Fernando?

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

Here.

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

Thanks Anura. Lauren Fifield?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Present.

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

Thanks Lauren. Robert Jarrin?

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

Here.

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

Thanks Robert. Meg Marshall?

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

Here.

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

Thanks Meg. Jackie McCarthy?

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

Here.

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

Thanks Jackie. Joe Smith?

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

Here, thanks.

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

Thanks Joe. Any other workgroup members on the line who I didn't mention? Okay. And for the ex-officio representatives I have Matt Quinn.

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

Good morning.

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

Thanks Matt. Simon Choi?

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

Good morning.

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

Thanks Simon. Steve Posnack?

Steven Posnack, MHS, MS, CISSP – Office of the National Coordinator

Here.

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

Thanks Steve. Jodi, Bakul, are you on the line? Okay. And any – is Mike Lipinski on the line? Okay, with that I'll turn the agenda back over to you Paul.

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

Okay. Thank you and welcome. Thanks for taking time out of your day. We sent – sorry about the last minute, Keith and I have been working on this up until this point, trying to organize ourselves for one, a very challenging task but two, also one under a lot of time constraints. So, Keith and I have been trying to figure out how to organize ourselves so we get the most accomplished out of this meeting and all the subsequent meetings. Could we go to the next slide please? And these are the – this is the agenda for today's call, we'll start out with what are the objectives for today and then we'll have two very closely timed 30 minute – the total time for this call is 90 minutes, so we've broken it up in 15 sort of background, 30 each for the different framework – the draft, strawman frameworks for discussion and then close with next steps and public comment, which is 15 minutes. Next slide please.

So the objectives for this call. You'll recall that this is a group that was asked by Congress to help provide input, so we're not coming up with regulations or even proposed regulations, but there are three agencies, FDA, ONC and FCC, that are working together to produce a report on risk-based regulatory framework that promotes innovation. So, their output in January is a report, not even proposed regulations. So, we just want to separate ourselves from what is it we're here to do versus what ultimately has to be done in the future. This subgroup was asked by David Bates, the chair of the FDASIA Workgroup, to add – assess a couple of things, the risk of software to patient safety and the risk of regulatory approaches to innovation. So in a sense, it's a risk assessment for both of these things and we're to provide some thoughts, some input. Again, nothing like proposed regulations.

So, this is – the way Keith and I constructed this is one of several iterations, it's only the first of many. And the output of this call is to be some draft concepts for the rest of the workgroup to react to in our face-to-face meeting next week. And we'll use that feedback to continue our iterations until we're satisfied with the deliverables from this subgroup and then eventually of course it goes up to the full workgroup. So, this first iteration on this call is by no means not even close to the end, a way to get started in our discussion. Next please.

So the problem statement's fairly simple, this is a quote from the IOM report where it talks about when there are serious issues, serious risks for harm, like to patient safety, then chances are there's a need for some government oversight. And the weightiness or the stringency of that oversight needs to be balanced against the cost of that or market's innovation. So this is – balance is the key word and I guess in David Bates' wisdom, putting this together in this group, not that we talk about them – the balance part together all the time, but we'll frame – we'll try to develop two frameworks that think about these two different kinds of risks, and then leave it up to further assimilation to do the balancing act. Next slide please.

So what I'm going to do is start out with a strawman, and Keith and I have figured it's much easier to sort of react to something than obviously to come up with something de novo, particularly with a larger group. So we've put together a couple of different frameworks in these two areas, risk to patient harm and risk to innovation, just to get the discussion started, and we've allocated precisely 30 minutes to each, and we're going to time each other because we just – we really do have to get through this so that we can have our first draft strawman to present to the full workgroup next week. Next please.

So here are, and as I say, this is just a strawman, just a way to get the discussion going. We may add to these dimensions, and you'll see a matrix later on and we'll be sort of adding to things and what Keith and I will do is take the input from this discussion and further revise it, send it around and get your feedback, and that's what we'll use as a kick-start to the discussion next week. So here are some examples of categories, some dimensions of risk to patient safety. So one type of consideration about a piece of software that's going to be used, something related to health and healthcare, would be well what's the purpose of this software and who's the intended user. I've sort of clustered those into sort of our purpose-user as one dimension.

Another dimension and we're going to go into more examples of details of what – these things in the next slide. Another kind of dimension is how you characterize the actual risk to patient harm. Well one is the size of the risk that could be involved, is it like a risk of an inconvenience or is it a risk of – a life threatening risk. And then, well what's the likelihood of such a risk arising in nature. And what's the ability to mitigate the risk, if that were to arise. So these are examples of how you characterize or how you might think of characterizing the risk for patient harm from a piece of anything really, in our case it's software.

A third kind of dimension, and this is like a big one, but it's in one line, which says it's really the complexity of everything from how you conceive the piece of software, its purpose and use, to the development, to the QA, to the way it's implemented by the end-customer and the way it's used by the end-user. Any of those things can affect the risk to patient safety. So, how do we characterize that? Fourth, once you ship the product, then all kinds of things could happen, or not, to it. It can be customized in software point of view and it could be integrated with other system components. So this is sort of the post-shipping, the post-marketing changes that occur and those, of course, affect patient safety risks. And then as it's streamed through Ether, things can get potentially messed up on the way of between where it's emanating and where it's received. Next slide please.

So let me try to go over this matrix and try to walk you through it and then we'll just open it up for discussion. So the first piece is that purpose and use, and I sort of clustered together by the green. And so thinking about it low and high risk, and then these are just my thoughts to sort of state what did I even mean by that row, and we can discuss this. So the purpose could be just merely information, and that's pretty low risk from an invasiveness point of view. On the other hand, it could be operating all on its own in an automated way, like controlling the infusion of chemotherapy or vasoactive substances into a human without – and by the way, being non-transparent in a black box way. Well, that certainly could be potentially dangerous; if it's doing the right thing then it's wonderful, it's very automated and efficient. But, it certainly presents some sort of risk, and I sort of said, well that's an example of a high risk. Or an automated electrical defibrillator where you basically, it does everything including shocking the patient.

What about the intended user? If it's intended to provide some information and potentially even recommendations to a licensed clinician. Well, that person is already certified to have some knowledge of this topic and makes independent judgment there's a human intermediary. On the other hand, if it's going to be giving advice directly to the patient, and you don't know how much the patient knows about something that could be potentially high risk. So that's what I meant by the purpose and intended user dimension.

Next is sort of trying to characterize risk. So the magnitude of the risk could be very low probability of harming somebody, it could be annoying if it's a bad color on the screen or something, but it's not going to probably harm the patient. And on the other hand, it could be life threatening, let's say in the infusion pump, for example. The likelihood of something happening, yeah, I can see how this could happen, but it's really rare, it'll happen once in a 100 years, I mean I just made these up – these examples up, that would be low risk, I think that could be great. On the other hand, it could be 1 in 10 or something very common, and that could be much higher risk.

The ability to mitigate. If there's a human intermediary and the human's constantly aware of how the software is putting together its advice, that seems like it's a manageable risk. And on the other hand, it's closed loop and the human can't even see inside the box to see what is – how is this – what's the input being used by this software and how's it arriving at that decision, that could be potentially high risk.

Next is this big category of the complexity of the software, implementation and use. If it's self-contained, it doesn't connect to anything, it's used exactly as the developer meant it to be and there's really no way to change that that could be low risk. On the other hand, something complex, like an EHR system in a comprehensive way, it goes through a development phase, things could happen during the development, things could happen by the way that the customer builds – configures this system, and things can happen by the way the user, the end user, configures or uses it. And in a high-risk situation, if anybody can do anything all along that pathway, without any guardrails, that could be pretty high risk.

Customizability and part of a bigger system. Customizability is sort of minimal to none, it just sits out, let's say, the blood pressure. Or it could be highly configurable and so at each step of the way, and the things you could configure could make it really hard for the users to understand or to even get the right answer, as one would expect; that might be high risk. Similarly, in the way the product is used, it could be stand-alone, and it always puts out the number of steps, for example, and is unambiguous, yep it says steps, I walk and there are steps, and that could be very low risk. On the other hand, if it is going to be providing input into a larger system, and the output is subject to misinterpretation or configured in a way that's unexpected by the end-user, that could pose a risk.

Now none of these risks means that, wow, it should never be done; it's just that we just recognize the framework for assessing the risk of harm. An example there, let's say with DDI, drug-drug interaction, that's a classic example where the threshold can be set low, high or medium. And if the user's expecting, wow, this is going to catch every single drug interaction that's important to me, if that's my expectation and I have no knowledge that, well actually, it's – the threshold's set very high and I'm relying on something and acting as if it was going to catch everything, that's a risk to a patient's safety.

And finally the wireless connectivity. There can be either none or it's in a very protected spectrum where there's no interference or it could be the opposite, and there can be a lot of competing devices or software for those resources. So I'm going to stop here and sort of get people's general reaction to this kind of framework, so without talking about the details, but a list of dimensions and a way of characterizing it, that we're not talking about regulation at all. We're just characterizing this piece of software's risk to patient safety and sort of, in the end, we might come up with very precise terms for whether the dimensions, they may be more or less or edited, and the way of characterizing risk, by the end of this, not by the end of this call, by the end of the – so, let me get some reactions.

Geoffrey Clapp – Better – Co-Founder

Hey Paul, this is Geoff Clapp; can you hear me?

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

Yup.

Geoffrey Clapp – Better – Co-Founder

So, first of all, we've got the easy job, so thanks for putting this together for discussion. Because it's really easy to comment, it's pretty hard to put something like this together. That said, obviously that's my nice thing to say before I jump in on something, right. So, I think that the one that stuck out to me maybe the most was, and I don't mean the details, but the intended user, I think is good. But I think that the presumption of knowledge of a certain type of user, and that's a reduction in risk, while logical in some cases, I'm not sure, like that one was a little hard for me. The one that said, well, we're going to assume that physicians know better and when we talk about the way that we think this policy governs the next, hopefully 10 to 15 years, the amount of information is probably overwhelming to anyone. So I would hate to start by saying, well that immediately reduces the risk de novo. That one felt a little like certain types of people reduces risks, it just feels – that one stuck in my craw a little bit, but, for whatever that's worth.

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

That's very, very helpful. So your commen – what I'm going to do is write down these comments –

Geoffrey Clapp – Better – Co-Founder

Sure.

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

– and then we'll try to incorporate them. And so what you're objecting to – so it's possible that you could reduce the risks, but classifying automatically as low risk is probably not safe.

Geoffrey Clapp – Better – Co-Founder

Yeah, and maybe it was that – maybe it's that there is, because it's a proxy for patient safety, there's an assumed – there's assumed value, right, that everyone in that group, whether it's physician or any other skilled person. At that point we could then argue that, well a person who spends a whole bunch of time on the internet reading, are they educated, you know, it opens up a door for a bunch of risk reduction techniques that I think might not be good for us in a world of exploding volume of knowledge.

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

Okay. That's very fair. Next – other comments?

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

Hi, this is Mike Swiernik. Thank you guys for putting this together, I agree with Geoff. I had a number of specific questions, but the more general one, I think that's relevant is I think this framework works for probably 80% of software. But I'm thinking of software where a large part of what it does is based on the content that's put in it that isn't the software, and as a thought proc – or as an idea, I was thinking, well how would a simple text message from a doctor to a patient work in this framework. And it would actually, I think, wind up pretty high risk because it fits into highly configurable, it's complex, there's lots of risk for wireless interference, etcetera. So, but that's mostly because it's, I think content, and also when we think about decision support and those kinds of things, that could be categorized as content that the software could say well, that's not me, that's the use, but then there should be some way to capture that in this. I don't have a great idea for that, but it's just a comment.

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

No, but excellent point. It's something that's not here. Excellent point, we'll work that in. Next.

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

This is Robert Jarrin.

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

Um hmm.

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

Hi. So two comments ago, I agree with the commenter which for me it just brings me back to, I know that we're not discussing necessarily regulations in detail and we're trying to come up with policy levers. But that said, when I read the purpose, user and the characterizing patient harm/risk, it just really feels to me close to what the FDA already has, and when we're talking about intended user, I mean the FDA does away with the user specifically by just talking about intended use. And I'm referring specifically to 201H, which is where a lot of people get caught up in, because I think that's a main – a big area of either misunderstanding or different interpretations of what that means and what it should mean. And obviously, we should all get into that later.

But then to the last caller, when he said that, I think he said something to the effect of wireless and some aspects of wireless, like a mobile phone, being susceptible to harmful interference or something to that effect, I don't want to put words in his mouth. But that triggered something that had already been kind of in my mind when I read the wireless connectivity and low risk and the comment that you put in as high risk. There's a common misperception that if it's a cell phone, it's subject to harmful interference one way or the other, and that's actually not the case. If it's using licensed spectrum, which cell phones must use licensed spectrum, they are not subject to harmful interference, that's why they have a li – that's why they have a right to the use of the licensed spectrum.

If they're using a part of their capability which deals with unlicensed spectrum, like either Bluetooth or wireless VLAN or ZigBee or some other interface, that part of that cell phone's service is subject to harmful interference, because on that aspect its using unlicensed spectrum. And the majority of products that are out in the marketplace right now that are mHealth related are, in fact, using that kind of connectivity. So, I just wanted to make those two distinctions, because I think they're actually pretty important and we can obviously get into the reach of things later, but I wanted to bring those things up now.

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

I appreciate that. Next comment.

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

And this is Mike; I was the one who made the comment –

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

These are general comments and then we're going to go row by row. I'm trying to watch the time of course.

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

Oh, and I was actually thinking too of interference, not spectrum necessarily, but does the user even have their phone on, that kind of more basic, and maybe that's a different category completely, but that sort of idea.

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

Okay. Sounds like –

M

Hi, this is –

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

Let me just see if we're ready to transition into describing – looking at rows. Is the general concept okay, in terms of coming up with dimensions of patient safety risks and then trying to figure out how, and these last comments were good examples of what kinds of more suitable wording we could put in, but is this general construct okay, and then we can start working on the dimensions?

Geoffrey Clapp – Better – Co-Founder

Paul, I guess I would add maybe one – or I'd ask the question about if we have a missing row. This is Geoff again. We don't have anything specific to security and I don't know if that's necessary per se, or that's out of context. But I feel like we should at least say whether we think it applies or not in terms of the idea of a text message, or other types of interference that was just introduced does bring up things like man in the middle and other kinds of potential security issues and whether we think that should apply to a risk framework or whether it should not.

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

Okay.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

So, this is Todd Cooper and I think that actually begs one of the questions that I had, which is a little bit more fundamental. We're very focused on patient safety here, but when you look at the standards that were called out, like 14-9-71, it talks about freedom from unacceptable harm and harm there is defined as physical injury or damage to the health of people, not necessarily only patients, damage to property or the environment. And when you also looked in at the IEC 8001 standard, which looks at risk management from network technologies after they're deployed, that actually then does also add to safety effectiveness, risk that it won't perform the function that it was intended to function as well as security. And so my, kind of a foundational question I think is, how narrow is our idea of risk that we're assessing and I think we really should make it an appropriately wide model. Prioritize the patient safety and general safety, but also to include effectiveness and security.

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

Okay. Thank you.

M

Great comment.

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

Let me move into the rows; we have about 13 minutes left. Let's take them by color then. So the first, purpose/user, and I've heard already a couple of comments. One has to do with the license, does that automatically make you low or high risk and the other is user versus use. Other comments about this purpose and use/user.

Michael Flis – Roche Diagnostics – Regulatory Manager

This is Mike Flis. I'm having a little trouble understanding what – how we're going to use this stratification. Because I can imagine a mobile application that's intended for a patient to have access to say for food and calorie tracking, one they could be using to decide how much insulin to take, but another they could just be using to track to make sure that in any given day, they're not above a certain total calorie. So the one with the insulin taking, I could perceive that as being high risk –

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

Right.

Michael Flis – Roche Diagnostics – Regulatory Manager

But if all you're doing is keeping track of your total calories that would be a low risk. So just because the patient has access to the technology, wouldn't automatically mean it's a high risk.

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

So, well, as we work through this, we'll drill down, but let me give you an example, so that's why I used the qualifier, advice giving. So in your example, keeping track of food wouldn't qualify, but recommending an insulin dose might. So we can add more precision to this as we do our work, but those are great examples of things. And what we're going to use is, just like you suggested, exemplars. Hmm, I have an application to track food where would that fit, do we have a way of describing it. Or, I have an application that uses your exercise and your food – your activity and your food intake to recommend insulin, and your glucometer reading, that would put it in the high risk. But we would work through these kinds of exemplars and come up with more precise wording, just to handle questions you raised.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Sounds good.

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

Other comments about this row, this might not be the biggest row to focus our attention on, but it's just barely –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna McCollister-Slipp; I guess – I think I would want to think about the last series of comments as somebody who uses multiple mobile apps to dose my insulin. I think I would want to be sure that we're being clear about, is the software telling me a specific amount of insulin that I should take, or is recommending that I should take, or is it providing information that I could then use to make my own calculation. Because if it's the latter, there's all sorts of things that go into that calculation, when I make my calculation, and if we're regulating that, we're going to be regulating everything from fitness trackers to – I mean, everything goes into my calculation practically for the amount of insulin I take. Anything could be relevant, so, I think we need to think very clearly, is this doing calculation and not just in the case of diabetes, but since we're using this specific example, is it calculating a specific dose for me based on information that's been entered into an algorithm, that's one scenario. If it's taking data from various devices, maybe even an insulin pump, and displaying it in such a way that I can have it all in one place to make a decision on my own, then that to me is just displaying the information in such a way that I can make a decision, if that distinction makes sense.

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

It makes total sense and I think the latter would not be in this category of high risk that you're referring to.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Thanks.

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

Let me move on to the next one, as I'm watching the time. The next one is sort of characterizing the risk, is that – are there any missing dimen – subcategories of that dimension or is this clear? A combination of the magnitude of the risk, the likelihood of that situation arising and the ability to mitigate the risk.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I would actually classify what we were just discussing not necessarily as a high-risk application, but more of a medium risk. It would be high risk if it were making the decision about the dose and then doing it, i.e. the closed loop. If it's just telling me – giving me a recommended dose based on a series of things that have been put into this algorithm, whether I put it into or other devices, and I would say that's medium risk, because you still have the ability to override that decision.

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

Correct.

Jodi Daniel, JD, MPH – Office of the National Coordinator

This is Jodi Daniel. Just one quick comment is that it seems to me that this may vary some, based on how mature the product is, so it may be that there, and I don't know if this falls in here or somewhere else, but the likelihood of the risk arising if 10 people are using it, it's going to be less – I mean, there's going to be fewer people that may be using a product, or more likely to have bugs in a software that hasn't been used for very long, or that sort of thing. So, there may be some magni – something that changes the magnitude of risk over time, based on how mature the product is, just want to throw that out there.

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

No, good point. I'll figure a way to include that in the magnitude.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Anyway, we could change magnitude to severity, which is the word you typically see.

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

Okay. Yup, it's the essence.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

That would then tie it in with the standards pretty well.

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

Thank you, thanks for the sug – that's the kind of stuff we're going to need. Let me move to the next one, because that's a big dimension. The complexity of the software. Is that clear, it's sort of from development through implementation and use. It's a really big thing and I think this is where there's a lot of potential risk. So maybe this gets broken out into the like 3 major areas, but let me get your thoughts on that.

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

Yeah, this is Mike Swiernik. I was going to agree that it probably should be broken out like the block above it. And then the idea that you – somehow to capture the idea that if you were using some sort of best in class software, even if it increased the complexity of it, that that somehow would actually diminish risk. So if I was, for instance, making my own decision support, that's probably more risky than if I was using a third party decision support application that was connected to my application somewhere. So somehow capturing that sort of –

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

That's a really good point and you made the point earlier about the content, which is so excellent, we'll incorporate that, too.

Geoffrey Clapp – Better – Co-Founder

And I wonder also when it comes to software, we could start to introduce some of the standards for measuring software complexity. I think it's similar to the comment about physicians, even homegrown versus third party, in some cases the homegrown ones might be better. Or the physician might be better, but the kind of – just like we would for risk analysis or mitigation of risk or severity of risk, we have measurements, tools, and standards for how we measure those things. There are some reasonable tools for even just a measurement of complexity to kind of slot things in or give people guidelines; it would be nice to get some of that into the framework.

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

Great. Who's speaking?

Geoffrey Clapp – Better – Co-Founder

Oh sorry, it was Geoff again. Sorry.

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

Okay. Geoff if you could pass some precise version that along, that would be helpful.

Geoffrey Clapp – Better – Co-Founder

Yeah, I'll send you an email Paul with a number of tools that we could use and then we can just introduce it to the note.

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

Thank you.

Geoffrey Clapp – Better – Co-Founder

Yup.

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

So far, we've talked about breaking this out into chunks like the development, the implementation and use. And then Geoff mentioned if there is a way of characterizing software complexity, now that's of course only on the software side. It would be nice if there was a way of classifying implementation and use. Thank you. Okay, moving on, customizability. Is that something we should include with what we just talked about, the complexity or is this separate? Oh no, actually, this is a 2-fer. So it's customizability and it's use within a comprehensive software system. And that came up, I think, in one of – in our last call actually, of the big group.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

This is Lauren Fifield. I think customizability is essentially an appropriate category to maintain, particularly given that as something becomes further customizable with the end-user, or in a particular context or setting, the developer may have less and less visibility. Whereas in a model where all users are using the same sort of customization of a given product, a given piece of functionality, the developer has better insights into how it's being used as how it's being updated. So I think it's appropriate – I don't know if it should be tied to different software models, so making a loose kind of proxy between cloud and maybe less customizable or if it should just be its own category. Or if the category should be tied more to the context of where it's been customized.

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

So you think, Lauren, that this could actually be words we could use under the implem – you know, we decided to break up the one above it into three steps – major steps, and customizability is certainly in the implementation. Is this something that would fit in right there?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Yeah, I think that would work.

Geoffrey Clapp – Better – Co-Founder

Could I – I know the group that does taxonomy is another group – this is Geoff again. But in this row we mix configurable and customizable and I think we want to focus on customizable and configurable being part of either complexity or validation versus customizable which is the amount of cha – I think those are different things. Because if I can configure it a certain way, that should be part of the validation process and should be part of that versus customizing it, which means I have one that is new to me and I was able to make a change or whatever, that is somehow different. I think that you either want to define how those terms are the same or different, because I think different people read them differently, I certainly did.

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

It's a really good point and to be honest, the only reason that there are two words is because if it was self-defined because of my ability to – the whole thing, it would look redundant. But let me work on – it's a good point let me –

Geoffrey Clapp – Better – Co-Founder

Oh, trust me, Paul I'm laughing because I would have done the same thing. So I guess it's easy for me to pick it apart on the screen.

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

Right.

Geoffrey Clapp – Better – Co-Founder

We would have flipped roles very easily here, so I don't mean to be nitpicky, but –

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

No, no, no, I need this. I want it to be better every time.

Geoffrey Clapp – Better – Co-Founder

There you go. Yeah, so that's just something I see. Yeah.

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

Yup.

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

This is Meg Marshall I just had a question. Were there any thoughts, and it perhaps may be more appropriate under implementation, but certainly under the customizability, however that ends up, thoughts around what the training of the user making those decisions could potentially look like?

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

That's a really good point Meg, and my thought is as we broke up the above category into three, I would include training as part of the use. Is that appropriate?

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

Yup, exactly. Thank you.

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

Okay.

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

Hey Paul; this is Matt Quinn. Question for the group and, one of the things that we focused on is the physical harm as a dimension of risk. And I think Geoff brought this up a little earlier, there are other dimensions of risk. There are dimensions like reputational risk, financial risk that could or could not be part of this, and I'm just throwing that out there as other dimensions that might be considered, and I'd love to hear the thoughts of the group on whether we're focusing too much on patient safety and harm, or maybe these other dimensions, too.

Geoffrey Clapp – Better – Co-Founder

Could you repeat the difference again? Sorry, I missed part of that and I think I really want to hear this, so, could you repeat that?

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

Sure. My thinking – I just wanted to throw it out there that some of the – most of the focus has been on patient safety and harm, but as we're thinking about a framework here, other dimensions of risk that are potentially appropriate could come into play. So things like reputational risk arising from security or lack thereof, or privacy issues and financial risk, for example buying something and it not working as you expected, or risk of investing money in something and it not working, and having to switch over to something. Those are all elements of risk that may or may not be appropriate here and I just wanted to get the thoughts of the group on those, and others that are appropriate.

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

I think that what I'll do is I'll ask Bakul and Jodi about whether that's in scope for this particular exercise. The reason is because I have one minute to go through the next two, and I want to give – we committed ourselves to giving each other our prescribed time. So, we talked some about wireless connectivity and I wonder if we could just spend a moment, sixty seconds to be precise, on the notion of is it an appropriate domain to consider whether this is stand-alone or how it interacts with the rest of the system?
Comments?

M

I guess I'm struggling when you say stand-alone, are you talking about a mobile app?

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

Well, a mobile app, if it is – if the input and the output are well described and the mobile – and the app controls everything, and it's not intended to go somewhere else where things could happen on the way to somewhere else. Or an interpretation of the output could be different than what was intended, that's where you get into risk, that's what this category's trying – somebody brought this up actually in our big call, as I said, and it seemed like a valid point. If you control everything about it, you the developer for this mobile app, then that's fine. If you are passing on your information, then all of a sudden we have other possibility of introducing risk, that's what this dimension is trying to call out. People agree with that.

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

Well I guess the distinction being that a mobile app that sits resident on your phone and does not need connectivity in order to operate versus a mobile app that actually does rely on the cloud and whatever service that cloud is providing that app, given the input that you're giving it.

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

That's a fair thing, too. Unfortunately that's the – a different conversa – .

M

I was going to – network connectivity kind of generally or connectivity risk generally is probably a good – and wireless would be part of that.

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

And that goes back to my previous comment that if you're home and you're using your wireless LAN, that's a very different kind of connectivity than if you're using your 3G or 4G cellular communications to do the same transmission.

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

Good point.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

So, this is Todd again. I guess looking at this matrix, one aspect that's not teased out well is the difference between infrastructural components and – which may be part of the health IT itself, as well as different components that might leverage that infrastructure and along with that, the systems engineering. So I'm not sure around this whether we need to have that broken out as a separate item in terms of rows, or maybe a separate dimension, but we should noodle through that a bit more.

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

Good point. I'll try to do something in that wireless row. Okay, I have an obligation to keep, so, I've taken my 30 minutes and thank you so much. This has – these are just the kinds of comments we needed. I will incorporate them into a next draft and circulate that around and send me any of your comments. As I say, we'll keep all the comments and we'll keep working on this. The main goal, and it sounds like we pretty much have that with the revision is to see if we can't put this kind of a concept in front of the bigger group. So, next slide please. And what we're going to do now is turn to the risk assessment for innovation. So, the risk to innovation of different kinds of regulatory approaches, and Keith is going to cover that with us.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Good morning. Again, this – I think what makes this whole exercise difficult is that we're putting together a framework and we talk in hypotheticals. But in this case, so we're trying to put a framework rather than reacting to specific regulation. Next slide. Just a couple of things that I'd like to put out there for the groups consideration is that as we look at this framework, we're looking at different regulatory options, trying to again balance the regulatory option with the risk. So not all risk is created equal and the regulatory options should be consistent or balanced with the risk, but again, the cost of the regulatory option is really its impact or its cost on innovation or just pure cost. I mean the burden to create or to respond to regulation.

When I looked at Appendix D in the IOM report, where it talked about the impact of regulation on innovation, it really talked about how stringent the regulation was and then how flexible or how many dimensions of – or how many paths to you have to respond to the regulation. I added one other thing, and I put it on this slide, which is the measurement burden. And what I mean by that is that again, if you look kind of at the progression of regulation, there's usually some kind of theory or goal to the regulation and then some kind of policy that you're trying to affect – that you're trying to get. Then there's the regulation itself, but then in the final action, is how do you measure the regulation or how do you measure compliance? And largely in the measurement is where I think that impact on innovation is really measured.

Let me give you an example that I thought of when I was doing through this. And that is that a while back the idea was with nurse care plans to involve a trained individual who was close to the treatment of the patient in the planning process and to carve out time for the nurse to apply their knowledge in creating a plan for the patient. Okay, so that's kind of the goal or the policy that was trying to be implemented. By the time it got to measurement, which was that there needs to be a nurse care plan filed on the patient each shift, it really became a to do and actually negated the original purpose, which was to have – to move the nurse from a task-oriented response to a planning response. And so as we look at these things, the measurement, how we measure the compliance, I think is a critical element to this, and how we set up that measurement process.

The other one that it's not on the slides is really, what is the target of the regulation. And this comes out in the next slide, is, if we're looking for a specific or prescribed specific behaviors of software, in order to, because we think that the risk is sufficiently high, that – well again, I think that when we prescribe specific practices, we're really reducing the flexibility, their paths to get to the desired goal. And that should really be reserved for things that we think that one, are high-risk to patient safety and two, where there is an understandable way to address that, a very specific behavior to address the risk. Other ways of assessing risk is one is process. And a lot of the regulation has to do with how I create the software, how I implement – it could be applied to implementation of software and customization of software. And the third way that regulation can be targeted is more on desired outcomes and which I think is the most flexibility. What I'm thinking about there is an example of the EPA on mileage standards for cars, where the goal is really set and then it's left up to the companies to figure out how to get to that goal, in a specific time. And so you're really not measuring how they got to the goal, but really the outcome of the goal.

So, I'm throwing those ideas out, again, it's the idea that the measurement is critical in the evaluation of the impact of the regulation on innovation. And also looking at the specific target as a dimension, like are we targeting a specific practice, a process to produce something or are we targeting a desired outcome. So with that, I'll open it up for comments.

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

This is Mike Swiernik. And thank you for putting this together, too, this is great. I would add a – either, I guess I would add a column to the left of all these risk columns that is truly no risk. Because I think of – I'm coming from the background of a bootstrap start-up, so for me, anything in the low risk category would have meant I wouldn't have done it, because that is still risky and it presents a barrier. So I would have maybe the concept at least of a no-risk thing which says that there is no – we don't have to certify anything, for instance, at the bottom and we don't have to meet any of these process models, just because that to me would be the – open it up for the most or the easiest innovation.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

So you're saying that for things that are not a risk, are you saying that they don't be regulated or that there's a suggestion that any regulation inhibits innovation.

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

Well I think this is talking about risk to – or something that would prevent innovation or limit it –

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay.

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

– and any kind of regulation – well, I guess there are two ways to look at it. There's if you're a very small company or a single person, then any kind of regulation whatsoever is going to push you away from going in that direction, so that would be a risk. But I think for some larger companies, regulation is actually an appealing thing, because they know that they're competing in a much smaller pool of people that can actually go there. So for them, and I don't know if anyone's on the call that can speak to that, but that would – they may actually look at a lot of regulation as not necessarily a bad thing or as a way to limit their threat from disruptive innovation kind of stuff. But from a pure innovation standpoint, I think there's – no regulation is best. Purely from innovation, not from patient safety, obviously.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

And what we're –

W

Your point is a valid one because a venture capitalist looking at the market will say, I want my company – I mean, it's the same reason people support patents –

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

Yeah, exactly.

W

My guy will be protected from the other guys. And so, too much innovation isn't productive, too little also isn't, but some sense that the market will be orderly actually is positive, but I don't think it necessarily applies – I don't think the risk is the place where you should be regulating. You should be regulating bad practices, fraud, and stuff not working.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

So, this is Todd Cooper again. I'm thinking in terms of innovation, one of the – and this is similar to the previous two comments. One of the big problems is a lack of clarity, people who do not have – who are part of smaller companies who don't have a highly evolved quality system and staff around that. A lot of times, they'll look at this and it's just like even getting their big toe in the pool is very daunting because it is such a huge area. So being able to provide very straightforward, clear guidelines for this and maybe even some level of automation or tooling, to facilitate at least this kind of an analysis would be extremely helpful.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay. I've heard a couple –

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

Hi, this is Joe Smith. I'd have to echo that from Todd. I think transparency and predictability are axes along which innovation experiences progressive risk. Laying out the hurdles to be overcome clearly is a bigger boon to innovation than debating what's the size of the hurdles. So I do get to play the venture role in sitting with a small company on Thursday and they say, you know, the HIPAA regulations are so complex, I cannot afford an attorney to read them for me. And so, you make it complex, you make it vague or unclear, and then you ascribe big penalties to missing it, I can't play in the space anymore. And so I think we have to be careful about transparency and predictability, as well as the process metrics that you've nicely put together.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay, so there are a couple of thoughts and let me throw this out. Okay, again, I heard the lack of clarity and really it's a transparency in the complexity of the regulation themselves, HIPAA being a good example, where again my, especially if I'm a small start-up where I'm getting into that is how much cost do I have involved in trying to understand and then apply those standards. Is that correct?

M

I don't think that –

W

I'd like to add –

M

Sorry, go ahead, I was after you.

W

Okay. I mean, one of the problems with HIPAA is, in many cases it uses a blunt instrument to deter innovation in so many ways, partly because it's misinterpreted and as somebody said earlier, you can't understand it so you just decide to take the low-risk approach, which is to do nothing. Don't give out the data, don't measure this particular item, don't start that product.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay. Well and when –

W

And I would add –

Geoffrey Clapp – Better – Co-Founder

I want to put a defending – I actually disagree pretty aggressively with most of the comments. I think that we're talking about innovation. HIPAA has been used as a blunt instrument for people not to buy things. HIPAA has been used as a blunt instrument on the distribution side. But in terms of innovation, we saw more innovation and more investment in this space long before the Omnibus clarification came out in February. I don't think the numbers actually back it up, that with innovation. Now distribution, sales, but investments and innovation, the last four years, all prior to, there was as much HIPAA confusion as there was from 1996 until February. I don't think that in pure innovation, between the number of startups, the money that's come into the field, the – that has been the field, I don't think the data backs up a lot of the statements that we're making.

W

But you don't know –

W

Well I think that was –

W

– you don't know what would have happened otherwise, what greater risks people would have taken, what pilots they would have run that would have given them more money. I mean –

W

Exactly. And speaking as, I'm sorry; I didn't mean to interrupt –

Geoffrey Clapp – Better – Co-Founder

But wait, the argument is the absence of – I don't get that.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Well, let's back up a little bit. I think it's interesting, how do you measure innovation? Because if you measure it just with investment, I mean then we're just saying that we discouraged innovation to a point that no one invests in it at all. Yet I think there was a comment earlier about how regulation essentially creates markets, and it creates investment, because people are trying to use it as a differentiator in the market or they're using it – and then they're responding to it. You know, the way that we've seen standards being used and in this case, HIPAA. So does pure investment equal innovation?

Geoffrey Clapp – Better – Co-Founder

No, but there was a statement earlier that the idea that people aren't moving into the space and investment dollars aren't happening because of the lack of or complex – I don't – of complex systems, I don't believe is – I don't think the data backs that up.

W

No, I'm sorry, that's not exactly what I said – it's –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, just because a lot of people are moving into it doesn't mean that there are plenty of others who aren't. So, I mean, and just speaking from the perspective of a patient –

M

But that's arguing a lack of data –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Well, that doesn't mean it's not happening. I mean, just because nobody's measured, it doesn't mean it isn't happening. So, for instance, speaking from the perspective of a patient who uses health IT to treat my multiple medical conditions, I frequently get the sense that HIPAA and FDA are just these catch-all mechanisms that many of the companies use to explain why they aren't acting. And I think that some of that is legitimate, I think there is a lot of lack of certainty about what is and what is not appropriate. But frequently HIPAA is just such, to use that as an example, and also FDA, there's just such a fear that it's so complex that it requires an army of lobbyists and attorneys to figure out, that anything that gets close to that, people just don't even want to go to. And I'm speaking in this case of people that I know who are application developers, mobile apps as well desktop application developers, who are interested in developing better ways of dealing with diabetes related information, but have chosen not to because it's just too regulatory. It's just too scary, it's too expensive, and they don't have the money to be able to figure it out.

Geoffrey Clapp – Better – Co-Founder

So just as a data point of the 4,000 applications that have come through the incubator, and of the 70 or so people that we funded, no one got more than \$100,000 and 50 of the 70 had to worry about HIPAA and 40 of them had to worry about the FDA. So while I agree it is daunting to understand, I also think that it's not killing innovation. There are people who do use it as an excuse, and there are people who it does scare the bejesus out of, don't get me wrong. But I think the idea that it has eliminated it is probably overstating it a little.

M

Well, I think that again, the discussion's interest from this standpoint, and again, we're trying to create a framework and it's easy to see, if we throw out an example like HIPAA or FDA regulation or ARRA certification, then we can make specific comments. But how do you incorporate that into a framework to evaluate future regulation, before they become regulation?

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

So I come from the approach of, all I see is a lot of venture financing and venture capital being interested in the nascent area of mobile health. And what I do see, and have seen in the past is that for the small developers trying to get into this market, those that are making low risk devices, which have to go through at times daunting requirements due to existing laws, they're the ones that get harmed. And I'm not talking about the medium-risk and high-risk, but if you're making a very low-risk device, sort of analogous to what Anna was describing. If you have to go through something like good manufacturing practices, which entails a number of different obligations that will end up costing in the hundreds of thousands of dollars, you're obviously not going to be able to do that. If the devices are that low risk, then there is a question of whether or not they need to go through – they need to endure that type of regulatory scrutiny. That's where I see an issue.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Again I think that that's kind of the focus again is that we're balancing – we want to be able to marry a risk with a regulation with its cost to innovation. So again, the statement is, if it is a low risk, the regulation should be low and that the risk to innovation should also be low. Because what you're seeing is asymmetric response, the risk is low but what we've done is put a large regulatory load on it. Is that correct?

M

That is correct, 100 percent.

W

You're right, but may I just add that no matter what you're doing, there is a big difference between regulations that are clear and ones that are not. And part of the challenge is simply – making sure the regulations do what they're intended to do and aren't incomprehensible, too long. I mean the quality is separate from what it is that they're trying to accomplish and so, it's not simply should you or should you not regulate, but how. And just in the other discussion, we don't know what would have happened without HIPAA, and so I don't think it's clear, no it didn't eliminate all innovation and not all innovation is good, but we just don't know and we should acknowledge that.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Well and I – let me throw out another thing is that, regulation – I think regulation again creates innovation, but because people try to respond to the regulation. They become very – somebody will find a market advantage to some regulation. But then you have to measure that against the broader goal of, did directing innovation by usin – did that regulation divert people into doing innovation in less productive areas? Because there's a cost there.

Geoffrey Clapp – Better – Co-Founder

So is it possible, this is Geoff again. I think one thing we can all agree on, independent of our different views of previous legislation, is that maybe one of the things they're asking for is actually post-market surveillance on the regulation, right.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Right.

Geoffrey Clapp – Better – Co-Founder

How do we actually monitor the effectiveness of what we actually ask for, so maybe the suggestion we want to make back to the bigger group and then on to these committees is, how do we actually start to measure the impact of legislation and therefore react to it faster, and maybe that's the fastest path for innovation? Which is, can we set up a feedback loop that we can react to, either positive or negative legislation, and do more or less of that versus a lack of measurement and its effect on innovation.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Yeah, this is Todd Cooper. I want to say that that's something I know that's been used extremely effectively in the NHS around their health software systems, where they actually started to capture that information. Obviously, it's mandatory for regulated medical devices, but they kicked in a system where they were able to track incidents around health software just not performing the way it was intended, and then they were able to establish a baseline. And then they were able to see how their policies improved that, and it was a striking difference. So I think that's an excellent idea. Just one other thought on here, NDDF also looked at what happens inside of a hospital when some of these systems are configured, and a lot of innovation happens by care providers who are looking at technologies in hospitals. So I don't know we've talked a lot about products and product development, but where is hospital innovation innovators on this work as well.

Geoffrey Clapp – Better – Co-Founder

Great. Great point.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

I think, I think that's an interesting comment, because as we talked about risk, we said that the risk can arise not only in the manufacture of the software, but in its implementation and its customization configuration. But what's the easiest to measure is the production of software. And so sometimes I think we go to the easiest one, but if you look at the implementation process that we talked about there, I think – I agree that people are very creative. And we talked about this in one of our general calls that they'll match up technology in a very unique way, in order to meet the goals that they personally have in using the technology. And so the implementation process and I put that on the spreadsheet that's there is, how do you measure – what is – do you go after a process measure. Again, we're not suggesting regulation in this part, we're just saying, how do we measure it, how do we measure its impact? So as you look at the types of interventions where you have a specific – a prescribed specific behavior or processes or desired outcome, more of a goal type thing. Any comment on the effect of those on innovation? And let me throw you out a strawman, on specific practices, if I had a regulation that for instance prescribes a specific user interface, it meets the standard that we talked about of being very clear, but what is the impact on innovation?

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

So are – so, this is Joe. Are you imagining that the regulations specify the products or the process?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Well, that's what I'm asking is that if I look at the, and we've all experienced some regulation, and the way that they've been implemented, and sometimes it's right down in how they choose to measure it. If it prescribes a specific behavior, it meets the criteria of being very clear, but what does that do to innovation versus the process measure or process regulation versus more of an outcome regulation?

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

I would find it difficult to support any notion of regulation that specifies the end product. That sounds overly constricting. I think the notion of arguing for clarity, predictability, transparency, all of that is around the process. I don't think we want big government picking out what products that it wants the industrial sector to provide.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay.

W

I would agree. I mean, I know you're throwing that as a strawman, so – I mean, clearly we don't want FDA to prescribe how a particular set of data is displayed. We want innovation to be able to come into the place and make it better, to have people who have different ideas about how that should be displayed and how it's going to be most helpful, to be able to come up with different models. So –

Geoffrey Clapp – Better – Co-Founder

This is Geoff. I'm going to say something I'm not even sure I believe in, but maybe so we can just scratch it off the list. But do we think that there is – I think some people might argue that there should be a lowest common denominator though, like data should at least look like this or should at least meet these standards. As a group would our position be, and like I said, I'm throwing this out there to kill it, but do we think there is a lowest common denominator, do we think there is a way to codify best practices that the government should do or that private industry should do, hint, I'm going to say private industry. But, maybe that's something we want to put in our framework.

W

My inclination would be to say that, do it more like the FTC –

Geoffrey Clapp – Better – Co-Founder

Yes.

W

– you can't lie and you have to disclose what you're doing, but then you should be free to do whatever you want and then people are free to buy it or not.

Geoffrey Clapp – Better – Co-Founder

Love it.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I completely agree. Completely agree.

M

You know, it's interesting because we do have somewhere where specific user interfaces are prescribed, the Surescripts certification process does that –

M

Right.

M

– for instance and what has been an effect of that? I would agree, I think it's stifling for innovation.

M

For having car accelerators and brake pedals in the consistent places.

Multiple speakers

Yeah. Yup. Yeah.

Geoffrey Clapp – Better – Co-Founder

So I'd like to put that in there somewhere that we've kind of all – there seems to be some agreement on that point that that is actually something we've talked about, because I would hate someone to take what we've talked about and turned that into those things. Where I think whoever it was that went right after me that said – that articulated it really well with the FTC example, I feel like we should capture that that was really well said.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Yeah, I got that. Good. Is there ever – well, going with that, is there ever – would you imagine that there is a patient risk sufficient that you would want to be able to prescribe a specific software behavior?

M

There are examples of consensus standards that are created by a combination of the industry, public and regulators. And then once those standards are made available, then the regulators can choose to acknowledge them. The American Association of Medical Instrumentation is one organization that creates those. So that's something that we could point to in our recommendation.

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

This is Anura Fernando. I'd like to sort of reiterate that last point. Also from the perspective that both FDA and OSHA rely on those types of standards already for things like basic electrical safety and so forth, so taking safety attributes and having those standardized, while leaving other product attributes completely open for innovation is something that's definitely doable.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay. I'm cognizant that I'm probably out of time. Is that right Paul?

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

I think you can go on for a couple of minutes.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay. So it's – I heard again, I think Joe was mentioning that his assumption in here is that we're mainly talking about process, regulatory – regulation of processes rather than specific behaviors. Is that correct?

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

Rather than specific products –

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay.

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

Help me with the distinction between process and behavior. Are you talking about product behavior or system behavior?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Yeah, product behavior.

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

Yeah, yeah, yeah. So more process than product, that's my view, but others chime in.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

That's what I'm asking.

M

Yeah, I'd favor process and maybe pointing towards some of the information in IEC 62304, which describes software lifecycle processes.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay.

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

So, this is Anura Fernando again. Along the lines of my previous comments, so while IEC 62304 addresses process from a risk management perspective, there is another emerging standard which IEC 82304, which starts to sort of fill in some of the product-specific gaps. Again, not to dictate specific product design, but rather to identify specific product attributes that are safety relevant that need to be addressed. Again, without necessarily constraining the design or limiting innovation, but to ensure that product-specific behaviors or product-specific safety attributes still are specifically focused on.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay. Can you give an example of one of those?

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

Sure. So, looking at industrial control, I think probably a lot of people are familiar with the big red buttons that you see in factories that if something's going wrong with the machinery, you can hit that and the system stops. Well, there are a lot of different technologies that can be used to implement that type of an emergency stop. It has some fundamental attributes that it has to have, though, one of which is a big mushroom shaped button, so that people can – that's red, that people can recognize and recognize as something that's safety related that they can hit and put the system into a safe state. That – those particular attributes of having that mushroom shape and the red coloration are those things that are controlled in a standard and through regulations that the technology, whether there's software behind it, whether it's purely electromechanical, etcetera, those things aren't dictated or constrained in any way.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Okay.

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

This is Meg Marshall. I just want – did you need to follow up on that?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Sure.

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

Actually – so, I'm moving to a new topic, so if you wanted to follow up with –

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Oh no, no. Go ahead.

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

Okay. Thanks. So, I just wanted to point out that the ONC Meaningful Use Program does regulate certified electronic health records and does discuss some features and functionality. So that may be one, as you're looking to inventory what's currently going on in the industry, that may be one to reference as well.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

I would agree. And it's interest, because it's a certification model I mean, or implementation, and so at some point in the process it gets very specific on its – on what's expected. And how that has impacted innovation would be an interesting discussion.

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

Is that about it?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Yeah, I think that is.

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

Great. Thank you. In both these cases, very healthy discussion, we have definitely good input to incorporate in the next draft of this that we can circulate, and also present to the rest of the workgroup. Can we go to the next slide please? So as I said, we'll be presenting a revised version of these. I'm not sure what the agenda is, unless somebody at ONC, FDA know what the agenda is for May 30-31. But I think one is a report out from our small groups and two, I believe there is some dedicated time, I don't know whether it's before or after those report outs, for us to work – continue to work on these. It seems like it would be helpful to have it after, I mean, if there's a choice, because then we'll get some more input from the rest of the group that we can incorporate.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

So we won't be having any other calls before the face-to-face.

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

Not before the face-to-face, but the next step is to have, and I think what we'll do is pretty much after this call, put out some Doodle Surveys to try to get some more time together, I'm imagining somewhere in the neighborhood of 2-4 maybe, calls before we present back to the full group. But it will sort of depend on additional feedback we get, but we'll probably need to try to secure time from all of our calendars.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Because our report out isn't due in October is it – I mean in August, is that correct?

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

That's a good point Keith. So our first report out, typically what we do at the Policy Committee is we get sort of a draft recommendations from a workgroup and then the rest of the Policy Committee weighs in and then the workgroup goes back and revises, based on the feedback, before presenting something for final approval the following month. So our scheduled call for us to present our – for the workgroup to present its first draft recommendations in the August – and usually our meetings are in the first – in the early part of the month, August and then get feedback and then present our final in September. And all this is so that we can turn around and give final recommendations from the HIT Policy Committee to HHS and then they go into their preparation and clearance, so that they can provide their report in January. Any other final comments about either the process or the schedule or any logistics before we open up to public comment?

Michael Flis – Roche Diagnostics – Regulatory Manager

Hi, this is Mike Flis. I wanted to bring something to your attention. The Mobile Health Regulatory Coalition has put some effort into analyzing intended use cases for the risk stratification of mobile medical apps, and they've identified five different categories. And then each of those categories they broke them down, based on the risks and I think this might be a pretty insightful tool to share with the group, to see how mobile applications, one way to look at how they might be looked from a risk assessment and then how that bleeds into innovation decisions. Is there someplace that I could post that so that everybody would have access?

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

Well we'll figure out either how to post it or if you could send it to one of us, we'll give it to HHS and they'll redistribute it. So, we'll get it out. Thank you. Which brings up another point, and it came up to this conversation, it's very useful as we put together these frameworks to have these exemplars, so hey, what about the case of "X." If we have exemplars of different kinds of cases, and it sounds like what Mike just mentioned is an example, then that can help us think of some of these other situations that we want to make sure we try to cover. If you want to forward some of those in the interim, we can start building up that exemplar cases and discuss that at our face-to-face as we meet. Okay. MacKenzie, you want to open it up for public comment please.

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 are listening via your telephone, you may press *1 at this time to be entered into the queue.

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

Well while we're waiting for public comment, I'll just mention, we also do have the online resource to post documents through the FACA portal as well.

Rebecca Armendariz – Altarum Institute

We have no comment at this time.

Operator

We did have a comment just come in, Mr. Michael Marchlik. Please proceed with your comment.

Michael Marchlik, MS – McKesson Provider Technologies – Vice President Quality and Regulatory Affairs

Yes. This is Mike Marchlik at McKesson. I think this is great work; there are a lot of people who have been looking at this. Just one thing to consider is that when you look at what you put down in terms of likelihood, especially when you were talking the risk of the software, a lot of what you had below that, complexity, customization and everything else really become proxies for that likelihood, right. Because for software, it's not like manufactured goods where we can look at process capability and look at potential failure rates of equipment, it's really trying to create proxies for what that frequency is. And therefore, I think at the end, a model like this, your frequency isn't something that you'll be calculating directly, what you'll be doing is looking to things like complexity, customization and those other factors. I think it's good.

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

Thank you. Any other comments?

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

Thank you. Are there any more public comments?

Rebecca Armendariz – Project Coordinator, Altarum Institute

We have no further comment at this time.

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

Well, on behalf of Keith and I, want to thank you, thank the workgroup for – the subgroup for your vigorous and rich discussions. Our strawman frameworks are definitely going to be better off for it. We'll try to revise it based on the discussion and we'll see what the rest of the workgroup thinks. But thank you so much for taking the time and for your thoughtful input. Keith, anything else?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

No, I think that that's it. Appreciate the comments and I know it's – the challenge here really is the quick turnaround and not being able to get together as often as we need to, to do that. So, I look forward to seeing everyone in Washington and maybe we can make some progress there.

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

We will make progress –

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

We will, sorry. I should be more optimistic, we'll nail it in Washington.

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

There you go. We finished precisely on time. Remember that MacKenzie. Thank you everyone. See you next Thursday.

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

Thanks everybody.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

Thank you.