FOOD AND DRUG ADMINISTRATION (FDA)

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

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PROPOSED RISK-BASED FRAMEWORK AND STRATEGY FOR HEALTH INFORMATION TECHNOLOGY

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PUBLIC WORKSHOP

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THURSDAY
MAY 15, 2014

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The Workshop met in the National Institute of Standards and Technology, Red Auditorium, Building 101, 100 Bureau Drive, Gaithersburg, Maryland, at 9:00 a.m.

PRESENT

JODI DANIEL, ONC, Moderator, Panels E-F
MARGARET BINZER, Alliance for Quality Improvement and Patient Safety, Panel E
GERARD CASTRO, The Joint Commission, Panel E
SHERYL DYNER, NextGen, Panel E
THOMAS GROSS, FDA, Panel E
RORY JAFFE, CHPSO, Panel E
DREW LADNER, Pascale Metrics, Panel E
WILLIAM MARELLA, ECRI, Panel E
GREG NELSON, MITRE, Panel E
STEVEN POSNACK, ONC, Panels E-F
MATTHEW QUINN, FCC, Panels E-F
MARK SEGAL, GE-EHRA, Panel E
JEFFREY BRADY, AHRQ, Panel F
JULIAN GOLDMAN, Partners HealthCare System, Panel F
MICHAEL HODGKINS, AMA, Panel F
WILLIAM MAISEL, FDA, Panel F
JANET MARCHIBRODA, Bipartisan Policy Center, Panel F
DAVID MAYER, NTSB, Panel F
TOBIAS SAMO, Allscripts-EHRA, Panel F
JEANIE SCOTT, VA, Panel F
RONNI SOLOMON, ECRI, Panel F
JAMES WALKER, Siemens, Panel F

T-A-B-L-E O-F C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(9:04 a.m.)

MR. PATEL: Good morning, if we could get everybody seated, we can start Day Three, an exciting day. I think this is what we heard a lot about people waiting for the third day discussion. Right from Day 1 we wanted to have continued learning environment, was one of the top pillars that people identified, as the panelists discussed. So this is the opportunity.

And Jodi's going to do a fantastic job all day. Poor Jodi. I'm sorry.

MS. DANIEL: This is what happens when you miss a planning meeting. You get volunteered for things.

(Laughter)

MS. DANIEL: So morning to everyone. Make sure you're at the planning meeting. I'm kidding. It will be great.

MR. PATEL: All right, so before we kick off, I think we'll do the usual video, and then I'll go over the logistics again. And we'll turn it over to the panelists.

(Video plays)

MR. PATEL: Welcome to Day 3 of the FDASIA Health IT Report Public Workshop. I'm Bakul Patel and Senior Advisor at Center for Devices and Radiological Health. As you guys heard me say yesterday and day before, a few weeks back we published a proposal on a strategy and a framework for health information technology.

We identified a whole bunch of items in the report, primarily focusing on key things that we need to sort of focus on. And we've been talking for the last few days about those areas and the pathway that we proposed. Today's actually, like I said earlier, it's the

most important day, at least from my perspective, because this is going to help us sort of create a new framework for the health management, health IT and how do we do that?

I think we are looking for an engaging participation from the audience as well as for folks on the web. So let me give you a few logistical and housekeeping items. The Wi-Fi password is available at the registration desk. So if you need your Wi-Fi password, please go and get them at the registration desk. Make sure, like the video announced, that your cell phones are silenced.

Also, I'm encouraging everybody to be stepping up to the mic, announcing who they are, and engage with the panels. I really encourage you engaging with the panels, because the audience is going to be the fifth or the tenth person on the panel, just not sitting at a table, but here. So this is an opportunity for you. For folks on the web, this event is webcasted live. It will be transcribed later on after the event is done. The webcast will be recorded.

So they're available for viewing as well. We also have set up an email address for folks to submit comments, which Aaron here will read to the panel moderator for reactions to the panel discussion, or questions to the panel discussion. So I encourage you to do that, people on the web. And, of course, and the last thing I do want to encourage people; I'm hoping there's discussions that you had for the last two days and today will generate thoughts that will provide the agency's feedback that's very specific and also help us take the report to the next level, where we can be more specific and be clear in what it is we want to articulate. So with that, and I'll turn to Jodi and ask the panel to come join us on the stage.

MS. DANIEL: Thank you, and just while the panelists are coming up, I want to just reiterate that we would love to make this as interactive as possible. This is the part

where we're talking about how the public and private sector can really come together to help develop a culture of safety and an opportunity for learning.

So we'd like to that to be woven into our approach as well today. And I also want to let folks know that we have two panelists who were not able to be here today, that were scheduled to be here today.

The first was Dr. Randolph Miller, and the second was Sally Okun. They both had emergencies at the last minute and were unable to attend. So just one small change in our plan.

MR. PATEL: I did miss out on one important announcement, and it's really important, to acknowledge the folks who helped put together this workshop, and an incredible job they've done in not only arranging for all the logistics behind the scenes, but also helping. I'm going to start with Karen Jackler who's been monitoring and tweeting the panel discussions for the past two days, including today. Aaron Josephson, who has been monitoring the email box and helping us be more interactive.

Simon Choi, who I hope he's not here today. He had to go home yesterday with a slight medical condition. Susan Monahan, Carol Krueger, Joyce Raines, Peggy Roney and Maggie Fu have done a fantastic job of making sure the logistics, and getting people into the facility and getting here so smoothly that I didn't have to worry about it. I also say the biggest thanks to all panelists who spent time to be on the panels and provide thoughtful discussions for all three days. With that, Jodi.

MS. DANIEL: Okay. Thank you very much. So we have a big, busy day today, so thanks for joining us for our last, final and I will call it finale day, where hopefully a lot of the comments that have come up over the course of the last two days can be kind of brought together when we talk about leaning continual improvement.

It is something that's come up throughout our discussions over the past two days. So panelists over the last couple of days have identified the complexities of thinking about health IT and safety in the context of the development of the products, the different users and uses of products, integration with other systems, the modularity of products, and that oftentimes new products are actually put together from components of other types of health IT, and the fact that health IT product may cut across multiple categories that we identified in our report.

And that also raised some questions on how we put this all together. We've talked about health IT being part of a sociotechnical environment, and that there needs to be a way to engage all stakeholders to learn, identify best practices, educate others, improve transparency, et cetera.

So we will spend this morning discussing this issue broadly and how availability of information, safety reports and data analytics is critical to environment of learning and continued improvement. In the afternoon we'll talk about Health IT Safety Center, which we proposed as an action item in our report and how a safety center can support this environment of learning.

We'll get input to help us think about how we can effectively set up a safety center and get engagement from all stakeholders that are part of this ecosystem. So I just wanted to start with a couple of comments before we open it up for questions and discussion from the panel.

The importance of reporting adverse safety events and unsafe conditions to improve patient safety, and the specific role and focus on health IT has been a priority for the department for several years, and with FDA, on the device side, for decades. Recently the

department had emphasized the importance of reporting on health IT safety plan, which we put out on July of 2013. And this was building on the recommendations of the Institute of Medicine Report on health IT and patient safety that was 2011.

And that was commissioned by ONC. AHRQ, working with ONC and FDA, developed common formats for reporting adverse events involving health IT devices, as well as adverse events more broadly. And ARHQ has published The Hazard Manager, a more in depth taxonomy for describing unsafe conditions associated with health IT. ARHQ also expects to identify data to be available on Network of Patient Safety Databases, or the NPSD, on adverse events from all causes, including health IT later this year.

ONC has sponsored research on three adverse event databases, looking specifically at the role of health IT. And we have some folks here who can talk about some of the work that they've done in this space, in collaboration with ONC.

In December 2013, ONC published a guide, How to Identify and Address Unsafe Conditions Associated with Health IT, in part because our experience is that healthcare organizations often want to do the right thing, but don't know what steps they should take or could take to help improve the safety of health IT and the use of those products.

And in January of 2014, ONC published nine SAFER guides in areas of recognized risk, associated with the use of health IT. And these SAFER guides are a tool for assessing risk and include recommended practices and monitoring and reporting, as integral to optimizing the safety and safe use of health IT.

There's also been a lot of active private sector engagement. I'm not going to walk through all of the great work that many of the panelists have done, but I expect that they will talk about some of that work and some of their findings as we go through.

We have folks that represent PSOs at the table and who can talk about what their learnings have been in looking at the adverse event databases they have and some of the research they've done.

Our goal in discussing reporting today is to consider health IT safety in the larger context of patient safety. At ONC we have two goals that are articulated in our health IT safety plan: one is to make sure that health IT is safe, and the other is to leverage health IT to improve patient safety more broadly. I'd like to challenge folks to think about that broader context as well, as we're having this conversation today about a learning environment.

How can we use health IT to improve patient safety overall, as well as to think about the safety of the products themselves and the use of those products? We have folks here from EHRA who have put forward a code of conduct, including statements about EHR developers working with PSOs in reporting. And I look forward to providing some input on that as well. And then we have folks who can talk about, particularly Greg Nelson, who could talk about safety reporting in the context of other industries as well.

And, of course, I'd like to welcome our federal government colleagues Steve Posnack, Matt Quinn and Tom Gross from ONC, FCC, and FDA. So we will start our panel discussion. Again, this morning we will start with talking about reporting of safety events and then later this morning we'll talk about analysis of that data and use of that data.

So first, I'd like to start off by asking the panelists, we want to be cognizant of the current environment in which health IT and safety reporting and data collection exists. And I've talked a little bit about some of the ONC's activities, but I wanted to ask the panel if you can describe the current state of adverse event reporting, as it relates to health IT.

What data is available or should be available to support better understanding

around health IT safety? And how and when do organizations report such events either through their organizations or to others, such as to PSOs, or the Joint Commission? And for folks who haven't been here for the last couple days, if you can put up your tent cards if you'd like to make a comment. And I will try to make sure I get to everyone. Rory, would you like to start?

DR. JAFFE: Thank you. I'm Rory Jaffe, the California Hospital and Patient Safety Organization, also co-chair of the Structure Data Capture Workgroup for Adverse Events and Patient Safety Events. One of the challenges we have is that people don't see health IT events as health IT events. They see it as a part of their other events, whether it be medication safety, wrong site surgery, et cetera.

So we have, in our events, we have very few, right now we have about 150,000 events in our database. And we have very few, if any, that are actually labeled HIT. And yet, there's a large number that are. And part of it is your perspective, whether you're even thinking about HIT when you're thinking about the event, how when people think about alarm management, for instance, they rarely think about the fact that the alarms aren't, systems aren't integrated.

And that's one of the contributing factors to a lot of alarm events is the lack of communication between systems, so that you don't get a coherent picture of what's actually wrong. So we have to, when we're looking for events currently, actually go through and try to read the events and look for issues that present as HIT events. So it's very difficult currently to identify specific HIT events without a lot of manual work.

MS. DANIEL: Okay. Peggy, and then we'll go to Drew, Bill and Mark.

MS. BINZER: I'd like to echo Rory's remarks. I'm Peggy Binzer. I'm

Executive Director with the Alliance for Quality Improvement and Patient Safety. We are a professional association, organization for patient safety organizations and their members, and the patients that they care for.

When you look at collecting HIT events, we have to remember that there's a small subset of functionality events that are near misses or issues that are very easy to see. It's like a medication error.

You know that it was the medication that caused the event, but in most cases, in the clinical setting, what we see is really a shared responsibility event where either a patient has been harmed, or there's been a near miss that's been so significant that we need to further investigate and analyze what happened.

And so as we go through the peer process and peel back the onion of what really happened, a lot of times, is what you see, is there is systems failure. There is a contribution, perhaps, from HIT. There is the contribution of human error, and then there's always the notion of if we had the different functionality, could we have prevented this event, even if HIT wasn't a contributing factor. So, again, HIT isn't like a medication event. It isn't very clear to see. It takes a lot of work, really to peel back the onion and determine all the causes.

MS. DANIEL: Great. Drew.

MR. LADNER: Thanks. We should find it --

MS. DANIEL: Can you just introduce yourself?

MR. LADNER: Yes, sorry. Drew Ladner, Pascale Metrics, a PSO. We should find it less and less surprising that it's harder and harder to differentiate the health IT aspect of healthcare safety issues, in part because when a field is in a nascent stage with

respect to technology, it's easier to identify and isolate: oh, here's the technology.

Here's a very, kind of, tactical tool that we're using to let's say support our process. But as we go through this significant transformation in the field, what we're finding, and obviously the IOM was thinking along these lines, is that the technology becomes integrated with the socio part, the cultural part and becomes less and less distinguishable.

So I think it's maybe helpful to recall that at the time of the publication of the oft cited To Err is Human Report, society was going through a huge transformation. And whether it was travel, or buying food for your pet, or whatever it was, everything became "E" something or other, e-travel, epetfood.com, et cetera. And there was this distinction between the "E" part and what you're trying to accomplish part.

And after awhile, people began to see it as, it's just travel. I may go to my travel agent, or I may actually buy my ticket on my iPhone. But the outcome is what matters. And I think what we need to think about is focusing on the outcome and then using a sociotechnical lens, try to understand the many root causes that are part of driving safe and reliable care.

MS. DANIEL: Okay, Bill?

MR. MARELLA: Good morning, Bill Marella from ECRI Institute PSO. So to kind of put reporting in context, one of the messages that I wanted to communicate this morning was the importance of not siloing health IT as a different animal in terms of evaluating safety. There's already an existing infrastructure in many of our organizations and in the healthcare system at large. There's already an infrastructure for dealing with safety issues.

What I would hope that ONC and the government's Health IT Safety Center would do is help up break down some of the silos that exist. So even within a single

institution we frequently find instances where there's not really good communication between the IT department and the patient safety group, which could, is it feasibly risk management or there's a separate patient safety unit.

Those people don't necessarily communicate very well, and to echo Rory's comments, the clinicians who initiate a lot of the adverse event reports that many of our patient safety organizations get don't always recognize the role that health IT played, either in mediating that event, or the opportunity that maybe was missed for preventing that event.

So we're here to talk about safety issues with health IT today, but the flipside of that is the ability for health IT to address errors that it is related to as well as many patient safety events that maybe have nothing to do with health IT. To give you a quick example of that, we have an organization that participates in one of our multi-facility quality improvement collaboratives focused on reducing overdoses of opioid narcotics.

And what this facility found, when they looked at all their cases of overdoses, they found that most of their patients were opioid-naive. They found that most of them had been prescribed a dose that was four times the dose that's recommended for somebody who has not built up tolerance to opioid narcotics.

And here, that was the default value in their CPOE system, and simply by changing the default value, they eliminated most of their problem overnight, because they changed the default from the most commonly ordered dose to the safest dose.

So there are two aspects to that. One is health IT actually helped them diagnose their problem in ways that, imagine doing that same study with paper records. What it would've taken them days to do, they did in a matter of minutes. Secondly, health IT was actually the solution to that problem as well. So I would hope that the IT center would

focus on the pros and the cons.

MS. DANIEL: Great, thank you. Mark?

DR. SEGAL: Thanks. Mark Segal with GE Healthcare IT, and I also serve in a leadership of the EHR Association. So I'm going to join the echo chamber, because I think it's a really important point in terms of not siloing health IT for safety.

Having said that, and we've been working closely, particularly through the association with Peggy and her group and folks from ECRI and others, it is important that organizations that are dealing with patient safety and the environment we're in, which is in no small part due to the work of Jodi and her colleagues.

We are a much more digital environment, so it's important that PSOs and other organizations that are dealing with safety events have the capacity to recognize and deal with HIT issues. In terms of what's sort of most important, I think, from a developer perspective, the most important surveillance is actually that surveillance that happens in terms of the relationship between us and our customers and with our complaint handling units and all of the formal processes we have to recognize, respond internally and externally to events.

In terms of external reporting, which is really sort of for non-FDA regulated in its infancy, I think our view, as a company, and I think certainly as an industry is that working with PSOs is extremely promising. We've been very involved with the work of the Bipartisan Policy Center. Janet Marchibroda talked about that earlier, and have supported that approach. I think, from a reporting standpoint, and I think we heard over the last two days how important localization is, configuration, customization, what have you.

And so while I think there is value in reporting from vendors, I think the most value you're going to get is reporting from the end user, who is going to have the most

complete picture. And then there are the opportunities for vendors to work directly with their customers, as well as with PSOs. ECRI's doing a pilot on that, that our company will be participating on.

And then finally I just, again, in the context of how the developer community has been dealing with this, I appreciate, Jodi, you were mentioning our code of conduct. And we had, as one of the elements, there working with the PSO or similar organization and having that kind of relationship to identify the issues we're dealing with. So again, and just thank you for organizing this conference and the panel.

MS. DANIEL: Thanks. Mark, can I just follow up with you for one second before I go off to the next? Can you talk a little bit more? You brought this up about the relationship between you and your customers. Can you talk a little bit about how developers and healthcare organizations currently track safety events, and how you identify incidents, and which ones are risky or not?

DR. SEGAL: Sure.

MS. DANIEL: Thanks.

DR. SEGAL: Sure. So we have GE, which as some of the companies that you heard from, we have both FDA regulated, non-regulated products. And our general processes are the same, regardless.

But I think, in talking with my industry colleagues, I'd say most vendors have fairly similar processes. We have complaint handling units. Issues come in. There are formal requirements about -- and obligations for company employees, including, I was just talking with a colleague. If I happen to be at a party, and somebody comes up and for whatever reason wants to talk about health IT and mention and they're a customer -- and that's

happened to me. And they mention an issue, I have an obligation to treat that no differently than if it came in formally and to get it in the system. So we've got processes to identify, to categorize by risk.

At the highest levels things go up all the way to our CEO, and then you'll basically do root cause analysis, all those acronyms that we were hearing about. And then we notify our customers. In addition, we have, and again most companies do, very active user groups. And, not surprisingly, they have listservs and things of that sort. So issues also come up to us through usability kinds of discussions, through the listservs of our user groups.

So there's a variety of ways, but all of that ends up then getting captured and put through a formal system. And I think, again, you're going to see variation across companies. But I think the general kinds of steps will be common in the industry.

MS. DANIEL: Okay. Thank you. Gerry?

MR. CASTRO: All right, I'm Gerry Castro from the Joint Commission, and the ONC funded a project to have the Joint Commission look at our sentinel event data, and actually perform four learning visits of organizations and learn about their implementation and use of health information technology. So for those you unfamiliar with the way that the Joint Commission works with its sentinel events, and what a sentinel event is, if you can think about it, visualize a picture of an iceberg.

The very tip of the iceberg is what makes it to the Joint Commission. Those are the catastrophic events that have lead to death or serious permanent harm of the patient. Now what we require organizations to do is a root cause analysis of these types of events. And what they can choose to share with us are their findings, or the results of that root cause analysis.

So it's a slightly different data set from general patient safety reporting. It's very in depth, and it looks across all, not only from the device side, but also at the system failures. So the types of events we see may be slightly different across the board, but what I wanted to say about -- and touch upon several of the panelists' comments here is that well, first of all what we're finding is that a lot of these events that make it to the Joint Commission have started very much distal to the patient.

They're not at a device side. They occur at scheduling, at ordering the medication. So there are functions or a design component of the health information technology, which actually contributed to the event. But also, we find that the work flows and the processes that we humans build around these devices, they also fail. So it's multiple points of failure. So there's a design issue, and then there is a failed double check or failure to perform the universal protocol to prevent wrong site surgery, those kinds of things.

There are multiple components of failure that have led to the actual event, and that's when it reaches the Joint Commission. I also wanted to touch on Bill's point about the siloing of health information technology. During our learning visits, the folks that would actually let us in the door, those are the folks that were doing a great job with health information technology. They were on top of their game or trying to be on top of their game.

They're very engaged with their vendors. Their clinical team was engaged with the health information technology team along with their safety team, so it was all integrated. Everybody was talking to each other. But one of the interesting things, and what Bill touched on, is that a lot of the errors that they see, they will manifest as a complaint ticket in their information technology department.

But what they are able to do is make that link to the outcome, which is what

Drew pointed to. So it manifested as a medication error, or wrong site surgery or retain foreign object, those kinds of things. So that's the type of events that we're seeing.

MS. DANIEL: Great. Thank you. Sheryl?

MS. DYNER: Thank you. My name is Sheryl Dyner, and I'm with NextGen Healthcare. We're a vendor that provides solutions for the ambulatory market. And I can echo Mark's comments on the support processes that we have in place. I mean, I've been with the company three and a half years. When I arrived there, there was a very robust system for supporting customer incidence.

It doesn't matter whether it's a first event, or a perceived adverse event, or an issue with training. They all go in and get funneled, and they're triaged according to what we perceive the risk. One of the greatest problems we have is that, well, there's actually two. One is if we get a large influx of potentials, which is fine, because we want to triage them. But we need to get back to the customer who reported the issue to find the details.

And frequently, they're not available anymore. They reported it. They entered the ticket and then walk away. And we're chasing them for sometimes weeks or months. And so we've now changed the process to escalate to the safety officer or privacy officer or a security officer in the hospital, in the physician's office so that we could get the response we need to appropriately triage the issue.

And the other is that these are perceived issues, and we have to separate out the perceived from the actual. The software, usually there is something that makes it detectable, the issue. So the customers will report something that could be a safety issue but has not resulted in a safety issue. And I guess I hope we can get some clarification on how we report those types of issues versus ones that actually have resulted in harm.

MS. DANIEL: Okay. Thank you all for those helpful comments. So I'm hearing about some of the -- making sure that we keep thinking about health IT safety events in the larger context and not silo those events. We also heard from the Institute of Medicine that we don't have good data about safety of health IT. So how do we improve the amount of information we have about potential risks of health IT so that we can help mitigate those?

Do we need to increase reporting among particular types of stakeholders? What are some of the suggestions folks have for how you can increase the quantity and quality of the information that we get to help us understand where there may be problems, where there may be risks. Since we have a lot of cards, why don't I just kind of go around the table. I'll start with Greg since he hasn't had a chance to speak yet.

MR. NELSON: Thank you. This is Greg Nelson from the MITRE Corporation, and we are a non-profit research and development center that, among other things, operates a public/private partnership on aviation safety and trying to learn, apply some of those lessons to the patient safety domain.

And I think one of the things we've learned over there in the aviation world is if, about 20 years ago there was a shift into the cockpit and the other items of aviation went digital. And suddenly there was a whole wealth of information that was not available before, and tapping into that information and looking at it, not so much for root cause analysis, which is still important work and continues to be done. But trying to look at that data from a predictive analytics point of view and really finding, using that to find all the near misses that are never going to be reported in a voluntary reporting system, which also continues to be important and is a source of data.

But I mean, Jodi, taking your point of how can we leverage health IT to make

care safer? All right, the other side of the equation there are, I would state, lots and lots of opportunities to utilize all of the data that's now being collected by these systems and mine it for those precursor events. And bringing those diverse data sets together, not relying on just any one single set of data, not exclusively on series event reports, not exclusively on EHR reports but together you see a lot more than you do through any individual one.

MS. DANIEL: Great. We'll just go around. Mark, do you want to go next?

DR. SEGAL: Yes, I think building on the conversation we're having about the role of PSOs and the Joint Commission, I think that you want to look to existing bodies that are gathering data and will be increasingly gathering data, as well as focused research by folks at ARHQ and other situations where you're not just doing a case study.

But it may be more focused, formal research and then whether it's everybody, I'll have to say it, probably the first time of the day, big data, building on what Greg was implying, or meta analysis, another buzz word. And I think we've seen some very powerful work where you look at good -- it's not aggregated data sets but it's aggregated, formally analyzed research reports. I think one of the things that is appealing about the PSO kind of model is that it looks below issues of death and serious injury to hazards and near misses.

And there are benefits for that. There are also risks, in terms of introducing noise in the system. Many of those may not have gone through the same level of root cause analysis. And that's why aggregation and sort of that safe environment which we've been talking about is so important, so that you can find patterns without trying to say it's this product or this company or this facility.

So that would be, sort of, what I would look at is larger data sets, multiple

sources and then sort of a meta analysis kind of rigor of really building on the work that's done. And I think the safety center has some good opportunities there to bring some of that together.

MS. DANIEL: Great. Peggy, did you have a comment?

MS. BINZER: Sure. PSOs have been working very, very hard, and with our culture of safety and confidentiality we've been able to collect very rich data sets from providers, because there's no fear of reputational harm. We've done a fabulous job, individually, within the community of working with providers to improve patient care. The thing that we haven't done very well has been transparent about the hazards that we're seeing, and about the best practices that we're developing.

And AQIPS has been working on this for the past year, on how to develop a transparency program for HIT events as well as for the broader kind of focus, again, we can't separate those aspects in those silos. The interesting thing is PSOs were developed and a law was passed to break the silos that were created by peer review laws that all the great information about what was happening in healthcare has to stay within the four walls of the hospitals.

So we realized that the PSO system was creating our own silos, and so we have been talking with the National Patient Safety Foundation to serve as our best practice disseminator and developer. They are a trusted source of information. They have collaborations like ONC with all of the different stakeholders. They develop and forge consensus.

And we're working with them on a validation process, a meta analysis process so that we can be sure that we're trending and collecting the analysis but also that the best practice is the best practice, and is the right practice for healthcare or different segments of

healthcare. NPSF has been a central voice in patient safety over the years. They actually worked with us in developing the Patient Safety Act, so I think a lot of the pieces fall together.

So I would hope that we'll move this piece with the National Patient Safety Foundation and integrate it with the ONC's Health IT Safety Center, because then we wouldn't separate the clinical from the HIT and then develop additional problems from a siloed type of approach. So we recognize that we've had a problem in not being transparent, and we've been working to break those silos and work with other organizations.

MS. DANIEL: That's great, and we will make sure to raise that question to our panel this afternoon as well, ask their input when we talk about best practices and dissemination from the safety center. So thank you.

MS. BINZER: Okay. I wanted to add that the National Patient Safety Foundation isn't represented today. They have a Congress annual meeting, and so Tejal Gandhi couldn't attend. So I thought I'd just follow the comments this morning. They're not here, so I'm volunteering them.

MS. DANIEL: Perfect. Bill?

MR. MARELLA: Yes, I just wanted to pick up on a comment that Greg made. There are a lot of patient safety organizations on the panel here today, but I think the adverse event reporting from clinicians is really just one mode in which we need to collect information about the safety of these systems.

I think the other sources of information that we should look to are observations. We use these pretty extensively in our patient safety work where hospitals will actually invite us into their ORs.

They'll invite us to the floor, as Gerry was describing, to observe how these

systems are used in the wild. And I think that is an eye-opening experience, and one that would benefit the implementers of these systems as well as the designers of them. The other sources of information we have available are lab evaluations under controlled conditions, scenario-based evaluations. ECRI's being doing those with medical devices for many years, and I think that approach is easily transferable.

The other sources of information we have are the metadata that are underlying these systems, to the extent that that's accessible. If we're not studying how these systems are used, and these systems are collecting a lot of information that would be valuable for that purpose, it's not clear that most hospitals have the ability to mine that data. It's not clear how accessible it is to them, so I think that speaks to the need to involve the vendors as well as the providers in investigating individual events. And as Sheryl brought up, many of the reports that come from clinicians are missing a lot of information that you would otherwise want.

And the follow up can be very difficult, so it's only by looking at these reports in the aggregate that you can get a decent picture of what's going on with any one system. But when we investigate accidents in healthcare, we're generally on the ground within 24 hours. And people talk about the NTSB model. I know David Mayer from NTSB is on the next panel.

That approach is very powerful, and that's where a lot of our recommendations have come from, are those investigations that in our case are usually initiated by the hospital, or by their insurer. And there you're getting a much smaller set of events, but much higher quality information.

MS. DANIEL: I'm going to ask you Mark one other question in follow up to

that, which others can weigh in on when you speak. But what about information from patients as contributing to our knowledge base on what's working, what's not and where they may be safety issues?

MR. MARELLA: Patients don't interact with the medical record directly unless they, once they request it. But I'll relay a quick anecdote. I recently got access to my patient portal through my own provider network. And the problem list was interesting. There were some diagnoses that didn't resonate at all, and others that I have chronic issues that I've had for 20 years that were missing.

The quality of the information that's getting into these systems is every bit as much something that we need to pay attention to as the system design, and I think patients are in an interesting and unique position, to point some of those problems out.

So I think we, in terms of risk management, we have to have processes for things where patients can contribute that kind of information. Patient portals seem more relevant than the EMR. But going to a consult with my mother for surgery several years ago, watching a nurse take the medication history was painful, because the nurse was clicking down through a list of about 6000 drugs, page by page by page, paging down.

And I'm sure there was probably an easier way to use the system. It was probably a training issue, but it took half an hour to do a medication history. And it didn't matter, because the doctor when he came in didn't look at it. So we've got a lot of work to do.

(Laughter)

MS. DANIEL: Thanks. Drew?

MR. LADNER: Sure. I suspect that there's broad consensus around the

need for more data and more types of data. And I think Bill mentioned a couple additional types. We've also seen the value of high quality survey data being used in this manner, in the PSO context because, if nothing else, insignificantly adversarial context requests for high quality survey data that show significant risk at the unit level is material.

Another area, clearly, given the changes in health IT, is clinical data and not just clinical data but using clinical data in real time, which adds an entirely different dimension, because now we can not only get insight about adverse events or harm that is existing, but actually use that data to anticipate potential issues and the related cost, which now introduces an ability to make the model sustainable.

I think one final piece I would add, especially given conversations yesterday around, how do we convert the IOM sociotechnical model from policy to practice, brings up the opportunity for PSOs, given that privilege that exists, given the significant data that they already have, and given the relationship that they have near the point of care and with health IT is to analyze not just data after an event has happened, but to be engaged across the life cycle, design, implementation, first deployment, there's an opportunity. So I think that's an item that hasn't been discussed as much in our experience that is worthy of being considered as we continue to develop the framework.

MS. DANIEL: Okay. Thank you. Tom?

DR. GROSS: Yes. Hi. Good morning. Tom Gross with the FDA. I have a staff who oversees our national system for medical device reporting. So I just wanted to explain a couple things. Jodi, you kicked off the session by referring to quantity and quality of reports. Currently we get over a million medical device for adverse event reports per year. It's increasing by 15 to 20 percent per year.

So from the quantity perspective we get plenty of reports, but what's really important for us are the quality of the reports. We can act on one or two, three or a handful of very good, high quality, complete reports. That's all we need to take action, to work with manufacturers to solve problems, so I would underscore the absolute need for quality reports. I know it's easier said than done, but from my perspective that's critical.

And to expand on that point, as part of our surveillance system we have something called MedSun, which is a medical product safety surveillance network. It's constituted by 250 hospitals in the United States who voluntarily participate with us to report and figure out medical device related problems.

A huge component of our partnership is education and outreach, so we work through biomedical engineers and risk managers at these institutions, number one to educate them about what we mean by device-related events. There were earlier comments about adverse events may occur, but there's no attribution to the health IT system, or in my case, to the medical device. That's a big problem.

So how do we address that? It's by education to these institutions by what we mean about device relatedness. Also, we help them understand what a good report constitutes, completeness. It may vary by device type, in terms of the types of information you want included in reports. The last thing we want is yet another report on adverse outcomes related to devices that we're very, very familiar with.

We are looking, again, for high quality reports, and we also emphasize reporting near miss events. User facilities are mandated to report to the FDA deaths related to devices, as well as serious injuries. But we also emphasize the importance of near misses, because when we hear about near misses, these are potentially preventable serious injuries

and deaths. And that's why they're so important to us. So, that's it.

MS. DANIEL: Rory?

DR. JAFFE: Thank you. This is going to be an answer in three parts, because I wear multiple hats. The first thing I want to say about getting more reports is that we don't necessary need to. We have one advantage in healthcare in that we're a low reliability industry, and we have, events don't come as singlets. They come as multiples. And what we're seeing are groups of vulnerabilities.

When we look at the events, we're able to group them into actually failure modes. And one of the things we have by stating is almost, for instance, alarm management, which I talked about before. We get almost a library of failure modes, and you can start testing the failure modes against the devices, against your controls to see whether you've addressed it. So we don't necessarily need to get more.

We need to get higher quality. I remember going through the MAUDE database and having great difficulty in just the fact that everything's misspelled. That alone causes a great problem with identifying things. What we need to do is a better job with the information we have. The idea of an NTSB type reports on some of these events, I think, is very important. There is a huge difference between healthcare and aviation.

I know I'm stating the obvious, but I'm going to state why I'm putting it here. And that is the comment about the cockpit. In most high reliability industries, there's a technological object at the center of what you're doing. In aviation, for instance, the airplane is a central object to all the interactions that are going on. In healthcare, we don't have that. We have a human that is our patient at the center of our interaction.

We can't instrument the patient like we can instrument an airplane. To give

you a more concrete example, look at barcode medication administration, one place where we're able to get, like, a trail of what's going on. If you look at that, the reason we're able to get the trail is not because the technology can record this information, it's because we've told a nurse to start taking these steps to record everything they're doing.

And yet, the most critical part of that, which is actually handing it to the patient, or putting in the IV is not recorded. And we're seeing a lot of events that occur between the gap and the last barcode scan and the medication getting to the patient. Something that isn't recorded, and can't be recorded unless you have a video camera in there watching every move and automatically recording it.

So I think we have a fundamental challenge, and probably insurmountable challenge in healthcare that we don't have in some of our other industries is that the human interactions are critical to the success or failure at the end point. Of course, in aviation there's a lot of human interactions, but you can see the artifacts of that through what happens with the technological devices they're interacting with. So that's the one thing on aviation.

On sharing information, as Peggy mentioned with the alliance, we have also a nationwide alliance of patient safety organizations, around 30 or 40 PSOs in them. And we recognize the need to share and are doing so more at that level and able to identify, more rapidly, events.

Getting engaged across the life cycle, we've been very active in that. As I mentioned before, I co-chaired the structural data capture initiative on adverse events and patient safety event reporting. We also sit on the ISO committee for ALT69 for small bar connectors seeing that as a risk as well. And we've been working with manufacturers and identifying risks for them. I think one of the important things that PSOs are able to do is help.

See, we're all, To Err in Human was written in 1999. A lot of people started thinking about that even earlier. I mean anesthesiologists, we think about human factors even though there really isn't that.

But there's still a great knowledge deficit. And one of the things we're able to do with the manufacturers, we're always looking and going but then our product worked exactly as we designed it.

If only they hadn't made that mistake, things would've been fine. And so, in getting people to understand that making a device that works as intended is not sufficient anymore, that we have to look to see, especially with very high risk devices, to make them in such ways that they're intuitive, that they work well.

We do a better job with Kleenex boxes than oxygen tanks. You know immediately when the Kleenex box in the hotel is near empty, because the Kleenex changed. Oxygen tank, we expect somebody to crouch down below the gurney to look at the regulator.

So that's one thing. So I'm saying that we don't necessarily need a lot more reports. We do need higher quality reports. I think that needs education of the front line people to actually understand this because, again, they usually only report an HIT event when the HIT doesn't work as designed.

They don't report an HIT event when the HIT works as designed, but in an unsafe manner. That's one of the basic problems. Structured data capture initiative is going to be another way to handle this. And the structured data capture initiative, for those if you're not familiar with it, is an ONC initiative looking to enhance the ability to capture information from EHR for use in other purposes, eligibility, determination -- I'm going to get this wrong. Patient -- public health reporting, patient safety event, the reporting and adverse of

that reporting. And there's one other that I forget.

And the point there is that it is hard for a person to actually accurately fill out, this goes back to the MAUDE system, to accurately fill out a report and get in there the information needed. It takes them time. If it's already in the EHR, it's a shame that you can't just pull it out of there. And that's what this initiative is about, and the hope is that eventually the EHRs, with all the data that they are collecting, even though it's not everything, it's a lot.

We should be able to pull that information out and enrich these reports. The last thing I want to say is just a little side comment. The sociotechnical model, the worst part of that is the name it has, and that I've started discussing that model in detail with people at hospitals.

And they get it. And I was shocked, absolutely shocked, because it's very complex. There's all these components, but you start talking to them. And the people at the front line see all these pressures on them, the legal pressures, the time pressures, the societal pressures, how the HIT systems have information in them or not, how, the difference between patients and such. The entire model, they actually get that intuitively. I think that's important to keep on bringing forward as part of the whole milieu.

MS. DANIEL: Thank you. Okay. Let me go to Gerry, and then we're going to go to the audience. And then we'll come back.

MR. CASTRO: Okay. Well, first of all, I want to thank the panel, because you're making my comments a lot easier. You've covered almost everything that I wanted to touch upon. So I just want to highlight: definitely better data. When I'm going through the reports and when I'm reading the report, and they identify a health IT component, I'm asking myself how exactly, what about that display caused that error?

Was it how the information was organized, or was it in a different screen? Did you have multiple view screens, information on more than one patient up, those kinds of things? Those are the types of questions I would like to know more about.

But, unfortunately, since it happened in the past, and the analysis happened in the past I can't get those questions answered. So to the extent that we can help end users identify and characterize those types of errors, that type of contribution, that would be great.

And I will also say that, to the extent that we can bring all of these data sets together, and I think Peggy and the AQIPS group and then also ECRI is also trying to pull some groups together. So we need the vendors, the patient safety organizations, the government, all in the same room trying to get a handle on this. And, of course, there are models out there. There's the commercial aviation safety team that's out there.

And then the Johns Hopkins group also did the P5S, which the acronym eludes me now, so you can look that up. There's a health affairs article. But at any rate, I did want to touch upon the patient contribution to this. And this came up during one of our learning visits to a large academic medical center, and so what they found is they wanted to give patients access to their medical information. But they had to control what to give the patient, because the patient may jump to the wrong conclusion, or there is a critical piece of information, like say for instance the results of a communicable disease test, such as HIV something like that, that was accidentally transmitted to the patient too early.

So what we found is that technology is great in helping folks communicate, but it also is very quick. So once you press that send button, I mean and we've all experienced this. It's like, no, bring it back. Bring it back. And so we have to be careful about those types of things, especially with the patients. And that's what they found, and that's one of the

incidents.

MS. DANIEL: Great. Thank you. I'm going to go to the audience.

DR. HODGKINS: Is this on?

MS. DANIEL: Yes.

DR. HODGKINS: Thank you, Jodi. Michael Hodgkins with the AMA. So far this has been a very interesting discussion, but a lot of it seems to center around the EHR and the hospital and where there are very well defined mechanisms in place for gathering information and acting on adverse events.

And, but as I interpret the middle tier of risk in the FDASIA report dealing with health management. We're now also looking at thousands, if not tens of thousands of mobile health apps that are in the hands of consumers and physicians, where I don't think the same mechanisms necessarily apply.

And I think we need to consider an additional regime for surveillance and reporting, and though some people may object, I think part of that regime may need to rely on social media.

Today, the most likely avenue through which a consumer might complain about a mobile medical app is through the iTunes store or Google Play or more specialized app stores that are coming online as we speak.

There's also really interesting evidence that's accumulated over time that patients are much more willing to share information about their health with Facebook than they are with their physicians. There's been suggested evidence that Twitter is a better source of detecting postpartum depression than the office visit.

And I think that we're going to have to get very creative if we're going to start

to capture the potential for adverse events in the mobile app space where there's accumulating evidence to suggest that there are some very dangerous apps floating around.

So I'd be curious to hear from the panel what your thoughts are about that.

MS. DANIEL: Why don't we take some responses to that. Drew, would you like to take that?

MR. LADNER: Thank you, very helpful comment. And I couldn't agree more. I think what, in part, that points out is the immaturity of safety in the healthcare industry versus, again, some of the other high risk industries that we've heard lots about whether it's aviation, nuclear power, petrochem, et cetera.

And I think in the case of, NTSB's been mentioned a few times today and yesterday, and to be clear, it wasn't the NTSB that made aviation safe. It was organizations, people, process, technology, external factors, the IOM sociotechnical model being applied.

How do we develop cultures of safety? How do we make our organizations highly reliable. What do we need to do to make sure that Sully can kind of land that plane on the Hudson River successfully?

So what that suggests, getting back to your question, is that while we certainly benefit from a public/private partnership that provides oversight, distribution of best practices, et cetera, we also need, on the other side of maybe a hybrid model, a let a thousand flowers bloom approach.

And if we can leverage, and I would suggest that with the PSO community that already exists, maybe it's not adding a regime but extending the regime and providing a way, for instance, in a more formalized way in the framework, as our government colleagues develop that, for PSOs and others to help those consumers.

I'd also say that it doesn't make sense to make that the exclusive province of PSOs. Heck, if somebody can engage with a PSO but also at the same time potentially there are other innovators who are mining Twitter or mining other social media. Terrific.

Let a thousand flowers bloom. So I think it is an issue. We need to address it, but probably more and more in more of an ecosystem approach where we kind of foster innovation.

MS. DANIEL: Okay. I'm going to go to Matt since he hasn't had a chance to speak, and then I'll come back to the audience.

MR. QUINN: This has been a really instructive panel, but we've talked a lot about sort of high level systems and processes where we can get better data and get better engagement and think about using that.

But I feel that there's a real urgency to attack some of the most urgent issues immediately while we're getting these bigger issues addressed, and the data issues, et cetera, in place.

Is there consensus here on what the top say three issues are that need immediate attention from a patient safety, health IT perspective? And what can we do now, soon, to get the data to understand where vendors, implementing organizations and other stakeholders can be assessed on those most important aspects and thoughts on what we can now to address those.

MS. DANIEL: Does anybody want to answer Mike's question?

(Laughter.)

MS. DANIEL: Okay. So we'll have a few quick responses to that, and then we'll go to the audience. Rory, you want to go?

DR. JAFFE: I'm going to just put one problem on the top of that, there's a zillion problems. But the one problem we're seeing, it's the biggest one, is the human-technology interface and all that entails, whether it's to display the PAC system where the correction will be at the very top and at the very bottom of the reading, but in the middle, you have the old reading. Or whether it is the inability to ascertain which alarm is going off and why it's going off. So that's one of the common areas we're seeing.

MS. DANIEL: Bill?

MR. MARELLA: Hard to know where to start with this, but I would say the usability is probably up there. Maybe that's just another way of saying what Rory brought up. I think problems of interoperability are another major issue.

We've seen cases where critical care ventilators alarm in high alarm mode, and that gets translated, at the patient monitor, into a lower level alarm. That's a pretty dangerous situation, and it's not clear who's responsible for that. Is that the one vendor's responsibility? Is it the other vendor? Is it the middleware vendor? And so it's not clear who owns those problems.

Another one, and I wouldn't call this a short-term thing. I'll just put in the plug for my long-term issue, is getting to a point where we have context-sensitive clinical decision support. And the decision support that we have today is great as far as it goes, but there are still hospitals that I think of as being among the best hospitals in the country who have a lot of override rates in the 80 percents and 90 percents. And they think they're doing better than they were. We can do better than that.

MS. DANIEL: Okay. Let's go to the audience, if you don't mind, and we'll come back. We have a whole other session where we can talk a little bit more about some of

the priorities and how do we leverage the data that we do have.

So I'll start in the front, and we'll just kind of bounce back between the two mics. If you can keep your comments fairly concise so that we can get everybody's comments in, that would be great.

MR. OSBORN: Hello and thank you. I'm Dave Osborn from Philips Healthcare. A follow up on some of the comments from Peggy, Mark and Tom. Given that healthcare IT and medical devices are commingled, how many users know where to report in our voluntary reporting system if we have different reporting venues?

And I think this is particularly an issue for the PSOs and Tom. And I'd also like to echo the fact that HIT is not just the EHR. We have alarm integration. We have CDS, mobile apps, et cetera. The scope is way beyond the EHR. And Rory, thank you so much for your work. I'm into that up to my eyeballs.

MS. DANIEL: Peggy, do you want to give a quick response to that?

MS. BINZER: Sure. PSOs don't distinguish between categories. We have events that are reported that might be related to a medical device, might be related to technology, might just be related to clinical workflow.

And the job of a PSO is to help the healthcare provider work through the event to determine the root cause of that event. We've actually had a number of convenings, safe table exercises with medical device manufacturers.

There has been problems with medication pumps, for example, where we invited the manufacturer in. That manufacturer's still required to make its reports to FDA within the 24 hours if it's something that could cause a serious harm. We don't take responsibility for that, but we've been able to work with manufacturers to improve how

healthcare providers use the product and improve the quality of the product.

And that's also what we're trying to do with the HIT industry as well. We've had great successes, and with the HIT industry we want to get to the place where we can improve the quality of patient care through the use of HIT because we've seen many events where we've said if we could just change a functionality, this never would've happened.

So in essence, PSOs take all reports, but if there's other required reporting, the manufacturer or the provider is still responsible for making those reports.

MS. DANIEL: Okay. Let's go back to the audience and back mic.

DR. CLASSEN: Hi. It's David Classen. I'm with Pascal Metrics and committee on patient safety, and I just wanted to amplify some things that Rory said. First, we're waiting on the sociotechnical framework because we've talked to a lot of hospitals about it as we looked across industries at the most effective framework.

And most of the response from hospitals as we were putting this together was very positive. That model made more sense to them than anything else, including our reliability. And it just struck me that integrated technology, in a way, that it was most effective in using that technology to improve safety. The critical issue for us as I ran the regular report is there were two issues here in safety.

Is HIT causing harm and is HIT preventing harm to its full extent? And if you ask members of the committee, the bigger issue was the second one. We're failing to prevent HIT harm that we could with the systems if we effectively use them. And that came in the discussions in yesterday and the day before's panel. When you look at these systems in actual operation, we're not doing nearly what was promised or claimed when they were developed and implemented. And they are very dynamic. They are complex, adapted systems that are

changing all the time. And what a terrible, unsafe drug order today might be stopped tomorrow. It might not, given how adapted they are.

So if you asked us the IOM what was the critical issue, making sure we're safely operating the systems we have now, if you will, is a priority. And the challenge in doing that is how do we find out about the problems. And having sat on several IOM committees on patient safety, we've always come back to the point that voluntary reporting, which we're talking about today, takes up a small slice of the pie. Less than 10 percent of the safety problems are picked up with voluntary reporting, even in the best of circumstances. There must be other mechanisms to find safety problems.

So if the IOM in all the reports, we've said, voluntary reporting is part of a solution but not all of it. We need to have surveillance mechanisms and other ways to pick up safety problems because we can't design the system based on knowing just about 10 percent or less of the problems. So we really push that hard, and I do think that's something PSOs can do and can move down the road to.

What I would add sort of to finish is that we know, even in the basic area of safety, medication safety where we started this journey, we still have huge gaps. So if you wanted a priority, let's focus on more safe operation and medication safety, which we know still, in all studies, is the number one safety issue for patients in hospitals.

And then back to the AMA comment. In our IOM report, we cited an AMA ambulatory safety study, which most people have ignored, unfortunately. It is a great study, and it showed that ambulatory patient safety is a bigger issue than inpatient safety.

And we are doing nothing in that particular area with HIT. The ability to leverage HIT or just improve the detection of the problems, let alone deal with them, is still far

and few. So, thanks.

MS. DANIEL: Gerry, did you want to make a comment in response?

MR. CASTRO: Yes, actually I wanted to echo David's comments and then also respond to Matthew's question. So in our analysis, what we found is that using the sociotechnical model, many of the contributing factors fell into the category of human/computer interface, right.

So what's happening is that either there's some part of the interface that will confuse the human mind. Bill talked about the long medication list scrolling through, inability to find the correct information or having the critical information rise to the top amongst the masses of data, right.

So what one person said was when we were doing our learning visits is what happens is they lose clinical context for that patient. They lose track of what's going on because of this massive amount of information, or the information that they really, really need is not rising to the top.

And then I'd also steal a comment from another one of our learning visits. They said that documentation in the EHR is not the same as communication. So there's an expectation, well, I'm going to put this in my nursing note. I expect the clinician that's coming online next will read that. So it's very tough.

MS. DANIEL: So I'm going to jump in because I've heard a couple of comments and a few here, and I'd love some folks' thoughts about this is I heard a few people on the panel talk about usability and user experience is one of the key priorities that we need to focus on. We've talked about reporting of safety events, but not necessarily about how do you learn about some of those user related issues and usability issues.

Do folks on the panel have comments on how we can better get an understanding of usability issues or user experience and how do we get good reporting of those kinds of safety issues or potential safety risks with respect to use of health IT products?

Okay. I got a couple of cards on that, so we start with Mark. I'll hit this row first.

DR. SEGAL: Yes, so usability is absolutely critical. And from a GE standpoint, one of the things we're doing is we have the advantage of being a large company that cuts across multiple sectors that use software and ones you wouldn't think about. Airplane engines, power turbines.

And so we are basically building and implementing in increments across the business a common software platform that's modular in nature and drawing on usability lessons that are common across software as well as those that are particularly relevant for healthcare and healthcare IT. And we have usability war constructions and are sort of progressively, you have to implement usability changes like any other changes in sensible ways that can be done.

More generally, at the industry level, one of the things we've been doing, the EHR association is working with some of the professional groups to discuss at a policy level and sub-policy level both what are the usability perspectives, which gets you into interesting areas like where Steve lives in terms of interactions between certification and usability.

And I think we have all, those of us who have been participating in that, I think we've learned from each other and gotten a sense of where the hot buttons are particularly where, as I said in part with certification just as an example, where you wouldn't necessarily think it's an issue.

And again, I think usability is one of those areas, thinking about the center, thinking about some of the work that ONC and ARHQ have done that, and NIST while we are here, that identifying best practices, whether it's based on consensus or based on science and then thinking about how one disseminates those in ways that they can be implemented is absolutely critical.

But I can assure you that from the developer community standpoint, it is a very high priority issue.

MS. DANIEL: Peggy?

MS. BINZER: PSOs generally don't collect a lot of usability data. We do have one PSO that is exclusively collecting usability data. That's Texas A&M, and I just don't think that a lot of organizations know that they're collecting that information. So it's a knowledge issue.

PSOs do see usability issues turned on its head. We see where the user uses technology in a way that the vendor could never have conceived it to be used because they've invested a lot of dollars in the technology, they may have customized it in a way.

And they just want to continue to customize it without spending extra dollars. That's just one thing that we see commonly. We thought that we could do it this way.

And so the PSOs uncover these issues and then we can work with the vendor as well as work with the provider to make sure that the product is actually used as intended and patient care is improved.

MS. DANIEL: Sheryl?

MS. DYNER: Usability is a big issue for us as well, as the providers of software for the ambulatory environment. We have all different levels of users. You've got

some who are experienced IT. You may have patients who are not experienced with IT. And to get them the right training so they know how to use the system correctly, I think we referred to this in an earlier panel, that training the user on the system is imperative to help with usability.

But we encourage our customers to report all usability issues as if they were software breaks so that we can, if we need to, improve the usability of the systems.

MS. DANIEL: Bill?

MR. MARELLA: A couple people have mentioned the Partnership for Health IT Patient Safety that ECRI is trying to facilitate. And I'll give you an example of how I see that working, and it relates to the usability question.

One case that we've seen involved a wrong site surgery. I mean people were, I think everyone understands medication errors and lab errors are the kinds of things we see related to the EHR. This was actually an HIT-mediated, wrong site surgery in which a patient consented for one procedure, later changed their mind and de-consented the original procedure and a second consent was created. Both consents got scanned into the EHR and were rendered to the end user, the circulating nurse, during the time out in a way that led them to do the procedure the patient did not want.

And that's an example of a usability error. It's also an example of a clinical workflow error, and there are a lot of parts to that. But the way I see this partnership working with the vendors and the providers, as well as patient safety organizations, is I don't want to just investigate that one event. I don't want to see screenshots of just that one EHR. I want to see how consents are rendered in all the EHRs from all the vendors that are participating because someone's probably figured out how to deal with that in a sensible way and in a way

that is less likely to reproduce that error.

So, and one of the things that I've learned about reporting systems is that it is critically important to get information back to the clinicians who are originating these reports in the first place because otherwise they'll dry up. And I think if we do that as a communal activity, we have a much better chance of making that work well.

MS. DANIEL: Great. We're running low on time. We've had some folks in the audience waiting for a while, so I'm going to go to the audience. Julian, if you have some comments?

MR. GOLDMAN: Thank you, Julian Goldman from Mass General Hospital. About ten years ago, I was anesthetizing a patient in the middle of the night. He was deathly ill and he was having his leg amputated. It was being amputated because he had a blood clot that couldn't be retrieved, and it was killing his leg. The blood clot had been formed and thrown because he had had a balloon pump in his aorta keeping him alive for a few days after a heart attack.

And when the balloon -- and he had atrial fibrillation intermittently and some other problems. The balloon pump was removed, and the anticoagulant which was required for his disease was not restarted. So when the procedure was over, and he fortunately survived the procedure despite having had just had a heart attack and a whole many other problems, I talked to the surgeon and asked him what happened.

What was the root cause? And the surgeon said, we failed to restart the anticoagulant after removal of the balloon pump. And I dug into that to find out what could have triggered the reminder to restart. And in our current systems, we really can't do that in a reliable, effective way because of the obvious reasons of identifying an event that occurs to a

patient that may or may not be documented in the EHR.

These and many other cases like it, we ended up classifying within our research activities at MGH as clinical scenarios that cross the boundaries of many different technologies and workflows. And somehow it needed to be captured, and we set out doing some of that capturing through focus groups and other work like that.

And about two years ago, the DoD was kind enough to fund a project on something that we call a clinical scenario repository, which is intended to capture events that are not triggered by a medical device that goes up in flames, in which case one calls the FDA, or an obvious problem of another sort.

But something that crosses these boundaries, and as yet, there is no way to report, there hasn't been a way to report these things. And our system is still not up and running. It's under development. It will be piloted at Mass General Hospital for nurses to use to report problems like this, and we have an excellent adverse event reporting systems across Partners Healthcare. But it's focused either on a patient, an adverse event or other specific episode. And it isn't a way, necessarily, for people to convey their vision of a better future leveraging health IT, medical devices, better workflow, et cetera.

And I believe that we are discovering, as a community, that with a repository of information like that, it will provide opportunities for manufacturers to build better technology, for us to integrate the technology better, to generate the requirements that we need for interoperability and system integration and, of course, better methodology to in the future automatically identify events that should never happen.

MS. DANIEL: Thank you, and let's take one more comment from the audience. And then we're going to take a break. So let's go to the back mic.

DR. LATKANY: Hi. My name's Paul Latkany. I'm a clinician and informatician. I have no vendor affiliation. All my views are personal. I thank the organizers for this conference for the opportunity for dialogue.

We need more regulation of this industry and their products immediately, profoundly and granularly. I think it's quite shocking, some of the comments that were mentioned on the panel today. There seems to be a major disconnect between reality and folks in the trenches who have no stake with industry.

John Oliver on HBO had this, I'm not sure if you folks are aware of it, had this skit where he has the climate scientist represented normally 50/50, he had 97 people reflecting the reality of the viewpoints of climate science sort of argue with the people who were against the issues regarding climate change.

And I feel there's a parallel here. Ironically, some of the comments used to reject more detailed regulation are apparently, actually to me, highlight the need for implementation of more granular regulation.

For instance, the use of opioid four times the dose as a default dosage, not being able to find the provider. We need to have holistic mechanisms of surveillance that have been mentioned by the predictive models, as mentioned by the gentleman from MITRE, from the gentleman from Mass General talking about a surveillance model that reflects reality and regulates this industry very profoundly and granularly. Thank you.

MS. DANIEL: Thank you. Well, why don't we take a 15 minute break? It's 10:30 now. We'll be back at 10:45, and we will come back and talk a little bit more about surveillance and then analysis of some of the data that we've been talking about collecting. Thank you.

(Whereupon, the foregoing matter went off the record at 10:31 a.m. and went back on the record at 10:50 a.m.)

MS. DANIEL: Okay. So we're actually going to be moving to talking more about analysis, and I'd also like to talk about surveillance. We talked mostly about reporting, so -- and I know there were some folks who I cut off at the end who may have some comments they want to add back on usability as well.

So we'll be very fluid here, and we will bring back in the audience so folks who didn't have a chance to get their comments raised in the last conversation, we'll try to get back to you all in this conversation.

So we've talked a lot about reporting of data. We've talked a little bit about the kinds of data and from whom. We had some comments from the audience about some more non-traditional health IT devices and getting good data there. I'd be interested in the panelists' input on how we can, and we talked a little bit about some of the collaborations that are going on.

I'd like to talk a little bit more about how we connect some of this data that we do have or that is being reported or that organizations have. And how do we look across the various different types of information that we have to see trends to do some of the analysis and to think about where we there may be some risks that folks may not be able to see by looking just at one particular event or one particular organization?

And I will open that up. Okay. So I will start on this side this time, so we'll go Matt, Rory and then Greg.

MR. QUINN: This dovetails perfectly with the usability comment. So I talked a couple of days ago now about the CHPL, the ONC's Certified Health IT Product List, and

it's showing for the first time as part of certification, participation in quality management systems.

And that's a reporting requirement. There's also in there something called Safety Enhanced Design, and this requires certified vendors to list some of the usability tests that they've done, describe them using the common industry format and to report results.

That's there today. Raise your hand if you've looked at that. Awesome, for something other than your own product. Raise your hand if you've used that in purchasing or deciding on going with one product or another.

I mean, that's something that exists today. I'd also highlight the great work that ONC did in its SHARPC program and the research and the development of a tool called TURF, which is developed by University of Texas, Houston, Jiajie Zhang and his crew, which is an excellent tool that's out there for evaluating and incorporating usability into this as well as the work that Lana has done at NIST on evaluation protocols on NISTIR 7804.

So the data is out there. It might just not be in the form or the location that folks need it. And I would say why don't we start on something that we have today and that we can move forward with quickly in this domain and perhaps in other domains like security, interoperability and others and get that low-hanging fruit.

MS. DANIEL: Okay. Let's go to Rory.

DR. JAFFE: Thank you. When it comes to analysis of this, one thing I want to push back on is the idea of doing trends or even counting things at all. What I say to our members is we're not in the business of counting stuff.

We're in the business of understanding what's going on. And so it is amazing even at our level, we have about 300 member hospitals. The spectrum of experience

we get and the ability to really get the higher picture from that. But that requires a lot of legwork, or eyework really because what we have to do is read the darn reports. Anything short of that doesn't give you the information you want. Even if all the common format fields were filled out, they don't really give you the critical information you want.

The only thing that all this structured data -- and here I've been advocating structured data capture -- but the only thing the structured data really does is allows you to winnow down the reports to the area that you're interested in by looking at characteristics. We found that putting hospitals together, in the safe tables that Peggy mentioned, is extremely useful because you will find a lot of islands of excellence out there in terms of understanding human factors, understanding failures interspersed among a lot of people with the experiences that will feed those islands of excellence. So there's a lot of talent out there, and getting them together in a room and talking about these events has been remarkably useful in getting advances.

And the last thing I want to do is harp on what I've said before about improving the sophistication of the people at least at the hospitals or the clinics, if not at the very front lines to understand this better.

And, for example, to understand that when we're talking about usability, we're not talking about how happy they are with the system but rather how well the system supports the goal of safe care, whereas most of the time people buy the systems now for how happy it makes them, frankly, how easy it is to use and see that as usability rather than saying well, how do we make it safer for our patients.

How will this information, how will the way it's displayed make things safer? I'll give one example on that. I may have already given it earlier today. I'm a little jet-lagged

still. And that is the PACS systems where the radiologist can set which side he or she wants the old film to show on. And so whenever anyone else is looking over somebody's shoulder, they really should not, they don't know which side it's on. They may think they do, but they don't. And we had one very serious near-miss that would've been a death if the nurse hadn't thought, well, something's wrong with this order.

And the order was based on the misinterpretation that the old film was the new film. The new film was an old film. You don't need many of those to identify a problem, a very specific problem, but you need the stories behind it, just like the explanation at MGH and the stories you have. That, indeed, is really what we're looking at is identifying these clusters of stories and clusters of scenarios that show you what the issues are with the way the whole sociotechnical system works and hopefully points to ways to how to fix that.

MS. DANIEL: Great. Drew?

MR. LADNER: Drew Ladner, Pascale Metrics. I would offer an additional perspective which is, I think, rooted in our view that just as we've seen transparency come to pricing of late in healthcare, transparency will come to safety.

In our view, it's not a matter of if, but when. And as that happens, I think that we're going to find that however hard it is and however steep the hill, patients want us to count. Patients want us to measure. When my wife gives birth next, she would like to know what is the rate of harm at this hospital. This is a very basic question that most industries can answer. Based on work and the literature in recent years, we can answer that now in healthcare.

But there needs to be an imperative, going back to your question earlier, Jodi, about needing to measure. What is the rate of harm at each hospital? What is the rate of

defects? And certainly given how the world is transfixed, as we lost regrettably hundreds of people in Malaysia 370. And many of us, most of us, all of us know in this room how many people we're losing every week, every year. Now it looks like it's $200,000 to $400,000 -- I'm sorry, 200,000 to 400,000 people every year, lost, who died due to adverse events in healthcare.

This is a burning platform, and I think that the most important thing that we can do is really move aggressively from deliberation to action. And the start should be measuring and disclosing.

MS. DANIEL: Thank you. Bill?

MR. MARELLA: I just want to pick up on Matt's comment about safety-enhanced design and that criterion and the ONC listing process. One of the things that we have to watch with that is we should expect that our expectations around safety-enhanced design should improve over time.

The technology's evolving rapidly. Features are evolving rapidly. The manufacturers are still trying to differentiate themselves with these additional features, and everybody wants to develop the new killer app.

And some of those things are going to win and some of them are going to lose. And I think as the evidence develops around some of those features that have safety implications, we should look to build that into our understanding of safety-enhanced design.

A good example that I don't think is in the current model, and correct me if I'm wrong about this, is tiered alerting systems. We know that clinicians accept much more readily tiered alerting system as opposed to just sort of a one-sized fits all alert. And that's the kind of thing that I would look for the vendors to incorporate into their systems.

MS. DANIEL: Thank you. Peggy?

MS. BINZER: I'd like to start by echoing Rory's remarks, an n of one can turn out to save a lot of lives because when you get an event and particularly if it's serious and rare, if you respond to that event, then you can prevent those very serious events from ever happening again.

And that's what surveillance is all about, is collecting information and seeing what needs to be investigated and followed up upon. So, care that can affect the bedside and the clinical care and the workflows is local. But I do see a need to collect information and look at trends to be able to use the information to become predictive. And I do see a need for validating the information to ensure that what we're seeing really is an HIT event or not and other processes in that.

I also wanted to just point out we've been kind of looking at one environment. I'm talking primarily about the hospital community because they've been collecting events for a long time. And the issue here is that, particularly with PSOs, we're asking them to collect different and more information, the information that they never collect because of fear of reputational harm, certainly information that they'd never share outside of their hospital walls.

And so the response we get from the hospitals is, you want us to collect something else? Are you new? We're collecting information for 37 different reasons and different organizations. And you look to the other environments that we see, ambulatory care for example. It's an environment that I know that a number of health IT vendors are working with to help them develop reporting, particularly around HIT, and so that's very exciting. Athenahealth, for example, is a leader in this area. I know Allscripts has been doing some

work as well. When we look to long-term care, there's really a paucity of data.

Rehabs, we have one PSO that really focuses exclusively on rehabs. EMS, they use it as certainly different type of software than other type of vendors. Ambulatory surgical centers, another different type of care point.

So I think we have to be cognizant. Different specialties have different software and different changes that they make to that, soft modifications. Anesthesiologists, for example, we have a PSO that is working very heavy within health IT issues related to anesthesiology.

So I think when we look at data aggregation, that looking to one body to say, let's just send everything to one place probably isn't the best idea. It has to go to different places that understand the clinical aspects so that we can determine, again, separating the clinical aspects from the technical aspects.

It will lose half the richness of the data and the analysis, and so it seems to me that there's a lot of different players in the market, a lot of different PSOs and other folks who can contribute to this body of data and transfer it and share it. So again, we're working with the National Patient Safety Foundation to do that.

MS. DANIEL: Mark?

DR. SEGAL: I'd like to build off of something Matt was talking about, sort of two threads. One, we've heard this a few times in terms of, in effect, sort of a bias for action.

And I'd suggest that, and I think we've seen this in some of the recent hearings and others on aspects of meaningful use and certification that government action is not without cost, and particularly in healthcare where we're arguing with so many inputs, but at the same time, there are opportunities for action.

And I think a theme -- and I was thinking about this over the last two days and I think it's relevant here -- a general theme is that we need to have evidence-based regulation or evidence-based oversight in confidence that the benefits exceed the costs in all of that. Having said that, Matt, your example which you asked about today and I think it was yesterday in terms of people using the results of the safety-enhanced design.

One of the opportunities we have, and I'd urge ONC to do this and others who are able is let's look at how that information is used. Let's actually identify ways in which it can be used. I mean, there's a lot of focus now. We've seen this with CMS' recent release of the data on physician payments. The department and others are encouraging people to do mashups and other things with that.

And so we've invested. We all invested collectively a lot in doing the summative testing and having the display. And there's this tendency to want to move on to the next thing. But I think this is a really good example of where there's been an investment made.

And we ought to learn about whether people will use that, what kinds of changes might make it more usable, and things of that sort. So to me, this is a good natural experiment that can be done pretty quickly around, in pursuit of transparency on one of the main things we've heard about, which is usability.

MR. QUINN: Certainly I mean, I would put the quality management system documentation and the summative usability test documentation as things that I hope every vendor was already doing and that putting them in a format that is standard.

An industry format is one way of making them more transparent, but I really like this idea of opening that CHPL up, no pun intended, and mashing it together with other

things and opening it up to social media and displaying other ways so that we can get an idea of crowdsourcing.

So what do these shifts mean? What does the results of the summative usability testing mean? What does this mean right here when quality management system says ISO yadda yadda yadda, and making it transparent and usable, making that information usable for decision makers. And I think that's a great place to start.

MS. DANIEL: Greg?

MR. NELSON: If we go back to, Jodi, your question about analyzing data and how do we get the value from it, if you were to ask the airlines who participate in our partnership and how it's grown from seven to 48, why does that happen. I think their number one reason is data visualization. They are able to read really sophisticated analyses, but we are able to put them on a portal that they are able to access on a daily basis. And it is driven by, they've defined what they need. They've defined the metrics, and they utilize that everyday to make decisions and to take actions.

And the most sophisticated analysis in the world is of no value if it never gets back to the user, especially in this construct I think we're talking about here in healthcare of voluntary partnership, right.

Where is the value proposition? Why would someone want to participate in this? And one of the ways that they're going to gain value is putting that data back out into a form that they can utilize and they don't have to be statisticians and very sophisticated PhDs, but they are able to utilize it. And it is very intuitive, so I put that out there.

The other, I would just mention with Rory's talk about looking at all the good data is in the text right. You are exactly right. When you look at these structured reports, I

mean, structured is good, but the real nuggets are in the text.

And we certainly see that in aviation and in the healthcare, the reports we've looked at. And I think when we think about that, we've got to utilize technology such as natural language processing and other things because we're never going to, at scale, we're never going to be able to hand-review these reports. And so seeing those bigger trends underlying that and thinking about using those kinds of technologies will really help us gain those new insights.

MS. DANIEL: Thank you. Sheryl?

MS. DYNER: Yes. So I know, building on a couple points that I heard earlier, and I'm kind of action oriented myself. And so I want to do something, right.

So I'm wondering, we have already identified some, there pretty much is a consensus on the top areas, medication management, et cetera. If we could collectively or if we could collaborate, pull all the data together from the various sources and look at that and come up with recommended actions for the patient, the providers, the providers of the software and make that information transparent and consumable.

And then we have a baseline to start with and then we should see if there is positive improvement, result in that. And I think that will build a momentum and visibility into the problem and to how we can fix the problem.

MS. DANIEL: Rory, you had a brief response?

DR. JAFFE: Yes, I just wanted to clarify something because Drew was talking about measurement is important. And I do agree on that. The comments formats, as they're designed and as hospitals report them to us, are spectacularly unsuited to measurement and trending because of the anecdotal nature of them.

And ARHQ has seen as well and is developing the common formats for surveillance. And that's when you start seeing this, and then you have your measuring for accountability. So those are all important.

But when you look at the things that the PSOs are getting in particular, you have to be very careful about trying to get trends from them. My experience at a multi -- I used to be the CMO for the UC system, you know, with its medical schools and hospitals all using the same system for reporting, all using it in very different ways, very different reporting rates, none of which had anything to do with the amount of safety that was in that particular hospital.

MR. QUINN: To clarify, there's a common industry format for reporting incidents, and there's also a common industry format, NISTIR 7142, for reporting the results of summative usability testing. And they're different things.

MS. DANIEL: So I want to pick up on something that you said Rory, and Drew maybe this is where you were about to comment is trying to shift from reporting to surveillance and how we can best leverage surveillance as a tool for better understanding of where there might be safety risks related to health IT or where health IT may help improve patient safety in general, also welcome any of the government folks to talk about surveillance that's been going on at the government level and where there may be opportunities to leverage some of the learnings or policies that we have in place.

Drew, did you want to start that?

MR. LADNER: Sure, sure. I think Rory, your comments were helpful and I couldn't agree more. And again, I think it goes back to the fact that as a field, we're at an inflection point.

So when the Patient Safety Act of 2005 was passed, it provided for PSOs. The number of hospitals who have complete EHRs was in the single digits. It's a very different world, and most hospitals relied exclusively on voluntary event reporting for understanding what's happening, what's going wrong.

And I think as a number of folks pointed out earlier in the day, including my colleague, Dr. David Classen, there are other types of data that we can use. And what the literature has shown in recent years is that there are additional evidence-based measures of generating rates beyond voluntary event reporting.

And so Pascale and our PSO and others have kind of gone down this path as well, have used the global trigger tool as an evidence-based approach as a platform to begin to generate rates but going beyond that because notionally, theoretically, the number of potential clinical triggers out there is infinite.

And while I think you made a great point earlier, Rory, that there are limits to which we can instrument the patient, we certainly can instrument the system. And so what we've done at Pascale is go down the path of automating the global trending tool and it's a tool that many large sophisticated systems have adopted but then recently stopped using, but why?

Number one, it's not actionable in its manual form. But if one is taking data electronically out of health IT systems from the EMR and then using clinical validation and confirmation which can be scaled to develop rates, now we have a basis upon which we can begin to make basic measurements and then build from there. So again, this is one among many different approaches I can use. But there are ways to go beyond and start to develop rates that we can kind of use to manage more effectively.

MS. DANIEL: Gerry?

MR. CASTRO: Well, and I completely agree with Drew's comments, but I wanted to touch on something. And I don't have the answer to this. I will preface my comment saying that I don't know. I'm not sure how this can be done.

But as far as surveillance for usability, I want to say that is important but we also have to consider the workflows and processes that the people build on top of those devices. And I think that should be considered as part of the usability discussion because what we're seeing, especially in our data, there are these workflows and processes that they build around this component, but then they may not be optimal.

So the example that Bill shared with the obtaining the informed consent, and there are the two scanned documents for the informed consent. Well, what is the optimal workflow or process that organization should use, using that particular technology. So I think that is definitely a component of usability. I don't know how to keep track of that and I'm not sure how we can do that, so. Sorry.

MS. DANIEL: Bill and then Matt, and then I have a question that I'm getting a couple times on Twitter.

(Laughter)

MS. DANIEL: So we're going to be really multimedia here. If there's something trending, I will ask the panel.

MR. MARELLA: I just wanted to kind of echo what Drew and Rory said. I think we can get useful information out of the case studies. I think we can get useful, and I definitely think we need to get to the point where we can actually measure safety more effectively than we are.

One area that I think could be a model for us is the area of infection

prevention, so the infection prevention field has spent years developing very carefully honed surveillance definitions, validating them where we are getting very good and valid and reliable rates of infections. And CDC administers a program called NHSN that collects this data nationally.

Many PSOs are users of that system, so we've actually gotten to the point where we can pinpoint the problems individual hospitals are having and how those are different from the overall general trend. So Jodi, you were asking about what do we do with all this data now that we have it. So one of the things that we did, there's been a push to reduce what are called central line infections when they put a catheter in and it positions over your heart. If they give you a bloodstream infection while they're doing that, that's a big problem if you're the patient. So, and we've actually made great progress in reducing those over the last ten years.

One of the ways that we've done it is by getting hospitals to adopt a bundle of safe practices around how to insert and care for those catheters and how to get them out as soon as they're no longer necessary. What we're seeing is that there's a general trend toward having solved a lot of the sterile insertion problems, but there are some hospitals that still seem to have a problem with maintenance of those catheters. So if you line all the hospitals up and split those infections into those that you attribute to insertion versus maintenance, you can actually give the hospitals very specific recommendations that they need to follow, even if that's not the general trend that you're trying to promote nationally.

MS. DANIEL: Matt?

MR. QUINN: Just a quick comment on surveillance and what FCC does, which it's maybe not what we all think. We have an authorization program so if you look at

your cell phone or your baby monitor, anything that's a transmitter or spectrum or receiver, you see an FCC stamp on it. And the manufacturer gets that stamp probably from a private sector ATCB or lab through the FCC by agreeing to comply with certain bandwidth use, spectrum use as well as power use. And a certain percentage of random certifications that we give each year or authorizations we go out and check. Or actually our ATCB's do to make sure that they're complying with what they're authorized to use.

The other is that we have a method of people contacting the FCC if there's a problem. And believe me, the FCC gets contacted about problems and a whole array of things that we regulate from, obviously television and radio and stuff like that, too, where there are interference issues. So you turn on your microwave and you hear something happen or you put things together, and we get those, both from people and from manufacturers. So something to think about.

MS. DANIEL: Okay. So as promised, I've gotten a few comments I keep getting re-forwarded about reporting information so I will ask the panel what I see here, which is about contract restrictions that may inhibit the transparency of information about issues of reporting or publicizing information about safety problems or usability problems that occur with health information technology.

Who would like to start with that one? And it's been re-forwarded as big problem exclamation point, so couple people are passing this one along, so Mark would you like to start?

DR. SEGAL: Sure, and I'm glad you asked that. I was noticing that on Twitter, too. That's an issue that certainly we've been hearing about for the last couple, three years. I know it's come up at various ONC sessions.

My sense at one level is it's a bit of an urban legend but nonetheless an important issue. I think there was a meeting on patient safety that we had at ONC a year and a half ago and this came up. And I remember someone sitting to my left who was a hospital counsel who pretty much said she had never found, even if there was contract language that conceivably, in terms of protecting intellectual property, what have you, could be interpreted that way, as a practical matter it had not and would not affect their ability to report.

Nonetheless, I think it's something you have to take quite seriously. You mentioned the EHR Association code of conduct, so we added a specific provision in there basically saying affirmatively that our customers' ability to discuss patient safety issues is important and we would not have contractual provisions that limited that.

From a GE standpoint, I worked with our counsel to evaluate our contracts to see whether we had provisions. I believe not only were changes made for clarity's sake, but the position of our counsel was that we would not be enforcing provisions that could conceivably be interpreted. Because again, all contracts, I mean health IT, other industries have provisions around protecting intellectual property but that we would not be certainly enforcing any of those in a way that would limit the ability of our customers to report patient safety issues, whether in PSOs or in other venues.

So I think it's an issue that's a serious one and deserves to be taken seriously again as shown by the trending today, but also one I think that the industry has really tried to take a proactive view on.

MS. DANIEL: And just a clarifying question. Does that go not only to patient safety reporting but how does it apply for usability or surveillance or other kinds of transparency about experience with products?

DR. SEGAL: Let me just look at the actual language here real quick.

MS. DANIEL: Not to put you on the spot.

DR. SEGAL: No, that's fine. I expected to be on the spot, so the language we adopted was specifically referencing patient safety because that's where that came from. So I would think that to the extent it's sort of a usability kind of issue, that relates. It would fall within that.

At the same time, contracts do have intellectual property provisions, and that's important for the industry to be able to move forward. So I can't speak beyond what it says, which is it's referencing patient safety. But I would also think that some of the examples you gave would reasonably fall within that umbrella.

MS. DANIEL: Thank you. Okay. I have some more questions, but I'm going to go to the audience and get some of the questions that we didn't get to last time, and please state your name and affiliation.

DR. LATKANY: Hello, hi. Paul Latkany, no member affiliation. All my views are personal, as well as speaking for a larger group that doesn't seem to be represented here.

You know, these products can kill people and harm people. The data in other areas of clinical medicine are open for analysis. We have multiple different fields that could take the data and make it optimal for to have the best outcomes.

So fields like engineering, usability metrics, these are all very, very mature fields that just need to be applied to this domain openly.

Restricting the contract language to patient safety is an admirable first step, but it should involve regulation from the government regarding what would be

permitted in a contract, to allow them to receive any type of federal dollars.

I find it personally disgusting that that language is permitted in any way. So I look forward to future action from the ONC and other federal agencies into this space and, you know, it's almost like a child who's learning how to drive and, you know, keeps driving off the road. There's time to take action as soon as possible.

MS. DANIEL: Okay. Let's go to the mic in the back.

DR. SAMO: She's been waiting a long time.

MS. DANIEL: Oh, I'm sorry. Okay, thank you.

MS. STANFORD: Hi. I'm Jean Stanford. I'm with Georgetown and I'm absolutely speaking for myself. I just wanted to mention there's another aspect of patient safety that I'm not hearing anything about, and that is the amazing proliferation of PDFs.

It's sort of like the more structured data, the more PDFs, just like we were -- things that we were putting down on paper. So a lot of the HIEs are getting their meaningful use data in the form of PDFs. I've talked to clinicians who have said that as a transition from one EHR to the other, all their old EHR data was made available for them, if you call that available in the form of PDFs.

I spoke to the clinicians on the floor, and they said I look at two, and then we have to stop, because they've got things to do. They can't index them, they can't find what they need. Critical data can be in there, that they're never going to see.

This is a just completely never commented on problem, but it's getting bigger not smaller, as people are doing meaningful use and expressing their meaningful

use exchange of data via Direct on PDFs. Thank you.

MS. DANIEL: Gerry, did you want to expand on that?

MR. CASTRO: Yes. Actually, I just wanted to comment on that quickly. That is something that our learning visit sites echoed, especially when they had -- when another organization is transferring medical records directly to their organization, you know.

So you want the past medical records of your patient, but when they're transmitted or faxed or PDF'd, then it becomes a dumb document, right. It's just -- it's there. So the clinicians are stuck sifting through pages and pages, trying to find the relevant clinical information.

So that whole theme of lack of clinical -- or losing clinical context has been emerging in our research.

MS. DANIEL: Now I'll go to the back mic. Thank you for waiting.

DR. SAMO: Yes. I'm Toby Samo. I'm the chief medical officer at Allscripts. You know, each one of the reports that have come out about patient safety, whether it be from the IOM, the ONC and now this report, has stressed the importance of having a learning information system.

I think it's key, it's vital, it's the only way that we are going to look at trends, as if we have some centralized data repository that has de-identified not only patient but also product de-identification, so that we can identify specific trends that exist across the industry.

Each one of those reports have brought it up, but none of the reports have said this is what we should do, this is the first step. We've had a lot of excellent

comments that have discussed the incredible complexity that's associated with identifying patient safety events, are they HIT?

I won't, you know, repeat all of those. But we have to do something to get started, and so what's the data flow? What's the relationship between the vendor and a PSO, you know, about going information both ways? How do we take information that has been validated as being correct, as best as we can, and move that data up? How do we get rid of the erroneous reports before all of that gets aggregated?

So I think one of our challenges, and the move that we need to make, is let's make a first step. Let's start making some of those decisions, and whether or not any of the panelists -- I have some proposals. Obviously I've thought about this, but you know, I'll ask the panelists what they think should be our first steps and what some of that data flow should be.

MS. DANIEL: Mark, did you have --

DR. SEGAL: If I may response to the PDF comment?

MS. DANIEL: Oh, okay.

DR. SEGAL: --if I just could, because you know, that's an important issue, and Direct as a protocol, and Dr. Kibbe was talking about that yesterday, can be used for any kind of attachment. We all do email, right? But my understanding, and Steve will certainly correct me if I'm wrong, is that -- although it actually probably should be someone from CMS, that to count for the meaningful use item, it actually has to be a structured data, a CCDA to use an acronym, that in fact is more than a PDF, and it has structured data that can be parsed out.

So again, while Direct is certainly permissive of sending PDFs, and there are any number of reasons why you might want to send it, I think the work by ONC and CMS around particularly Stage 2 of meaningful use was specifically designed to move well beyond PDF documents, for exactly the reasons articulated.

MR. POSNACK: So I'll do the fact check, right. So that is correct for Measure 2, for transition to care, for Stage 2. Stage 1's first measure is more open, in terms of the data. So but I would say explicitly for the Stage 2, Measure 2, that is focused on electronic exchange. It is only permitting the consolidated CDAs, the summary care record standard.

MS. DANIEL: Okay, in response to the last comment in the audience, Bill and then Peggy and then Greg.

MR. MARELLA: Yes. To respond to Toby's challenge, I think one of the first steps that we would recommend, and obviously I have a significant bias here, is that we are encouraging vendors and providers to sign onto the Partnership for Health IT Patient Safety, and a number of the leading vendors have already done that.

We also have a number of individual hospitals as well as health systems that have signed on to do that. So that coalition is growing, and I think it will continue to grow, and many of the organizations in the audience and on the panel today are collaborating organizations in that initiative. So I think we're looking for the next first step; I think that would be a good one.

MS. DANIEL: Peggy.

MS. BINZER: Great, and I'll build on the next first step. The AQIPS and the PSO community have been giving a lot of thought to how to best aggregate

data, collect the data. But not only collecting data, because right now, the IRM report and others, we have a paucity of data.

So pilots like ECRI and other organizations, I think, are really helpful to start building the body of data that we were looking for. We've got pockets. But they do have a lot of pockets, and we have a lot of organizations that are sending out their own alerts.

We have multiple academic medical centers that are doing their own alerts, and they've been turning to us and saying you know, we have some very valuable information to share with the entire health care community. How can we do that?

So not only are we looking at aggregating data and looking for terms and making it predictive, and then looking at ways to feed that information to governmental bodies that are responsible for certification, that are responsible for standards or other areas, FDA for example as well, but looking at it as practices, because we have to be transparent on how to do we respond and fix the problems.

Because a lot of that has to come from the health care community, when you look at work flows and other clinical practices. So AQIPS is looking at having a place to work with PSOs, collect all of that confidential information, work to validate the confidential information, ensure that the best practices are the best practice, ensure that the information that we're receiving is quality information, is valid information, and then working to feed that to -- or organizations that can disseminate those.

So again, we're looking at the National Patient Safety Foundation, because they also have the ability to convene experts and all stakeholders, because a lot of what we're seeing, there isn't a consensus on what is the best practice.

We're getting a lot of information that people say well, there's lots of things that we can do, or we're not ready to fix this yet or those types of very knotty issues. So we have to have a place where we can go and sort those out.

So working with ONC, which I think the Centers have had this idea. If we can bring all of the different resources together, that we can start doing that and creating solutions.

MS. DANIEL: Thanks. Greg.

MR. NELSON: I guess I would just echo the thought that there's not going to be one -- think there's one solution, right? We're going to have to tackle this at multiple levels, and at a national level with the Health IT Safety Center, and at other levels with existing networks and PSOs and ECRIs, pilot project, and then at a, you know, local front line provider level, minor starting up pilot, to try to see what we can -- how this might work at the local level, and direct intervention with providers.

So I think all of those are going to bring something to the table, and they're going to address different needs. So part of the thing I would say it's kind of a thousand flowers blooming.

There's some -- we're going to be learning about this together, and trying to have one master plan is what I think has limited us in the past in trying to move forward, right.

So let's try a number of different initiatives, and I think they're all going to have their successes and disappointments. But we'll learn how they together form kind of a network that addresses all of these issues, because it's such a multi-faceted issue, you're not going to be able to have one solution.

MS. DANIEL: Okay, and one more comment on this point.

MR. LADNER: Yes, I'll be quick. You know, I believe that aggregating and engaging in pattern recognition is an extraordinarily sort of valuable enterprise for the country.

But what we must recognize, not to send it back to you Greg, but I will, but you know, Greg mentioned earlier and the importance of a value proposition, and you know, tending to be very kind of operationally oriented.

We need to make sure that we're aggregating data that's flowing from the use of data, where there is clinical and financial value being generated from these safety activities. The good news is, is that you know, recently in the literature, safety has been tied to enormous, you know, cost reduction opportunities, and we're seeing this in the hospitals we work with.

So you know again, not to beat the drum, but I think measuring and measuring where the clinical care is happening is the most important thing, and as we demonstrate the reduction in harm, as we demonstrate how that's related to cost, that will only make the aggregation of data and the insights we can derive therefrom even more valuable.

MS. DANIEL: Thank you. I'm going to ask one question and then I'll come back the audience, because I want to make sure we get to this question. It was something that we put forward in our report.

What do the -- can you on the panel provide a perspective on the role of government in reporting surveillance analysis, any of the conversations we've had so far, and where the federal government, you know, where the private sector has a better

role to play and the federal government should kind of support but not lead? Rory.

DR. JAFFE: Thank you, and here I'm suddenly going to be in Drew's camp, in that one of our great challenges is that we -- that patient safety data is not first class data. It's difficult to -- it's derived. It's not generated in the normal course of care. You'd have to do things to the systems to collect it.

I do think that systems need to have basic requirements for being able to measure performance. Again, part of this is through the structured data capture initiative. We're looking at specific things.

But you know, getting more deep than that, there should be expectations on the ability of you to look in a system and be able to monitor its safety. So I think that is a place where there is some requirements.

The other thing, and it's a little bit disconnected from what we've been mostly talking about today, is the interoperability question, and this gets more into the distributed systems, the alarms and such like that, that there needs to be a common language that systems speak to each other, so you don't have these quote-unquote walled gardens, where you have to get products from a particular vendor to satisfy your needs for interoperability, even though there isn't a single vendor who has best in breed.

What happens is you have to make lots of compromises to serve interoperability and to get some of the benefits from HIT, because without interoperability, you get very few of the benefits from HIT.

So I think those are very important. I think those are things that the market itself can't really drive and, you know, I have business background. I think, you

know, the market's great when it doesn't fail. But when it fails, that's where government comes in. I think this is one area where the market won't drive it properly.

MS. DANIEL: Greg.

MR. NELSON: One of the items that comes to mind, which has been brought up before in this conference is a lot of the success around reporting revolves around trust, right, and the people trust that they can share and that it's not going to be punitive and all of those things.

Part of that from a government perspective is to respect those orders, right, and not -- the thing that will shut down reporting the fastest is someone suddenly uses some data that you thought was in a non-punitive manner, and it gets used against you

The other issue that's been brought up here is the challenge in this space, as we've seen at this conference alone, sponsored by three different entities, right, and then you think of all the players at the government level who have a role here. Ensuring that there is coordination between those, and that unintentionally or intentionally that there isn't cross messages going on, right, and whether that's in reporting or any of those different aspects.

Because the very fact that it spans so many agencies also gives it an opportunity as a giant lever, I guess, that if those -- the government kind of aligns what they want and how they want it, they can get the regulatory and the financial incentives and the -- it can really make a lot of difference, and that's going to be work up front.

But I think there's an opportunity there that could really benefit this

room.

MS. DANIEL: Mark and then Drew.

DR. SEGAL: Yes. I think the issue what government should do is an important question, and I think it also needs to reflect that there are a lot of things government does that are short of or entirely different than traditional regulation.

ONC, for example, has been very effective in a couple of initiatives that you've done, that are really outside of traditional regulation. Whether it's the SAFER Guides, whether it's the document base -- I think you discussed, Jodi, about a guide for people -- was it around patient safety?

I forget what it was exactly, but it was how providers should, I think, work with patient safety data or something like that.

MS. DANIEL: Yes to address, identify and address some safety issues.

DR. SEGAL: Thank you, and then something that's been, I think, enormously important is something called the value set authority that you worked on with National Library of Medicine, to come up with the various defined co-sets and value sets, an important part of interoperability around quality measurement and quality reporting.

So I think we need to be judicious, and I think Bakul used the phrase yesterday sort of the Pareto principle, of going for the right 20 percent of action that's going to get the most leverage.

Because as we've seen in many areas, including certainly our involvement as an industry in working with providers around aspects of the meaningful use program, it is not costless. There are benefits and there are costs, you know.

Market failure is one of those things where it's a really powerful and important concept, but it's also what I've seen used as, I'll call it a market failure if you're not doing what I'd like you to do. But I think if you apply that concept, again interoperability is a great one, where there are clear --

I mean interoperability can't happen without people operating collectively. There are aspects of interoperability that involve things like ONC, recognizing standards. You go a step further and you say the government, federal government procurement will require things procured by the federal government. You go a step further and you tie it into certification.

So there are a whole series of steps that government can do here, including convening things like this panel. Again, where I would be careful, given things we heard, particularly over the last couple of days, about how much innovation is happening and needs to happen in this space, is the area I'd be most judicious about are those that are closer traditional regulation.

But I think there are lots of areas where the federal government can be a really powerful lever.

MS. DANIEL: Drew.

MR. LADNER: I would, you know, echo some of the comments. Clearly this is about public-private partnership. Both the public sector and the private sector have been involved, and so to kind of say what Mark said a different way, whatever success there's been or whatever failure there's been, both the public and private sector have been in it together.

And so likewise, as we look at solutions, there's clearly a role for both to

play. On the government side, you know, we wouldn't be here if it weren't for the government convening. So I think the convening power is extraordinarily important, particularly given all the issues we're talking about.

The coordination, I think, is the swiftest thing of best practices and what's working, and clearly as we look at the different agencies involved, there's certification and reimbursement tied to safety. There's research. There's other regulation around medical devices.

All those things are very, very important if we're going to solve these problems. On the other side, on the private sector side and, you know, this is a country that happily is a source of great innovation, and we need to take advantage of that, because a lot of that innovation can address a lot of the issues that we're talking about.

I think the one piece I'd highlight there is that -- and this was discussed a bit yesterday -- because of where we are in the maturity cycle, which is not very mature, we need to be open to taking more risk, and risk comes with cost.

So I think as the public and private sectors collaborate, we need to be open to taking risk. We need to be open to affirming innovation that is happening within the context of being at the table with regulators, ensuring that, you know, standards are being affirmed that are emerging, and that the direction is being driven in a more certain way, so the field has more certainty as to where all this is headed, so we can make investments accordingly.

MS. DANIEL: Thank you. Okay. Let's move back to the audience, and we'll start with Lana.

MS. LOWRY: Okay. Lana Lowry. I'm with NIEST and I'm a project lead for the Health Information Technology Usability. I think it's extremely encouraging to hear from this panel, and the recognition of the importance of visibility and user experience, and I will briefly address two things that I think are important in today's discussion.

The market data that will be collected is very important. But I do have to make it clear there is a difference between use error and usability error. If human being commits the error of not or not completes the task, they have no way to know and they really don't know what course, whether it's functionality problem, use problem or usability problem.

So as we get this data, describe this data to try the innovation and then pose safety, it is very important how this data will be analyzed. I think that will be analyzed in this data will have to possess clinical expertise, will have to possess human factors, human factors expertise to make a determination why this error occurred.

And the second statement that I would like to make, I appreciate it very much that Matt addressed the fact now, on the public domain, we have some testing reports available for review. The truth is, because it's in public domain, I looked through those reports, and I need to report to you that there is a great inconsistency in completion of those reports.

So maybe for those reports to become efficient tool, and some of the testing is a golden standard in human factors in the performance of the system, they should be come more consistent.

I guess what the role of the government here is to provide training to

those people who evaluate the report, those who submit report, in support in science and technology, the ability to evaluate those reports and make them consistent, I'm sorry. Then they can compare oranges to oranges and apples to apples. Thank you.

MS. DANIEL: Thank you. In the back.

MR. VARRICCHIONE: Hi. My name's Tom Varricchione. I'm in charge of Clinical Research and Regulatory Affairs for Ximedica. We're a research design and development service provider. So we get hired by companies to develop products for them.

I just want to make a couple of points about human factors and usability. We do an awful lot of human factors and usability evaluations, and somebody, a couple of people have made comments about the importance of summative usability testing.

I just want to make a point that oftentimes that's just too late. You've really got to get the safety information, the problem information to the product development engineers during the development phase. It's really all about the formative usability evaluations that really influences the product design.

By the time you get to a fixed design and do summative testing on it, there's so much ownership there that you're going to have to overcome attitudes with regard to problems with the design.

The other comment I want to make is one of the gentlemen mentioned that they hope that industry is consistently and always applying human factors discipline to product development. Well I can tell you, having done regulatory affairs for 25 plus years, industry watched FDA preach about human factors and usability for decades.

Only when those experts inside FDA got assigned to product review teams, did it really change the way industry started behaving with regard to product development.

So I want to make the point that the pre-market phase is an absolutely critical phase for, for lack of a better word, forcing industry to do its best job of developing usable products. Thank you.

MS. DANIEL: Thank you. Brian.

MR. AHIER: Hi, I'm Brian Ahier, and this is slightly off topic from usability. I apologize, but I wanted to make sure that I got this on the record, that is a significant issue around patient safety and health IT, specifically to electronic health records and the way contracting takes place was raised in the Institute of Medicine report in 2011, "Health IT and Patient Safety: Building Safer Systems for Better Care."

The issue that was raised is that almost always, the contracts have hold harmless clauses that do not allow the EHR vendors to be accountable in any way for safety problems. There's also additional clauses that don't even allow the reporting of software glitches, bugs and issues related to the usability of the software that could cause patient harm.

The Institute of Medicine, that report in 2011 made some recommendations on the various aspects of patient safety relating to health IT, and Recommendation No. 2 is the one that they made on this.

So I would encourage the FDA, the ONC and FCC to revisit that report, in light of this new FDASIA report, and maybe find ways that we can implement some solutions to that, because it's -- as you know, yesterday we talked a lot about the

analogy between the auto industry or the airline industry.

I couldn't imagine if I bought a car that the manufacturer of the car made me sign a contract that said will not be responsible for anything goes wrong, and your family is killed because of a defect in our manufacturing.

Yet with our software vendors, those clauses are in place in contracts, and it can create problems. Thank you.

MS. DANIEL: Thank you, and one more comment from the audience?

MR. REID: Yes. This is Matt Reid with the American Medical Association. I'd like to echo this gentlemen's comment regarding the hold harmless clause.

We had engaged with EHRA, that was brought up earlier, regarding their code of conduct, which states that they would not hold providers or customers accountable for making mention of patient safety or usability issues.

We didn't ask them what specifically they meant by hold individuals accountable. They said that providers or organizations would be able to address this at appropriate venues. They did not clarify what an appropriate venue is.

To us, an appropriate venue would be any place that a physician would be able to discuss openly with other providers or other consumers issues, usability and patient safety issues.

We are in partnership with American EHR, with ACP on a -- basically a bulletin board where providers can register, make comments about their EHR products. We asked if that's an appropriate venue. They did not reply back. They said that was something they'd have to talk about and get back to us on.

We have not heard back from EHRA. So I would like to ask that EHRA would clarify what they mean by an appropriate reporting venue. I think that would definitely help move this ball forward. Thank you.

MS. DANIEL: Okay. So we have just a few more minutes. Thank you for all those comments. What I'm going to do is quickly go around the room and give everybody 30 seconds, if you have one last point or comment you'd like to make. If you don't and you want to pass, that's fine as well, to give somebody else a little more time.

Why don't I start -- I'd like to -- why don't I start with Greg?

MR. NELSON: I knew I shouldn't have looked up. So 50-50 chance between me and Matt. I've got one thing, 30 seconds. I guess I would say that we have the opportunity -- today we have lots of data that's being generated every day by all of these systems.

So we don't have to collect something new. We don't have to create new systems. We don't have to put new burdens on people. If we think creatively and we have the models out there, we can use what we have, and what's being generated every day to identify new patient safety insights.

DR. SEGAL: I think just to reinforce something that we've heard multiple times about not siloing HIT safety, but making sure that our patient safety systems are competent and more than competent to handle the increasing digital world that we're living in.

Then a second sort of related point is to make sure that we're acting on evidence, that we learn before we act, and that the next panel, which I think you'll be

leading as well, in terms of the Patient Safety Center I think provides a really good venue for thinking about how do we structure getting the information we need to make the proper decisions and effective actions.

MS. DANIEL: Peggy.

MS. BINZER: I'd like to also echo the no silos comment, but in the relationship between the need not to separate HIT analysis from a clinical analysis, that we have to do that together. I'd also like to echo all the comments that we need to be transparent about potential hazards and also potential solutions to those hazards that have been validated and gone through patient safety experts and panels and other things.

MS. DANIEL: Cheryl.

MS. DYNER: I agree with my colleagues. I think there should be a venue for where you can consolidate all the work that's being done, optimize the expertise of those who have been doing this for years, and to push forward, you know, information that can be used by the providers of care, providers of software and the patients, to help engage everyone in improving patient safety.

MS. DANIEL: Thanks. Bill.

MR. MARELLA: I guess you asked a question earlier about what's the appropriate role of government, and one of the things that I think the government would be in a unique position to do is to develop clinical quality measures around EHR implementations.

We have thousands of measures, many of which are now being used for -- to create financial incentives for providers to perform better than they are.

I think the safer guides are probably the best work that's been done in this area so far, and I think those are going to be a fantastic tool for prioritization. They're going to be a great tool for self-assessment.

But there's still a lot of subjectivity in there, and I think we need to get to a point where we can be -- have a little bit more clarity around what is the best way to do this, and you know, hopefully that will be a form of measurement as well, in addition to measuring the outcomes at the patient level.

MS. DANIEL: Great. Drew.

MR. LADNER: In almost every sphere of life, we measure. We measure because something's important. We value it and, you know, even in love, you know. How much time did you spend with me, right? The measurement is always there.

So you know, we know that one out of three patients are getting hurt. It's a huge problem. I think that we need to start measuring rates of harm at a most foundational level, and when we do that, we'll start to find that we can actually attack one of the other big problems, which is cost.

MS. DANIEL: Tom.

DR. GROSS: So I've gotten a very good appreciation for how complex this issue is this morning. The topics touched upon certainly resonate with FDA, particularly the importance of the quality of the reports over the quantity of reports.

I mentioned that we do have extensive experience in this arena, and we're more than happy to share our experience as sort of lessons learned as you go forward. So I think that's about it.

MS. DANIEL: Roy.

DR. JAFFE: On train people to identify HIT issues better, improve analysis of events, I think something like an NTSB-style review of some of these events will be very useful for the industry.

I'd like to see the analyses being multidisciplinary. It would be great to have the EHR vendors as part of this, similarly as in aviation where the manufacturers are.

We need to improve interoperability. Again, that's one of the key issues we have, and we need to improve safety information capture, and in terms of the measurements and all, I think we need to get -- start working with the NQF to get appropriate safety measures up.

Because for instance, one thing you were bringing up with measure, measure, measure, I think is well, what do we measure against? We can, for instance, do you know, wrong medication -- I mean wrong patient measurements through the people who cancel medication, go to a different patient, order the same medication again.

There was a nice study on that. But how do we get people to use this data properly? We need something like NQF and standards like that to have it happen.

MS. DANIEL: Steve.

MR. POSNACK: I've yielded my time to everyone else.

MS. DANIEL: Gerry.

MR. CASTRO: Again, break down the silos absolutely, but I think we need to do a better job of pushing out what we do know, those risks that we have

identified out to the end users, and help them get back to us as well, you know, open up the communication a little bit better.

I would also that we can't forget about other settings. I mean we at the Joint Commission are absolutely guilty of this. We focus on the hospital setting all the time. But we credit over 20,000 organizations. That includes home care, behavioral health care and then so on and so forth. So we cannot forget about those kinds of other settings.

MS. DANIEL: Matt.

MR. QUINN: I would just leave us with a question. Should there be special considerations?

We've talked a lot about EHRs for truly consumer products, and where consumer products touch the health care world, you know, how people without medical training and actually with medical training use things in unanticipated ways, and how we provide transparency around that and what works and what doesn't work is sort of a different domain. So comments appreciated there.

MS. DANIEL: Great. Well, please join me in thanking this panel for a very rich and thoughtful discussion.

(Applause.)

MS. DANIEL: And please do join us this afternoon. We'll take some of this discussion and further flesh it out as we talk more about the Safety Center and how we can leverage the Safety Center to take on some of the tough issues that were addressed this morning.

Thank you, and Bakul you -- okay. Bakul will lead us through the next

phase with public comment.

MR. PATEL: Great panel. Great panel discussion. As for the last two days we've been doing, this is a period where folks that signed up for making public comments can step up to the stage. I have probably two people who had signed up, either indicated that in their reservation or not, but see if they're still wanting to do this.

Margaret Binzer and Ronni Solomon had indicated they would want to make comments, and if you still are interested, should come up here at the podium and make your comments for four minutes.

(Off mic comments.)

MR. PATEL: Ahh, I see. So we had a little confusion in the past. So I take it, is there anybody else in the audience want to make comments in this time, you're open to do so, and please limit your comments to four minutes, and please not any advertisements for your products or services.

MR. CHAMBERLAIN: My name is Dick Chamberlain, and I do consulting for the pharmaceutical industry. There is one area where the pharmaceutical industry has done a lot of work, and when I mention it, I don't want anybody to jump out windows or anything.

But they've learned that there's a right way to do these things and a wrong way to do these things. But the one thing I think is missing from a lot of this is more written standard operating procedures, that are closer to the people doing the work. So it's written down what you're supposed to do.

You can't do QA if you don't have some of that stuff written down. It's hard to do it without it written down. So I know it's written down some place, a

medical school or whatever. But it's got to be closer to the people doing the work. Thank you.

MR. PATEL: So if we don't have anybody else wanting to make public comments, we'll adjourn for lunch, and we get extra half hour, almost a half an hour extra lunch for lunch. We'll be back here by 1:30 for folks on web, so they can be dialed in at the same time. So back at 1:30. Thanks everybody.

(Whereupon, the above-entitled matter went off the record at 12:06 p.m. and resumed at 1:33 p.m.)

A F T E R N O O N S E S S I O N

1:33 p.m.

MR. PATEL: Welcome back. We will begin our discussion on the Safety Center value proposition. If everybody could get back to their seats, we can begin the discussion, and I'll request the panelists to start joining the stage and in their seats.

Welcome back from lunch. The last stretch. I think this is -- we saved this most important discussion to the end. So hopefully we'll have a robust and engaging conversation now. Jodi, take it over.

(Pause.)

MS. DANIEL: Okay, welcome everybody. Our last two panels of the day -- or last panel of the day, last two sessions of the day, and while everybody's getting settled, thank you for joining us.

We had -- I hope that most of you were able to hear our morning discussion, because I think that we will have a lot of continuity in our conversation and pick up some of the issues where we left off, as well as have some further conversation.

So just by way of introduction, the draft report, the draft health IT report recommends the creation of health IT safety center. It's something that we've been thinking about at ONC for some time, and there is -- we did put a proposal in the 2015 President's budget for a health IT safety center.

So it's something that we are committed to moving forward on, and we really envision this to serve as a trusted convener of health IT stakeholders, to focus on activities to promote health IT as an integral part of patient safety, both to make sure

that products are safe, as well as to make sure we're leveraging health IT to improve patient safety.

We wanted to create a venue to assist in a learning system. We heard this a lot from the Institute of -- back from the days when the Institute of Medicine did their report a few years back, and has been a consistent drumbeat throughout, that we need to think about learning and continued improvement as an effective way to promote health IT and patient safety.

We had put forward in the proposal, and we envisioned the safety center doing three primary things, Steve Posnack calling them the three E's. So it helps me to remember, even after lunch, before I've had m second dose of coffee, and there are three things, three E's: engagement, evidence and education.

So we talk about engagement of stakeholders to support a culture of safety and shared responsibility, and we've heard this morning about some of the stakeholders that we may need tot make sure are included at the table, who may not have traditionally been included at the table when we talk about patient safety, such as some of the mobile app developers.

We talked about patients. We talked about some of the small health care providers that are less likely to provide safety reports through PSOs and the like. The second is evidence. We wanted to see the safety center as a way of building on and improving the evidence for health IT safety.

We did hear this morning a lot about reporting evidence. We heard about PSAs and the work that they're doing, the Joint Commission, and we're looking at how can we build on that evidence base and we'll be interested in the panel's thoughts

on how we can leverage what we have where there may be gaps, and how we can leverage to safety center to address both of those.

Then third was supporting learning through education. So 30 is education, on best practices, on identifying risks, mitigation strategies, usability, work flow. All of that is potential for our safety center.

So that's just our initial thinking on this. I look forward to this panel to help us flesh this out, to think more about what this could look like, how we can engage stakeholders, how we can provide value to all the stakeholders, as well as ultimately to improving patient safety for the patients, and how we can leverage existing bodies' efforts and make this a collaborative approach.

So by way of introduction, I will, for those who have been here before for the last two and a half days, you've seen sort of how the process works. I'll ask folks if you have comments to put up your tent cards and I'll either call on folks as they put them up, or go around if everybody seems to want to make a comment.

We will try to also bring in audience comments like we've done in the past, and I will pull up my iPad in case the Twitter feed starts trending again, and I see something that comes up that seems to be a burning issue that folks want the panel to address.

So I will start out with the first question. I just want to ask kind of an overarching question to start out. I'd like to hear the panel's thoughts on creation of the safety center, and how to be sure we're thinking about this not just in the limited context of health IT, but in the broader framework of patient safety.

We've heard a lot in the panel before this, and a couple of the summary

comments at the end about maybe we don't have silos of information, because oftentimes a safety event has a blending of both health IT-related issues as well as non-health IT related issues.

So how should we be thinking about the creation of the safety center in that broader context of health safety, and in the context of the broader activities that are currently going on today? Who would like to start?

Okay. Janet, then Ronni and then Jean. And please, the first time you speak at least, state your name and your affiliation, so folks know who your representation is.

MS. MARCHIBRODA: So Jodi, thank you for having us today, and just thank you for this incredible workshop and all the listening and sharing that's been going on.

We're delighted to be here. I'm Janet Marchibroda. I direct the health innovation initiative at the Bipartisan Policy Center, and we've actually been thinking a lot about governance and how to move all of these elements forward, the elements that you put in your report.

I don't know who was here on Tuesday, but you know, we spent a couple of years, almost two years engaging more than 100 organizations, consumer groups, patient safety organizations, technology companies and clinicians and hospitals on so how do you move this forward? How do you implement it?

I'd like to just share some key principles, how they align with your report, which they do, and then key considerations fo governance, and I'll be really quick here.

So I mentioned this on Tuesday. I know a lot of folks have talked about this, this notion of shared responsibility. So governance should have everyone at the table, those who develop, those who implement, those who use health IT, those who are impacted by it, consumers, government and the private sector. So of course having everyone at the table, developing or addressing all aspects of the life cycle.

What we also said, you know, in this environment, at the Bipartisan Policy Center we did a lot around policy, and what's going on on the Hill. As you all know, it's really hard to get anything moving, and it's even harder to get anything done that costs a lot more money, because there isn't any.

So leveraging existing processes and systems, as you've outlined in your report, I think would be really important, as opposed to creating something new.

In terms of governance, public-private partnership, we commend your comments on that in the draft plan. We think it should be funded by a variety of folks. Government, but also folks in the private sector, across the continuum.

In addition to your three E's, I might add a fourth, and I don't know if I could make it an E, but this notion of getting agreement. We don't know right now what the right standards are for effective, safe, development, implementation and use. So getting to some agreement on standards for that I think should happen in this center.

OMB Circular A-119. I know, you know, government is always -- they've got some key attributes for organizations that sit in the private sector, that federal government can rely upon. Openness, due process, appeals and consensus. So we think the organization should reflect those principles.

We'd love for the agencies to play a critical and important role at the

table with others, as you've laid out. Lots of public participation. So open meetings. Everyone gets to come. Everything comes to mind, you know. What you see is what you get. There are no back room discussions. Fair, trusted.

I talked about this notion of agreeing on standards. I know we're going to talk more. But really fast, one more. Talked about leveraging existing organizations. As you mention in your report, the Patient Safety and Quality Improvement Act took a long time to get through, bipartisan support several years ago.

So leveraging the authorities in that Act, and maybe using administration ability to extend some of those protections, to have all the parties at the table, developers and users, will be important. Leveraging those PSOs. I think the Alliance for Quality Improvement, I know Ronni is here, Drew Ladner is here.

There are a number of PSOs leveraging what they do for reporting, and leveraging other organizations that are really moving forward on safety and health care like the National Patient Safety Foundation. So those are my brief remarks. Thank you.

MS. DANIEL: Thank you, Janet. Ronni.

MS. SOLOMON: So I think that to talk about governance, it would help to have a vision of where we see this health IT center going, because you know, the purpose of governance is to carry out the mission.

And so I think we need to ask ourselves those kinds of questions, you know. Is this a learning agency? Is it an accountability agency? Is it an enforcement agency, you know. What are the big goals that we want to try to accomplish here. I think that those three E's are a start, but I think that in order to

really figure out a governance structure, we're probably going to have to get a little bit more specific about what we see the center doing.

Is the center about making change. Is the center about helping to sustain those changes? So I think that all of those things will make a difference in how we set it up.

That said, having had the experience of working with a lot of learning organizations and reporting organizations, I think that there are some characteristics that we want to make sure are there, especially if it's going to be a learning organization, and we've learned these.

So we need a non-punitive system. You know, if we expect to get honest information from people, then there's got to be some way to incent getting that information.

I'm going to give you an example in Pennsylvania, because I'm very familiar with it. But in Pennsylvania we've got a Patient Safety Authority. It's an independent safety agency, okay, doesn't have regulatory authority.

It doesn't have enforcement authority, and what it does is get safety information, not siloed but safety information across the board from all of the hospitals and ambulatory surgical centers and other types of providers, not physician office, not ambulatory except for surgery, in Pennsylvania.

Before the agency was created, there was actually a mandatory reporting law for patient safety events. Maybe a 1,000 came in a year. Once the agency was put into place and learning was put into place, but also confidentiality and a non-punitive environment was put into place, we're now getting about a quarter of a

million reports a year.

Now I noted that at the last panel there was also a lot of discussion of quantity versus quality. But I think that, you know, this Pennsylvania, it's a model for how to get this data, because it's quantity and it's also good quality information.

So I think the non-punitive piece, confidentiality. I think that independence is key based on expertise; that there's timely response, that people don't feel like they're providing information to an agency that goes into a black hole.

So you've got to have people there who can respond. All of these are really important characteristics to making a center have trust and be sustainable.

MS. DANIEL: Thanks. Jeanie.

MS. SCOTT: Hi. Just introductions. I remember from the last two days. Hi. Jeanie Scott from the Department of Veterans Affairs. I'm the Director of the Informatics Patient Safety area, which is just a little bit different. I'm not with the National Center for Patient Safety, but work very closely with them.

I think that's a distinction here, because what -- and I made myself a little note here. Are you setting up a health IT safety center or a safety center?

In the discussions the last couple of days, we've heard about PSOs, which are collecting safety events, but which is going to health IT, if you're collecting about health IT safety.

So are you collecting about the event, or are you colleting about -- are you collecting about the product or are you collecting about the process, and the product is part of the process. I think that's part of what your structure has to begin to tease out.

We work very closely with the National Center for Patient Safety. We are one of the products. We work with the investigator there. So I think that's one thing to consider in your governance structure, is how you're going to be working with the process of event reporting and to distinguish that.

The other points that I wanted to make, I was making some notes over the next couple of days is one of the things as I've been working with this is there is health -- there are some software that is regulated that not medical device, as what we think about as ventilators and the biomedical type of equipment.

It's blood bank software. It is that, you know you -- the coding software. But it's regulated under blood bank. It's not regulated under health IT. So I think that is an area that needs to be clarified in part of this, but it is setting a precedent. It is software that is regulated in there.

But one of the things in working with that is if you don't have to report it, you won't want to report it. If you don't have to report it, they won't report it. There's always this fine line of when I've been working with it in the VA is oh, we don't have to report that, so we won't report it.

There's been this discussion in here, some of the governance thing is thinking about the parameters of reporting. Reporting is very important, and how you're going to collect that. Then one of the other parts is this is -- there's a different workforce that is going to be needed to do this governance here.

I know ONC is really working on your informatics workforce. There's going to be challenges to be looking in that, is -- you have your clinical people, your docs and your nurses, and you have your IT people. There's a whole new workforce that is

going to be needed, and your patient safety people. Consider your human factors and your informatics. Human factors people are not easy to get by. There's not many out there, and they need to be considered in this as well.

MS. DANIEL: Thank you.

MS. SCOTT: And just my last point is litigation, you know, transparency. There's no guarantee on litigation, you know, to folks that protect them about that. We have in the VA, we have open -- we have open disclosure. It doesn't mean people can't sue you. So I think we can put that out there. But that's still something that can happen. Thank you.

MS. DANIEL: Thank you. Julian.

DR. GOLDMAN: Thank you. Hi, I'm Julian and my mic isn't on. Hi. Julian Goldman from Mass General Hospital and Partners HealthCare. Last summer, as people know it's called the summer of FDASIA, that's how we spent our summer vacation, many of us here worked on that.

I was asked to develop a webinar, and that presented on July 3rd. So the attendance, while I was on the call, I think I was the only one. There was a webinar on July 3rd, and the webinar was on safety, on reporting paradigms. So you know, there actually were quite a few people on the call and a lot of discussion about reporting paradigms.

We listed many reporting paradigms that exist today. Maybe there's a better word than reporting paradigms. But they included things like looking at how the Consumer Products Safety Commission addresses reporting, the aviation safety reporting system, of course, many of the things that we've already talked about in terms

of patient safety organizations. So I think this committee and this environment is a good place to raise these as possible sources or references that need to be examined more closely, and also the opportunity for us here to gather requirements, and to think about the needs and the spectrum of the need.

One of the things, therefore, that we could target here is perhaps looking at the three -- you have the three E's I think there are. Nothing quite as -- you're giving awards out today for, you know, no? No awards today. Okay.

MS. DANIEL: Well, if you come up with a better -- a better description of what the safety center should do and come up with a good, a good way of describing it that's better than the three E's, I'll give out an award for that.

DR. GOLDMAN: Well, I'm sorry to say, I'm not a contender. However, I think it's helpful to break the process down into three steps. The first step are the inputs. The second step is the analysis, and the third step is the output or how to affect change.

Each of these are massively complex and vitally important to think through ahead of time. So as far as inputs, for example, just to touch on some of these, one of the use cases that was presented in the Summer of FDASIA was an example of a wireless infusion pump misbehaving at a patient's bedside, not receiving a command through the wireless network, and causing a patient injury.

Now the only thing perhaps that the hospital knows, the nurse or physician or patient's family, is that there was a problem with medication administration. But what if the problem was caused because -- by something else, another wireless device brought in proximity to the patient?

How do we determine what happened? How do we trace that? How do we figure that out, and who should do that? You know, at the time that the report -- that the event happens, it isn't clear whether it's a medical device-related problem, whether it's a spectrum issue, whether it's a health IT-related, kind of core health IT issue or IT infrastructure. So it isn't going to be known at that point in time.

So I think one point is that determining too early or attempting to know, to expect to know early in the process is probably unrealistic. The second point is that we have to know the context and the outcome. So we have to tie together as much as we can. We need to know under what circumstances it happened. Does it have to do with the training environment, with the complexity of the environment, and so forth, and what was the outcome? Was there truly an adverse event?

The third point is expecting that we use adverse events as the trigger for understanding problems with the system, I think, is just a bad idea to begin with, to depend solely on adverse events. First of all, they're typically not reported. We know that it's a tip of an iceberg problem. We'll be able to learn a lot more about trends, for example, before there's actually a patient injury, if we put our focus there. We can start to see changes in practice or behavior, or things that are addressed.

I'll conclude by pointing out that in 2011, I mentioned previously that I'm involved with a federally funded research group at Mass General Hospital on medical device interoperability, and we thought about this for several years.

In 2011, we presented to a White House Senior Steering Group the concept of a Health IT Safety Administration, a HTSA, which received interesting

comments and discussion for quite some time, and published some information about that in a white paper, pointing out some of these core issues.

So that information is still available, even though it's -- some of it's stale and some of it's been refreshed. The down side of that was using the word "administration," and it produced an allergic reaction by some people, thinking that it was calling for more, you know, a new agency, I'm sorry agency or administration.

But that really isn't the point, and I can just -- I can tell you that many -- I and many people that I've spoken with are just thrilled that finally we're seeing the federal and national level of recognition, that the only solution to something this important is a broad horizontal perspective, a multi-stakeholder perspective with sharing of information, and hopefully we can all help in some manner at some point get that done.

MS. DANIEL: So I'm going to -- I've got on the list Toby, Michael, Jeff. I mean I'll throw out a little bit more. That kind of helps narrow the conversation a little bit as you're responding. If you could also kind of start targeting the focus on value, which is what this particular panel in this particular discussion is about.

So we've heard a lot about the need to get all the different stakeholders to the table. We have -- in the report we talked about it in the health management, health IT column that the category, FDA has talked about not actively regulating in that space.

So the question is is what's the value proposition to the various different stakeholders, that we want or need to participate in the health IT safety center, and how do we get those folks who may not either be in the health care world

currently or not be as engaged on patient safety issues, or just don't have the resources and time to participate.

How do we -- what's the value proposition for various different stakeholders, to bring them to the table so we make sure that we have that engagement piece, so that we can get the right evidence, get the right analytics, get the right best practices and all of that.

So just as you're responding on the broader question, if you can also start thinking about the value, and if folks want to jump in after those three, that would be great. So I had Toby next.

DR. SAMO: So I'm Toby Samo. I'm chief medical officer for Allscirpt. So I will take ownership right up front to being the evil vendor, just get that out of the way. So a few points relating to the value proposition in particular, and the work done by the FDASIA Group, I think, is excellent.

The direction that it's taking us of, you know, clarification of issues. I mean I read through this, and I said, oh, somebody finally got all the things that we have been talking about. Not to belittle the other events but, you know, there has been over time a refinement of the thought process, and I think that the group really identified that.

However, of course, there is a however, when we asked about the health safety center and what did I think about it, I said, well, you know, the concept is a great idea, depending on what it is. I understand that it was not the purpose of the committee to really define that. But the way it's described in the report is pretty nebulous. So therefore, I mean I think it's very important that we identify what should

be the function, you know, to Ronni's point.

So how much of influence, let's say, or how potent will this entity be, and is it going to be an entity that is -- is it an influencer? So let me start off and say let's go with the assumption that it has the appropriate multi-stakeholder composition. So with that, we can talk about what that means. But with that, is it an influencer? Is it a place for all of us to get together and vent our frustrations, and somebody says good, you've had a chance to vent your frustrations, now we're going to go off and make the decision?

Is it an oversight committee? I don't think it can or should be a regulatory entity, but that doesn't mean that it can't have some oversight in certain areas. Is it actually a decision maker? Can it be, and I understand, or I'm getting educated as I talk to people that there are regulatory requirements associated with where a decision can be made, but how much of a, you know, decision can we make?

Should it play a role, for instance, in defining those gray lines that we all talk about? You know, so CDS. It's a great huge term, and I'm sure if we went around the table here, we would get twice as many concepts as to what CDS is. So however, what about defining what part of CDS should be FDA regulated, and which is the rest of it, the great, great, majority of it, I believe, that shouldn't be, who makes that decision? Can the safety center at least be, you know, significantly involved in that decision-making process?

So that's one part. The other part that I think is vital is the influence over the learning system itself, and I say "influence" to say -- to manage not only what we do with the data, but how do we start off, and the comment I made this morning

with it, what are our first steps?

What's the data that we should bring in, you know? What sort of terminology do we use to try to get it? Can we get multiple vendors to go ahead and put their, you know, patient safety information into some common overriding de-identified database, so that we can start getting information across there?

So I think that that would be an important role for the center, to have maybe say management oversight responsibilities of the multiple decisions that will have to be made. So I know that there's a lot of nuances, but those are some of the ideas about where I think that this -- the center can play an important role.

MS. DANIEL: Thank you. Michael.

DR. HODGKINS: Michael Hodgkins with the AMA. I'd actually like to start by also commending the efforts of those you that participated in the Summer of FDASIA, and subsequently -- and you know, there's been a lot of talk in the last few days about well, we need more specificity, we need more detail and what have you, and that's all true.

But you know, 80 percent is pretty good in my book, and I think you guys have fashioned at least an 80 percent framework that, you know, is more than a good start. So really from an AMA perspective, we feel very strongly that the report is a leap in the right direction. Having said that, you asked about value propositions, and I guess I would echo actually some of the things that Toby had to say. You know, if you don't have a product, you can't define a value proposition.

So I think we have to spend quite a bit of time defining what the product is in this case, in terms of the advisory committee and rather the safety

committee, and Ronni and Toby have both talked about, you know, what that could be.

But I'd also like to suggest that there's an opportunity here for this Health Safety Committee, or whatever we're calling it, to take a different focus. Over the last three days, you know, I and others have brought up, on more than one occasion, that we keep on talking about hospitals and inpatient settings and devices, and we're not talking at all enough about the ambulatory environment.

You know, Dr. Classen in the previous meeting, you know, referenced for instance a study that was published by the AMA a couple of years ago, and you know, what we know about the hospital environment in terms of patient safety far exceeds what we know about the ambulatory environment, you know. It's very opaque.

I think that, you know, one of the things that the patient safety, what are we calling it?

(Simultaneous speaking.)

DR. HODGKINS: PSC. We're going to have to have some alphabets -- you know could do is really shift the focus to, you know, the pointy end of the spear, as I like to call it, which is, you know, the point of care in the ambulatory environment. You know, that's still where most care is delivered, and it's the unknown, and we have PSOs in place. We have other entities in place, and within hospitals, large and small, more large than small I suppose, you know, we have resources that are applied to patient safety.

We've heard that it's imperfect and there's still a lot that gets through, but just imagine that what's happening in the ambulatory environment, where most of

the care is being delivered. In addition to that, I would say that, with respect to the ambulatory environment and patient safety concerns, that the two things that are of greatest importance are software usability and interoperability for the purpose, turning to Steve, of dealing with transitions in care.

Transitions in care between physicians, between physicians and other health care professionals that are part of the system of care that surrounds a patient, between ambulatory practices and hospitals and, you know, then on to intermediate care facilities and so forth.

I think a lot of the patient safety events can be tied to the usability of software, especially when we're talking about the EHR. I think this has been well described by the Institute of Medicine, by AHRQ, by -- and by many others, you know. But I'll stick with the Institute of Medicine and AHRQ.

So rather than, you know, sort of saying well, how well did this device communicate with another device, why don't we sort of look at the usability of the software that people are, you know, being tasked to deliver care with, and recognize that it in itself is a patient safety issue.

And the transitions of care are where things get dropped. Dr. Classen yesterday was talking about his mother. Every time she goes in the hospital, she comes out with the wrong dose of anticoagulant.

Well, I'm not sure exactly what the circumstances are, but I would surmise that it might have something to do with the fact that, you know, the person that was treating his mother in the outpatient setting knew what the dose was, and somehow that information didn't get well communicated to the inpatient setting, and

the lack of communication between the two caused this event that he described, which is a patient safety event.

So I think interoperability and usability ought to be an important if not primary focus, and you know, let's not let this new body focus where we've been focusing all along on the inpatient setting and large hospital systems. Then I would add that we have to then expand beyond the usability and interoperability for the purpose of dealing with transitions in care in particular to, you know, this discussion that we're having about mobile health.

So now we have the phenomenon of the consumer being very engaged and increasingly so through the use of mobile health apparatus, devices, sensors, applications and so forth, and they have three issues, I think, that we need to address, and that I think this patient safety entity needs to address, and that is the security of those mobile applications, the way it handles privacy.

I mean HIPAA takes care of EHRs. What about what's happening with PHI and mobile health applications? And lastly content. You know, we have significant evidence from recent reports from the IMS and from the Institute and from others that, you know, the mobile health application environment is the wild west, and nobody found the sheriff yet.

You know, we know that a lot of these apps are misleading and inappropriate, if not dangerous in terms of the content. We know that a lot of these apps, you know, unbeknownst to the end user, you know, are not protecting personal health information or not secure, and yet they're going to play a vital part in the health care delivery system going forward, especially as we see a shift in payment models.

So I think we need to engage the consumer. I think we need to engage the inventory space, and I think we really do need to focus on these issues of usability and interoperability, and to get back to your question, how do we get people to participate, I think the people that have been excluded the most are right to participate, and I think if you do make the focus more on usability, interoperability in the ambulatory environment and the consumer, that you're likely to see a great deal more engagement.

MS. DANIEL: Thank you. Jeff.

DR. BRADY: Good afternoon, everybody. I've unfortunately not been able to participate in the earlier parts of the meeting, but I understand that you've been very successful working through them, a lot of the challenging issues. My name's Jeff Brady. I'm representing the Agency for Healthcare Research and Quality. Thank you for mentioning us. My role at the agency is to lead a center that is responsible for the patient safety research that AHRQ currently engages in.

We've had a fairly robust portfolio of research focused on general patient safety, for I think more than a decade and a half since, you know, it's sort of becoming increasingly -- since the awareness of patient safety sort of, you know, permeated health care.

So that's kind of the perspective that I've sort of come to this panel with, and I think your question is particularly helpful for me to sort of make some observations that I hope are helpful. So I guess the main point I would make is that I'm representing the generalist perspective, not the HIT specialist perspective, although I think the point that I would make is that I would hope that one output or one function

of this center would be able to help merge and reconcile those perspectives, because I think, you know, clearly both are important and both are valued.

But I think actually to achieve some of the goals that Michael and others have described, that's really going to be a critical function, to sort of make sure that the depth and technical complexity that's necessarily to really get at some of these issues and challenges is appropriately represented, whether it's human factors or other, you know, needed disciplines that need to be at the table. Whatever they are, pulling all of that specialization together in such a way that it actually can be conveyed, you know, to the folks that really need to use it, that are at the cutting edge.

Similarly, I think the converse flow of information is important, you know, usability and making sure that needs are really reflected. So those are just general points. Another general point, I think, is that influence of this entity as sort of -- one way to think of it is in my assessment most likely to be successful if it's through the knowledge and understanding that it sort of commands and possesses. That's really what it seems like is the needed role here. It's not that it wouldn't need to have the heavy interface with other entities. But that seems to be, from our perspective, you know, one of the most important needs to fill.

So back on the more general point about how does this topic fit within the broader context of patient safety? I actually think it's critical to continue to revisit that point, not just as a conceptual question but actually as a practical consideration, to achieve the three E's that you've laid out.

We know from our experience in patient safety and quality that this is an increasingly crowded space. Lots of folks are sort of placing more and more

demands on providers in terms of quality and safety.

That's a good thing in general, but it's also a challenging thing to manage, to make sure that we're asking the right things in the limited bandwidth that we have, that you know, others have attention for, that we're using that appropriately.

So that's within that context, I think, of bouncing generalists' and specialists' perspectives, so that we don't necessarily pull stakeholders that don't want to be down at the specialist level to that level, as a requirement to engage. So that's hopefully --

Again, that should be a function that I think is explicitly addressed in the center. So, and just to be clear, we're not -- I'm not suggesting that this specialty focused or generalist perspective is an either/or, but it's a both/and, you know, proposition.

So I guess, you know, maybe to cap off some of my comments, not only is that consideration of the broader context of patient safety going to be important for the success of this center, but I think it's a way to think about maybe a fourth E, and that's efficiency. You know, how efficiently can this entity operate, so that it's giving appropriate attention and special consideration to the issues that matter?

But it's then translating those in an appropriate way, so that you know, true engagement is accomplished, and people actually understand whether they're contributing information to or pulling information from this entity that, you know, it serves that purpose of kind of being a hub for various stakeholders, that don't all come with the same perspectives, but clearly they're important to be at the table around this issue. So I hope that helps with just some broad framing.

MS. DANIEL: Thanks, Jeff. So I'm going to move to Jim next. As folks are -- I'm being cognizant of the time, and there are a couple of issues that I think you both raise that I want to get back to. So I'm going to ask the panelists to be a little bit more focused and crisp in their responses, so we can try to -- I mean get a little more concrete on some of these issues, as we progress through the panel discussion.

MS. MARCHIBRODA: Great.

MS. DANIEL: Jim, go ahead.

MS. MARCHIBRODA: Thanks, Jodi. Jim Walker, Siemens. It's a pleasure to be here. So value proposition. Number one, it's system-focused. Everything we know about systems engineering, particularly outside health care where it's actually practiced, is that to improve safety, you have to improve the system, not individual actors, individual components.

So the first value is that it's system-focused. What does that mean? First, I think it ought to be the place that receives all potential patient safety issues of any sort, and it should provide the intelligence and the analysis that figures out what kind of issue it actually is and where it should go, if it should stay in the center or if it actually belongs somewhere else. But that shouldn't be laid on all of the people who we want to provide input into the system.

System focus means that it ought to include the whole team, and we still are leaving lots of the team out. Almost nobody knows more about patient safety than the clerks in hospitals and clinics, and by the way nursing homes and other providers, I know for a fact home health agencies.

Patients, lay caregivers, consumers of health care services who are not

patients, we really need to be smart and express it about the entire team, long term post acute care obviously. System focus means any information system that contributes to a patient or health care consumer's care -- consumer apps, Patients Like Me, social media, any information system.

Clearly, the two or three that have been found in a recent study to likely miss 30 percent of lethal melanomas present a huge patient safety risk and need to be part of this system. I would think that a model like the ASIAS NTSB system would make a lot of sense in this setting.

ASIAS takes only non -- only hazards that haven't yet become incidents. It's voluntary. It receives input from all across the system. It produces 200 reports a year, which have been a key part of the dramatic improvements in air travel safety during our lifetimes.

Does it for $8 million a year. It has no regulatory responsibility or authority. Its reports can be picked up by the appropriate FAA in this case, and turned into regulation, and occasionally are. But that is not the point of the organization. So I think that kind of model is feasible, has been demonstrated to work, would be cheap and so forth.

MS. DANIEL: And in the health care space, do you think we have -- we would get -- you talked about all of the different kinds of players that need to be at the table in a voluntary way, without you know, any requirements for folks to come to the table. Like how do you get all those folks to the table to make that kind of model work?

MS. DANIEL: The other thing, a big system designer would depend

much more on positive incentives than on negative incentives. Positive incentives have been proven in all kinds of settings to be far more powerful. There are some places where negative incentives can be direct enough that they work.

But I think the issue would be to identify positive incentives. Does a hospital that submits patient safety issues in a confidential way get an extra six months on their JC interval to be reviewed? You could -- so I think one of the things we need to do is think outside the box and say what would be the incentives that would motivate people?

One of the things we noticed in the beta test of the Hazard Manager for AHRQ, or we think we observed, is that when you think about how many care delivery organizations would have to actually contribute for us to learn an enormous amount about what's actually going on in health IT safety, if ten percent of organizations, and many of them are actually highly motivated.

If just the organizations that were highly motivated and are sophisticated about it, had a confidential way and a usable way to do it, I think it's worth at least testing the hypothesis that we'll get more -- we'll get enough reports to make significant improvements, and then we could sort of see what's left.

MS. DANIEL: Thanks, Jim. Janet.

MS. MARCHIBRODA: I'd like to quickly respond. Jeanie, Jeff and Jim had talked about this notion of reporting, and I'll tell you, we had a lot of conversations about it with a lot of different people. I really caution us against setting up a separate silo that just focuses on health IT events.

First the research, and I think you actually had it in your earlier plan, at

least the final of which was released in June, you know in one study, and I think Ronni it was ECRI that did the study, 43 percent of the health IT events weren't reported as such. They were reported as medication errors.

You don't know that it's a health IT event until you peel back the onion. So let's just say we set up this separate structure just for health IT, and we pump in, I don't know and I heard it was 40 or 50 million dollars, $8 million a year, and everybody reports only their health IT events.

Now we've got PSOs that are capturing health care IT events or health care events, maybe 43 percent of which are health IT -- or no, don't quote that, but you know, some of which are health IT. Then we've got this new structure with scarce dollars in a silo. I just worry -- I worry about that. I worry about providers, I worry about the confusion there. So I'm beating a dead horse with that one.

Value, Jodi, value. So I'm thinking dollars and cents, lives. The first thing, the biggest value proposition, I think, for all of us is if we can understand the near misses, things that are happening earlier, and that can get rapidly disseminated, so we can avoid problems happening in the future. That does turn into dollars and cents from a legal standpoint.

The second is now if we took those three E's and we added consensus on standards and best practices for development, implementation and use of health IT, then you've got a whole set of valuable things that occur, and I'll just run through it very quickly, because I know we don't have much time.

So if we agreed, the country agreed on this common set of standards, the federal agencies were at the table. They agree to rely on those standards. They

agree to rely on independent accreditation and certification bodies that would evaluate against those standards.

Now we're reducing regulatory burden, bodies, people, jobs, for these organizations that go through this. Secondly and I know, if we have a common body, all of the sudden we're starting to target limited resources, and God knows, you know, everybody is really overwhelmed, whether you're a small physician practice, a small or a large hospital with all the things that are going on as our health care system changes.

The third, and this is really important from an American competitiveness standpoint. If you've got this health IT safety center, now large and small physician practices, hospitals, large and small companies, level playing field at the table, understanding what these best practices are, and we're moving away from, you know, traditionally regulatory approaches. You have to be pretty big, right, in order to have all the compliance people and the lawyers to help you.

So I think there's a lot of merit, and I think a business case could be made for everyone jumping on board, if you were to get agreement on standards.

MS. DANIEL: Thank you, Janet. Matt.

MR. QUINN: Jeff made me -- Jeff brought something up about, you know, putting something in and getting something out, and I think that that's an essential component of this. Too often with the reporting quality measures or other things, you put -- health care organizations have requirements to put stuff in, but they don't see anything out.

And a real incentive and value of participating is getting something out of this that is of value in the short term. A way to think about maybe the focus of this

is what are some immediate or near term hazards that we want to deal with, some that are emerging and then some that are in their horizon, further off.

As we identify especially these near-term things, it's convening folks to bring together existing tools to solve priority issues and really focus deeply on short-term on these, you know, putting stuff out in the field tool kits, handbooks, best practices, getting folks to talk to actually address these issues.

A lot exists, and as we get this cycle of, you know, what are the near-term things, what are the emerging, then we can prioritize this. I think that this actually works well with the federal research and development enterprise, folks like AHRQ and NIST and NIH and others who develop these tools, and want means of disseminating them, getting them into people's hands.

But it also works really well with the disparities among providers, where some are doing this work and some have, for example, really good wireless test beds and expertise in that area, and a lot don't.

So you know, think of it as by participating and contributing, that you're actually getting something out of it as an organization, that can help you implement better, faster, cheaper, safer.

MS. DANIEL: Thank you. Jeanie.

MS. SCOTT: I wish I had like the eloquent words of everybody else. I'm a very simple person. But I just -- I think the value that you have, and I wrote down two words, is you can be the convener of transformation. Those are my big words of this.

Just a little history about our program. We started in 2002, and it was

a simple emailed and IM. You know, reporting is way down here. That's the very beginning, and it's just the very beginning. But it is about the -- Julie, I love how you said it's the inputs, the analysis and the outputs. It's the change. It's that transformation.

Our reporting system, we were talking about really, really bad things happening. That's where we started in 2001-2002 in the VA. There were bad things happening in our imaging software, and that's where we started.

The reports that we are getting now are -- it's so much further up. It's not the bad things that happens. Sometimes, it's the point where I'm going this is so early on that it's reporting; it's in the developers. We have -- we have the programmers reporting things to us. It's very early. It really has changed.

I have staff right now that we talked about mobile apps. I have staff right now that are working on mobile app development, and helping our mobile apps changing before they get out there. So in that decade period, it's been a transformational change.

I think that's the value, is if you start, it's kind of like the Field of Dreams. If you build it, they will come and they will change. So you can be the convener of transformation. There's so much out there that's all the person yesterday with all their hands out there. There's so much out there, and you can be the area that could help bring it together.

MS. DANIEL: And we go to David.

DR. MAYER: I hope you understand this, because I'm also not a big fan of big words. But I just wanted to echo a few things that I've heard that have been

really, I thought, particularly important points.

I'm David Mayer. I work for the National Transportation Safety Board, although for the last almost few months, I've had a wonderful opportunity to serve in a rotational assignment actually at ECRI Institute.

So I've had a little bit of an exposure to some of the work that goes on there, particularly the PSO activities, as well as the health IT partnership that's gearing up there. But I just thought I would make a few general observations, I guess. First of all, Jim made a point that one thing that the industry has in common with ASIAS, and I think it was a pretty astute commonality to notice, is that we're both non-regulatory activities.

I do think that's important to bear in mind as you move forward and create a health IT safety center. I think it's important, because regulation is generally an inherently governmental activity that brings with it all sorts of overhead and all sorts of compliance activities and all sorts of well, frankly, bureaucracy.

So when you're asking what kind of government structure should the health IT safety center have, my thought is that it should have only as much as necessary to accomplish the three E's, or whatever other mission activities you want it to accomplish.

I think what Jeanie just said is very accurate, that if you create the environment for collaboration, then it will happen, and I'm not sure that the government needs to specify precisely at what moment the collaboration happens or exactly how it will occur.

I do think that what you had asked a little while ago is particularly

important, that you do have to have a value proposition. Whatever it is, the stakeholders who engaged in the activity need to be getting something out of the safety center that they aren't getting elsewhere.

Where they are getting evidence-based recommendations, whether they're getting analytics based on a data set that isn't otherwise available. They need to be getting something out of the safety center that just simply isn't available to them elsewhere.

In other words, if you simply require reporting, then I'm sure you'll get some reports. But I'm not sure that you'll really find value in it. You mentioned the aviation safety reporting system. Throughout all of the aviation system, that's not a program that's run by the NTSB.

But throughout all of the aviation system, pilots, mechanics, air traffic controllers are all familiar with ASRS, and on the one hand, one bit of value it does provide them is if they fess up on their own mistakes, they do get some limited immunity out of hat. So there is some value there. But they just have faith and confidence, too, that ASRS will do something useful with the data, and communicate it out, which is a type of value as well.

MS. DANIEL: So I'm going to shift a little bit to follow up on what you were talking about, about the functions and how we structure this, and follow back up on something that Ronni started us with, talking about the functions and the governance, and get some feedback from folks on what should the governance structure look like.

We talked about -- there are a couple of things that have come up as

important principles. So, kind of, think about governance and principles for a safety center, for about the convener of transformation. I'm going to use that simple term.

(Off mic comment.)

MS. DANIEL: Yeah, that's perfect. I love it, to serve as a convener of transformation, to serve as a trust place for folks to come. I've heard things about confidentiality; I've heard about transparency, and then I've heard some need for clarity on the functions.

I would love folks' thoughts on that, and maybe Ronni, if you want to start, I would be -- I would also be interested in hearing about the Partnership for Health Education Safety, and that convening, and what are the governance and functions of that and where you see there are some lessons learned that we could benefit from.

MS. SOLOMON: Yeah sure, and I have to say that in convening a partnership for health IT patient safety, there is not a dearth of interested parties. So I think that people do see the value, and I only got to be here today. But every stakeholder has so far stood up and said we need to know what's happening.

We need to know what bad events are happening. We need to know why they are happening, and unless we know what's happening and why it's happening, we're not going to be able to fix the problems.

So we convened a Partnership for Health IT Safety. It is multi-stakeholder. It involves various vendors, and I think that's really sort of the innovation here, that you know in the past we've had PSOs and we've had hospitals and researchers and academics doing studies on patient safety. But this does bring together a multidisciplinary group.

We're bringing together safety scientists and researchers and of course many providers, many other PSOs, a lot of medical societies and professional associations, because they need to disseminate and to adapt for their constituents.

And we're going to be looking at events. We're going to be looking at near misses and hazards, because we're able to use actually the Hazard Manager Ontology that Jim Walker came up with, as part of an AHRQ project, and we're going to include all of those, because we all have shared responsibility in figuring out what's happening and what we should prioritize and fix.

I want to thank Janet, because really, for the past two years, the BPC has brought together these organizations, and I think that the aha went off in everyone's mind that we all need to work together on this. This is not just a provider problem. This is not just a vendor problem.

If you buy a car, you might drive a Chevy or a Ford. Some people might get into accidents and some others don't. You can, you know, put the same technology into place in many different organizations and get different results.

Sometimes there's potholes around the road. Sometimes drivers go through traffic lights. Sometimes you take a car made in the U.S., you put it into London and you're driving on, you know, the wrong side of the road and, you know, you're inviting issues.

So this is truly a shared responsibility. So confidentiality is, I think, extremely important. The reality is that we do live in a litigious society. I think Jeanie brought it up. So unless there's a measure of confidentiality, it's just not going to happen. We've learned from too many reporting systems. The ASRS, the Aviation

Safety Reporting System, confidentiality is one of the tenets. Non-punitive. We're not here to punish people, as Jim mentioned. That's not what this is about. It's to really figure out what's going on, why, how we can solve it.

I'll tell you where we have some issues. There still has to be accountability, okay, and so I think one of the things that has to be sorted out is whether the most serious of events, you know, whether there has to be more in the way of accountability for a very serious event not, you know, the hazards and the near-misses.

So let me use Pennsylvania as an example. Pennsylvania created this authority. We had a terrible medical malpractice system. The most serious of events, where there's been serious harm, do go to the Department of Health, because there has to be some accountability. Nothing else does. All of the near misses and the hazards go to the Patient Safety Authority, and to ECRI as the contractor for that work. About 97 percent are the latter, are the near-misses and the hazards, and there is a tremendous amount of learning.

We have very little information right now about the hazards associated with health IT. I think that's one of our biggest opportunities.

MS. DANIEL: Thank you. Bill.

DR. MAISEL: Thanks. Bill Maisel, Deputy Director for Science and Chief Scientist at FDA Center for Devices and Radiological Health. I'm struck by the need to define the mission of the health IT safety center, and certainly this is -- I'm not the first person to think about it.

But to me the mission would be something like creation of an environment of learning and continual improvement in health IT, you know. And so

whatever that mission ends up being, whatever the multi-stakeholder group that gets convened should focus on defining the mission, and then that same group should develop the priorities for achieving the mission.

And some of those priorities, the safety center may be uniquely qualified to implement or define, and some may be well taken care of through other groups. So part of the group should be -- or part of the goal of the group should be not to be redundant, as has been said, but to be complementary to ongoing activities.

The final point I'll make is that in the FDASIA draft framework, we highlight some of the barriers to developing an environment of learning and continual improvement, and they're not our barriers. They're the barriers that the IOM work group identified, and these aren't novel or new or unique.

But there already is a list of identified impediments and I won't read them all, but some of them are things like the adoption of a philosophy of shared responsibility, a term we all use very liberally, without well-defined individual stakeholder accountability.

So one task might be to define the accountability for the individual stakeholders. Focus on the role of technology when safety is compromised without addressing the human interaction component. Restrictions on the transparent release of safety information.

So there already are a number of barriers to creating this environment, and one role of this group could be to select prioritized areas for focus, recognizing that there could be a laundry list of dozens of these, but focusing on two or three may at least move the ball down the court.

MS. DANIEL: Thank you, Bill. Toby.

DR. SAMO: So two things. First of all, this may be a career-limiting statement, but I agree with the guy from the FDA. But as far as, you know, defining, you know, coming up with a definition, a mission statement shall we say, you know, for the center, you know, is key and important.

So I want to address the governance issue and then a little bit more about data. So you know, I don't know who gets to be in charge, but I think, you know, we've all alluded to the fact that there has to be a broad spectrum of representatives.

Whether you know, representatives from the FDA, from the ONC, you know, from you know, AHRQ, FCC, but also vendors, representatives of ambulatory practices, hospital practices. Patients need to be represented, you know, the general public. So you know, I'm sure that we can do that. How you manage that large of a stakeholder group, yet still make it an entity that can actually get something done certainly would be a challenge. But somehow those voices will have to be heard.

The other point I wanted to make has to do with data. You know, we keep on talking about, you know, well we've got -- you know, you've got a silo of data, you know, Ronni, of what's happened in Pennsylvania and Jim has a whole bunch of data I'm sure at Siemens, just as we at Allscripts have implemented, you know, a shall we call a quote-unquote "standards-based reporting process," classification process, that goes across all of our products. So we have lots of data.

So yes, we learn internally, and we do RCAs and make changes. But the bigger value is if we bring as much of that those areas into some sort of centralized de-identified repository, where we can now start looking at trends across products and

across locations, and I mean, we all know that that's where, you know, the best and most information comes.

So I would say that that should be one of the primary responsibilities or major responsibilities of the center, is to figure out, albeit I understand it will be complex, process of bringing -- and again, not boiling the ocean initially, starting off with limited, identifying the data set that needs to be done and working out a way to bring that together.

MS. DANIEL: Thank you. I'm going to take Janet and Julian, and then we are going to take a break before our last and final panel of the day and at the workshop.

MS. MARCHIBRODA: So Jodi, this is really quick, and I was listening carefully about your three E's, and I know I came up with a fourth one, and folks maybe were confused about that, or disagreed. It strikes me -- you know, you always -- when you're moving forward on anything, you're always trying to decide well, do we just have one in our country, or do we have many?

I think it will be really important, as you look at the mission, that Bill talked about a mission, whether it's engagement -- I mean I see engagement as being distributed, or it's dissemination or education. That's probably decentralized or distributed. What are the things that you need to centralize? That's why, you know, for me reduction in burden comes from centralizing on a common set of standards or principles, or maybe setting, you know, broad national goals for improving safety.

But I don't have any brilliant answers. But I wonder teasing apart the different functions, and where do we benefit from centralization? You know, the

other thing is, you've got reporting to different PSOs. Do you want to move to a national PSO? We already have AHRQ, you know, the aggregation of current PSOs. So suspending not only time on the mission and the purpose, but also where do we centralize and where do we distribute is important.

MS. DANIEL: So very thoughtful comments. Thank you, Janet. Julian, you can go. Last word of this part of the panelists.

DR. GOLDMAN: Right, thank you. I'd like to speak to again towards the -- at the value proposition, and some of the things that we struggle with -- what's that? Sorry, okay. Something that we struggle with, for example, within our health care system at Partners HealthCare.

When we have a problem with equipment whether it's directly within what we would consider health IT today, although frankly the definition of health IT is quite expansive, it is very difficult to identify how to resolve that problem initially. Should we contact the medical device manufacturer? Should we contact the middleware vendor? Should we contact the IT equipment vendor?

We have literally hundreds of points of data interchange in a system like that, with all the different interfaces that have to be developed. It's extraordinarily complex. There is value in having a single point of contact, to ask questions, report problems and get answers.

Whether or not they're actually harming a patient is not necessarily the issue up front. Whether they're interfering with our ability to deliver care is relevant, and whether it's interfering with its taking time to try to solve and address, if other organizations have already addressed it.

This gets to the data sharing. It isn't the patient data sharing or device data sharing, it's the problem and resolution data sharing, which would be enormously beneficial. Our hospital system, as well as many others, most around the country are investing enormous amounts of money trying to resolve these basic issues.

They apply to the hospital, whether you're within the patients' environment in the hospital, it may apply to the outpatient environment. We have, of course, numerous outpatient practices, as do other health care organizations. These issues are pervasive today.

So there's real value there to our national health care agenda, to our institutions, and that has been touched on here. We have to see a benefit to the reporting. Everyone needs to see that there's something -- the what's in it for me concept is really relevant here.

If putting it in and getting some help back out that saves resources, dollars and time, and reduces the likelihood of error and harm is tremendously valuable, and I think that is a powerful incentive to participate, if it's effective in delivering back to the participants.

MS. DANIEL: Thank you very much for that comment, and I forgot to check in with our audience. We do have one audience comment. So let me turn it over to the mic in the front.

MS. STANFORD: Jean Sanford from Georgetown, though I'm not speaking for Georgetown. I just wanted to mention that for a software developer who's sitting there at the bench trying to figure out what to do, maybe there's a way of giving you an incentive to collaborate with all this and move from all these things.

So if we take, way outside of the box, the concept of substantial equivalence, and which is used for learning device regulatory purposes in the 510(k) process. If we could come up with, for example, a pattern of good interaction for software, that said if we could develop those patterns, put them out there and say here's your incentive.

You could use it as a substantial equivalence method for presenting your software and getting it through, for the ones that are FDA 510(k) regulated software, you will get more adoption. People will actually read it. People might use it, and patterns are a lot easier and faster to develop than a standard, a lot less heavy weight.

MS. DANIEL: Thank you very much. Thank you for your thoughtful comments on this first part of our discussion on the safety center. We will be back at -- what time is it -- let's say three o'clock, and so a 12 minute break, according to the time on the clock.

We will come back and talk about how to use the safety center to think about evidence, education and dissemination. Thank you panelists. We'll see you in ten minutes.

(Whereupon, the above-entitled matter briefly went off the record.)

MS. DANIEL: Okay. Welcome back for our last and final session. We are talking about Health IT Safety Center with a focus on evidence, education and dissemination. So, we have until the rest of the day. We have until four o=clock we will be talking about this topic. I will try to be better about paying attention to the audience. And then we=re going to have a period for public comment.

Do we have folks who are signed up? Okay. So, maybe we=ll go B if we go a little bit long, that would be okay? Okay. So, we might go a little longer than four o=clock. We have public comment, and then we will do our closing remarks. And with that, I will get started.

So, in talking about evidence, so we had a long conversation this morning about reporting, about analysis. We=ve heard from different PSOs, we=ve heard about this Health IT Safety Partnership.

How can the Safety Center advance the evidence base, as opposed to replicating it? I=ve heard also a lot of let=s not reinvent the wheel. We have a lot of data.

How can we advance the evidence base? How can we provide the B fill in the gaps, address some of the, you know, see some of the trends, figure out some of the places where there may be hazards based on what is already out there, and how can we bring some of that together? What can the Center do to fill in the gap and provide something different with respect to evidence than folks can get elsewhere, as I think David had mentioned? Steve.

MR. POSNACK: Yeah, I pre-loaded. So, maybe this would be a good segue or pick-up from what Janet and Julian ended with. And I was thinking, so, Janet asked the question, you know, what are the things that need to be centralized? And Julian made the point of problem and resolution data sharing.

And this morning=s sessions really dealt with we have a lot of data, we don=t necessarily need more reporting in all cases. There are the ns of one that are good enough for people, or serious enough or interesting enough, or novel enough that people have concerns about them that a response, a problem and resolution to the n of one would be value added to all stakeholders-providers in terms of credible, actionable advice and practices that you say you

need to avoid this, because, you know, we think that=s a concern.

Or to EHR technology developers that someone=s identified this, and it could be the first of many to come and they can go back and look at it and question whether or not it would occur with their system, before it becomes an issue. And so, that seems to be an area where some centralization or one place which gets to some of the other B the efficiency or B there=s one place for people to go to, to get some of that information in a quick manner.

And I don=t know that that would deliver all of the B it=s not a silver bullet and I know that people could argue against having ns of one and reacting to ns of one, but that may be, you know, something that could be part of the dialog today.

MS. DANIEL: Okay. I=ve got Jim, Michael and Julie.

DR. WALKER: This is Jim. Because it=s been said a couple times, I would react to the idea that we have enough information. David Bates in one of their papers, mentioned that they had documented thousands of what sound like they were probably hazards. Nobody, maybe not even anybody left on the team knows what they were.

In the beta test of the hazard manager, just in six months, and not trying to capture large numbers, the four participants who really were active documented 500. Over the years, at Geisinger we documented and fixed thousands. So, there is information out there.

I don=t know how many organizations manage hazards in that way or even identify them in that way, but say there is 50. That means there=s a lot of very relevant information out there about people who have thought carefully about this, actually been running systems, found problems that got -- rose to the level of needing to be attended to, that it would be very useful for us. So, we don=t have to do n of one. N of one is better than n of

zero, God knows, but we don=t have to do n of one.

And, again, it=s to Ronni=s point when -- you don=t have to scratch very hard to find lots and lots and lots of people who are willing and eager to share what they=ve learned, but they or their legal officer or somebody else says not in this environment you don=t.

MS. DANIEL: So, is the issue, Jim, about having that trusted environment and the either confidentiality or protections non-punitive? Is that the B is it not about getting more data or evidence, but making -- set it in an environment where people are more willing to share that --

DR. WALKER: Yeah, I think that=s one. I think the other, as I understand it, although David knows this much better than I do, but as I understand it, ASIAS spends 40 percent of its budget dealing with the fact that they weren=t able to come up with a standard terminology at the beginning. And so, they have to do all kinds of translation and normalization.

So, I do think the other thing which we have never seemed to be able to actually do since we=re near the beginning of this, is to have standard terminology, a useable tool that makes it much easier for organizations who are motivated to report things at least in some ways in a standardized way.

I think that is the other thing, sort of usability and standardization. Because as someone said in the earlier session, say we succeed and get B well, the scale that Ronni gets in Pennsylvania, hundreds, tens of thousands, hundreds of thousands of reports, there=s no possibility on earth to read all of those. No one is going to pay for it.

And while information extraction NLP can be of some use, I think its use in

this setting would be speculative for a long time, say. And so, that is the other. Usability, standardization so that we all are speaking the same language. And, by the way, when you talk about education, my tool, Candidates for Education, because they=re never mentioned, are systems designers and health IT designers and the last people who need more education are users of health IT. So, that=s the other thing.

MS. DANIEL: Thank you. Julian.

DR. GOLDMAN: Thank you. Maybe I can inject a little controversy here. I think that we either have and can easily have more identified signals, events, numbers of either bad things or near misses. But when it comes down to being able to drill into the details of the event for an appropriate and complete root cause analysis, it is extremely difficult.

We still have patients that are found dead in bed in every hospital, and we don=t know what happened. We don=t know what came first, what was the chicken and what was the egg. And a significant component of that problem is that medical device information is not necessarily complete or timely, as part of the data log or record or EHR, if that=s the appropriate data log and record.

We don=t know whether the patient reacted to a medication first, or whether the medication was administered, or whether it wasn=t received in time, because of time stamp issues. And without the complete dataset when one tries to drill down into this to perform a root cause analysis, in a hospital with patients, or outpatients, or any setting or home environment, and we have patients at home on chemotherapy and all sorts of other therapies, it is extremely difficult.

So, I think what we have a problem with now is incomplete data. And if we had the black box recorder that exists in other domains, in other high-risk domains with a more

complete dataset that included the things that we will learn over time or more are important -- we can=t do that to begin with, but I think we have a pretty good idea of what that is, it would change what we could do today.

So, that's a real world problem. We deal with this all the time in our B within Partners Healthcare System, at Mass General Hospital. This is a common issue when we're trying to find out what happened. The other challenge, I think, to just add, again, to the discussion, is that we have to think about the richness of the data and how we start to lose data as it's filtered through the system.

So, there's a lot of data in the hospital, for example, and there may be less data available at the PSO level. And as we start to look at the dissemination of information if it's tiered or hierarchical and shared from the PSOs, how much data will we still have and how much might we lose in terms of the contextual information that might be needed for an appropriately detailed analysis, so that a manufacturer can come to the table and actually provide a solution.

In looking at this several years ago at the VA National Patient Safety Center, I remember the conversation with Dr. Bagian at the time, and there were a set of problems that could be addressed, and there were another set of problems that could no longer be addressed, because the richness of the data had been lost at the level of the individual VA hospital entity.

And we clearly have barriers sharing data today between PSOs. So, we have to think about how -B what will be the implication of the reduction of data if that's the approach that's used in terms of a tiered approach, or, as was mentioned, I think, by Dr. Shuren yesterday -B I'm losing track of time, you know, should there be a single point of entry into one

PSO, or, as has been mentioned today, a single point of data collection?

But I think we at least have to think about this, and I don't think it's cut and dry and I don't think it's obvious that we have an excellent system in place today for sharing data through PSOs.

It's been an incredible useful step in patient safety, but it's not at the all end all yet.

MS. DANIEL: Thank you. Michael.

DR. HODGKINS: Michael Hodgkins, the AMA. I want to go back to this theme of the ambulatory environment. And Julie and I were talking during the break and, you know, obviously Partners has an extensive ambulatory care delivery process. And Geisinger and others do as well, but, you know, there's still a lot of people out there practicing, you know, outside of systems in much smaller settings and groups and, you know, who I think by and large haven't had a voice in this process. Haven't had a voice in terms of what's happening in the EHR space.

Certainly, you know, they aren't at the moment going to have a voice in this patient safety discussion, and I think there's a lot of experience out there that could be drawn on that isn't being accessed today. And if nothing else, you know, we ought to compare what we're hearing from those areas to what Julian and others here in their more established systems, in their ambulatory environments. If we find that everyone is complaining about the same things or finding the same issues, so be it, but we don't know.

The other thing that I want to come back to, again is this mobile health environment and the increasing use by consumers of mobile health sensors, devices and applications. You know, no one's going to be collecting information from them about patient safety events. And I go back to a comment I made earlier from the floor today, you know, I

think we have to get creative here.

And, you know, we ought to be having conversations with the folks at Google. We ought to be having conversations with the folks at Twitter and others, you know, because they reach a very broad community, and how could we tap into the community in a useful way? I mean, obviously there could be significant issues there. You could be flooded with a lot of irrelevant information.

But, you know, as Google Flu, as an example, showed us, you can distill that information. It wasn't perfect. It missed the outbreak in 2009. It overestimated flu counts in subsequent years, but, you know, it still contributed valued information. When people matched it up with other information from CDC and others, it actually enhanced the quality of information that we had about flu.

So, I think we need to talk to those people and engage with them, whether they're stakeholders or are simply looking to them as additional sources of information so that we can get into tapping into this mobile health space that's going to become an increasingly important part of the environment in which healthcare is being delivered.

MS. DANIEL: Thank you. Toby.

DR. SAMO: So, to kind of support Jim's points, you know, we get B- I think all vendors do, get lots and lots of calls about what B- and a great, great majority of them are hazards. And we have, therefore, a lot of experience at taking a look at those events, or those potential events, and classifying them.

And we, you know, we've used the hazard manager, you know, as our baseline. The EHRA Patient Safety Committee, you know, evaluated that and said that this should be a standard that we should use, you know, across all of our, you know -- client

member should use to have some standardization. So, we adopted that.

And so, what that allows us to do is to be able to most of the time, okay, not a hundred percent of the time, because nothing is a hundred percent, classify the hazard or if there is, you know, fortunately we have not seen harm, but if there is harm B and this is both acute and ambulatory. It goes through the exact same process, regardless of where it came from. And with that, we are able to identify what type of hazard is it? Is it a usability issue? Is it a data integrity issue? Is it a network issue? Is it not IT issue, et cetera.

And, yes, we don't have B and this is where I'm going to divert from your point. Sure, you know, would I like to be the engineer and have, you know, a hundred percent of the information, like in my little black box? Sure, but we're dealing with humans and not airplanes. And so, we're not going to end up with, you know, a hundred percent of it.

So, once that information is all available, you know, then to have some safe harbor to be able to go ahead and take that information and take that classification and combine it into, you know, into a format that we can now start to do, you know, the big evaluation, rather than just the n 1s, I think, is vital.

MS. DANIEL: Go ahead.

DR. WALKER: A little vignette. The reason I started on this, we were about to put in order entry and we had the best, hands down, standardized pharmacy system in the business, and it started very well.

DR. SAMO: Except for ours.

DR. WALKER: Except for yours.

DR. SAMO: Right.

DR. WALKER: But it wasn't B it wasn't anybody's in this room. And our

teams came back to us and said, we cannot create safe workflows between this order entry system and this pharmacy system that uses another database. And so, we took our hearts in our hands, went to executive leadership and said, we need another $500,000, nine months in the schedule. We don't think this is safe. We didn't know if we were right or not. And if we hadn't been doing it ten years, you know, if the people who are actually doing it, not me, hadn't been geniuses, I don't know what executive leadership would have said.

Fortunately they said, well, rip it out. And we did, still not knowing if we were right. Led a meeting for AHRQ in 2007 about two years later and related this story, and David Classen stood up and said, oh, yeah. He said, we've looked at 160 organizations and we believe it's never safe to use order entry and pharmacy that are not based on the same database, or something close to that technically.

And I said, oh, okay, well, then we were right. So, I went back and told the CXOs that we were right. That has never been published and it has, I think, become a folkway. I don't know how widely distributed a folkway it is. I assume it's probably right, since David did that kind of research on it, but that is the problem we're up against. A big deal.

I mean, you get drug orders wrong at that level, chemotherapy drug orders wrong, you have created huge patient harm. And that is, I think, at least part of what we want to do. I agree with you about richness, and about being able to drive all the way down into complex situations. That's absolutely a need, but there is this other need to identify large trends that have big potential impact, and somehow get them out to the whole industry so people can make their own decisions.

DR. GOLDMAN: Jodi, if I may, I just want to respond to something Toby said, because it's a point I've heard a number of times and it requires clarification. Just because

human beings are complex, it doesn't mean that we can't get the IT infrastructure and the medical device infrastructure to work right.

We talked about how we can't compare aviation to medicine, because people are more complex. This came up yesterday. But we're not comparing the person, we're comparing the technology infrastructure and it is possible for us to get that right. Even if we can't make people perfect, we can make the technology better.

MS. DANIEL: Thank you. Janet, Jeannie, Ronni and then we're going to shift gears. And I'll take a comment from the audience after that, and then we're going to shift the conversation a bit.

MS. MARCHIBRODA: So, Jodi, you asked, how can we advance the evidence base? And I'll be really quick. So, I think the first thing is we encourage safety B we encourage reporting of everything, you know, the healthcare and the healthcare IT together using common formats, right, so I've learned from folks who are working on this, leveraging existing structures in non-punitive, and somebody said it, David, non-regulatory environments. That's how you encourage reporting.

And it can be distributed leverage of current PSOs. And what I've learned in this two-year journey is it's not just the death and serious harm. As Jim said, you know, you need to understand broader, the near misses in order to, you know, prevent things happening in the future.

Secondly, you need to expand the culture of safety by enabling Dr. Smith to talk to his developer and to talk to the PSO all in the same room without breaking that chain of confidentiality. So, we do need changes in law around that, which the administration can do without congressional action.

Three, I think PSOs B so, this whole out in the hallway, this whole national versus distributed, maybe what you do B so, all B PSOs are already collecting all the data. They peel back the onion. When they figure out, oh, this is a health IT event or it isn't, maybe you aggregate, as Jim says, the health IT event somewhere, whether it's a PSO or some other body so you can analyze, as he said, bolster the evidence base, but you don't make everyone go through the national thing in order to, you know, you learn at multiple levels. You rapidly disseminate lessons learned.

And then this is an important point, and I know it's not part of this panel, but it's something B it's the question we get over and over again. What if B what if there is death or serious harm? You know, what happens in this system?

And I think we have current laws in place today both at the federal level and the state level that require reporting of death and serious harm and that happens. It continues to happen and it B but it's not part of this learning system. And the mechanics of that, I'm not really sure how you figure out. Ronni probably knows, but B so, that's quick.

MS. DANIEL: Jeanie.

MS. SCOTT: Okay. And I'm a little nervous saying this, because I think there's some informatics professionals in the room. You know this model, but we've been talking about the data. And one of the things, and I'm going to make this clear I'm not the expert here, we talked about how to advance the evidence base.

You have the data, the information, the knowledge and the wisdom. And I think one of the things is for ONC to determine is at which level are you going to sit at? You know, we have this data layer. We have this rich data layer, and to decide where are you going to be, are you going to be at the data layer? I think we already have that data layer.

Are you going to be at the information layer? Are you going to be at the knowledge layer? And then how to make that into the wisdom layer. And I can go into more, but I know there are some informatics folks who could probably give a lot more detail about that. The other part is looking B I think your three Es, the engagement, the evidence and the education, can sit at all of those four layers.

At the data layer, you can have your engagement, evidence and education. At the information layer, you can have your engagement, evidence and education. At each one of those, you can have those three Es, and that's how you can help advance that evidence base is taking those three Es at each one of those layers.

The other point is this B we can keep talking about all the different B we've got mobile, we've got telehealth, we've got the B that list is going to change, you know. I look at that clock and I say it's now. It's now. It's now. Now is relative and now is changing. One of the things I'm talking about is I'm arguing back home with someone about, what's the most recent weight. Was it the weight that was put in yesterday? Was it the weight that was put in B so, what is recent? What is relative? Those are relative times.

So, there's a lot that's happening right now and it's changing. And what's happening is: we're going through this period that's so fast and changing and we have to be thinking about B Matt was saying there's things to be thinking right now that evidence B advancing evidence right now, but really thinking about what's that transformational in the future.

And what we're talking about today is probably going to be much different in a year. I have no way to predict what's going to happen in a year. It's moving that fast, and I think that's one way to think about it is think of having a new model.

And not just giving ourselves a box, but making the box B where's that Jell-O, you know? That's what we have to be thinking about is the Jell-O mold, you know. It's there, but it's got a wiggle.

MS. DANIEL: Yeah, and for those who weren't here, that was the leading analogy of the day yesterday and Steve's panel was Jell-O nailed to the wall. So, you have to be here for the whole time to get all the jokes. Okay, Ronni.

MS. SOLOMON: I'm sorry I missed all that Jell-O. I personally like green, but B so, how can we enhance the evidence base? I think that we, by collecting this data in standardized formats and other ways, we are doing that. The evidence base is being developed as we speak.

What we have to do is be better at sharing it beyond our four walls, where it's useful to generalize, we should, and to get the most out of it.

So, for example, we already have a thousand hospitals that have access to a health IT hazard manager reporting program and the AHRQ common formats. We have a way to bring in standardized reporting. We have a way to collect root cause analyses. And we have hundreds already on health IT issues and systematically review those.

So, I think that there's a way to take this PSO data and help inform the HIT Center. I don't think the HIT Center needs to go there and recreate it. There are a lot of efforts on the ground. So, I think, you know, I'm not sure exactly how that can be done, but I think that many pieces are in place and we sort of need to thread them in a way that makes sense.

So, I'll leave it at that.

MS. DANIEL: Okay, great. Let's go to the audience. Right here in the front,

you've been waiting some time. Thank you for your patience. Can you turn on the front mic?

MR. FERNANDO: Anura Fernando from Underwriters Laboratories. What I wanted to mention is we've had a lot of discussion around what the value proposition previously, as well as some discussion of systems engineering, and those kinds of things which I think are very, very valuable here. When we look at those concepts from the perspective of evidence, one of the things that may be of value to consider here is that there are a lot of industry standards, or private sector standards, consensus standards that are explicitly focused on safety.

Safety across the entire ecosystem of products comprising the healthcare network, ranging from wearable technologies that might be used for telemedicine and home healthcare applications to technologies that might be used in medical devices. Technologies that may already be used in other sectors like industrial control and automotive and so forth would have gone through rigorous safety testing and analysis from a component perspective.

When you take these components and integrate them into a new application domain, like the healthcare environment, leveraging those standards and the learnings from the test results from those standards and be immensely valuable in this type of a forum. And so, I just wanted to bring that up and make sure that everybody is aware to look at those existing resources, look at how you can actually look at component tests.

In the automotive industry there's a concept called system element out of context. And so, if we look at the EHR as one component of this overall healthcare system, if we look at the telemedicine device as another component of all this, if we define that system

context while up front by gathering evidence and gathering information, then we can make some arguments about the safety of individual components.

And an organization such as the Safety Center that gets this patient safety information and understands the top-down drivers for why these bottom-up safety issues need to be addressed from a design perspective, that can be immensely valuable in the industry.

MS. DANIEL: Thank you. Janet, you want a quick response?

MS. MARCHIBRODA: Can I just say for the record, you know, at the beginning when you said the Center could gain agreement on standards, I wanted to, for the record, say it should leverage existing recognized standards such as ISO and others. We actually have a long list of existing standards that should be leveraged. I just wanted to say that.

MS. DANIEL: Thank you. Okay. Go ahead.

MS. DURKOVIC: Hi, Vesna Durkovic. So, a couple things I want to say is I completely agree with Jeanie where just even convening conversation is going to transform that, and as we're becoming more sophisticated with health ITs and asking questions, bringing lessons learned, I think, having that type of information.

I do think that there are things that you can leverage from other industries and, yes, with the aviation yesterday -- being biological, there are some things to also leverage of what makes aviation safe.

It's not just the one-hour cockpit checklist and a 20-minute walk-around for every single flight. And they do that because of stress. I'd love to have that type of a check with the doctor, every time I go through a stressful thing. It doesn't happen. It's true though.

I mean, they also have regulations of check A, B, C and D -- and, oh, by the way, my husband is a private pilot and has run airline operations for regional and commercial.

So, that's how I know these things. And you have a check every 500 hours, four to six months, 20, 24 months and every five years where the airplane is taken out of the circuit and has hours and hours of inspection.

So, if we did that to every patient, I'm sure we'd all be a lot healthier. So, in that sense, there are things to leverage to think about what it is to be healthy and as well to create that conversation on what we need to check. And that's just why, you know, we can leverage some things, but we also have to recognize in a 10-minute visit - last time I had a lot of health prevention checks was in my third trimester.

So, outside of that - and that's expensive. OB/GYN is expensive. So, we have to kind of balance the expense with the reality.

MS. DANIEL: Thank you. In the back.

AUDIENCE PARTICIPANT: Hi. Thank you. The panel discussions this afternoon were much more productive than this morning. And so, I appreciate that. One thing that's been omitted is quickly being able to report things. So, you know, people who are in the trenches, you know, in ambulatory settings, they don't have, you know, a huge IT staff behind them.

And so, the quickest way possible in their crazy day that's getting more and more regulated by the minute with more and more education requirements, et cetera, if you ask any of your physicians who are using EMRs, is there something that you'd like the EMR to do better or safer? I would suspect that they would all have something to say. So, you know, if there's a way to aggregate that quickly, that would be one point.

The second point, with all the aggregation and with all the data and with the scope of the center that I understand, a second point to utilize that aggregated data would be

to de-identify that aggregated data. So, a second step in the process that maybe hasn't been emphasized enough is to de-identify the quickly aggregated data to utilize it more effectively.

And then I definitely agree and I'm excited by the concept of having this be a non-punitive environment. And I wonder if there's any discussion points maybe from the FDA regarding the vaccine injury compensation program, where a similar type of environment could be created around the Health IT Safety Center where you have a, you know, still people can litigate, but the award is non-punitive to the person reporting it. And then the last point was B well, I'll stop there. Thanks.

MS. DANIEL: Thank you. So, I'm going to sort of move the discussion a little bit to follow up on something that Jeanie was saying about the different layers and talking about data, and then information, knowledge and wisdom and having moved from the data up that chain more toward information and knowledge.

I'll stop at knowledge for today, you know, you got to start small and hopefully to wisdom down the road, but how do B what are some the pathways for taking learnings from the evidence, from the engagement of various stakeholders, and identifying best practices and then disseminating those best practices so that they become B it isn't just, you know, one person or two people who realize that there's this huge system problem, but that that information gets out and people are able to incorporate that in their implementation and their product development in their use of the products.

Jeanie and then Jeff.

MS. SCOTT: Well, actually, I was kind of looking over at David. Maybe he put up his card over there. One of the things that B and I almost want to start the discussion a little bit B

MS. DANIEL: Should we volunteer him?

MS. SCOTT: I'm going to ask him to maybe be called on, and maybe to speak a little bit from B I think one difference is B and I do agree that healthcare is a high-risk area and we want it to be B we want it to be a high reliability area. We want it to be high reliability.

Is it there? I'm not really sure. And I think that's part of why we're having this conversation. One of the difference between B and this is my opinion, is one of the difference between healthcare and aviation is in aviation you have the cockpit and you only have a certain number that fly and you have all the passengers.

One of the things that's changing in healthcare is the patient is now going to be able to get into that cockpit, okay, and that's going to change. And in some ways, I say that healthcare is going to be more like the automobile industry, where the consumer is buying the car and driving the car and going on those traffic highways. And that's more the safety thing.

I mean, I put my kids in the car and I've got an 18-year-old going off to college that's going to be driving back and forth five hours. That scares me. I've got a 16-year-old about to get a permit, and another one. That scares me. That's kind of like taking my kid into the ER. That kind of thing, you know. My kid coming home at midnight, that's the same type of thing that I feel going into healthcare.

So, you know, this, how do we feed that back into it? I think we need to look over at how do we learn that type of knowledge from B how does the automobile industry get that back? So, I hope I didn't get too far away, but I think we can learn from them.

MS. DANIEL: David, did you want to respond, since you got volunteered?

(Laughter.)

DR. MAYER: I'll try. I don't know that I can B I certainly can't speak for the

automobile industry, because B but I'll say a couple of things, perhaps. And I certainly agree with you that I'm not here today thinking that there's a specific model from aviation safety that can just be transplanted to healthcare and then we could all just go home, but I certainly see your point that the advent of patient center care, mobile medical apps and all of the stuff that is designed to move the patient more onto the flight deck certainly presents challenges, you know.

When the automobile industry was able to make safety desirable, you know, multi-curtain air bags and all sorts of great features that truly improved passenger safety, I think that was a great thing.

At the same time, this is just the outsider speaking here, but, you know, healthcare is really beginning to recognize the value of true evidence-based medicine. And by all means where you can give the patient the opportunity to make choices and provide direction, that's great, but right now in the automobile industry a lot of drivers and consumers want technology that the NTSB thinks is particularly distracting to the driving task, things that will read out text messages or provide the opportunity to tweet from the road and do all sorts of stuff that's B the automobile industry will probably find it advantageous from a profit perspective to provide that kind of technology, but whether or not it's going to yield better outcomes for driving is another question altogether.

I don't know if those are helpful comments, but the gatekeepers at healthcare still have a responsibility to make sure that medicine gets practiced well.

MS. DANIEL: Jeff.

DR. BRADY: Yeah, I was just kind of introduced into the conversation or maybe reintroduced having not been here for the full meeting. A lot of talk about reporting,

which is clearly an important component of advancing the evidence. An acknowledgement AHRQ's work in this area and our attempts to standardize reporting writ large in the field of patient safety.

The point I wanted to introduce or, again, possibly reintroduce is just how, while that's an important source of information, it really is clearly just one source. And in the general patient safety world and part of our research program, we also operate surveillance systems that provide data that clearly in some cases is structured in very similar ways to reporting, but we do recognize that it's clearly a different source of information and a complementary source.

So, just in terms of setting the scope for the Center, some access to that capability whether it's internal or through stakeholders, but B or partners, I should say, and then even further expanding that notion, other methodologies to answer questions, and I guess just that simple function of the ability to not be completely passive in terms of what information is received through reporting, again, acknowledging that as a clearly important source of information, but in performing its functions, questions will no doubt originate in this group.

And so, how will this handle what's done with that? Because I think that's just an important function to think about.

MS. DANIEL: Thank you. Julian.

DR. GOLDMAN: Thank you. So, we've talked, I think, kind of circling back and tying some of these conversations together and particularly what David said and listening to Jeanie's comments. If we separate again into the input stages that you just addressed again, Jeff, and then the analysis stages and then the output stages, the analysis stage is an

opportunity to apply systems engineering principles and a lot of stakeholders, to try to come up with possible good solutions.

And NHTSA, the National Highway Traffic Safety Administration, it's funny, just as David was talking, I have the NHTSA website up on my iPad, because I like using that as an example. And I think we can learn from the website. There's a lot of excellent communication on the NHTSA website. Sign up here to get notified of device recalls, and consumers can sign up, for example.

Here are grants that are available. Here are the recent things that we've learned. A lot of documents on the NHTSA website. It's really quite good. So, we look at B let's take NHTSA for a second. There have been problems historically, you know. I'll just make up a problem. Let's say we detect an increased number of cars off the road after some, you know, in the last six months in a certain state.

It's possible to convene the groups and say, what changed? Did the tire composition change? Is it a change in the reflectivity of our signs? Is it the headlight law? What within a system could have changed that contributed, and then how do we address that? That's what takes all the different stakeholders B that's one of the values of diverse stakeholders.

But then the recommendations that come out of that may require a level of thoughtfulness or even a different type of stakeholder, because we don't want to start necessarily recommending the best texting options for use while driving if that's a solution, because that's the consumer demand.

It may not really be the best and safest approach. So, that's that output side, the recommendation side and why I think there's some value in clearly demarcating these

and looking at the differences that might be required to optimize that.

MS. DANIEL: Thank you. Ronni.

MS. SOLOMON: So, Jodi, I think you asked how we can B putting recommendations into action. How can we get change to happen.

MS. DANIEL: Yes.

MS. SOLOMON: Okay. And last week HHS issued a report saying that there has been success in patient safety as a result of the hospital engagement networks that have been going on for the past two years.

We have reduced harm associated with pressure ulcers. We have reduced harms associated with infections and patient falls.

How was that accomplished? It was because there were collaboratives developed and hands-on work being done.

And so, the little brainstorm I just had is maybe the Health IT Center could help take the learnings and the toolkits that we get, and we've got some of these already.

Translate those into educational materials and practices for how we make change and then we get it out there not just to the hospitals, but to the ambulatory care settings. And that might involve a lot of adaptation.

So, I think that we do have some existing toolkits, existing best practices. If we don't have them yet, we can refine them. And then I think we need to adapt them for the audience and create campaigns to make things stick.

And maybe that's something the health IT center can help with, because that's what ultimately is going to make change.

It's not going to just be publishing reports that makes change. It's going to

be getting people involved that makes change.

MS. DANIEL: One quick follow-up on something that Julian asked and, Toby, I'll go to you next unless Julian wants to respond, but you were saying on the NHTSA website that there is public communication not just to the participants, but broad publication to the public about either, you know, issues particularly with a product or, you know, perhaps with B it could be with practices or things that folks should be paying attention to.

What do folks think about communication broadly to the public versus just to kind of the participants that are actively engaged in the Safety Center?

DR. GOLDMAN: I think the NHTSA site does have a lesson there. The material is quite sophisticated and we shouldn't underestimate, you know, our customers here.

There's diverse information, safety reports, analyses, publications, but there are also pretty pictures and eye candy and things like that.

I don't see why in this modern world we wouldn't be trying to, you know, have all the ships rise with the tide by improving education and a shared message of a national healthcare improvement.

MS. DANIEL: David, did you want to respond to that specifically?

DR. MAYER: Yes, I think he just probably said it better than I could say it. But that in with modern communication tools, we've talked about social media earlier in the day and modern communication tools.

One of the things that I grapple with back in my own organization is, you know, there are so many different ways to communicate and sometimes the traditional ways, let's write a 200-page report, may not necessarily be the best way to share information and share the learnings and communicate it out, you know.

People look for information in a whole variety of ways. They're looking for videos, they're looking for podcasts, they're following Twitter feeds and there's no reason why as long as the information is accurate, there's no reason why it can't be communicated in all sorts of different ways.

MS. DANIEL: Thanks. Toby, did you want to B

DR. SAMO: Yes, actually to follow up on what Ronni said, I mean, I love the idea of identifying best practices and putting together a toolkit to say, you know, this is best practices, here are the pieces that you need to go ahead and do that.

The only thing B and we alluded to it a few times. But if we look at the name, it's Health IT Safety Center. And there has been another one of those lines that we've talked about back and forth, is it just health IT safety, or is it patient safety as a whole?

I don't have the answer to that. That's clearly a definition. And the only reason I bring it up is because actually the example you gave I would say, you know, health IT can -- and we actually have toolkits that we give to our clients to help decrease pressure ulcers, okay. So, health IT can play a role in improving patient outcomes, but is our goal rather of this center to improve health IT patient safety?

And so, as an example, instead of having a toolkit for how to reduce pressure ulcers, we have a toolkit as to how to implement, let's say, SAFER Guides.

MS. SOLOMON: That's exactly what I was thinking, Toby. Exactly. So, yeah, I just gave the examples, because HHS issued that report last week, but I think that there could be implementation toolkits for health IT that could help.

Because as I mentioned before, you know, you might buy a Chevy Impala and, you know, Organization A might drive it safely, and Organization B might not drive it safely.

So, we need to share how to drive it safely.

MS. DANIEL: Jeff and then Michael, and then I'll go to Kathy and --

DR. BRADY: Real quick point on your specific question about, as I understood it, direct information to the public, yes or no. I think it really depends on what's the information, I mean, an obvious point.

And a lot's been said about actionable, you know, action-oriented information. If there is information that you want the public to take action, I think the simple answer B or take action about, the simple answer is yes for that set of information, but I would be very cautious about, you know, considering the audience and, you know, at the risk of maybe confusing things, I'll offer an analogy in terms of how we think about this within the general patient safety scope, if you will.

For problems like central line-associated bloodstream infections, primarily we're dependant on providers for the solution to that, how they insert the central line, do they take it out on time.

The patient is not really that involved. Clearly they have some role in terms of awareness perhaps asking about, you know, is it time for the line to come out? But relatively speaking, less involvement in comparison to something like drugs that, you know, have a very narrow, therapeutic target range, anticoagulants and insulin, especially used in outpatient settings where they are the primary, you know, action point, if you will, for managing the drug overall and the safety, you know, potential safety effects.

So, again, those two safety problems, if you will, in comparison, suggest different target audiences in terms of, you know, where's the real push and the focus and the emphasis on trying to elicit action.

MS. DANIEL: Thank you. Michael.

DR. HODGKINS: I don't know if we're calling it the HIT Safety Center or the Patient Safety Center, but I actually like Patient Safety Center, but the point I want to come back to is one that was made at the beginning of this series of panels.

And that is, you know, really where the rubber meets the road is going to be with the Safety Center. Everything that's gone on in the past few days is all very constructive and there are important things that we need to address, but let's step back and recognize that what the framework has done is it's moved a lot of stuff into an unregulated environment, you know.

We've basically said, and I think appropriately, and this isn't to disagree with the basic structure, that the FDA is not going to expand its regulatory purview.

And we've got this big category now called Health Management and the HRs are in there and a lot of CDSes in there and mobile applications and sensors are in there, many things that, you know, that might have otherwise or some people have suggested belonged in the device category, you know. There should have been pre-market approval. And there should have been, you know, a process around that such as FDA conducts on their medical devices.

So, let's recognize that and then, you know, I think if we agree with that, let's recognize the importance of getting this right.

And I think that the first priority coming out of this three-day meeting should be that, to focus on what do we need to do to get the Health IT Safety Center, the Patient Safety Center, whatever we're calling it, right, get it off the ground, get it working and, you know, because the time is now.

Going back to Jeanie>s comment yeah, the time is now and, no, I don't know what it's going to look like a year from now, but that's not what our concern should be.

Our concern should be we've just pushed all of this stuff into this unregulated category, if you will, and the Safety Center, to me, is the safeguard that needs to be in place as soon as possible.

MS. DANIEL: Kathy, you wanted to make comment.

MS. KENYON: Kathy Kenyon from ONC. I run a bunch of the health IT safety contracts. One of the questions that I have is, where did the private sector step up and see value in the Safety Center offering and publicizing opportunities that are really generated out of the private sector for others to be involved in health IT safety activities that might come from a lot of different places?

Part of my reason for asking this is that one of the contracts that I manage is with RAND where they looked at risk management interventions with help from ECRI, by the way.

And what we have found out of that is that the ones that were the most successful B and I will say that by and large they had a hard time being successful, but the ones that were most successful were the ones where the organizations actually identified the risk themselves. They said, we know we've got this problem.

My guess is that you would find that a lot of people would identify the same problem. And then we also know that we've got a private sector where you have a lot of different organizations, you know, working on different aspects of health IT and safety.

We know that Toby's Allscripts has a help desk and he's clearly going to work on a SAFER Guides toolkit either with ECRI or maybe with the AMA.

I mean, so, the question would be could you B could in the private sector, would you have some combination of stepping up to the plate using the Center to say, I have a program and I want people to participate in it, this is what it looks like, and then just offering that to the private sector.

MS. DANIEL: Toby, did you want to respond?

DR. SAMO: Since you called me out. So, I would say, I mean, the short answer is yes, you know. I mean, it's something that I think, you know, two aspects. Our transparency is important, but to share the knowledge that we have, I mean, I think I have been fairly clear that, you know, we like, you know, multiple other vendors are proud of what we are doing, but for a variety of reasons it's, you know, that information is not out there because there's not a good place, a safe place to go ahead and put that.

So, if there was a safe place that would enable the various constituencies to put that information out, then I think that there's a much better chance that that will happen.

MS. DANIEL: Janet and then Ronni.

MS. MARCHIBRODA: I've really been amazed at the level of leadership that I've seen from hospitals, technology companies, PSOs, medical societies, you name it, you know, wanting to move forward together on this.

And I would say, you know, like what B why did we need a plan, you know, why should something happen in the government?

And I think what I hear over and over if we're going to invest, if we're going to step forward, we want to be sure that we're jumping on the right train, you know.

Where is the anointed one, if you will? Am I going to do this nice thing with all of these people, but we'll still have to do all these different things for different agencies or

different organizations?

So, I think key to the success of your safety center is to say we'll move forward together. And as a result, we won't do some of these other things. And then I think folks will come in droves back to your value proposition, Jodi.

MS. DANIEL: Thanks. Ronni.

MS. SOLOMON: So, as a private organization, but with a public mission, our answer would be yes, but I think it would have to be highly planned. There needs to be focus.

I think that you can't expect the private sector to just get around and, you know, sort of do this, you know. There has to be an initiative. There has to be an approach. There has to be responsibility. There has to be a plan and then I think it can get done, but we sort of really need to shine the spotlight on it and, you know, create the road to make it happen.

MS. DANIEL: So, one other question I'd like to ask. It=s a slightly different tack. It's something we heard about from our summer of FDASIA, FDASIA Workgroup. We heard about it from the Institute of Medicine report, and that's about product listing.

And whether or not the Safety Center could play a role in that space, what the B whether there is value to that, how we would determine products that would be listed, I'd just like folks' thoughts on product listing as, you know, one piece of what you communicate and provide transparency and share with the public and how that could work effectively to be more successful.

DR. SAMO: Point of clarification.

MS. DANIEL: Yes.

DR. SAMO: When you say listing, listing of what?

MS. DANIEL: Of the products.

DR. SAMO: These are all the B

MS. DANIEL: Well, that's B

DR. SAMO: These are all the products that are available, or the products that have been, what?

MS. DANIEL: Well, that's the question. As we've heard, we've heard kind of mixed things on product listing and, you know, is it only products that meet certain standards that have been valued to meeting those standards or where a developer or test that they have comply with certain standards that's gone through some process or not, and how B so, one is their value in having listing outside of our chapel for meaningful use purposes, but more broadly for health IT.

And if you ask them what level of, you know, of sort of compliance or validation with some set of standards or process would folks want before a product would be listed and then how would that be -- even more challenging, how would that be managed and to make sure that the products that are listed are maintaining that level of standardization or a process.

Julian.

DR. GOLDMAN: Thank you. So, like the notion of listing or a list of products or an index of products can mean many things, clearly.

So, I think it might be helpful to think about what doesn't exist today in terms of the access to product information and what might be different in the Center.

So, today there are companies that evaluate medical devices. There are companies that evaluate HIT products. There are organizations that put out information and

the criterion vary. Usability, all sorts of things like that.

But if we're talking about a learning environment and we're talking about relatively B potentially complex products, health IT components and systems, much of that has to do with configuration.

And I think if we look at the configuration aspect, and I like to use the example of a network printer. You buy a network printer and you spend a lot of money, because it has certain configurability that standards base built in and you can read about that before the purchase.

And then someone who's knowledgeable can set up the printer in the office or the building, be on the network and function as needed, but we don't expect it to just be dropped off by the delivery person and plugged in and work. It has to be configured.

So, in the health IT world, configuration is frequently a key part of the implementation and use of a system.

So, we could comment or address capture information about the appropriateness, the performance and the ease of configuration, because then you have the ability to have shared best practices of configuration for safety purposes and things that shouldn't be configured a certain way because they might be hazardous or they might introduce uncertainty into the system.

So, and that then becomes part of a learning environment where the different stakeholders can contribute, manufacturers can clarify whether configurations are done correctly or not or might be hazardous. Instead of waiting for a problem to develop, they can provide guidance on the best practice for implementing that technology.

So, that's a subset of the scope of listing of information. It isn't really

certification of that, but it becomes part of the learning environment and it addresses what is today a very B a significant national gap.

In fact, it can be difficult to share that information today and there are B and as talked about in the summer of FDASIA and leading up to it, there are, you know, potential legal barriers that exist today to sharing of critically important safety information.

MS. DANIEL: Okay. Jim, and then Jeanie and then Janet.

DR. WALKER: So, I=m just as sure I love the Joint Commission. I could imagine a world in which we said every information system developed to assist patients or healthcare consumers, so that means consumer apps, as well as the HRs, as well as PHRs, shall have a published safety plan.

How do we B what are the things that we do to make sure that our product increases rather than decreasing patient safety, and shall follow it? End of sentence.

And every implementor of any information system designed to support, blah, blah, blah, blah, shall have a public safety plan. This is how we decrease risks to patient, increase patient safety and shall follow it. End of sentence.

And then somebody with the appropriate authority would pose the possibility that they might come actually inspect and say, okay, where is your safety plan and how do you actually follow it?

And it seems to me that would have all kinds of benefits. It doesn't require us to know anything in advance. It really genuinely would inform the market. Markets have to have information for them to function. And it would create a situation which people who had high quality, credible safety plans would be advantaged in the market.

And the people just trying to slide by, maybe that could become a little more

obvious.

DR. GOLDMAN: Just a question for Jeff.

MS. DANIEL: Sure.

DR. GOLDMAN: A question for you since you've brought up the systems engineering perspective several times.

Identifying things and their requirements separately as components of a system may not allow us to address the emergent behaviors that might be hazardous.

How would you address that?

DR. WALKER: Absolutely. I wouldn't with this. I'd say this is a baby step that is -- absolutely has the minimum regulatory content that has extremely high face validity, would be hard for Google or Microsoft or the guy in the garage or Siemens or Allscripts to argue with or Mass General or Geisinger or Living Hospital to argue with and would be a start toward some progress.

DR. GOLDMAN: I would not argue with it, by the way. It's a great idea.

MS. DANIEL: Jeanie.

MS. SCOTT: So, I really hate to B people tell me I do this all the time. I would almost answer your question that product listing instead of the for what, the for who, okay. So, it's not a one-size-fits-all.

Julian and Jim both talk B I think you talked more about the bigger products out there that are going to be used for the hospitals, but when we're talking, you know, where's the future, I think that the for who when we start talking about the consumer, I mean, a story that I just had, I was just writing B I just did a class in consumer health informatics. And I went up on ONC's website and I was looking at some mobile apps. And I was looking at some of the

manufacturers.

And like, the first thing I saw next to it was a disclaimer by ONC that they did not endorse any of the privacy statements that the B and so, first of all, I was turned away from it. So, I think there has to be a trust thing.

So, that what I would say on the product listing is the for who. And then there has to be a trust that if you are going to do a product listing, that ONC has to stand behind it, or don't do it.

MS. DANIEL: I mean, it is for the Safety Center.

MS. SCOTT: For the Safety Center. If you're going to do a product listing either B you can't have a disclaimer behind it.

MS. DANIEL: Uh-huh.

MS. SCOTT: And that was one of the things I saw up there. There was a product listing and it listed privacy statements. And then it said, these are up there, but we don't really endorse these privacies.

I don't have the correct language there, but if I was a consumer, I would have lost all trust because there was a disclaimer.

And no disrespect to ONC. I think it was a very B we're going through a maturity phase right now.

MS. DANIEL: Yes. So, can or should the Safety Center have that as part of its function that it has B that it has a list of products either with some, you know, set of criteria folks agree to, adhere to with, you know, something like Jim was saying where they at least publish, you know, you have to at least publish your plan and say you're going to follow it to be listed or with some kind of, you know, more, you know, more stringent validation process.

Is that a function that the Safety Center can or should B-

MS. SCOTT: I think the Safety Center can begin with maybe B- begin with a criteria list.

MS. DANIEL: Uh-huh.

MS. SCOTT: That could be a start. If you're looking for something, here's what you're looking for. For the for who.

MS. DANIEL: David.

DR. MAYER: Just a couple of quick comments. I don't pretend to have anywhere near expert level knowledge on the notion of product listing, but I had mentioned earlier my concern or at least implied my concern that if you create a model for Health IT Safety Center that requires more governance than absolutely necessary, you may create something that's really difficult.

And product listing strikes me just personally as more of a government function and it might be something that could be at odds with creating the trust in stakeholder engagement that you'd like to have particularly out in the vendor community. Like I said, that's just a reaction to it.

If I could also just respond very quickly to Jim's notion that system safety plans, it's certainly something that we see in transportation across all B- most modes of transportation where providers in transportation services may be required to produce a safety plan.

And as a personal observation where I see that work better is when there's some thought given by how those plans are going to be evaluated and what constitutes good content for those plans.

Without that up front thinking or possibly even peer review without that up front thinking, you can run the risk of it becoming more of a writing exercise and exploitation of templates rather than real thoughtful safety plans.

I mean, it's a good idea. I just offer those thoughts.

MR. POSNACK: I'm talking about a really light model that would let the market do that. I=d let the Huffington Post and Consumer Reports and whoever whip up on the people that have bogus plans.

MS. DANIEL: Janet. Sorry, I overlooked you.

MS. MARCHIBRODA: So, Jodi. This addresses your listing question, but it also addresses a comment that Michael Hodgkins made about moving things from regulatory to a non-regulatory environment.

I actually saw the plan as not B it was, you know, recognizing a new oversight framework or a way to assure patient safety, which would involve both development or where the underwriter B adoption of the existing standards for the most part. There might be some gaps. And then assuring adherence through independent accreditation and certification bodies across the life cycle.

So, back to Jodi's question. I mean, we've got lots of precedence for this in healthcare whether it's Joint Commission for, you know, hospitals or NCQA for health plans.

So, I think the listing is actually building on David's point, it's probably not in the Safety Center. It's probably part of the pseudo oversight regulatory component around adherence to standards.

MS. DANIEL: Okay. Let's get a couple comments from the audience, we'll take those and then we're going to wrap up, so I=ll start with Anura.

MR. FERNANDO: Anura Fernando from UL again. I just wanted to make two points. First, those of us who had the privilege of serving in FDASIA last summer talked quite a bit B or at least off and on about this notion of Class Zero as an FDA classification.

One of the things that might be a point to consider is since Class Zero, as far as I'm aware, has never been formally implemented, coming up with a mechanism to map health IT into a Class Zero so that it goes through the due diligence of being formally analyzed to ensure that it's not a medical device that falls into the established classification, but then also providing a mechanism for a listing and so forth. That's one potential scenario.

Second is, again, if we want to look to the non-governmental side of this, the private sector side of this, a lot of safety critical systems that are currently serving society, things like elevators, escalators, electrical systems in buildings, when you look at the codes that are supported by the safety standards and the codes then tied to the regulations and so forth, those codes often talk about listing a recognition of components that are used in those systems and those B- that type of listing a recognition is handled in the private sector through nationally recognized test labs like UL and many others.

And so, there's already the investment in the infrastructure there and the certification and conformity assessment programs there.

And so, I would urge that groups such as this also look to leverage those private sector capabilities.

MS. DANIEL: Go ahead.

DR. MAISEL: Jodi, this is Bill Maisel, FDA. I just wanted to comment just so there's no ambiguity about the position represented in the report.

FDA does not intend to require listing a registration for health management

functionality products whether or not they meet the statutory definition of a medical device.

MS. DANIEL: Thank you for that clarification. You probably just put a lot of people at ease.

So, we're running late. So, I want to get to the three commenters in the audience. I'm going to ask you to keep your comments very brief just to like less than a minute, 30 seconds if possible so that we can get everybody and then we're going to wrap up.

So, in the back, please.

AUDIENCE PARTICIPANT: I'm sure everyone is aware that when development of products occur, the developers and the vendor that's supporting it is making a decision whether to code to meet a certain standard or not.

And so, I feel like there's been sort of an over rosy decision tree without a listing that would be problematic.

So, I guess I encourage listing the products to give people incentives to strive for and then make it a meaningful representation so that it drives the market to go for those products and incentivize the vendors.

MS. DANIEL: Thank you.

AUDIENCE PARTICIPANT: Thank you. So, when it comes to the product listing, I know for the last six months, nine months I have been heads deep in angel invention incubator areas with this health IT, enough folks that are building platforms to list and score products.

I think the place where the Safety Center can really provide a lot of value is defining what does that mean. What is safe? What is reliable? And being able to provide that to those that are building those platforms, because those platforms are independent and

allow consumers to score as well.

MS. DANIEL: Thank you. And in 30 seconds, last comment.

MS. SMITH: I just want to say thank you. Mary Ann Smith at Novartis. As we look at this, I was just going to challenge as this is being developed, to develop this for what the system will look like five and ten years from now, and not what it looks like today.

Because whatever we set up that's good for today, will not accommodate when the car is going to tell us our pulse ox or reroute us directly to the ER and populate the new medical record before we even get there.

MS. DANIEL: I think that is a great finale for our discussion. As we're thinking about all of this, we do need to be thinking about what we need today and what baby steps we can take right now, but also making sure that we're thinking about the potential products of the future and how we might have a bright path to addressing the safety issues that may come about for those unknown products.

Please join me in thanking our panel for their thoughtful discussion today.

(Applause.)

MS. DANIEL: And I will B the panelists can go back to their places and I'm calling up Bakul Patel to help us in our last steps of our workshop. Thank you again.

MR. PATEL: Thank you. Thanks. So, this is where we do the public comment sessions and I would invite Brian Ahier to the podium to make his comments.

If there is anybody else who want to make the comments to the public comment session, please come by and you'll be allowed to make those comments. Does anybody else who wants to make the public comments, please come by, and you=ll be allowed to make those comments.

We may have ten more minutes B eight, nine minutes, maybe, to make those happen. So, Brian, please.

MR. AHIER: Thanks, Bakul. So, my name is Brian Ahier and I'm really speaking today as a citizen and sort of as an activist for open government and these are my personal views.

I appreciate the flexible approach and the gentle regulatory touch that's proposed in the report. I believe that this collaborative approach by the FDA, the ONC and the FCC is a remarkable example of what Tim O'Reilly has termed government as a platform for innovation.

Technology advances exponentially and it can take sudden turns. In the ponderous nature of regulatory activity, you can sometimes find it difficult to keep up with new and innovative technology solutions.

Technology development and deployment is a dynamic process. Developers and marketers are constantly inventing new products and we're finding existing products to satisfy new market demands and consumer needs.

While the pace and the dynamic nature of health IT makes technology innovations possible, it is also these characteristics that can sometimes present regulatory challenges.

Striking the right balance between regulatory certainty and consistency and regulatory flexibility is essential to ensure that innovations in healthcare technologies will continue to persist.

In order for the health IT Safety Center to succeed at the dual goals of ensuring patient safety and spreading innovation, it's going to require a public-private

collaboration, will include the diverse group of stakeholders, I think that could be the fourth Ae@ and that=s everyone that we need strong buy-in from the health IT community.

There may also be other policy levers outside of regulation that could be brought to bear, some of which were discussed in the panels during this workshop that would promote patient safety without stifling innovation.

Developing a flexible and adaptive governance model for the Health IT Safety Center will help in the ability to respond to market changes and technology advances.

I look forward to seeing the next steps that are brought forward at the end of the comment period and I'm willing to help in the process as we begin implementing plans and developing them. Thank you.

MR. PATEL: Thank you, Brian. With that, we'll turn it back to Jodi for just a reflection on the day and the panels she ran tirelessly all day and the punishment for not being at a meeting.

(Laughter.)

MS. DANIEL: Thank you very much. First, I want to thank all of our panelists for a really thoughtful discussion and comment beyond just sort of the things we've heard before.

I heard and saw people really starting to think outside the box and proposing some new approaches, some baby steps and first steps in priority areas that we could take on.

We started this morning talking about evidence and analysis and heard from a lot of different folks about how we can leverage existing evidence that's out there.

I heard a lot of caution about creating silos of information just focusing on health IT, because often the evidence may B the reports may not be clear as to whether or not

something is a health IT event, or whether it is an event that does not involve health IT.

We had a lot of great discussion just this afternoon about the Health IT Safety Center and thinking about who should be involved, some of the principles, how we bring folks to the table, the value propositions.

One of the key things I heard was about providing something to participants that they can't get elsewhere either through collaboration, by providing information or data that they couldn't get elsewhere, bringing together some of the different pieces of information we have.

I heard folks saying that we shouldn't recreate some of the processes we have in place for collecting data, but really build on that and move from data to knowledge information and wisdom. I will take that one with me.

And some great ideas and some baby steps that we can take to encourage folks to be more focused on safety to think about safety processes to disseminate best B to develop and disseminate best practices, and how we can include some of the players like the ambulatory care providers, like the mobile apps providers, as well as thinking through how we can take some steps today that can help us in the here and now, but also thinking about where we can go in the future.

This has been a fabulous day, a fabulous workshop. I would like to thank our FDA and FCC colleagues, as well as my own colleagues back home and here in the room who helped put this altogether.

I'd like to thank the participants and the panelists for their active engagement and participation. We couldn't do it without the thought leaders that were in the audience and up on the stage.

And any last remarks, Bakul, about next steps?

MR. PATEL: Yes, just to close out on so, people ask me in the hallway between, I mean, today was the only day I was able to actually do a little bit of running and getting coffee. So, people ask me, did you get what we intended to? And my answer was, absolutely.

Our intent here was to bring dialog from many different perspectives to the table out in the open so we can actually exchange those.

I think they accomplished that. I would say all three days, people are not shy about exchanging information and not just saying things that will make us feel good about the report was good, but in addition to that they also pointed out very specificity was needed. And also that details were important, they actually pointed out.

So, one of the things I'm looking at in my notes, I'm saying the pillar for continuous learning was the most important pillar that I took away that people took unanimously sounded and resounded over the last three days.

I am hoping that people on the web who are watching this patiently and engaging, as well as people in the audience and people - some people may have left. I'm hoping the discussions in the last three days will inspire you to provide some very powerful comments so we can take that into consideration when they finalize the report or take it to the next level.

So, I'm really hoping that input will be helpful for all of us as we look at the comments we get back by July 7th is the date. So, thank you again.

Next steps, comments for you guys. Action items for you guys is comments. Action item for us is going to be taking those comments, working tirelessly again to make sure

that we got and heard all your input.

If it's any reflection that we are not listening, that's not true that's false, because we heard during the FDASIA process everybody's comments, everybody's opinions and you saw a result in the report.

I can almost guarantee you that we will take everything you say to heart and will make sure that the path and the next steps we take will be a reflection of your input. Thank you very much and have a great day and a great week.

(Applause.)

(Whereupon, at 4:27 p.m. the meeting was concluded.)

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