

**HIT Policy Committee
FDASIA Workgroup
In-Person Meeting
Transcript
May 31, 2013**

Presentation

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

Good morning, everybody. This is Mackenzie Robertson in the Office of the National Coordinator for Health IT. Welcome to the second day of the HIT Policy Committee's FDASIA's In Person Work Group Meeting. As a reminder, this is a public meeting. There is time for public comment on the agenda, and the meeting is also being recorded audio wise and also there's a transcript being made, so I'll just remind everyone again to please identify yourself when speaking.

I also want to note on the agenda, at 12:00 we have a break for lunch. We're actually going to be adjourning at 12, so you don't have to have lunch. *[Laughter]* And then, since we do have a little bit more time today, I just want, instead of doing a formal roll call, I'll just ask that we go around the table and if everyone can identify themselves, state where they're from, and if they do have any conflicts of interest, if you could just state them now, since this is the first in person meeting. I will turn it to Mike Lipinski.

Steve Posnack – Office of the National Coordinator

Steve Posnack, ONC.

Matt Quinn – Federal Communications Commission

Matt Quinn, FCC.

Bakul Patel – Food and Drug Administration

Bakul Patel, FDA.

T. Drew Hickerson – Happtique

Drew Hickerson, Happtique.

Elizabeth George – Philips Healthcare

Elizabeth George, Philips Healthcare.

Mike Flis – Roche Diagnostics

Mike Flis, Roche Diagnostics.

Lauren Fifield – Practice Fusion

Lauren Fifield, Practice Fusion.

Rich Eaton – Medical Imaging and Technology Alliance

Rich Eaton, MITA.

Esther Dyson – EDVenture

Esther Dyson, EDVenture. I'm not sure what I should disclose. I'm an investor in a lot of startups that are very interested in this area. I'm on the board of Voxiva, and if someone gives me advice later, I can list whatever might be relevant.

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

Okay. Thanks, Esther.

Esther Dyson – EDVenture

Thank you.

Todd Cooper – Breakthrough Solutions Foundry, Inc.

Todd Cooper from San Diego, America's finest city.

Participants

[Laughter]

Meghan Dierks – Beth Israel Deaconess Medical Center

Meghan Dierks from Beth Israel Deaconess Medical Center in Boston.

Farzad Mostashari – Office of the National Coordinator – National Coordinator for Health IT

Farzad Mostashari, National Coordinator for Health IT.

David Bates – Brigham and Women's Hospital

Dave Bates, from, from Boston, I'm the Chief Quality Officer at Brigham and Women's Hospital. I'm involved with a few startups and I'm on the board of a company named—called SEA Medical.

Paul Tang – Palo Alto Medical Foundation

Paul Tang, Palo Alto Medical Foundation—no conflict.

Keith Larsen – Intermountain Health Care

Keith Larsen, Intermountain Health Care, Salt Lake City.

Brad Thompson – Epstein, Becker & Green

Brad Thompson, Epstein, Becker & Green, and I have dozens of conflicts.

Julian Goldman – Massachusetts General Hospital/Partners HealthCare

Julian Goldman, Massachusetts General Hospital and Partners HealthCare.

Robert Jarrin – Qualcomm, Incorporated

Robert Jarrin, Qualcomm, Incorporated.

Mary Anne Leach – Children's Hospital Colorado

Mary Anne Leach, Children's Hospital Colorado—no conflicts.

Meg Marshall – Turner Corporation

Meg Marshall, Turner Corporation.

Jonathan Potter – Application Developers Alliance

Jon Potter, Application Developers Alliance. I avoid conflict at all costs. You can ask my wife.

Participants

[Laughter]

Martin Sepulveda – IBM

Martin Sepulveda, Health Systems and Policy Research, IBM.

Joseph Smith – West Health

Joe Smith, West Health. I have many interests. I think they largely align, but they probably conflict at some point.

Mike Swiernik– Mobile Health Rx

Mike Swiernik, Mobile Health Rx, no conflicts.

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

And do we have any work group members on the phone?

Mohit Kaushal – Aberdare Ventures

Good morning; Moh Kaushal here with Aberdare Ventures. I'm an investor here with a number of competing ...

Jackie McCarthy – CTIA, The Wireless Association

Good morning. Jackie McCarthy, CTIA, The Wireless Association. Thanks.

Jeff Shuren – Food and Drug Administration

Hi, this is Jeff Shuren at the FDA.

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

Okay. With that, I'll turn the agenda over to Dr. Mostashari for a few opening remarks.

Farzad Mostashari – Office of the National Coordinator – National Coordinator for Health IT

Thank you. On behalf of the Department of Health and Human Services, our colleagues at the FDA and the administration as a whole, and our partners at the FCC, I want to welcome you to this in-person meeting and welcome those who are listening in. This is a—as you know, this is being taken place under the auspices of our Health IT Policy Committee, Advisory Committee. Everything that we do is really guided by the recommendations of people who come at the issues from different perspectives, and we do it in the open, and we think that that transparency and that open dialogue has been critical to being able to have a forward looking strategy with some predictability for industry to understand what the issues are, what the different perspectives are, and what's the emerging sense.

I think that this, the conversations I heard yesterday again show how important it is to do that when we do have such complex issues, and these issues are complex. If they weren't complex, we wouldn't be here—and to have such different perspectives, the different tribes who come at this from really very different starting points in terms of their own person experiences that they bring—all, all correct, but in terms of being able to yield the best product for public policy in terms of a public benefit, our need to make sure that we really do get that best distilled sense from, from you all, as we then take it back and produce a draft report, then, for public comment. So it's, it's very much, the public input is very much baked into the process. I just want to underscore the importance of this issue—not only for the regulated or non-regulated industries, but for patients and for the health of our country as a whole.

Health IT is—I think Thomas Friedman really distilled it very well in a recent editorial in the *New York Times*—is best understood as a part, a critical part of the innovation agenda for bringing innovation in delivery systems aligned with innovations in new payment models and really the democratization of information and information tools in the hands of consumers. Those are really dovetailing, and quite deliberately so, to the policies of this administration. To really attack this most important issue that we have in terms of health care costs and quality with America's strong suit, which is innovation, and as we do so, that data that is increasingly digital, being able to be used to manage health and health care better, help patients manage their own health and health care, health providers in hospitals manage the information. As that data becomes more central, it also becomes more imperative for us to make sure that there are protections in place for the security and privacy of that information and also for the safety of the products and services.

So this could not be more important, and I just want to personally thank you on behalf of the administration for the really important work you're doing here, and just to, again, thank you and encourage you to keep doing what you've been doing, which is to recognize that there are different perspectives, there are different tribes, there are different ways of looking at the world, and we all have to work hard at understanding the other side's perspective as well as articulating ours as best we can. Thank you.

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

Thank you, Dr. Mostashari, and I'll turn it over to David Bates for a recap of day one.

David Bates – Brigham and Women’s Hospital

Thank you, MacKenzie, and thank you Farzad. So yesterday, as you know, we heard from our regulations subgroup, we heard from the risk assessment innovation subgroup, and then spent a lot of time with the taxonomy subgroup, which basically helped us frame what’s in and what’s out. We then did the face to face break outs, in which we—on risk and, and regulation in which we had an opportunity to talk some more.

Now, a couple things that I have been asked by several people to, to go through today—one is to be clearer about what the work product is and so, what we’re aiming for. It’s always helpful to have an end in mind. Our work product will be essentially a PowerPoint, so it’ll include bullets, it can include visuals. It’ll be delivered in August in a preliminary form, and then it’ll be finalized in September. It can be backed up with other materials like appendices, if that would be helpful. It does need to be supported by exemplars or use cases, so we’ll try and embed some of those.

The taxonomy group, we think, is largely done with its work. I want to thank you for, for doing that, and—Meghan and Patty, thank you, in particular for doing a lot of work over a very short time frame.

The, the—the risk and innovation group is, was asked to, to do several things. You have the list of questions, but basically to produce a framework that enables assessment of the types of risk from various HIT modules or systems, something about the magnitude of risk, the likelihood of harm, and then the opportunities for, for prevention or, or mitigation of that risk. The regulation group has been asked to consider what the regulatory levers are that are available, and whether or not there might be specific levers that could be used, for example, for specific systems. And then, and then how effective those levers are, what, what the—what the burden might be, what the impact on innovation might be, whether there are issues with duplication, with other regulations, and then also to think about ambiguity.

And the regulation group spent a lot of time yesterday on duplication and ambiguity. It will need to cover some of the other things that, that just mentioned.

So that—that, broadly, is, is what we need to do over the, over the next couple of, of months. So let me just stop there and ask if there are specific questions about that.

M

Yeah, David, so—we’ll deliver a PowerPoint. Is it going to be an associated document? Because we are generating a lot of information, here—or is it the appendices at the end of that PowerPoint, or how do we [Cross talk].

David Bates – Brigham and Women’s Hospital

We, we do not have to produce a, a, a document, although we could if we wanted to. Yeah?

M

Can—can you describe, mechanically, how you intend to put the PowerPoint together? Is it going to be broken into three parts, literally, that correspond to the three groups, or are you going to try and—I’m trying to get the sense if there’s an intermediate deadline. In other words, the working groups—the sub-working groups need to be done by the end of June so that we can spend July on integration? What’s your timetable for bringing this together?

David Bates – Brigham and Women’s Hospital

I think, I think it will; the hope is that we’ll be able to put together the, the, the, the three reports. The sub-groups do not need to be done by the end of June. That would be too early. I think it will be basically delivered in three chunks.

M

But—but we are planning a, a, a substantial amount of time at the end to make sure that the three chunks are consistent. My nightmare is that the three chunks are silos and they don’t interconnect.

David Bates – Brigham and Women’s Hospital

Yes, and you know, and, and a good part of what we’re going to try and do this morning is, is to, to, to talk about whether there are issues around interconnection—although we’ve got some other things that we need to do, too. Okay.

So let's, let's—there were a couple of outstanding issues around taxonomy that I wanted to go through, so I'd like to do that, and then, after that, what I would like to do is go around the table and, and we do have a lot of different perspectives as far as I'd emphasize. And, and what I'm going to ask people to do is, within about a minute, to identify some sort of exemplar situation that, that you think would be relevant for us to be, to be thinking about. This could either be from the, from the perspective of, of—you know, a case of harm that has occurred. It could be some sort of innovation that's you're considering or small company that you're working with and you're, you're concerned about regulations stifling thing. But—but be thinking, you will get your, you will get your, your minute here, shortly. And I would like everyone to, if they can, to offer something. You're also free to pass if you, if you really don't have something, although from the discussion yesterday, it seems to me like everyone has, has, has valuable perspectives.

Then, we're going to go through the innovation report, which we just did not get to yesterday, because of time constraints. And then what we'll, we'll talk about a few, a few broader issues, including some, some overarching issues and, and making things fit together. So that's—that's the plan for this morning.

Now, around taxonomy, one outstanding issues was, should we include health information exchange? And there, there were some exchanges, and there was some debate about that. I'll—let me just give you my thoughts about that. I think health information exchanges going forward are going to be quite important, and that issues around them will emerge, some of which we're not even really used to thinking about. I think it's reasonably important to consider them within, within frame, although I, I, I wouldn't want to, to be imposing any sort of very Draconian sort of regulation at the beginning. I think what we need to do is have an approach for seeing how things go with them and what the issues that come up are.

I'm reasonably confident that there will—that based on experiences in other countries, that there will be issues that come up. For example, there will be a large number of people who have personal information that someone becomes aware of, so that's my perspective. What do other people think about that? Should we, should we consider HIEs within the, within the scope of, of this report, or—or not? Yeah.

Lauren Fifield – Practice Fusion

Lauren Fifield. So I was thinking, after yesterday, about taxonomy in general. We've identified types of health IT, and I think that's helpful just to get a good survey of everything that's out there, but when it comes down to it, our end goal is to sort of preserve innovation and patient safety and sort of reduce harm in general. And I think that's more workflow dependent, and so the degree to which exchange is part of, say, e-prescribing, where a patient's health could come to harm or in the degree to which any sort of, any item from the list of taxonomy could be implicated in a workflow where a patient's safety could be jeopardized. I think it should be considered, but it's hard to say that HIE in general should be sort of considered, because it's—it's more of a, a very than anything. So I think, again, the degree to which it's part of an area where patient harm could, could result at the hands of health IT, it should be considered, but not as a category.

David Bates – Brigham and Women's Hospital

Patty?

Patricia Brennan – University of Wisconsin at Madison

Hmm. I'd like to ask that we think about the regulations applying to a number of different structures. The issue of that HIE, to me, is no different than the issue of public health surveillance systems or some of the other non-EHR related innovations that we've touched on but haven't really explicitly spoken about. There are aspects of engaging corporate players, clouds, unusual and dynamic integration of information tools for a momentary period and then breaking them apart again, as one might see using a transient pass through.

So I, rather than saying HIE explicitly, I would like to have, as we speak about our taxonomy of things that are regulated, emerging structures or emerging architectures of health information tools that rely on telecommunications and information infrastructure.

David Bates – Brigham and Women's Hospital

Okay. Meghan?

Meghan Dierks – Beth Israel Deaconess Medical Center

So I—this may just repeat, I think, the points that were just made, but some of the thinking about why we sort of initially proposed it might be in scope was returning to this idea of avoiding the term and what it is and instead, thinking about the functionality. And the thinking was, combined with that decision tree, was that the functionality really is the ability to access critical information which might actually be a primary source with no other source of information. And we thought that, in the future, a few forward thinking HIEs might actually be serving that role, so it's a sole source of information that might be critical at a decision point, and that the risks around it might be related to, really, revolving around correctly identifying and matching the correct patient to the correct information at that critical decision point.

So it was more returning—taking the, stripping off the term HIE and thinking about it as an object or a thing and returning to this idea of the functionality and the risks associated with it.

David Bates – Brigham and Women's Hospital

Farzad?

Farzad Mostashari – Office of the National Coordinator – National Coordinator for Health IT

The Health IT Policy Committee, perhaps in security work group, has divided health information exchange in a way that may be relevant to this conversation as well, where they've drawn a distinction between directed transmissions that really are more like conduits for information that may, I think, in an analysis way, be actually not dissimilar to the part of this discussion which is the FCC's domain around just basic telecommunications protocols, the integrity of—the data quality integrity and the transmission of information, but it's essentially a pipeline. Versus more advanced functions—and I like your use of that approach—where there may be analytic services, there may be, in addition to master patient index or record locator or mapping or other value added services, that we're right on top of that. So—and introduce, certainly, as the privacy and security integrity and the different privacy and security concerns, but potentially, as has been pointed out, safety issues as well.

So I think, if we do talk about health information exchange, it may be helpful to again think about those two different patterns and functions within the broad concept. Thank you. Mike?

Mike Swiernik– Mobile Health Rx

Thank you, guys. Mike Swiernik. Well, a couple points I don't think are completely duplicative. So yesterday we said, just because it's in frame doesn't necessarily mean it's regulated, so I think it's safe to have it in frame and then leave whatever happens up to the regulators—but I also think, what we call an HIE, aside from the acronym, which of course has changed a number of times. Just that concept is, is probably going to change, and it's changed a lot over the years, but maybe what Farzad just mentioned may address that. In other words, if we make what HIE is a really, really small thing and then everything else on top of that is something else that may be regulated differently, then maybe that fixes that issue.

But without that sort of—if I think about, like, game theory, there's like gaming and anti-gaming, and if you say HIE is out, then a lot of people are going to say, "Well, my thing's in HIE, so don't touch it, please, but"—but one minor point, though, is that, with the current regulation, if I understand it correctly, something as simple as taking clinical data and putting it on a graph, which I can do in Excel in five seconds, that counts as transforming the data and therefore makes it regulated. And I think, again, maybe if that's a modular thing that gets regulated in its own way, but I think HIEs are always doing something like even if it's just as a conduit. You're always touching the data a little bit, and maybe we need to re-look at what transform actually equals in terms of regulation.

David Bates – Brigham and Women's Hospital

Thank you. Meg?

Meg Marshall – Turner Corporation

I think that my comments are going to be fairly duplicative of Meghan and, and Farzad, but perhaps as, as emphasis—HIE is a verb, such as the blue button that we see. It's certainly one option, and then understanding that HIE is part of an infrastructure, and it's a mechanism to receive and exchange and store data from another source. And I'd like to point out that HIE has evolved over the years, and this concept will continue to evolve, so as we consider it and look at how and perhaps the level of oversight, if any, that we understand that five, 10 years down the road, we don't want to be convening again to try to have the same discussion, so that there's opportunity for innovation in both the verb and in both the, the actual, the storage and transmission of that.

David Bates – Brigham and Women's Hospital

Okay, thank you. Let's see—Elizabeth?

Elizabeth George – Philips Healthcare

This is going to be a little bit duplicative as well, but I thought one of the things we talked about at the beginning on taxonomy was, was that it was really to decide what was HIT or not, and not to discuss whether it's regulated or whether it's risky, because that's where that list would move on to the other two groups.

David Bates – Brigham and Women's Hospital

That's actually the next topic that I wanted to address. So—okay, okay, Paul?

Paul Tang – Palo Alto Medical Foundation

I was going to use this example when you, when you were going to ask for us for examples of potential risk, but this seems very appropriate to the question. You just asked about HIE, so we do uploading from home devices into our EHR, so there's a regulated home device, there's an EHR, and we contracted with an HIE, in a sense a conduit, really, from the home device to the EHR, which seems pretty innocuous, but it turns out that there was bad data being put into our—into different people's records. And, and that calls to question what—what would make that either more traceable or more accountable [*Laughter*] or how could we get to the bottom of that more easily, and is there a role for, for regulation, end-quote?

David Bates – Brigham and Women's Hospital

Okay. Last word, Todd.

Todd Cooper – Breakthrough Solutions Foundry, Inc.

Yeah, Todd Cooper. So I guess, just to follow up on that, when you said bad data, was it from the quality of the origination data, or was it actually mismatched or something that happened within the HIE function?

Paul Tang – Palo Alto Medical Foundation

So the device data was not transmitted and stored in the EHR. This—the data that was emitted from the device was not stored in the EHR.

David Bates – Brigham and Women's Hospital

Okay, so one other thing that I just wanted to confirm that we have consensus around relates to Elizabeth's point. My, my thought was, after listening to your report yesterday, that we should use the definition of HIT that you've put forward as, as, you know, perhaps one way of, of—one sort of key starting point around how big the umbrella is. Is that, is that—

Elizabeth George – Philips Healthcare

Well, we—we ultimately didn't come up with a specific definition that would frame it. We actually struggled because the federal agencies for whom we're doing this work each have a slightly different—one's very broad, and one's very narrow, but I would say we sort of went with the broadest definition, and then said, "Given the task that we're charged with, what do we think should be on the table for discussion?" And, and that's, that was, that's what I was trying to emphasize yesterday is what ultimately came in scope was, we felt we would be remiss if we didn't talk about it and not necessarily come up with a specific recommendation around it, but make sure that it was discussed and, and vetted.

So I would say, if anything, it's the broad definition by ONC that we're probably going to ... yeah.

David Bates – Brigham and Women’s Hospital

Right. That’s, that’s what I thought you were—okay. Okay, so at this point, what I’d like to do is, is, is go through a quick round robin in which everyone puts forward one example from your experience. Mike, I thought I would start with you, if that’s all right.

Mike Swiernik– Mobile Health Rx

Thank you. I was just telling Joe, we’re at the end, so we’re going to get in trouble on this one. Mike Swiernik. So I think I mentioned this in a comment yesterday and I’ll, I’ll just use it again, which is the disparity between the health and wellness apps, and how you, you have a—at the risk of repeating myself, but I guess in the context I will, that there’s an app that might manage my hypertension, but what’s also relevant to that is, [coughs] excuse me, the amount of exercise I get, my, my weight, maybe my stress level, my mood.

Those kinds of things play into it, but the way I, I think regulation, at least, plays a big part in that now, because I think a lot of the wellness companies come from a nonmedical direction, maybe a, maybe a health or a fitness direction. They’ll understand the space and they kind of avoid it because of the FDA regulation piece of it. At least in part; some of that’s expertise in other things, but—but it also means that if you’re an app maker who makes a, a, a health app that would manage your chronic disease, you’re stuck in a position where you have to ask for that data in addition to what they already put in the other system, and right now I think it’s hard to find companies that intercommunicate, just because of that fear of regulation, I guess, so.

David Bates – Brigham and Women’s Hospital

Thank you. Joe?

Joseph Smith – West Health

Yeah I’m, I’m just probably going to take my one minute her to, to put in a different pitch around the concept of functional interoperability. I think much of HIT doesn’t diagnose or treat, it’s merely a tool and an enabler for, for seamlessly moving information. It’s the electronic pen and pencil and assistant and chalkboard, and that we frustrate the value proposition and we gravely miss the opportunity to enhance every aspect of diagnosis and treatment if we don’t allow the information to seamlessly flow. And the market forces that have been phenomenal in response to meaningful use have, have fractionated the market, understandably. And I think there is an opportunity to enhance the space for innovation by creating a substrate of a true functional interoperability, and I think that—that’s the only way we’re going to realize the ultimate potential of moving the data seamlessly through all its applications.

And so one can point to many different current safety hazards, and I think Julie has done a great job of illustrating many of those. So I think we have an opportunity to both enhance the innovation space but also address safety and notably, also, improve costs. You know, we put together a little bit ago, a back of the envelope calculation that we’ve put out around about \$30,000,000,000 of annual savings if functional interoperability were brought to bear. And so I think it’s one of the few opportunities when everything aligns, when we can, we can improve diagnose and treatment, we can remove an awful lot of cost and waste from the system, and we can make health care delivery so much safer around functional interoperability. And it’s been a market failure and a legitimate opportunity for government intervention.

David Bates – Brigham and Women’s Hospital

Thank you. Martin?

Martin Sepulveda – IBM

Yes. I don’t develop software, I’m a systems and a, and a policy person. I’d like to use my minute just to make a couple of observations. One is, it’s around innovation. We spent a whole day on the issue of risk and harm, and intermittently, there were comments about why innovation is important, and it seems to me that the effort really does need to spend as much time on discussing the issue of innovation and the way that we discussed the potential for harm so that we have a matrix on the framework for assessing harm to people. There is a matrix in one of the documents that tries to address the issue of innovation, and I think that discussion needs to be as robust as the discussion on, on harm. It, it should be a back end, and therefore what should we do now that we’ve determined how we’re going to manage, manage risk?

The second is that, that we need to be careful about the impact that decisions that ultimately get made on the ability to be able to test, because innovation is full of failure, one, and secondly, innovation is occurring increasingly in non-traditional spaces, particularly in the research domains and academic medical centers in an integrated delivery systems, and the ability for those entities to have a space to be a protected space to be able to test just as we do on, in clinical trials, or to be, or to be thought of so that we don't impair the ability of, of innovation in that space in protected environments to be able to determine both the effectiveness and the safety of the things that are coming up in those environments.

David Bates – Brigham and Women's Hospital

Thank you. Jon?

Jonathan Potter – Application Developers Alliance

... I don't think the mic is working. Is it? Thank you. So in regards to hitting upon the innovation, you know, we talked about the innovation in different areas, we talked about commercial innovation with organizations, but I think one of the areas that we need to look at is the correct guidance and oversight when you look at noncommercial organizations and their innovation. When they look to evolve, to innovate, to improve clinical process; when they look to evolve to improve collaboration between physicians; when they look to improve collaboration between patients and providers—I think those are some of the areas that we, we're seeing innovation, we're seeing a high pace of innovation, and from a perspective, what is the right guidance and oversight to enable that and to continue that?

There's a lot of challenges. There's a lot of challenges that organizations are trying to address, and innovation is key, and to be able to address that with the right risk and guidelines to be effective and to fail, also, too, which is key.

David Bates – Brigham and Women's Hospital

And is existing regulation getting in the way of that? Excuse me, I'm sorry—Dave. Is existing regulation getting in the way of that?

David Bates – Brigham and Women's Hospital

I don't know. I don't know at this point—likely I think you all have different perspectives across the board from different organizations. Okay. Jonathan?

Jonathan Potter – Application Developers Alliance

I would echo what these three have all said. I do think the focus on innovation and the focus on information exchange, I think it reflects also the commentary earlier about whether health information exchanges are themselves an activity that needs to be addressed or whether they're just, they're just a thing, they're a foundation, a building block for what people do with that information and how to explore it.

And as I mentioned yesterday, I think the extraordinary opportunity for people to have access to data in a HIPAA protected environment, but have access to vast amounts of data, whether it's at a local level, if you will, at the micro-level of a practitioner or a practice group or a single facility, I would have access to more data, is something that we can do. And I have spoken with developers who talked to practice groups or developers that are individual practitioners who, they just don't want anything to do with it, with that work opportunity, with that business opportunity, because they are afraid of stepping into a, a legal minefield that they don't, they don't know well enough.

And so, in a sense, if the practice of medicine is a protected environment and a practice group comes to a developer or comes to their internal development team and says, "We want to do this. We want to do this to improve our practice of medicine," is that a protected environment or not, and how do we let that, that flourish? I think it's a real opportunity that we'd be missing if we focus on a regulatory minefield and how to sell the regulatory minefield. What's really outside of it is very important.

David Bates – Brigham and Women's Hospital

Anna, what we've been doing is going around the table and everyone gets a minute to come up with some sort of exemplary use case that either represents a safety issue or a place in which regulation is, existing regulation is getting in the way, making things better, and I'll let—give you a second to, to think about that.

Anna McCollister-Slipp – Galileo Analytics

Can you come back to me? *[Laughter]*

David Bates – Brigham and Women’s Hospital

We’ll come back to you.

Anna McCollister-Slipp – Galileo Analytics

Thank you.

David Bates – Brigham and Women’s Hospital

If you could just give me a sign when you’re ready. We’re going to next go to Jackie McCarthy, who’s on the phone. Jackie, are you there?

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

She’s probably on mute, trying to find the right button.

Jackie McCarthy – CTIA, The Wireless Association

Yep. Hi, sorry about that. I was just in a meeting. I think one thing that bears repeating from yesterday’s discussion from the sector of wireless network operators is something that Matt Quinn said in his taxonomy discussion in the morning. You know, we talked about the need to be much more agnostic, but Matt brought up a really important point and an important distinction that you need in a mobile environment to consider things like spectrum availability and also there is telecom generally, you consider the robustness of the network and of the infrastructure.

I think, another item that is of particular interest to our stakeholders is the—there’s a station between, you know, whether it’s the download or the attachment, or the item that is traditionally the regulated device and the network that it rides on, which, you know, is not great. They tried yesterday in our discussion, and it’s regulated by the FCC according to kind of, you know, very different—very different standards than those that, those of you who are, you know, versed in the, in the world of ... and health regulations might be, might be more used to.

So I think those are important distinctions to be educated about and also to make people aware of in our, in our further work.

Meg Marshall – Turner Corporation

I think for mine, what I, I’d like to do is get back to the IOM report and the definition of, of the ecosystem and the discussion on the shared responsibility, so understanding that patient safety, it, it involves technology—people, processes, organization, external. And the comment that I would like to make, for those not familiar, and many of you have heard this several times, I work at Turner Corporation. We are a manufacturer of covered medical devices, but what we have done is, we’ve implemented the same processes for a quality management system, for reporting across all of our HIT.

So many of the, the fears that those of you have around, *[clears throat]* excuse me, experiencing regulation or oversight, we have experience with that, and we still have challenges. We still have challenges in trying to understand what the implementation of our software looks like in a provider environment. So I, I think the challenge—and I’m not sure it’s quite an example—is for a closer relationship, it’s an opportunity for a better and closer relationship between all of those in the ecosystem and perhaps focused on, on patient safety. A lot of times issues that are reported as HIT initially aren’t HIT related, and sometimes the ones that we don’t think are, maybe in hindsight after the analysis has been done, we do recognize that it is—that it is HIT.

The environments are becoming much more complex at any given institution. Many, many sources of data, many interfaces, many folks are touching what this looks like, so the challenge is, I’m afraid, upon the providers in understanding when an event potentially does happen, they’ll have to have a very aware, a good awareness of what the environment is of their HIT environment.

So, I guess to what you said, and perhaps we'll see this as a, as a mitigator around risk, the, the challenge of reporting and closing the loop and learning from what that looks like and understanding that it's not just a develop ratio or not, just a provider issue, but perhaps we'll have opportunity to work much more closely together to understand when a provider reports an issue and when Turner reports an issue, they're not two separate issues, that perhaps they are related.

David Bates – Brigham and Women's Hospital

Can I just ask you, when you, when you do have the, have the reports that identify something that appears to be a systemic issue, what—what do you do about it? That is to say, is there anybody that you report to outside, and how do you interact with your user base?

Meg Marshall – Turner Corporation

Well, it—it would depend on the issue, the severity of the issue, but in—in general, the process that we have implemented would have us reporting to MedLogic if the, if the issue crosses that material—that threshold.

David Bates – Brigham and Women's Hospital

Mary Ann?

Mary Anne Leach – Children's Hospital Colorado

Mary Anne Leach, Children's Colorado. We have an initiative under way reducing preventable harm, and our biggest issue is pressure ulcers. Not so much HIT related, but health technology related, and we have seen examples of biomedical devices interfacing not correctly, right, with EHRs. So about 81 percent of our pressure ulcers coming from these biomedical devices are typically EEG, CPAP, and other machines that are already FDA approved. So yes, I would be very concerned if we were to now—and I know I may be jumping ahead—looking at some kind of FDA certification of interfaces and integration.

You know, despite the fact that we hear examples of issues, those seem to be potentially issues of design or testing or vendor compliance with standards, and I think maybe the right way to approach this would be to publish testing standards and publish transparency around issues that are reported. And let the market drive this, a little bit, because we do successfully interface, you know, thousands, millions of transactions every day.

You know, just at our hospital with our integrated systems, we have over 100 interfaces. We don't have these kind of issues—not to say we won't, but I think a lot of these issues can be mitigated with testing publicly reported issues, testing guidelines, things like that rather than potentially slow down the pace of innovation. I think a lot of our vendor partners have been consumed by meaningful use and ICD-10 and getting ready for accounting of disclosures instead of innovating the next generation of applications. So I guess I would plea for a market driven approach.

David Bates – Brigham and Women's Hospital

And I would note that some vendors have, have actively discouraged people from publicly reporting, which is—

Mary Anne Leach – Children's Hospital Colorado

It would be nice to, to clamp down on that. It would be.

David Bates – Brigham and Women's Hospital

Yeah, and, and some—there are legal forms of discouragement around that, too. Moh? Are you on one? I'll give you a second to unmute. Moh, are you there? Okay, I think we'll go on to Robert.

Robert Jarrin – Qualcomm, Incorporated

Thank you. Robert Jarrin, Qualcomm. So, so I've been uncharacteristically very quiet during these meetings, because I've been trying to put my arms around how to, you know, provide input for my one minute, so here we go.

A lot of the things that I hear in this room are about innovation and innovation potentially being stifled by perceived obstacles via regulation—not only with the FDA, but also with ONC, and to a very much lighter degree, even FCC. What I posit is the following—from an FDA perspective, we have a number of mobile medical applications that are out in the marketplace, some of which have come forward and sought the proper course of general controls, have sought a premarket notification, they've gotten on the market. Others potentially that should go through that have not. We have this whole world of health and wellness staff that don't know what to do and, and a lot of them are saying things that may actually, you know, make them a regulated device.

What we need is guidance, and that's the ability of the FDA to provide that guidance, and not just in mobile health apps, or mobile medical apps, but also in areas like CDS software and the ambiguity and the accessory rule of where a nonmedical device would interface with a medical device and suddenly the nonmedical device becomes a medical device, depending on what it says.

That kind of stuff is within the grasp of the FDA to be able to clarify today. They can issue guidance in a much more aggressive, appropriate, quick way. They can exempt certain devices from having to go through process with the FDA by using it for some discretion. If things aren't low risk enough that they can't be taken of the table, they can then, say, register enlist and we can use that for event reporting and you don't have to go through quality systems regulations if you don't need to. There are a whole host of other things that the FDA can do.

From the other perspective, this report that we're supposed to, that the three agencies are supposed to give to Congress, is supposed to be a proposed strategy and recommendations on risk based regulatory framework pertaining to health IT. I like what the taxonomy group has done, because health IT is not just EHRs, it's not just CDS software, and it's not just mobile medical apps, it's everything from sensors, applications, medical devices, m-health, wireless health—you know, connected care. And that—that's the point of health IT, connected care. So I think that the ONC can go very far in actually not only focusing on EHRs, but also looking at medical devices to avoid some of the things, like what Paul was describing, where you have a medical device interfacing with an HIE and then giving the wrong data into the EHR. That's why ONC should be a leader in this space and actually also provide standards and certification for medical devices, not just electronic health records and electronic health record systems.

And from the perspective of FCC, you know, being the party that is not integrated into health care, but just very important, you know, mobile broadband and mobile broadband spectrum is a big deal, and it's a very scarce, finite natural resource. At some point, the more that we do with things like imaging and transferring these things wirelessly, it's going to be a drain on our spectrum, and we already know that because the FCC has said publicly that we actually are facing a, a spectrum crunch in the next two years. That's something that the FCC has at its disposal to manage. More spectrum is a good thing for America and all uses including health care. Those are my remarks.

David Bates – Brigham and Women's Hospital

Anna, you ready?

Anna McCollister-Slipp – Galileo Analytics

Yes, I'm ready. *[Laughter]* And I'm sorry that I was running a few minutes late this morning. My blood—since I'm partly here as a patient advocate, my blood sugar was too high to measure.

Participants

[Laughter]

Anna McCollister-Slipp – Galileo Analytics

So anyway, I'm here anyway with a couple of brain cells connecting. I think, from my perspective, as I sit back and look at this again with two hats—one is a company that does EHR data exploration, visual data analytics, and as a patient who uses four medical devices, all of which generate data, none of which connect.

I look at this from the context of a learning health system and where are we going. What is all of this going to turn into, and the IOM has done a lot of great work on learning health system, my company is fortunate enough to be part of the ASCO CancerLinQ, which is their prototype learning health system, and as a patient advocate, this is something I've been passionate about for years of, "Let's take all the data that we're already generating and putting it into something that actually generates knowledge," and that's what all the cool stuff is happening, both at the platform level as well as the mobile health level, et cetera.

So how do we create a structure from a government perspective, both in terms of regulation as well as incentives that promotes that? And I feel like we're taking a very piecemeal approach, and as I think about sort of the body of literature and the body of evidence that has come up around the notion of the learning health system and what that means, I'm thinking, how do we develop a learning regulatory system? So how do we create a system by which we're not doing a top down approach? You know, nobody is now talking about a top down approach to technology design, whether it's at the device level or the EHR level. Everybody is saying we need to come up with some basic parameters and let the marketplace take care of itself, let imagination take over, let innovators innovate.

How do we do that from a regulatory/government perspective? You know, can we create a new framework for approaching these things that doesn't get in the way, doesn't pre-design or pre-define, but creates the parameters in which the government knows where it needs to intervene and where it doesn't, but it allows things to happen on a bottom up, sideways, let the chaos of the market and innovation that works best bubble to the top.

And I don't know what the answer to that is. I'm certainly not a regulatory expert, but I feel like we're trying to use old school ways of thinking about what government can do to a completely new world of technology where we've already decided, from a technological perspective, that you can't have this top down approach, and I think that's where we're, we're clashing from sort of an overarching framework perspective.

What that means in terms of the context of how we develop our recommendations as a working group, I'm not completely sure, but I feel like if we're segmenting ourselves—and I think the work that we've done in the various subgroups is important—but if we're constantly segmenting ourselves, we're missing the possibility that we have as a working group to think about this in a much broader basis.

David Bates – Brigham and Women's Hospital

Yeah, good point. We'll come back to that later this morning. We're going to talk some more about innovation a little later. I will just note that some things like certification had been helpful in terms of getting HIT vendors to include a lot of things that they might not otherwise have gotten around to including, including things like public health tools which, you know, they've been on a list, but the list is so long that unless you're, unless there's some extra push, you, you, you might not have done them.

Okay. Julian?

Julian Goldman – Massachusetts General Hospital/Partners HealthCare

Thank you, Julian Goldman, here. Yesterday we went through several examples of medical device data not showing up directly in the EMR—data absent or data not being recorded correctly, and those are already part of the record. No need to rehash that, and that included pulse oximetry data, heart rate data, and also time stamps for clinical data.

Part of that problem—so what causes those problems, and how can we better understand them? So regulation for standalone medical devices is well established, well understood and certainly not something we need to spend time on—something like glucometers, for example. When it comes to a standalone health IT related device—in other words, a single device, a single charting application in a clinical environment, the complexity of that is not very great either, and in a sense, the regulation of that could be understood in the context that the FDA has exercised regulatory discretion, for the most part, for those, say, simple devices.

Where things get more complicated and where it seems that we are appropriately focusing our energy is on the systems of health IT products, so the, the systems of medical devices and multiple health IT components or elements. So, for example, laboratory data going into the EHR or perhaps that laboratory data going to the EHR and then being used to adjust the infusion rate of insulin or glucose, as is being done in some hospitals today.

So, in that sense, when we talk about health IT, we're talking about a system of systems, and, and where the elements of the system interact, the complexity increases, and the risks may be increasing. And in some of the examples that we talked about yesterday, that's exactly what happened. We're talking about medical devices with mult—with interfaces, several interfaces required to send the data all the way to the point where it's used by the clinician. And, as Joe Smith pointed out, the absence of standardized interfaces for medical devices, and especially in the sense that we don't have a certification pathway yet and we don't have tight oversight of the medical device interface is contributing to the problem, that gap of interoperability.

But that isn't the only challenge. The other challenge is, in the examples we already talked about, we don't have a, a process and pathway yet to capture those, those problems with the system. We, we don't yet have that national framework to identify the gaps in data, errors in data, omissions and so forth in a way that isn't heavy-handed; in a way that isn't too cumbersome. And as we talked a bit about yesterday, that is being done in several other domains, where there, where—and so I think, what I would emphasize, is that, as we move forward with regulation here or a regulatory framework proposal, we, we don't want more silos of data capture and reporting and to increase the complexity of that data analysis. If anything, that's already a problem today.

So we should be thinking about, how do we bring all the information together under one, under one umbrella, under one roof so we could look comprehensively at any issues of the entire system of systems, and that way allow all of the stakeholders, whether they're regulated by FDA, FCC, or other regulatory agencies or not regulated at all to collaborate in order to reduce the risk to the patient and to facilitate innovation.

David Bates – Brigham and Women's Hospital

Thank you. Brad?

Brad Thompson – Epstein, Becker & Green

I have a topic that I probably shouldn't raise, because I'm the least qualified in the room to talk to—to talk about it, but really I want to kick it over to Keith, and for all I know, in his report, he's going to address this. But, so—to my liberal arts understanding of how software has developed and what makes it different from hardware, you have the issue of software modules, and the fact that software, in this day and age, is really a compilation or an aggregating of many, many different modules. And you might put a number of them together into a software package and sell it, but at the same time, that software might interact with software located in the cloud or on a piece of hardware or any number of different places.

And so, from a regulatory standpoint, I'm trying to understand that process. Because I look at it from a regulation like a, a virus—sorry, Bakul.

Participants

[Laughter]

Brad Thompson – Epstein, Becker & Green

And, and I want to contain, I want to contain that virus with, with appropriate, get my arms around where the limits of it ought to be, so that if you have a core piece of the software, which is where the risk resides, really just focus the regulatory controls and that core piece and not let them infect other software that may only be very tangentially connected. It might provide a calendar function or something else that is, you know, completely unimportant from a functionality standpoint.

So I, I, I guess I need the help of the Innovation Committee to talk about how software is developed using modules, what that means, and give us some advice on where we could logically draw risk based lines around what software needs to be regulated truly and what software needs to be regulated, truly, and what software that is connected or part of a module is low risk and doesn't need to be regulated. So I would toss that over the fence and hope that the Innovation Committee can help us with that.

Keith Larsen – Intermountain Health Care

Keith Larsen, Intermountain Health Care. I, I think our, our task was, was to give certain exemplars and—so I think that it's interesting. When we talk about taxonomy and we talk even about our risk profile, we're really talking about what things are in and out, you know, subject to regulation or for—or to use a discretionary regulation.

I think that, as we talk about this, and even with our discussion with HIE, I like the comments that really talk about the function. And I think this is what Brad was getting at, too, is—what are the core risky functions, not necessarily what is the label of the product that, that encompasses that process. So one of the slides that, that, actually, the Regulation Committee put, put up yesterday was, you know, what are the sources of errors? Things like, very basic things is, “Do I know—am I on the right patient,” okay, which is a clear risk, okay? And wherever, whatever the label of the, the software on the outside is, that's the risk. It's—it's not inherent in just because it's wellness software or it's, it's HIE software, it's, “Do I have an identification issue with, with the patient, and is it, is it accurate?”

I mean, it is a very complex system that we're, we're talking about. If you look at, we tend to, even with the efforts to make one stop shopping so that I buy everything from a single vendor and that everything is tested with a single vendor, it is a system of systems, as Julian indicated. And so as we, as we look at these things, then I think that we have to, and, and as we use our standards and as we try to push standards that it's even going to make it more of a system of systems, where we have certain functions that I call that may be from two different vendors and going to what Brad says is that we're accumulating, even with something that looks like a single piece of software, it's actually using pieces from, from a lot of different sources.

So it's really, I think we need to focus down on the, the, the, the functions that we think are, are the ones that are risky and be able to have a process, then, to address those as far as testing, and not worry so much as to what the label is of the software on the outside. So those are my comments.

David Bates – Brigham and Women's Hospital

Now Paul?

Paul Tang – Palo Alto Medical Foundation

Thanks. Paul Tang. I'll submit my faulty transmission of data through an HIE as the example that you asked for, but the comments I want to make is, looking more towards the big picture. Yesterday we said our end goal really is safer innovation, so that's the end goal. If it were really easy to get there, we wouldn't have had this meeting [*Laughter*] or this committee. I have to say that it's been a lot of a recapitulation of the IOM Committee work that ONC charged, because we were looking at EHR safety. This is HIT safety, it's broader—but the challenge is (1) lack of data. There's a lot of reasons why there is lack of data, but that's the fact we have. The second is the complexity. It isn't the stand alone device which is more the norm that the FDA has been working with. We all recognize, including the FDA, how complex not only the software is, but its implementation, its use, and the ecosystem that it lives in.

So that makes it extraordinarily hard to set absolute thresholds or anything to, to judge these things by.

So I'll go back to something that's been said a lot on this side of the table, including Anna most recently, which is—how do we create the learning health system? I'm not sure we can prescribe what should or shouldn't be regulated or what should or shouldn't be done, but we better start learning how, how we're doing and how to improve on it, to make it safer and safer in terms of innovation. So the, the thing that has been mentioned here and the IOM Committee said was, “Let's start reporting.” So let's make it legal to report. David mentioned there are gag clauses in contracts that make it illegal, literally, for customers to report. Let's make it in common formats and let's go someplace centralized so someone can access it and analyze it and then feedback the, the results. Not so much for judgment, for—but for continuous improvement.

So the learning health system, the learning—I don't even call it a regulatory system, a learning system. And that may be one of the *[Laughter]* better ways we take this approach is, is along the lines of post marketing surveillance, but done with a lot of learning. We did propose, in our committee, this, this whole centralized repository and an NTSB like organization that's independent and can go investigate it and can go produce its results without any judgment. It doesn't have any regulatory authority.

So that model still seems to be reconfirmed by discussions of this work group.

And then the out that the IOM recommendations had was, "And if all else fails, give it back to the FDA." *[Laughter]* So that was the—that was the stick part. But I think a lot of the discussion we've had here really points towards a learning, post marketing learning system.

David Bates – Brigham and Women's Hospital

I'm going to go very quickly because I'm going to, I'll give three very quick cases. Physician encounters, a prescribing screen that results in their ordering a tenfold overdose of a drug and a life threatening adverse event for a patient. When they asked others in the group that had the same issue previously, they tried to share the story and post the offending screen shot, which has some serious human factors issues. The vendor involved then threatens to sue them for, for disclosing the IP involved in the screen.

The next one, from IP, *[Laughter]* the provider writes an order on the incorrect patient because they're going too fast. This happens all the time. They want to report the issue, but they don't know who to send it to. There are some strategies that have emerged that can decrease the frequency of this problem, but they aren't yet widely implemented.

And third one, provider orders a large dose of intravenous potassium, which would potentially be lethal. No warning is issued by the underlying clinical decisions support system. That last one is, is, is something that happened at our, at our institution. We actually had a patient die—not directly because of that particular issue, but it's the sort of thing that we should just not have happening, and, and there's some simple things in our health care system that we could put in place that would decrease the likelihood of those sorts of issues. Farzad?

Farzad Mostashari – Office of the National Coordinator – National Coordinator for Health IT

I just want to reflect a little bit on something new that I'm hearing today. Oftentimes, innovation versus regulation and safety are posed as a tension and the issue of interfaces, you know, just yesterday's discussion about master/slave and how that's no longer really the right construct, and that in fact, many of the modern systems call each other and there's a lot of more cross talk and modularity between different systems that do certain things and work together. And the classic regulatory approach would—might be to say, "Oh, you have to bring in things together as an integrated proof that they work well together." And if you want to use these three products together or these end products together, every combination of them needs to be integration tested and brought in right—and that gets you into the classic, you know, safety versus innovation trade off.

But what I'm hearing today is that the development of using regulatory or other means to encourage the development of predictable, safe APIs between different modules and the testing of those could result in both dramatic improvements in safety, but also dramatic improvements in innovation. And that's something new that I heard in the past two days. Thank you.

David Bates – Brigham and Women's Hospital

Thank you. Meghan?

Meghan Dierks – Beth Israel Deaconess Medical Center

Just help me with clarification—are you seeking exemplars where we think regulation might be inhibition innovation, or—

David Bates – Brigham and Women's Hospital

A lot of people have given examples like that. We're also interested in, in exemplars in which, in which the safety issue has emerged, but the current market approach is not effectively dealing with it.

Meghan Dierks – Beth Israel Deaconess Medical Center

Okay, so three quick examples. I just want to start by saying, it's my opinion, just my single opinion, that people hide behind the concept or the fear of regulation, and that the reality is, in the U.S. uniquely, that if there is a market demand, people will innovate to address that demand and they'll overcome even the most perceived, complex regulatory framework. That's my opinion, but *[Laughter]*—so there are other reasons for why we may not be seeing innovation.

But there specific examples where you could make a case that the perceptions about regulatory restrictions are inhibiting innovation. One is, for health IT and the potential for closed loop sort of decision support where, you know, you could parameterize a clinical phenomenon and the one system reacts to a value and automatically orders an adjustment in therapy. I think there is potentially great value in that where it could perform better, or in a more timely way than the humans in the loop, but I do know that, traditionally, anything that looks like a closed loop faces a very strong set of restrictions or, or potential regulations. So I think that's one area where there might be some inhibition of innovation.

The second is that, when it comes to visualizing things, like visualizing images, appropriately so, the FDA has very clear requirements about resolution and grayscale for when one wants to look at something and make a diagnosis, but the reality is that secondary visualization by secondary sets of providers can be incredibly important and valuable, and we don't necessarily need that level of resolution, but I think the ability to innovate and view things secondarily on mobile devices that don't meet the diagnostic criteria might be inhibiting innovation a little bit.

And then I think the third exemplar is that I think we're kind of stuck a little bit with the traditional framework of regulation, and health IT is—I mentioned this in the subgroup yesterday that the real value requires the ability to configure something so there really, health IT, uniquely, doesn't have that model where you can design and manufacture something and know that the model is going to be the same. So it becomes just fundamentally hard to assess the risk and sort of declare something where it is on a spectrum, because health IT, you can make a base product, but it is almost always going to require a lot of variability for each individual user. So what you end up with is a product that comes off the line, but for 2000 users, you have really 2000 different products. And I think, since the, that's where the current model of how you actually regulate a product falls short for health IT uniquely.

David Bates – Brigham and Women's Hospital

Okay. Patty?

Patty

This is Patty. I'm not surprised that in the taxonomy case, they're thinking a lot about exemplars, so I'm going to give you one that developed during our Project Health Design Investigations. Some of this is a true story; some of it is embellished for point.

So picture John Smith, who's a 47-year-old man who lives in Richmond. He has asthma. He's kind of depressed about his asthma, but he doesn't seem to be getting any better and he feels bad. He's cared for at the Nelson Family Clinic by Steve Rothemich, who is one of our investigators. He's been in the clinic four times in three weeks. Each time he seems fine, but he continues to say he can't breathe, he can't breathe.

Because Steve knows about decalthingzone, he thinks he can help John. If he knew John's data experience, he would like to know things like his peak flow measures in the moment, the date and time he uses each rescue inhaler, where he is when he uses it, the humidity and particulate count of that neighborhood. He might like to see this every day so he can take action in the moment.

He sets up a nurse triage dashboard, which is Sunbilt in Excel, that could receive HL7 messages from the HIE if these data were available, and from the weather reports. He also knows that there's a device made by Asthmapolis, which is a Madison company, that attaches to the end of the rescue inhaler that can capture some of this data in the moment for the patient, records it and sends it by Bluetooth to the cell phone every night so that at midnight, the cell phone can call the HIE and upload the data, and then push the information to the nurse triage dashboard.

The nurse, at the time, is operating on a protocol set up in the clinic to decide whether or not Steve should come in right away, needs to make an adjustment to his medication, or just should be called and said, "You're doing fine; keep going." And also, then, this information needs to go into the electronic health record.

This story is partially true. The names have been changed, and some of the problems are now, I'm going to identify, specifically related to regulation. There are also, as you can imagine, problems related to clinical practice and work flow.

So the first thing is, this scenario actually never could happen because, at the time this, the team was ready to start, Asthmapolis did not have permission to use the device for investigation, so it could not be, actually, put in place, and we needed to record cell phone—sorry, we needed to record locations based on cell phone text updated notations made by the patient when they stopped, took the rescue inhaler, pulled out the cell phone, pulled up the text file and put their information in.

Secondly, most but not all rescue inhalers are the same shape, so the device being made by Asthmapolis, which will capture things like location from GPS signals as well as the dosage definitely fit on all the inhaler devices—most of them, it does fit in.

Cell phones, Bluetooth interaction protocols can vary. The cell phone protocols themselves are not tractable by a typical person. It's difficult to know exactly how to make the cell phone call the HIE. In terms of storage, the HIE is generally lacking. There's no standards, and, and most HIEs don't allow patients to directly upload data anyway into the HIE; particularly directly from a device.

The dashboard is investigational. The Sun is a very good programmer, but it keeps getting changed, because he keeps finding new ways to make graphs and so it's not clear how often that would need to be updated and reviewed.

And finally and most importantly, the protocols that the clinic Steve—the group is operating on may call into action some other devices; for example, the peak flow assessment or a nebulizer and therefore add to this chain of care in an additional device.

So the challenges that I'm bring forward here are three parts. First of all, we have the moment by moment device needs. Each device needs to have a slightly different set of regulations. Secondly, we have the information flow, safety, secure, and an innovative approach to care that could be actually quite valuable, save a visit to the clinic, make the patient's life function better that can't happen now because it's not clear who's in charge of making all of this fit together. And third and most importantly is, we have the possibility of innovation in the moment that was brought up a couple of times, coming into challenge or to conflict with the need for tractable, stable, and well validated patient information flowing through.

I see the opportunities; I also see the challenges, and I think that as we look at our taxonomy of what kind of information tools need to be considered. We need to remember that there's a range of tools, some of them, as Jarrin pointed out, that were never intended to be part of the health system infrastructure like a cell phone, but seems to have become a critical part. Thank you.

David Bates – Brigham and Women's Hospital

Jon?

Jonathan Potter – Application Developers Alliance

Thank you very much, David. I was encouraged with the discussions yesterday, and especially in the regulatory group, in looking at, you know, duplication and ambiguity especially. I think, in terms of what I'm interested in and when I stand back and look at this, it's really the coupling, and we've said this a few times this morning, between a light but appropriate touch regulatory process at the front end, and then a robust, transparent, non-punitive, hopefully highly automated surveillance or monitoring process at the end, as Paul said, so we can actually learn and identify harms that, in resulting—can result in the usage of these technologies.

To that end, in working in this space, communication is one of the most important parts of this, and being able to clearly identify what are the hazards and what are the potential harms associated with any given technology, and what are the controls, for example, that might be built in that need to be managed when that technology is actually used, and to capture that quickly, consistently up front, and then communicate it to those who are responsible at the back end for the usage and utilization of that technology. And so I hope the process we come up with not only looks at the right touch of the regulatory process for these different systems at the front end and also looks at an appropriate surveillance mechanism at the back end, but also focuses in on how you identify those hazards, the potential harms and how you communicate that consistently through the ecosystem.

To that end, I have two use cases. One is really focused on distributed alarm systems. These are—both these use cases are looking at convergent network technologies, where you have some mix of regulated and non-regulated technology. In the distributed alarm system, obviously, you have a medical device that has some sort of an alarm or an alert that it can generate as the result of a risk management process, but then that typically go to a clinician by using some set of regulated and non-regulated technologies. And as a result of that ambiguity, you find clinicians that have, you know, an array of communication devices on them simply because they are not sure, with the regulatory process, how that should be handled. And the decision was made—and we hate to do this, but yes, you have to carry this other device on you.

So being able to address the clarity in that space for these convergent networks for distributed alarm communication.

The other is medication administration, especially error reduction systems where you—again, you have a mix of regulated and non-regulated systems. This includes pharmacy systems, maybe CPOE. It might include a BCMA system for doing five rights checking at the point of care. It might actually end up in pushing to that device a, a validated infusion therapy protocol for that patient for that drug that's been five rights checked. But because of the, the mix of regulated and non-regulated systems here, there is a fair amount of inefficiency and duplication that gets interjected into the system and complexity that obviously has a direct negative impact on overall quality. So I think those are two that I'd like to make sure that we address.

David Bates – Brigham and Women's Hospital

Thank you. Esther?

Esther Dyson – EDventure

Okay. I'll be brief because, who knows, maybe what I'm about to say was said yesterday; I apologize for not being here.

I'd like to focus less on the avoidance of errors issues and more on the, the long term assessment of safety and risks. And I think it's, starting with things like using some kind of universal time stamp. I travel a lot, and if I have a device that recorded local time, it would provide very misleading data. Things like that, so time, location—I guess what I'm suggesting is that it's really important, as much as possible, to collect a lot of meta-data around each piece of data that's collected.

And we—yeah, this is great news for the industry, 'cause we, we're going to need more storage, we're going to need more analytics and so forth and so on. But what one finds out afterwards is that a lot of the data that didn't seem terribly useful when it was collected actually is tremendously important—not simply in understanding overall risk, but in understanding which kinds of patients or which environment or which time of day produces better or worse results in whatever it is, whether this is something that should be required by regulation or market forces or whatever. But I think it's really important to think here not simply about individual cases, but about detection of mass, persistent across whatever kind of data you're looking at, risks.

David Bates – Brigham and Women's Hospital

Thank you. Richard?

Rich Eaton – Medical Imaging and Technology Alliance

My observations are a little bit more general. I think a lot of the examples people have already cited, one of them is the interconnectedness of various systems and how information is transferred from one system to the other. What my biggest concern, I guess, is that this is such a dynamic and complex area—that's been said 100 times here—we have to be careful that we are approaching this in a dynamic, ever changing way. I don't want us to communicate a message which implies that all these experts sat in a room, here's how we think the regulatory framework should be devised, and that's the end of it. If we do that, then it'll become less and less relevant what all the work that everybody has put in.

So, it's going to be a constant, changing equation of, of balance between innovation and, and patient safety. There are a lot of ways to, to hurt innovation and to jeopardize patient safety, but this has to be a very dynamic process and I think that needs to be communicated from this, from this committee. Thank you.

David Bates – Brigham and Women's Hospital

Thanks. Lauren?

Lauren Fifield – Practice Fusion

Lauren Fifield. I think—I think, for my comment, I'll sort of issue a cautionary for the group and for myself. I think, in some ways, we are conflating solutions to problems with pieces of technology. So we're saying that an EHR should be able to solve e-prescribing errors, electronic prescribing errors—and that's actually not the case. It should be that we're defining what the problems are, so there are errors of prescribing in medicine, and then let industry devise ways to solve those problems. If we try to throw health IT or technology through first, if we sort of define everything from technology, we're going to keep ending up in these wormholes where we have a million use cases and we can't seem to think about the system and the workflows.

So I think we might be best served by going to the actual problems in medicine, where technology is implicated. So where patient safety or whether it's privacy or their wellness, their health, where there are the highest rates of errors and then look at how technology may have an impact on that. And so if it's time stamping, then maybe set standards, look at how training, how physician education, provider education, workflows may have an impact on that. And then let the private sector do the fun part, which is to say, "Okay, maybe EHRs create X amount of errors now—how about I create a mobile app that can sort of help facilitate this" and so that innovation can be part of improving health, reducing errors.

So I think we might be best served at looking at the actual parts of medicine, the workflows where there are errors, and then addressing, again, the role of health IT in this. Because I think we could spend 20 years identifying all the different types of health IT, and that'll always change, I hope, but the actual sort of delivery of medicine is sort of always going to be at the root of all of this. So I really encourage us to go back to that, because that's, I think, how we're going to be able to get to real solutions.

David Bates – Brigham and Women's Hospital

Thank you. Mike?

Mike

Thank you. I'm thinking back to yesterday where the risk assessment team began by considering that intended use might be the most important aspect or factor that has to be considered. And I also heard yesterday that, for the most part, many of the regulatory decisions should be made by being technology agnostic.

My example, then, is two things that are happening today. Diabetes management, insulin dosage calculators—if the manufacturer of a blood glucose meter was to decide to embed an insulin dosage calculator within their glucose meter, from the risk assessment point of view, the health authority has guided the manufacturer into deciding that over the counter device should become a prescription device. And it becomes a prescription device because it is impossible for the manufacturer to provide adequate instructions for use, specifically because each patient has their own unique insulin sensitivity and carb ratio, and needs to be taught how to count carbs, and it would be very difficult if not impossible for a manufacturer to provide that type of service.

This regulatory decision means the manufacturer that made it will be subject to the FDA general controls. This is design control, investigating complaints, and reporting adverse events and malfunctions. They'll also submit a 510(k) for review before they commercialize a device, and while commercializing, each and every individual who receives access to the product does so through the prescription of a licensed health care practitioner.

What else is happening today? An app developer can put almost the exact same insulin dosing calculator on the market today without any of those regulatory controls—no design control, no complaint investigation, no adverse event reporting, no 510(k) premarket notification, and maybe most importantly, no prescription control. If we're looking towards establishing a level playing field, it really shouldn't matter whether the, the software is embedded within a medical device or is available as stand-alone software. The risk assessment should be made for the concept and applied regardless of the technology employed. Thank you.

David Bates – Brigham and Women's Hospital

Thank you. Elizabeth?

Elizabeth George – Philips Healthcare

This is Elizabeth George. First, thank you, Mike, because you teed up a lot of what I was going to say, but I'm going to give a little bit of a different example.

A number of people have talked about that the FDA doesn't allow innovation and creativity—well, I can say that they definitely have partnered with my company to help us be able to do that. Many years ago, we had a central station that was proprietary hardware, proprietary software. Very costly, because we had to do everything ourselves—we did our own print circ reports, we did everything. Today, we now have an off the shelf computer. We use an off the shelf operating system, and we have our own software. It is very interoperable with a number of medical devices, and it does have a 510(k).

But the concern that I have, similar to what Mike has mentioned, is—is that many of the parameters that are being measured and collected and the data analyzed and the interoperability that we have with our medical device that we had to go through the 510(k) and every time we make a change, you know, it's, it's 4000 plus for a 510(k), our site is registered. We have a, a quality system in place, we have a complaint handling that we monitor. Those same parameters are being measured using a mobile medical app, and those manufacturers are not regulated and don't have those burdens.

So my expectation is not necessarily to overburden somebody who wants to be innovative on an app or remove burdens from us, but give us a, a level playing field so people understand what the requirements are so that when they make a decision to target a particular area that they do have the right controls and requirements. So thanks again, Mike, for doing all the preamble. That wasn't even prepared.

T. Drew Hickerson – Happtique

Drew Hickerson. So I just want to echo a lot of the comments and, from everyone else on the panel, particularly Mr. Jarrin. In the mobile health space, you know, it's growing exponentially, and I think clarity is really needed from the market—not only from hospitals, from providers, patients, investors alike, and a lot of this waiting period, waiting from the FDA to come out with final guidance on mobile medical applications, waiting on clarity in terms of how are we going to define and who's going to regulate CDS software has yet to really unfold, and, and people are waiting. It's really, you know, whether or not you want to say it's stifling invasion, that's another thing. But I think, to echo what Mr. Quinn said yesterday, you know, innovation is always going to outpace regulation. And I think we need to be mindful of that when it comes to HIT, which is why I'm glad that the taxonomy group really didn't come up with a finite list of technologies that we want to regulate.

I think the reality is, you know, we're going to see technologies unfold down the road that take on all new sorts of forms. It's going to be an amoeba, so to speak, and I think we need to be nimble when it comes to regulation and how we're going to advise the committee. That said, you know, one example I'll give you is, you have a lot of applications that are being developed in new, you know, sorts of code, new sorts of formats. You have HTML5 applications where it, there's no clear demarcation in terms of version, you know, when technology is being modified, when it's being, you know, tweaked, when a bug is being fixed, and I think we need sort of a, a, a lenient system that is amenable to that type of development environment. And it's currently yet to be seen, but the market is really yearning for it, and the reality is, we have a lot of highly talented developers, but they're just unsophisticated and uneducated in this marketplace and I think, you know, clarity and, and guidance would be much appreciated. Thank you.

David Bates – Brigham and Women's Hospital

Thank you, and the, our federal colleagues, I welcome you to make a comment or not, but—Jody?

Jody Daniels

Sure. Jody Daniels. A couple of thoughts. So, as a regulator, *[Laughter]* I'm listening carefully to the conversations about regulations guidance, the need for guidance and clarity, and just had a couple of thoughts over the past 24 hours. One, I—I think I've said this before, but I, I want to just repeat it, which is that we have to make sure we're thinking really broadly when we're talking about a regulatory framework. I—you know, when we talk about what's in and what's out with the taxonomy group, people jumped immediately to premarket approvals, and that is one tool in the tool box.

There are many other tools in the tool box that FDA has, including, like, the QMPs and surveillance, post market surveillance, et cetera, and, and they have exercised a lot of, enforced their discretion in implementing their authorities, but also that we're not limited to FDA regulation. So there are creative things we can be thinking about with, in talking to our FCC colleagues, a couple of folks have mentioned this, you know, about making sure that products are meeting the claims that they're making and not being misleading to consumers as a lighter weight kind of approach, but also some of ONC's authorities. We've really taken a more market based approach by setting standards and certification criteria for products. We have really been just focused on the EHR side of things, but we have said in our rules that we have authority to expand our certification program to other types of health IT, so that's something that could be considered.

And we may want to think about what kind of capabilities to build into the technology that can help support risk management or, you know, safety management, not just the functionalities, you know, what, what does the product do. So I heard people talking about, you know, black box capabilities so that we can figure out, if there is an event, what happened so that we can fix it, or time stamps, I heard folks talking about. Another thing that I was discussing with some folks was whether that we can also make sure that the, the technology is designed so that it can be easily maintained and fixed so that, if there is a problem, you don't have to shut down an entire EHR, but you can shut down that little CDS functionality that's not working, fix it while the rest of the system is working, and then move on, you know, we were—that there may be some creative things we can do so that if a risk is realized, we can address it on the ground in real time rather than trying to prevent every risk from, from seeing the light of day.

So, thinking about how we can leverage our certification capabilities to support some of those kinds of things. We heard about standards for interoperability of health IT devices. I think that's an interesting area that would fall within ONC's authority and, you know, and, and thinking about how we can establish a regulatory framework that supports transparency in order to allow folks to determine their own risk tolerance, so we're not going to stop all risks. I was really taken by a lot of the comments, I think Lauren made, but others repeated it, that innovation—that risk is inherent in innovation and failure is inherent in innovation, and so, and health care can be risky. Health care delivery is risky, and how can we maybe be more transparent so people can make those choices as opposed to us regulating the risk, regulating the transparency of information.

So a couple of please. One, people always say that they want clarity, but we hear that all the time, but then we provide clarity and people tell us that we're being too rigid. *[Laughter]* They're two sides of the same coin. If we give clarity, somebody doesn't like what we say, so it'd be really, let us—you know, be really specific on where the clarity is needed and where it's not so that we don't over-clarify. *[Laughter]* It is a tough line to draw when you're sitting on this side of the fence and we want to make sure that we're doing it right, but please be more specific in that regard.

And I also want to make the plea that David has been making about specific use cases. If we're, if we're going to be going back and making, trying to design the—a framework, a draft framework, understanding what some of the use cases are so that we make sure that it works in a variety of different scenarios I think would be really helpful. We're having a lot of conversations and we get into generalities, and I think some of the specificity can help us to make sure we get it right. And I think that's—I think that's about it. I'll leave it there. Thanks.

David Bates – Brigham and Women's Hospital

Thanks. Bakul?

Bakul Patel – Food and Drug Administration

So it's probably worth repeating some of the points that Jody made, and I made this in my—this is the corporate health fairy. I made this in the risk group that I sat in yesterday, and I was, and I was telling folks to think about how you convey information to us as regulators, as we keep, as we prepare to make this framework, or we prepare to propose the framework—tell us what's important to you and to the customer.

I was talking this morning with some folks and I think I used the word marketing department or customer requirements. That's another way of looking at it. If you guys can all put together what the customer wants, and in this case customers are you and the community, the users, the providers, and patients at the end of the day. And if any of you are creating—the product we are going to create is that framework, so what's the requirement for that? And I think to think about it that way, to some extent, would be useful. So, to Jody's point, specificity is important. Don't jump to conclusions, I would say very strongly of how that is going to be, but it's going to be really important for us to know and highlight that this, the key I kept hearing the thing about learning system—it's great in concept.

I would like a little bit more specificity of what that means. It would be very helpful. What part of learning system you want to create, and I just was listening and I was thinking on my own about ideas of what, how I would go down to one level down and saying the user knowing before an action has taken place would be a part of a learning system. A regulatory learning system would be users and providers who are using technology can know. After they have made it, taken an action, either it's a good action or a bad action, it's a feedback mechanism. That would be useful.

And, in the regulatory process, I think I heard somebody said the regulatory system needs to have feedback to say what's working or not working. I heard somebody mention yesterday that, "Let's take a dry line in the sand, see how the things work and"—and that's how I think about learning systems—"and, and sort of just having a way a way to ratchet things up." We should also think about, are there levers, or are there signals that we could ratchet things down as well when technologies do work and the rest changes. So think—think about, from that perspective.

I do have, actually, one thing for folks to think about as an exemplar, as David asked is, and I was talking to folks this morning about is—one of the things I didn't hear a lot out in the open, people discuss this, after everything is in place and technology is in place, when problems arise, one of the things I've seen in our industry is still struggled on is, who, in an interconnected system where 15 members get their product integrated in one point, had a problem arise identifying who should be fixing, identifying the root cause, getting to the solution quickly. To me, it's really important for us in health care and not spend a lot of time determining which product or whose product actually caused that issue.

So I hadn't heard a lot, but I want to throw that out on the table for people to think about as an option to, to either, from a risk perspective, innovation perspective, to have—it could not necessarily be controlled, but also think about what could be in the technology that will help enable sort of the identification of where the problems arise, so I will stop at that.

David Bates – Brigham and Women’s Hospital

Thanks. Matt?

Matt Quinn – Federal Trade Commission

Matt Quinn. A couple of thoughts and—really good discussion as we went around here. The first is, while it’s important to ensure the diffuse parts of everything that we’re talking about, each piece of health IT, for example, are safe, well made, smartly implemented and used. The way to attach the taxonomy of what we’re talking about, health IT to risk in the real world is at the system level.

And so, to use the analogy of the, the Dreamliner or an airplane, it’s important to assure that the tires of the jet are manufactured properly and maintained so that they don’t blow out when you land. Whether you get from A to B safely depends on lots of things—the plane and all of its systems and components, the training of the pilot, the ground crew and that they’re working in conjunction with the other planes in the airport, and myriad other things. And so really, it’s looking at the system, and there are endless permutations and combinations of situations that could arise in health IT or in airplanes, and so having that—having the unit of analysis be realistic and to understand risk isn’t looking, isn’t looking at the whole thing, but looking at the systems.

Now, what we saw with the Dreamliner, I think it was a, a wire or something that ended up being the thing that grounded it, and maybe, you know, through understanding that, then that gains additional scrutiny, and that’s something that we maybe focus on more intently, but trying to do everything is impossible.

The second point is that we need to really think about the users, and I think Geoff Clapp brought this up several times yesterday—we’re talking about everything from consumer products all the way to professional use stuff. And in the risk group yesterday, we talked about MyTomTom, which is a navigation system. Before I can drive, I need to click through a couple of things that say, “First, these directions may or may not be 100 percent accurate, so open your eyes and don’t drive off a cliff; and (B) that not to use this thing while you’re driving.” I bet that there’s a similar thing in the cockpit of the Dreamliner that doesn’t have those requirements, but at the same time has other requirements that are around its proper manufacturing, its safe use, and there’s probably training around that.

And so, you know, we’re thinking about an array of things and what’s use—and oh, by the way, it was some months before I paid the \$30 and upgraded MyTomTom so that it wouldn’t tell me that I’m driving through the woods on the ICC. And so that’s part of the Intercounty Connector, which is a road that wasn’t on there. So that’s going to be inherent in consumer products and I hope not in professional ones.

And third, you know, to echo this idea of transparency, it’s important that we build the data collection system to monitor this initially in going forward. And we can start with evidence and Dr. Bates brought up, you know, I think three big ones around human factors issue, patient ID and matching and then interface issues, you know, that we know are at the heart of some of the risk. But really, to expand from there and to put that system in place so that we know what is—what’s happening out there. That doesn’t exist today, and that lack of intelligence makes it very difficult to, to think through this—so thank you.

David Bates – Brigham and Women’s Hospital

Thanks. The one other thing that the airlines do that we don’t necessarily do is, when there’s a crash, someone comes in and investigates. Steve?

Steve Posnack – Office of the National Coordinator

Thanks. I’ll try to keep this brief. Steve Posnack. So again, like Jody, I think I’ve been working with her too long, because I have the same thoughts.

So it sounds to me like this is a lot of—at least what I’ve been listening to kind of wants and needs, specificity, both from our perspective in terms of what we can deliver to you and then what you need from us. And so when I think about the output, I think about what you need to succeed, and so in terms of what you guys produce for us, hearing about what you need to succeed is, at least, important to me; I’ll speak personally. And then I also think what you need from us to fail is through innovation, as we’ve been saying, that what you need from us to fail, but fail safely, is another important point that I’ve kind of been reflecting on.

And so I think about that more along the lines of from, like, a regulatory structure perspective. So I'm, again, at kind of the tactical level, since I've been knee deep or neck deep writing some of the, the regs that we work on, is you need a regulatory structure that I would call kind of a quote-unquote "failure playground." Maybe we could create that, and we could say, "Here are the parameters of your failure playground and go ahead and go play on the swings, go down the slide. If you hurt yourself, you know, that's okay. If you hurt other people, maybe we have some parameters around those things. There are some rules on the playground, you know, when you play, to play safely, but overall, you can innovate, you can fail."

I, I've been toying with an analogy to the drugs world, and this may not be a very good analogy at all, but pharmaceutical companies produce drugs all the time, lots of them fail, many of them never make it to the market. So how does that work, relative to software, and are there analogies there? So those are just a couple points that I wanted to bring up in terms of the, the regulatory structures and some of the, the wants and needs that, that users may to help us think about other ways to help you both succeed and, and fail, but in a safe way.

David Bates – Brigham and Women's Hospital

Okay. Mike?

Michael Swiernik – MobileHealthRx, Inc.

I have no comments. I defer my ... [Laughter].

David Bates – Brigham and Women's Hospital

That's fine. And are we, are we going to be ready, do you think? Okay. Okay, so next, what we wanted to do is, is go through the, the, the Innovations presentation which we wanted to get to yesterday but did not get to yesterday. Clearly there's a lot of interest in that from this group that just came up when we went around the table, and we're in the process of loading the slides right now. Do we know if they'll be up soon, or—?

M

Take a five minute break?

F

I think you're getting a break.

David Bates – Brigham and Women's Hospital

How about a—half the room left. [Laughter] They'll take that as a 10 minute break. We'll have a five minute break and [Cross talk].

[Break]

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

If everyone can please take their seats, we'll reconvene.

David Bates – Brigham and Women's Hospital

Everyone for—

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

David, hold on one second—operator, can you make sure the lines are still open? Okay, David, I'll turn the agenda back to you, thanks.

David Bates – Brigham and Women's Hospital

So thank you again, MacKenzie. Thanks to everyone for their thoughts and comments. I think it was really valuable to go around and, and get an array of perspectives and use cases. And we are starting again, so please stop your side conversations.

And we're going to hear next from, from Keith, who did not get—who did not get to the, to the Innovations presentation yesterday. Thank you. Wait, so we'll, you have about 10—10, 15 minutes, and then we'll discuss it for 15 or 20. We'll spend about a half an hour on this.

Keith Larsen – Intermountain Health Care

Okay. Again, to identify myself, Keith Larsen from Intermountain Health Care. My background, again, is, is that we do our own development, we do a lot of integration of products and I also worked with a vendor for a while when we were rolling out software to other people. And so, because of that background, you probably can expect that the, the, the primary thing I'm here to say is—everything's innovation. Don't mess with innovation.

And so I want to attenuate that, that discussion a little bit, because, on the other hand, just as Ann has reminded us a couple times is that we're all consumers of this software. It's, we have a personal interest in making sure that this software is—works, because our family members are subject to our software. Ourselves, as I get older, I know I'm going to be more and more a consumer of this software, and I want to make sure it's right, okay?

So if we look at innovation in, in particular, I put this slide up before and, and we're—but I just wanted to re-emphasize, is that there's a lot of different levels of innovation. There's the develop the software, there's the set up and customization that we talked about. There's the integration with, with medical processes. There's the communication devices and then there's, there's how we combined software in these tools in a, in a hospital.

And so as we talk about innovation, and, and we've talked about this a lot, we have a vested interest in promoting innovation. If anything, I, I can see that, that what we're, where we're going with ONC certification assistance, we're describing systems that have the capacity to modify health, to act as a participant in, in providing health, with the expectation that we're going to give tools to hospitals and clinics where they can modify their processes and make them better.

And so, if anything, there's an expectation inherent in that software that innovation take place at all levels, not just at the manufacturing of the software, but in the use of the software, and how it's adapted into treating patients. And so, if anything, we're trying to promote innovation.

We also believe that—I mean, why we're even embarking on, on promoting, through ARRA, infrastructure change and our hospital use of software is that we believe that, that the use of this software is ultimately beneficial to patients, it's beneficial to, to the providers who have to do diagnosis and, and treatment, as we've heard a couple times during these, these talks.

And so the idea is that we really are trying to build something that promotes innovation. At the same time, we have the issue, like we said, that we're all consumers of it, and we want to know that we have a, we have safe systems, that they meet minimums. And so that's what we're trying to balance here, but in the end, the, the measure of the safety or the responsibility for the safety really comes down to the hospital to put together the unique combination of pieces that they take responsibility for because they've purchased them. They decided to put the unique combination together to configure the system, and so they have to know that the products that they consume are safe and have gone through a method of creation and testing that's safe for, for them to use. But then they have to ultimately be able to look at that software and be able to, the combination of the software and devices and know that their combination is safe. So different levels of innovation and, again, different levels of risk and accountability for that risk.

Okay. We were struggling a little bit in our, in our meeting, just like everyone else is, I think, is to, to define what is our final work product. Because, again, we're not writing regulations, we're, we're trying to do things and Bakul attended our, our work session and really came down to just what I think he said today is, is, "Give us—we all, we describe a system of creating product, in this case, the information system, that's based on collecting good requirements, good customer requirements, and being able to vet those requirements and then producing a product." And so we look at regulation as, as being the same thing, as "What are our needs?"

So, as we talked about those needs, we also talked about, and Mike referred to this from our session, is that we really looked at this thing because our cholesterol was not to reproduce what's already been produced. The FDA and other regulation bodies have the authority to regulate. I mean, when we've looked at those definitions, they're very broad. They, they use discretion on what they choose to regulate and, and so—and they have some criteria to decide where they apply that regulation, and with class 1, class 2, class 3, different other ways that they try to assess risk of different products.

So they already have those things, so what do we contribute? And one of the things was, you know, how can we think outside the box? And so this was an approach that we, we threw out in our work group and I'll report back on it, and that is that our standard approach, which I've listed there, is that we usually try to assess risk and then, with that risk, what we do is, we try to apply regulatory levers, and there's, there's varying amounts of interventions that can be done, there's not just a single type of intervention that, that we've all been reminded. And then we try to mitigate the harm to innovation, so we kind of go in that sequence.

What we were promoting, or what we've talked about, and started to develop in the meetings, was the idea that you reverse that, that what you're trying to do is promote innovation. You're trying to promote creativity in this space, because we're all dissatisfied with the cost of medicine, we're all dissatisfied with the care medicine, we're all dissatisfied with the whole process. And what we're trying to do, as we wrestle with these things, we have to promote creativity, and we have to be able to apply that creativity in a very timely manner.

And because it is a very creative process, we have to be able to tolerate some failures. Again, we have to be able to say that, that—I mean, I come from a ski area. We always say, “If you're not falling down, you're not really doing anything,” right? That, that what you have to do is, you have to push yourself and be able to, to learn new things. And right now, we don't have it all learned, it's, it's—we can't canonize what we have right now and say that that's what it is. And so the idea is really to, instead of looking at how do we prevent harm to innovation, it's how do we promote innovation? And then how do, when, while we're promoting the innovation, how do we address the issues of patient risk? Because, again, even though we say that we may have failures on the direction that we go with policy, with software, whatever, what we don't want to do is, is create undue harm to our, our patients.

As we talk about that again, the risks, although we can imagine a lot of different risks—you know, there are some basic risks that we can get. And, as we talked about in our innovation team earlier, or the earlier slides, using the paradigm of medicine of do no harm and then promoting wellness and care is that the do not harm deal in medicine comes down to very basic things, and likewise in software. You know, do we have the right patient? Do I have the data that belongs to this patient, and have I done anything to the data that would make it unusable or, or to promote a human decision? Because ultimately we're talking about, most of this is human decision, they're not closed looped systems—could I cause a, a wrong decision or a wrong perception?

And then, if I look at those two things, then—then look at regulation, about how do I address the risk and the innovation on an equal plane? What the idea did, that the status quo is not acceptable. What we're trying to do is do better on the status quo and so that would promote innovation.

So, going back to the idea of, “Well, what do we need? What do we need in order to support innovation?” And so these were some of the things that we came up in our group, which was the turnaround time—time to market, time to get things out and in use is an important principle. This idea that, that I'm going to do iterations, that I'm not going to have a perfect system—it should still be a safe system, but it may not be the perfect system in my iteration, and I'm going to, because I want to understand what the, the better system is by doing a system. And that I need to involve patients and physicians in the process and have informed risk.

I mean, we can do that on a hospital basis as you introduce decision support, you know, having tools to be able to contain that, to be able to understand it before it's in general use is, is an important principle, there. The idea of configurability is really promoted from what we're—in the desirable state of our, of our software, and it's described again in this idea that, and the certification process that we're going is the idea that, that I'm not provided just software, but I'm provided software tools that I can really customize and support my, my processes.

Standards and interoperability—we've talked a lot about interoperability which allows us to, again, make more complex systems out of parts, but the standards are really important for the whole idea of the innovation. Because if I can—if I can improve a part of an EHR without creating the whole EHR, then it lends itself to more creativity on those parts. But if I have to create a whole EHR in order to, to promote a single idea, then that really inhibits entry into the market and inhibits the creativity because I have to inherit too much stuff.

The final thing that's been talked about here many times is really the, the transparency. Transparency in medicine and transparency—transparency in medicine in general has not been very transparent. Transparency on HIT systems, we had a side conversation last night. You have the class group that, that probably gives, I mean, a small window of transparency into this just by doing consumer reports, essentially, on, on software that's out there. It's not very much, but everyone flocks to it, because we're, we're data starved. And so being able to have a transparency in, in this system is an important thing, and it's been really talked about.

As we look at, at this, too, and we talked about that the difference between a, a legal framework and a learning framework, very much when we talk about taxonomy in and out, when we even talk about which things should be considered, that's kind of a legal framework. And so the holy grail there is to try to be kind of like what Mike said—if you say HIE is out, I'll raise my hand and I'm in HIE, and then I, I don't inherit all that, that overhead of, of the regulation. But—but again, the idea is, is that the final consumer, that the patient in the hospital really needs to be assured that this is, that what I'm seeing and what I'm using has, has gone through some kind of process to, to do that. But in a legal framework, really again, is I can prevent then known risk, it can be very prescriptive. It tends to inhibit transparency because it's a legal framework, and the effort to mitigate—so then you really have to make an effort to mitigate innovation risk so it doesn't become too much.

It becomes more as we identify problems. It's interesting, because like the three problems that Julian presented yesterday, there was one that was a sampling rate from a device to the EHR, which the mitigation on that probably should not go all the way up to the FDA, in my opinion. I mean, that should go to the vendor, should say that, that because of your sampling rate, we're getting an inappropriate thing and, and vendors, we have to assume good intent. Vendors want their software to, to work in these areas. There's a lot of people that, that understand that they're consumers as well as producers of this software. The vendor should fix that.

The second issue on the time is an interesting one, because in that case, it could be solved locally, but a standard for time, because it's one of those things that crosses multiple vendors, may be more appropriate. Because, again, that unleashes some—actually helps innovation by defining some common platform to exchange and to, to standardize.

The third issue about opiates and depression—quite frankly, the tools, then, in the EHR should allow me to address that locally. You know, that I can, I can sense that data, I can set up my decision support, and I can do it. David's example of a potassium overdose or, again, I should have the tools in my EHR that I can address real problems in my facility and be able to implement those with low overhead and be able to go through a process of creating them with the tools, tested tools that I know that they do the right thing, and then be able to, to implement that.

So if you move from a legal framework to a learning framework, it's really predicated, again, no transparency, because a learning framework means that you have full exchange of data. Joe's talked about free exchange of data, patient data, and it improves care. Well, we believe that, and that's why we, we do these things. Likewise, the free exchange of data, of what we're seeing and experiencing that with our software is important—not as a punitive thing, but as a, as a, as a growing thing.

Again, this idea of the sampling rate, that should be something that really is known and should be considered by, by all the vendors, not just a single vendor, to make it more explicit. It does mean that you have acceptance of relative risk, and it is relative risk. Because, as we talked about status quo, my turnaround time to get the potassium alert is, is weighed against that I have patients out there that could have harm from monitoring; same thing with the opiates and the depression, respiratory depression. And then effort for those things that we know that cause harm, the processes that cause harm, not the category, we really should make sure that they're—they're errors, or that there's testing for that. I'll just—I guess that's the last slide.

Just one other thing is, then—okay, we did have this thing—is, again, the nature of the regulation intervention itself is important. And I tried to make this point with—that it's not just what the policy is, but it is the measurement. I mean, regulations can, can, can do a couple things—let me just pull up—so, I mean, regulations can give us the ability to know that the product that I received has gone through some kind of testing and that it, it does what it, it says it does. I think that's a reasonable thing for a regulation to do.

Regulation also does create markets. I mean ... because market forces don't always do that. Market forces, for instance, if you're a vendor, you're going to create things that, that you can market that people may not want in the medical community. What I mean by that is, if I take things like nurse care plans, med reconciliation, there is, there is good arguments for them, but to produce software for it when it became a, an accepted process and a standard of care, then the innovation happened to create good nurse care plans and good med reconciliation. So I think direction there, but that's not regulation necessarily on HIT systems directly.

And then the third thing that we talked about is solving problems that cut across vendors—the standards, the efforts to make interoperability possible cannot be done by any one individual, and so you really have to create standards for interchange of information. The time coordination issue may be another one of those issues.

Where I hesitate, and where I think that regulation does inhibit innovation, is when it's too prescriptive. You know, when there's a specific decision support module that is, is their specific care process that, that's there. Even if the intent was to just use it as a, a method of demonstration. I think certification—and this is now my personal opinion, not the opinion of the group—certification, because I have to have it reproducible and have to have it very clear, kind of going back to what Jody said, you want ONC to be clear, but then that, that translates into inflexible, okay? And that is a conundrum. So you want it clear and reproducible, but by writing certification criteria a specific way, it almost endorses a specific implementation, and so that you get away from the policy that had good intent to have a specific implementation of how—because you need to test it a certain way, and maybe that's a flexibility of the certification process.

Anyway, those were the thoughts, thoughts of both committees and that last one is just editorial comment from me. Okay, thank you, David.

David Bates – Brigham and Women's Hospital

Okay, so thank—thank you, Keith. Paul, any comments? Okay, so we can maybe spend about 10 minutes on this, and then there are few other things I want to do before we, before we wrap up. Any comments, or—? So let's see—Joe?

Joseph Smith – West Health

Yes, to pick up a, a point around the transparency and error reporting—so, you know, I spent time in the medical device regulated industry, and also on the practitioner. And on the practitioner side, we've got morbidity and mortality rounds where we make a point of publicly describing the failures that we have. It's, I think, part and parcel to the price you pay for having the kind of elevated posture of being able to practice medicine.

I think, in the regulated commercial industries, there's this notion of—there's, you know, there's enterprise value in the learning that you have and there's enterprise value in the intellectual property. And there's, you know, shareholder rights around that IP that can sometimes get in the way. This spot, I think, may be quite different, because this is an industry which is, has been largely accelerated if not even borne by government regulation and subsidy. And so it seems to me that part—that, while risk is the price we pay for innovation, when we subsidize that risk, maybe we, maybe we can ask for something back, and the public reporting of errors seems to be such a thing we might ask back.

Because, you know, unlike—unlike a drug or a device which is sometimes difficult to, to modify post creation, where those errors, the imperfections may be difficult to address. Here, it's a relatively fluid product being offered. And so, given, given that subsidy, given the notion that you have a relatively fluid product to deal with, it seems that that public reporting ought, ought to be a requirement. And, in fact, listening today—and I shared with Dave—the, the notion that, that we're using gag orders to keep people from sharing some of the observations around how these things could be and should be made better? That, that seems, perhaps, inappropriate in this and it's a bit offensive. And so maybe we can take that as a charge to additionally highlight the, the need for public reporting to, to improve the pace of innovation and get to a place that we'd all rather be.

David Bates – Brigham and Women's Hospital

Thank you. Mary Ann?

Mary Anne Leach – Children's Hospital Colorado

Yes, I would just like to—this is Mary Ann Leach. I would like to request that we consider ways to accelerate innovation. We—we're talking about making it safe and making it protected and allowing a tolerance for failure, but in the last few years, our meaningful use requirements have certainly spurred adoption. We have, we have a lot more adoption. We have a level playing field. We're getting close now to having an environment that would foster interoperability, but a lot of our development partners have been spending time on that and not on this next generation of population health, care coordination. You know, managing patients across the continuing, continuum—putting, pushing clinical decision support across the continuum of care.

So I guess I would just ask our group to consider ways we can accelerate innovation and foster and promote innovation in a safe and productive way. Thank you.

David Bates – Brigham and Women's Hospital

I—I would second. I've, I've written about that a, a little bit. I'm worried about whether we'll get enough innovation, because, because people are paying so much attention to, to meaningful use. Is that, is that, I can't tell who—is that Steve, or is it—it's Matt.

Matt Quinn – Federal Trade Commission

So to echo that a little bit, I, I think the important thing is to start with the end in mind here and to start with Farzad's comments this morning. The whole point of this, and perhaps it's a litmus to assess, you know, what this group develops and then what the, the three agencies write is to look at this in terms of public benefit and where we want to be with this.

The health of our country as a whole, widespread use of health IT aligned with new payment models—so accountable care organizations, coordinated care, patient centered care—is democratization of health information. So, you know, we have to assess, are we doing things and not necessarily regulations, that would impact negatively achieving that vision, and are we doing things that would accelerate achievement of that vision. And I would just add that lack of faith in demonstrated safety of health IT systems and their use is the quickest way to derail both. And so I think that that's a good way to assess whether we've accomplished our, our jobs here in the work group and, and the three agencies and our recommendation on this.

David Bates – Brigham and Women's Hospital

Thank you. Mike?

Michael Swiernik – MobileHealthRx, Inc.

Yeah, so my mother would probably say it's because I'm stubborn, but I think a lot if innovators would say—you guys asked, "What do you want from us?" I think we'd say, "Tell me what you want the result to be or maybe what you don't want it to be, but then other than that, don't bother me—like, I'll figure it out from there." And that, I think, is kind of an innovator's—I mean, that's kind of the benefit we provide is that we can, we can figure out creative ways to get to what the goal is.

And I, and I think there's probably—well, there's probably more, but in my mind, there's two types of innovation. There's kind of green field innovation where there's nothing there and we don't know what the best practice is, and for that I would say—I would put in things like user interfaces into that. There's, there's—there's some ideas about best practice, but one of the fundamentals of usability is that you don't really know until you test it. You build it, you try it, see if it works, and then iterate on it from there.

And then there's iterative innovation, which is—we talked a lot about this GFR calculator, probably too much yesterday in the meeting. But—and so in that case, you probably do want to, I think there's a role for regulation in those areas because we do know how to do math and calculate GFR and therefore it's not really ethical to just let people go crazy with that. But there might be a new way of doing that that's better. I can't think of one, but maybe there is and so we have to allow for people to iterate on known and then be able to play around in the—do the safe innovation that you talked about, Bakul, with the, with the unknown, the green field stuff.

David Bates – Brigham and Women's Hospital

Thank you. That's, that's helpful. Lauren?

Lauren Fifield – Practice Fusion

So—let's see. So in, in creating electronic health records the first time around, I think we digitized paper workflows, and it wasn't such a bad thing, but now I think we have a whole generation of providers that has started to use technology outside of health care. So whether it's Facebook or Gmail or in other parts of their lives—and I think doctors and other health care providers are now starting to see technology as a, as a way to make their workflows better to enhance their decision making, to make them better, faster, stronger, to make their lives easier. And so they're looking at technology in this completely different way and just now finally starting to ask for—to ask for things they want from technology and be real users of technology. And in the past, I think, a lot of the things that technology delivered was prescribed by system administrators or government or actors that weren't the users of technology, and I think that really created sort of a strange relationship, because in other industries, technologists and innovators respond to the needs and demands of users.

And, in health care, I don't necessarily think the users understood what they needed. Oftentimes, vendors will say, you know, even when they try to ask providers what they want from technology, they're not quite sure. And so, I think when it comes to innovation in health care, we've gotta try and help our providers be users of technology and help our providers understand what they want, what they need to be better, faster, stronger, smarter, at their jobs. Because otherwise we're never going to have the market ask for innovations in patient safety or innovations in workflow efficiency, what have you, which is how you actually get to innovation. It's—it's always this need, this, this desire of a user in getting to the best way, most creative way to do it.

So I guess I would maybe also say that we need providers in the room, more providers in the room or maybe even medical education leaders in the room to kind of help providers ask technology what they need and innovation, or to create innovation.

David Bates – Brigham and Women's Hospital

Thank you. I think providers are, are pretty unsatisfied with the current state of affairs. They, they want to see some iterative improvement. Todd?

Todd Cooper – Breakthrough Solutions Foundry, Inc.

Thank you, David. Again, yesterday, in the regulatory session, we discussed being clarity ambiguity as being one of the key barriers to innovation. Many, many vendors are, as Moh said yesterday, you know, venture firms are evaluating innovative technologies, look at it and say, “Well, is it regulated or not, and what’s the pathway?” And it, it just results in—that ambiguity results in quite a block. So the outcome of this, in terms of resolving that, will be a huge positive move in advancing innovation.

I think, on the other side, though, as we come up with this framework, drawing a line between hazards and potential harms and controls that might be deployed of creating tooling up front, especially for those who are not steeped in risk management and this kind of assessment to be able to facilitate it in their own language, especially innovators, so they can come and approach this and quickly understand, “Well, you know, what are the potential harms that could result from this? What are the hazards that I should be considering or not?” To do so in a, in a fairly straightforward way would be a great help as well. So my point is, consider a recommendation and develop tooling along these lines.

David Bates – Brigham and Women’s Hospital

Thank you. Anne?

Anna McCollister-Slipp – Galileo Analytics

I keep coming back to the sense that we’re, we’ve got this sense of—in my mind, there’s a sense of false dichotomy between innovation and safety. As a patient, again, I keep coming—saying this over and over again, I use, you know, type 1 diabetes, all the complications from that. I use 13 medications every day. I use four medical devices on my person, my body, 24/7. Innovation is the only hope. *[Laughter]* I mean—and that’s, that’s why I’m in this business, you know, starting in a career in journalism and then public affairs and now being a health IT innovator, quote-unquote.

That’s how I got into this business, is innovation is the only hope for people like me. It’s the way to improve safety. It’s the way to improve outcomes. It’s not the way to risk outcomes. Now, having said that, there are things that need to be overseen by FDA and ONC and other different government groups. I’m not saying that that’s not a critically, critically important role—but it’s not one versus the other. And I feel like—and I, and I give a lot of credit to Bakul yesterday in sort of stopping this when we were having our break out discussions and focusing so much on regulation, regulation, how are we going to regulate this. He said, “Just quit it, already. Focus on—focus your efforts elsewhere and let’s think about, how do we innovate. How do we—how to create, create a situation in which innovation can thrive, because we can’t pre-design it. How to create a situation in which government/regulatory innovation can thrive?” What exactly is that? I don’t know; I know FDA is investing a lot of resources these days into the whole notion of regulatory science, and that’s been a big push for Commissioner Hamburg.

I don’t—I feel like this group has the opportunity to sort of, you know, throw off the shackles of all of the jargon and what’s been discussed in all the trades, in all of the different trade groups, et cetera, et cetera, and think, sort of blue sky it. Say, “What do we need for this to happen, both from the government perspective as well as the industry perspective?” And that’s the opportunity here. I mean, we really have the opportunities for this blank slate. How do we want to craft this advice to the HIT Policy Group? You know, how do we want to, to advise ONC and FDA and FCC and HHS on, on creating his report to Congress? Because this is a huge opportunity that we’ve been given. We’re all investing all this time.

I don’t like that I—maybe it’s just my perception of it, but I feel like we’re, we’re—it’s, it’s one versus the other, or it’s a negative approach as opposed to, let’s blue sky it and say, “What can we do to promote it?”

David Bates – Brigham and Women’s Hospital

Could—could you tell a story about your pump that you related yesterday? Would you mind doing that?

Anna McCollister-Slipp – Galileo Analytics

Which one? *[Laughter]*

David Bates – Brigham and Women’s Hospital

The one—the one about, when it goes off, what happens in terms of reporting.

Anna McCollister-Slipp – Galileo Analytics

Oh, right, right. Well—gosh, there’s so many, and I’d love to talk about, you know, government as, as an opportunity for, for driving interoperability and standards along that, because I do feel like we’re missing an opportunity there, but I can have that offline discussion.

But one of the frustrations that I have as a patient who’s nerdy enough to be involved in these kinds of things is that—again, I have an insulin pump, I have a continuous glucose monitor. My insulin pump, if I have a—and I’ve had a number of pump failures. I no longer use one particular company’s model because I have so many, but there were a number of times where the pump failures would happen during the day and, because I was awake and I could see my blood sugar going up, I could do something about it. So I didn’t call my doctor, necessarily, but I called the manufacturer and said, you know, “This is what’s going on.” They FedEx’d me a new one the next day.

Well, if that would’ve happened at night, the exact same pump failure, the exact same thing happened at night when I was not awake, I could’ve had an extreme hypoglycemic episode and could’ve died. That happens more frequently than we like to talk about with, with diabetes. Insulin can be very fatal very quickly. Or it could’ve been an extreme high, and I could’ve gone into diabetic ketoacidosis and ended up in the ER. In that case, the exact same device failure would’ve been reported and would’ve been notified.

So part of my frustration—I think part of the opportunity we have in creating these kinds of, you know, in this group is how do we create either incentives or mechanisms by which we can access all of the data that goes into the manufacturer? Either through that of any downloads that happened through the cloud—because they’re collecting all this data about all sort of stuff that nobody has access to—or through the call center updates. And FDA, I’ve been told—I’m also on the steering committee for MDEpiNet, which is the device version of Sentinel—FDA, I’m told, does not have the statutory ability to access or require that data. I don’t really understand why that’s the case, but you know, I’ll claim ignorance there.

But I think that would be a very appropriate role for government to play. So in exchange for giving you the ability to market this device, let’s create a mechanism by which we can collect all of the data that you’re already collecting and make that transparent so that everybody can access it, everybody can understand it, and, you know, eventually I as a patient will be able to look at the various pump manufacturers and say, “This one has more failures, but had better human form factors, so I’m going to make that, I’m going to take that risk. This one has less failures, worse human form factors—I’m going to deal with the clunkiness and go for the safety,” so.

David Bates – Brigham and Women’s Hospital

Yeah. I mean, from my perspective—if, if there were some more transparency, everybody would be better off.

Anna McCollister-Slipp – Galileo Analytics

Absolutely, and I think that that’s one of the necessary—and I, and a lot of people in this room know a lot more about this than I do, but I feel like that’s one of the necessary conditions for innovation to really happen. It’s, you’ve gotta have that transparency. You’ve gotta have access to data, and it—it drives me crazy as a patient, and—and I think it should drive all of us crazy that every, every data download that anybody has, whether you’re with a hospital or an EHR vendor. And I do—I do health data analytics; that’s what my company does. I’m not criticizing this necessarily, but it drives me crazy that this data is all stored in silos and it’s not accessible, because at some point, along the way, every data point came from an individual who probably didn’t even know they were contributing it.

So I feel like there’s a, a responsibility on the part of everybody in this room to give that data back in one form or another to patients, whether that’s through donating it so that people who are experts in disease can come up with better outcomes measures or whether that’s through making it accessible so that more people can innovate and come up with better ways of problem solvings or putting it up on InnoCentive.com and letting people solve problems that maybe the manufacturer doesn’t perceive—whatever the case may be. But that I feel like is something government does have the capability to handle or to, to require or to set up a system for happening that just isn’t happening and it, it just drives me bonkers.

David Bates – Brigham and Women’s Hospital

Thank you. Mike? Mike Flis?

Mike Flis – Roche Diagnostics

Thank you. In addition to these regulatory solutions that we're considering, I'd like us to keep in mind certification process opportunities. I'm reminded that back in the 1890s, in response to electrical fire hazards, a private company, Underwriter Laboratory, was established and for over 100 years, they've been providing invaluable testing service and certification to companies.

What makes this appealing is, not only does it improve the overall safety, but it becomes almost a global approach, a market entry requirement not just to the United States but to many other countries, is the UL mark on your product. Wouldn't it be wonderful if, in the United States, we could come up with some type of interoperability or connectivity certification process that maybe isn't driven through a health authority, but rather through private entities. You know, several years ago, there was an organization that's called Continua Health Alliance that was formed with just this type of mission, establishing design guidelines, establishing a product certification testing program, and they're actually reaching the point of maturity, far enough along that health authorities in Europe are starting to rely upon their testing and allowing products to go to the market with this Continua certification mark on it.

Here in the United States, we haven't taken advantage of this particular organization yet, but it's something that perhaps this team could take a look at to say, "Rather than having one of our health authorities create a certification process which would be unique to the United States, perhaps not lead to global harmonization, and force companies that are trying to innovate software in the United States to only develop products for the United States. We'd like our innovators to have global penetration." Working with a certification company or an alliance might lead to that in, in a much faster manner.

David Bates – Brigham and Women’s Hospital

Joe, did you have another comment?

Joseph Smith – West Health

Just a—just a brief one, and I think it, I'm trying to loop back in with the making sure we accelerate innovation because it is actually the only hope we're going to get out for, for patients who are currently struggling but also for a health care cost crisis that's obviously unsustainable.

And, and it gets back to one of Brad's points early on about, you know, we've talked about relative risk, but where is the absolute line? What—you know, maybe, maybe we've talked about a lot of risks that are all to the left of the line and that, that we should think about a very light regulatory touch. And, and I think a point that Julian brought out about, you know, we have a systems of systems concern, and, and I think, while that's true, we all use a tool every day that has a systems of systems concern. It crashes about 5,000,000 times a year, 30,000 people die as a result, and there's a very light regulatory touch on the systems—it's the cars we drive in.

And so those have, you know—and, and I like a lot about the analogy, because it was actually interchangeable parts, this notion of interoperability that allowed it to be an American success story, but at the same time, we do recognize that there's a, a value in this that's worth that risk and we regulate that, those systems of systems quite minimally. We just advertise that there's a risk. And if you imagine, one of my favorite stalking horses here is, is cigarettes. You know, cigarettes are flammable drug delivery systems that deliver carcinogens to the lungs. They're regulated by the FDA, and the way we manage the risk is, we label on the side of it that this can kill you, and then we let people buy them in vending machines.

Participants

[Laughter]

Joseph Smith – West Health

So as we think about the regulatory burden that we're going to impose on this industry, which is the only hope for getting us out of problems we haven't addressed in health care, but costs we can't sustain, I would encourage us not to think about a heavy regulatory burden.

David Bates – Brigham and Women’s Hospital

Jonathan?

Jonathan Potter – Application Developers Alliance

Thank you. I’m struck by the challenge between clarity and ambiguity, and I don’t think that’s the challenge for innovators. I think the challenge for innovators is more about whether it’s a permission based system or a, a goals based system. And, thinking about what innovators want, if I go to see a doc or a provider group and I say, “What do you guys want?” and they tell me what they want, and then they say, “Go make this. Take—do this. This is our goal, this might be some interim goals—go do this.” That’s—that’s how innovation happens.

And so do we respond to demand, or do we create demand? There’s a real stress here, right? If you’re creating demand, especially if you’re trying to create a \$1,000,000,000 market demand—because in some companies, you have to hit \$1,000,000,000 of revenue to make a difference—and it’s different when we have to make hard products and it used to be that, of course, you made hard products and then they were fixed, right? You didn’t have updates every 60 days like you do in the software world. So we built a regulatory system around hard goods products that couldn’t be fixed. We allowed doctors to sort of bend the scalpel a certain way in the operating room, but we didn’t allow them to—but the, but the product was a big product.

Now we’re talking about small markets that suddenly explode, right? Whether it’s Facebook which started small on the Harvard campus and 180 days later, it’s a, it’s a, it’s a big market—and they’re still trying to figure out how to make money, but they, but they’ve got a big market and they’ve got big market adoption. But it started small, and it started because someone said, “I’m going to fix this problem.”

How do we create that energy? And I think we do that by—in, in some sense I’m going to say the clarity that the government can offer is to create space. And that’s why I go back to the, to the, to the what’s the practice of medicine, and if a doctor comes to me and says, “I want to do this,” I should be able to do it. I should be able to give the doctor the tool the doctor wants. If a nurse practitioner, if the head of nursing at a hospital says, “I think we can, we can do better care with, if you can build something that works with this, and these are the three machines it needs to interoperate with, these are the three systems—build this for me.” I should be able to build that. And, and, and that space will allow me to be innovative or allow my membership to be innovative, allow the, the health care practitioner to be innovative, and it’s not a \$1,000,000,000 market.

Now, at some point, going back to sort of the permission based system or the, or the goals based system, right, and back to the consumer protection analogy, the CPSC or the FCC—they don’t do a lot of heavy regulation. They watch the market, and they jump in when there’s a problem, and they, and they, and they either do notices of inquiry or maybe sometimes they… NITSA, right, or the FAA, or the NTSB—then they pick up the phone and they call people and they say, “Be here in Washington on Monday afternoon at 4:00 because we’ve got a big problem, or we sense we have a real problem.”

And that’s a, that’s a real challenge to balance what has traditionally been a—and this, and this isn’t meant pejoratively, right—has it been a prescriptive agency, I’m not sure, but it’s been a narrow agency where you need permission to go to the market as opposed to saying, “No, go create markets. Go do things and we’ll figure out along the way.” It’s really hard for the regulators to balance this, but I think it’s really easy, if you’re an innovator, to say, “I can’t ask permission every time I do something.” And if we think of I that way, doctors don’t ask permission when they want to do something different in the OR, they just do it. *[Laughter]* Then they say, “Wow, it works”—and sometimes it doesn’t. And, and, the, the—the last thing is to talk about, I think, I think there’s a huge issue on the data sharing. I think it’s enormous, it’s been based on the fact that we have a, a permission based regulatory system. It’s been based on, on risk management and fear.

And so I think we have to address that the lawyers—and I'm one—will resist, enormously the idea of data sharing, every step of the way, righteously, if they don't feel like there's a safe harbor, and there has to be an affirmative safe harbor, or an affirmative, private intra-industry group. You know, the airline industry shares instant reports, they share data, and sometimes they share it with NTSB or the FAA and sometimes they share it in this intra-industry group which has Boeing and, and Airbus or representatives of them, and they have confidentiality rules, and the airport guy is there and the tower guy is there. But we have to figure out safe places for people to share data about bad outcomes.

So the combination of not requiring permission and, and creating a clear space, right? So clarity in, if you do these things, if you work with these kinds of people—go forth and innovate to, to clarity around where there's a safe space for data sharing, I think will create opportunities for innovation and, and, and I think if that's the goal here, we can create systems to make those, to make those work.

David Bates – Brigham and Women's Hospital

Thank you. Esther?

Esther Dyson – EDVenture

Thanks. I wanted to—I was going to make the same airline industry analogy. Unfortunately, the airline industry is also pretty slow at adopting innovation, but they are good at safety. The point I wanted to make, simply, is—our goal should not be innovation, it should be the evaluation of innovation and the understanding of the risks and then, below some threshold, the customers, the doctors, whatever, should be able to evaluate those tradeoffs and understand them. The challenge here is that, if you want consumers to understand risks and benefits, it's—it's much more complicated.

So my personal hope would be the regulation was focused on data, evaluation of data, transparency and clarity, not just clarity of regulations, but clarity of risks and efficacy and appropriateness to both the medical community and the end users. And then let them decide, as long as the information is clear and, and vetted and—whatever the, like, what Anna was saying, you simply have to improve the reporting and have not just a safe place within the industry, but I think actually out to the users being aware of what these tradeoffs are.

David Bates – Brigham and Women's Hospital

Julian?

Julian Goldman – Massachusetts General Hospital/Partners HealthCare

Thank you, Dave. I'd like to speak to a few of the comments that were made, but really start directly with the example that Keith gave in his presentation and in the—it was based upon the discussion that we had yesterday with pulse oximetry data not being represented accurately in the electronic medical record. And one of the things, Keith, that you mentioned was that perhaps this is something that should be resolved by the vendor and that it, you know, maybe this is not something that would need to be escalated, for example—you didn't use that word, but I'll use escalated to the FDA, for example.

But I, I think that that's actually an example of, that can't be handled by the vendor, because there is no vendor, right? There's the medical device vendor that manufactures the pulse oximeter, and there's an integration vendor that's perhaps normalizing data and buffering it. There's the electronic health record manufacturer, another vendor.

So we—and this is part of the challenge, which is that it appears, initially, that we could address some of these issues at one device or one part of the larger system. But in fact—first of all, there may not even be a, a correct answer to a problem like that. There may be a matter of understanding the performance of that system and then optimizing it or configuring it based upon the needs of, of that environment or those patients or that population.

And, for example, in a sleep lab or in some other settings, it's important to know every desaturation, because a diagnosis is based on that. But, in other settings, it's actually more important to know about a trend. And so it ends up that this then ties into the idea that without sharing of the information and the characteristics and performance of these systems globally, nationally, and even more broadly, we can't optimize our systems and understand how to configure them or what the risks might be. Which speaks, then, using that as a specific example, it supports the idea that has been mentioned by several people of the need for open and protected sharing, because we need to understand what the safety implications are of not representing the data accurately. We need to understand how common the problem is. Maybe it's a rare event; maybe it's a universal problem, and we need to share it.

In, in the aviation industry, there's a newsletter reporting system that's been out, I, I think, for decades. It used to be a blue sheet called the Aviation Safety Reporting System. Now this little paper is gone, and it's not blue, but in that reporting system, I think it's very important that a pilot doesn't necessarily report a problem with the aircraft specifically—it could be any aspect of, of the system of, of aviation. And it could be, for example, that a pilot could report that there are spotlights at an amusement park that might blind the pilot on an approach or something like that. And, and in this way, there is a way to share the information and to address the information, and some of it may have to be addressed through regulatory channels in a somewhat very strict, formal way that some may consider heavy handed, but when it comes to aviation safety, we believe that's important, and for other reasons it may not be.

I think the National Highway Traffic Safety Administration also offers lessons for us, NITSA offers lessons, in that there's a venue to bring together all the different stakeholders, and I'm looking here at the NITSA website, and on the side, there's information and databases about crashworthiness, driver simulation information, event data recorders, and we talked about the potential value of data logging in health care. And, and so there's a wealth of information, test results, and other things like that, that all address the entire system, and so not all of it is necessarily kind of the feared, heavy-handed regulation. Some of it is with a very light touch; some of it is informational.

But until we find a way to do that with, instead of NITSA, with perhaps HITSA, the Health IT Safety Administration, again, in the spirit of, of having a venue for, for sharing of information and addressing concerns and opportunities including innovation, things like anti-lock brakes and better headlights and all these other things is a pathway to innovation. It isn't only a matter of, of heavy-handed ... and, and I don't know the subtleties and ins and outs of how NITSA works, and so hopefully I won't have to learn that, but I think that, you know, we can, we potentially could learn from some of these other models, their strengths and weaknesses and understand how to apply it to address what we just heard in this discussion, which are essentially a lot of requirements, as Bakul has told, and the marketing requirements for the regulatory framework.

Thank you.

David Bates – Brigham and Women's Hospital

So we're, we're at the very end of our time. I've encouraged any, any, everyone else to keep their remarks brief because we do have a couple of things to do before we, before we wrap up. Farzad?

Farzad Mostashari – Office of the National Coordinator – National Coordinator for Health IT

You mentioned the tribes this morning, and I think we heard very cogent, passionate arguments from the innovation tribe just now about the need to have safe harbor for innovation that can be evaluated before it's scaled up, perhaps, but to be able to just start. And I guess I'm, I'm wondering if there's someone from the regulatory tribe—I don't know, Brad, if you're willing to take a swing at it, as to whether there is existing or, you know, a model for regulations that would, that would permit that sort of, just to be able to have a safe harbor to just try something on a small scale, have evaluation and then be able to scale up.

Brad Thompson – Epstein, Becker & Green

So FDA does exactly that in the area of medical devices. There's a regulatory scheme for investigational devices, and it allows you to, to conduct the vast majority of investigations without FDA oversight at all if it's deemed non-significant risk. And most HIT would fall into that category. You operate under the oversight of an IRB, an institutional review board at a hospital as long as they bless it, as long as everyone involved who could possibly be at risk signs an informed consent, so that they're willing participants in the experiment. That's how medical devices are experimented with and then later brought to market. So FDA has that apparatus right now, and it works fairly well.

David Bates – Brigham and Women's Hospital

Okay. Keith?

Keith Larsen – Intermountain Health Care

I wanted to just endorse a little bit what Jonathan talked about, about permission versus more of an oversight. I think that, that what we're calling for—again, I, I try to make this the point of what I was saying—is that we're not saying no regulation. I mean, the, the, the ability of the government to sit apart from this and referee what's happening is, is very useful because—and I like the idea that if we had open communication, if there is, if they sense something that's, that's an issue, then jump in rather than the other way around, a permission model.

The other thing is, is to really become a partner in, in the development of these is, is really creativity—again, creativity in the application of the regulation. Again, moving from that legalistic approach, but being able to certify, for instance, a system that expressed what the issues are and being able to accept multiple implementations of that issue. Being able to articulate what the patient safety issues are and, and you're not going to be—I mean, the best thing to do with a patient safety issue is to make it an emphasis, how I solve that in my software, knowing that it is an emphasis and you've brought it to my attention is, is the best for, the best application of regulation is, I'm aware of it and I make sure all my testing procedures eliminate that risk. You won't be able to see all my testing procedure, you, you have a regulation that I do have testing procedures and that I do test my software, but it's really saying that, "Have you addressed this risk, and how have you addressed it, and were you aware of it, and how you got it in." But it's more of a give and take type thing rather than a gatekeeper.

David Bates – Brigham and Women's Hospital

Okay, so—I, I, I apologize, but I'm going to need to cut things off at this point. Could, could we have the next slide?

So, Meg, do you want to just say, say a word about this?

Meg Marshall – Turner Corporation

May I tie it in with the recently—

David Bates – Brigham and Women's Hospital

Absolutely.

Meg Marshall – Turner Corporation

[Laughter] Thank you. So, really, my comment is related to innovation and I sent this slide to David last night, just simply as—I took a stab at, at trying to understand that, or visualize that there are different levels of oversight. And so, for example, again, back to the innovation—you know, typically in a market, the laws of economics that apply and the consumers vote with their dollars, and if your product isn't doing what it says it's doing, they'll stop buying it, they'll tell their friends.

What makes this so passionate is that this actually affects people's lives and health and well-being, and the government's role is to understand, you know, the, the betterment of the public good, and that there is a responsibility to protect that public need. That does not mean that we're looking at a full blown level of oversight. I don't think innovation is hampered if you're creating a product and you are simply labeling it so that the consumer understands what you have created it to do, or that you have documented your processes that, as a developer—you know, I'll tell this to my 19-year-old son, "Do what you say you're going to do," so this is taking it to the step of document, what you say that your product is going to do. And then finally, monitor it so that you understand when it's failing and how you—again, it's back to the learning system, but how you, you take that back into the system.

So this is a first task and it's certainly up for argument and discussion, but the idea that, if you have, after the taxonomy decision tree or however that works out is considered along with the risk and the mitigation factors—you know, potentially this is something that we could look at rather than a regulatory framework that's a full blown class 3, you look at high, medium, and low. What levels of oversight, and what does that mean? If you end up on the low end of the oversight, perhaps you just register as a manufacturer. Maybe you have requirements around your product listing. Takes clues from the, the consumer protection laws, for example—you know, not just for the individual patients like Anna, but for the providers that are, that are using the products as well.

So just more as a discussion point and certainly as a reminder that we don't necessarily mean full blown regulation when we're having these conversations.

David Bates – Brigham and Women's Hospital

Well, thank you. I, I think it's, I think it's become clear that there's a, that there's a spectrum of regulation and that we need to, we need to come up with some sort of mechanism to, to convey that and then to juxtapose it with the, the—you know, what comes out of the risk group so that it's clear that things that are higher risk, whether that's relative or absolute, get, get more oversight, whereas others do not.

So I want to thank, thank everybody. I'm going to summarize where we are. We—the, the taxonomy group has done a lot of hard work. They're nearly done, but not quite; I'll come back to that in a, in a, in a minute. We have made excellent progress, I think, around risk and innovation and regulation. It's been really good to, to me, to get to know each other, to do this face to face. I now feel like I, I—you know, now I know who everybody is. So, from my perspective, *[Laughter]* that's been valuable.

You know, as, as Brad has pointed out, we really do have to try and, have to try and synchronize all these three things. You know, this meeting, I think, enabled that. It might—it may be a little more challenging as we, as we go forward, but I, I think it will be, it will be possible. It was also very good to have the chance to go around and present, present use cases. I think we can take some of those and then map them to, to the, the approaches that we come up with next.

We do have calls, fairly long calls, on both June 7, 14th, and 27th. The taxonomy group is planning to have a call before the 14th with the aim of, of sharing their slides. They got them done kind of close to the finish line, shall we say, so there was not a full opportunity for the group to review them before, before getting here. But they, they will do that, they'll refine them. They will take some use cases and map them to, to, to, to, to that. A couple people have suggested that we, it may be helpful to have a problem statement. I'll work on developing that together with staff and, and we have some materials which describe that a little bit anyway, but I think that is something that we'll need in the, in the final report. And then we'll review it with the group at, at one of the next couple of calls.

The aims of these next calls will also be to refine where we are with respect to risk and risk innovation and regulation. Each group is going to have to identify its plan and some specific, some specific next steps. One example is, within the regulation group, we agreed that we would go through the ambiguity issues which we listed, but we would prioritize them and, and try and figure out which, which ones are, are, are the most important, because we generated a very long list.

And I, I want to spend some time in the calls on a couple of specific questions. One, you know, what—what would, one is, what would need to be done to enable PSOs to share data so that there's a national resource to, to assess safety reports. Because it seems to me that we, we will need to say something as a group about that, and we haven't had a lot of discussion about it so far.

And, and a second thing, and also something that came up multiple times today, Jonathan just brought it up and Julian did as well, do we think—and Paul did, too—do we think that some sort of entity like the National Transportation Safety Board for health care or for HIT safety would be helpful? Is that something that we're going to recommend? Is that something that, that, you know, would, would fit well within a, within a framework?

And I just want to thank everybody, profusely, again. This, this kind of effort is, is a lot of work, it's a lot of time, there's a substantial amount of mental energy, but the—the concept, as Farzad underscored before, is to produce a product that will really result in the most benefit for the people of our country and, and I feel like we're headed in that direction. We've made some good progress; still lots to do.

Comments or questions about, about, about the next steps? Yeah.

Male

Would you like us, would it be beneficial to send you use cases by e-mail—

David Bates – Brigham and Women's Hospital

Sure.

Male

- if we have—

David Bates – Brigham and Women's Hospital

Yeah, absolutely.

Male

Okay.

David Bates – Brigham and Women's Hospital

Yeah?

Female

Do we know the dates in September yet?

David Bates – Brigham and Women's Hospital

Um, so the date in September—the, I believe the date in September is, is, is known. I can't remember what it is.

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

It's September 4th is the policy committee meeting.

David Bates – Brigham and Women's Hospital

Yeah. Go ahead and stick in the—yeah.

Male

David, can you just comment on what the expectation is for the September 4th report out—

David Bates – Brigham and Women's Hospital

Yeah.

Male

You know, who is—who is going to be here, and the report out?

David Bates – Brigham and Women's Hospital

So—so I think that's still to be determined and, and we'll come back to you on that. I mean, I, I certainly will, will have to be there, but, but then we'll have to, we'll decide on who else. Typically, we, we do not need to have the whole group there, so, so—yeah.

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

I can forward the appointment to, to the worker members just so they have it on their calendar, because we do have the virtual participation option with all of our committee meetings, so regardless of who's actually presenting, everyone would—would be able to listen in.

David Bates – Brigham and Women's Hospital

Other—other comments or questions? Okay. MacKenzie, could you open the lines?

Public Comment

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

Sure. Operator, can you please open the lines for public comment, and while we're waiting for the lines to be open, if there's anyone in the room that would like to have a public comment, if you can please come to the table.

Alan Merritt – Altarum Institute

I'd just like to make a public comment. If you're 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.

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

And we do have some public comment in the room. I'll just make a reminder that I'll be limiting the public comments to three minutes each so everyone does have time to speak. If you can please identify yourself. Thank you.

Glen Hill – Siemens HealthCare

Yeah, hi, my name is Glen Hill, I'm from Siemens HealthCare. So, first of all, I wanted to thank the agencies for pulling' this together. I'm just kind of sitting here and listening and we've been monitoring and kind of participating with members on the side. We find the comments very relevant, very encouraging.

I kind of wanted to start on a side note here. I was walking' around last night, doing—we were just walking out and taking' a breath, and was passed the Jefferson Memorial. And there was something' written there that I actually think is very relevant to this conversation, that it's very interesting that that many years ago, it's still this relevant. There's a quote on the wall that says, "I'm not an advocate for frequent changes in laws and constitutions, but laws and institutions must go hand in hand with the progress of the human mind as that becomes more developed, more enlightened, and as new discoveries are made." And it goes on, but I think (a) that's very relevant, because I think that's exactly what we've been talking' about for the last couple days.

So my background's in—I work for Siemens HealthCare in the software division. My background is in both traditional medical device and health IT, so I see a lot of similarities between these worlds that, you know, sometimes we're not harnessing. Process, standards, systems—you know, I've heard many comments over the last two days where we can look at that and try to bring in these best practices in a new way. But the one thing I'm stuck with is, I think the key question we need to answer is—what is health IT?

I echo the comments that were said that health IT is not—we need to, first of all, define it in a manner that will stand the test of time, kind of to the quote. And I think if we use labels like EHR, HIE, mobile apps, we're not really developing it. So again, I really congratulate the taxonomy group, because we need to focus on functionality. That's really what will stand the test of time, and that's really going to allow us to link risk to those functions, because we know all EHRs are not equal, and we know functions are equal, and I really encourage that group to really look at that and make that a focus.

I think if we do that, then I think we can use one risk based—one risk based approach that will bring clarity. So it's something to talk about. I know there was a question of what is clarity—I think product labels will not bring that, but functionality will, and that will allow us to be really driving for a level playing field, which is going to be so critical.

The other comment I want to make was on the learning health system. I'd encourage us to think about a separate incident management system versus a learning health system. They're different, and I think there's been confusions around that—so we've done work with the Bipartisan Policy Center, and they proposed a learning health system. And that is critical. It's what we've done—I'm really encouraged to hear it talked about so much over the last two days. It does not replace an incident management system, a singular reporting system—they need to go hand in hand. That's the first thing.

And the second thing, the other comment that I've heard made many, many, many times is, "Vendors are blocking improvement." I speak for Siemens, I speak, I would say, for most vendors—it's not something we encourage. And to that point, that's where we've been working through the Bipartisan Policy Center and other groups and PSOs to try to pilot exactly what you're talking about. So there's opportunities for the work group to look and learn and things that are currently in play, trying to develop exactly what's been asked for.

So—and we'd encourage, and we would be willing to, obviously, share that learnings as we move forward. Thank you.

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

Thank you very much. Perfect timing. Are there any more public comments in the room? Go ahead, and if you could please identify yourself, thanks.

Darryl Roberts – American Nurses Association

Good morning. I'm Dr. Darryl Roberts. I am an—a Registered Nurse, an educator, and an evaluation scientist. I currently work as a Senior Policy Fellow with the American Nurses Association. Some of my comments are going to be redundant with what we've already heard today, and please just bear with me as I try to put them into a context that I think will be useful.

Earlier today, Anna McCollister-Slipp proposed the development of a learning regulatory system. Such a system is necessary and should be integrated within a learning health system. The learning health system proposed by the Institute of Medicine, by the Bipartisan Policy Center, by Cancer Family Foundation should inspire and invite innovation, should tolerate risk, should include an openness to failure.

This openness should be tempered with vigilance in seeking failure modes in advance of and root cause analysis after the failure. A learning health system should disseminate findings from both this share—from, from both the failure mode evaluation and the root cause analysis. This sharing, which is really a small part of the learning health system, can inform regulators of where the market is succeeding, so it doesn't need to be regulated, and where the market has failed, where it needs appropriately placed regulation. It can also inform the market of opportunities for innovation and opportunities to bridge identified gaps.

Government failures, such as regulation in the absence of a market failure, or inappropriate application of incentives can stifle innovation, and we've seen that happen. Alternatively, unsafe innovations such as workarounds can come out over regulation, and we must be cognizant of stifling innovation in one way and stimulating inappropriate innovation that allows failures to build.

A learning health system that interactively incorporates government regulators and direct stakeholders can stimulate positive innovation, can inform the government of market failures, can inform the market of government failures. This would improve health care quality generally, patient care specifically, and satisfaction of those of us who are within that system as patients, as providers, as clinicians, and as those who are developing systems that make our jobs easier and make patient care safer.

Finally, as this work group considers what FDASIA should regulate, it should also consider what government should no longer be regulating. Thank you very much.

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

Thank you, and I see we do have one public comment on the phone. Mr. Cross, are you ready?

Dean Cross

Yeah. Dean Cross; I'm a physician, clinician, and user of these devices. I commend the group for putting this program together. Finally, something is being done to vet the safety of HIT. It's actually shocking to me that EHR, CPOEs, and CDSs have been deployed without any premarket or post market surveillance. There's no awareness of the magnitude of the injuries and deaths, near misses, and system unavailabilities that occur when doctors are tasked with taking care of sick patients.

That said, innovation over the past two decades has been de minimis, without any regulation. Regulation is not stifling innovation in the HIT components of EHR, CPOE, CDS, because there's been no regulation. Regulation would probably improve innovation. There have been innumerable news reports of EHR crashes, system failures, device failures, none of which have been adequately investigated for the impact on patients and their safety. Patients need to be protected during the innovation experiments, as was suggested earlier this morning, either by an IRB involving investigational device protocol.

One major thing that has not been covered, to the best I can tell, is system unavailability when a critical patient is in need of care and the system crashes—the entire EHR crashes in a hospital, and all screens go blank and doctors cannot even find their patients. Medicines are delayed, care is delayed, and the role of this neglect is really unknown. No one has investigating it, nobody knows the impact and magnitude of this. Comparing medical care and how HIT governs this care to a car or a jet is a gross depreciation of what clinicians do and what is involved in the care of sick patients.

In summary, there needs to be a robust system for reporting any adverse events, device failures, defects, near misses. There needs to be a robust system to report unavailability of systems, of EHRs, interoperability failures, and other problems. Patients need to be protected during the innovation experiments involving HIT infrastructure and there needs to be national standards of interoperability so that when I need data from another system that's really available, or if I need data from a system within the hospital, it's really available without concern of being adulterated.

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

Mr. Cross, your three minutes are up.

Dean Cross

Thank you.

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

Thank you. Are there any other public comments on the phone? Any more public comment in the room? Seeing none, I'll turn it to David Bates just for any last closing remarks.

David Bates – Brigham and Women's Hospital

I just would like to thank everybody again. I wish you safe travels. We'll be talking again soon and your work group may be talking before then, so thank you, again.

Participants

[Applause]