



## HIT Policy Committee Safety Task Force Transcript May 29, 2014

### Presentation

#### Operator

All lines are bridged with the public.

#### Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Safety Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. David Bates?

#### David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Here.

#### Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, David. Jeannie Scott?

#### Jeanie Scott, MT, ASCP – Director, Informatics Patient Safety – VHA Office of Informatics and Analytics/Health Informatics, U.S. Department of Veterans Affairs

Here.

#### Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Is it "Jenny" or Jeanie?

#### Jeanie Scott, MT, ASCP – Director, Informatics Patient Safety – VHA Office of Informatics and Analytics/Health Informatics, U.S. Department of Veterans Affairs

It is Jeanie.

#### Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Jeanie Scott. Jodi Daniel? Jon White?

#### P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Here.

#### Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jon. Marisa Wilson?

**Marisa Wilson, DNSc, MHSc, CPHIMS, RN-BC – Assistant Professor – Johns Hopkins University School of Nursing**

Here.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Mary Beth Navarro-Sirio?

**Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation**

Here. Good morning.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Good morning. Paul Tang?

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

Here.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Paul. Peggy Binzer?

**Margaret “Peggy” Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety**

Here.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Peggy. Steven Stack?

**Steven J. Stack, MD – Chairman – American Medical Association**

Here.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Steven. Tejal Ghandi?

**Tejal K. Gandhi, MD, MPH, CPPS – President - National Patient Safety Foundation**

Here.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

And Toby Samo? From ONC do we have Ellen Makar on the line?

**Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Consumer eHealth – Office of the National Coordinator for Health Information Technology**

I’m here.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Ellen. And are there any other ONC staff members on the line?

**Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

Amy Helwig.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Amy. Okay with that, I'm going to turn it over to David. David, I know this is the first call, so if you want me to run through things and get us started, I'm happy to do that as well.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

No, I just want to thank everybody for agreeing to serve on this group. The backdrop, as I think essentially everybody knows is that the FDASIA subcommittee convened over last summer made a set of recommendations to the Policy Committee and then FDA, ONC and the FCC convened over the fall and issued a report. I can't remember exactly when, probably February, which summarized a set of recommendations around the whole FDASIA area. And what our task is really is to respond to that report, and Jodi is going to very shortly make some suggestions about how specifically we should respond to it.

In particular, our understanding is that ONC would like feedback about what the HIT Safety Center might look like and might do. There's a strong recommendation that an HIT Safety Center be established in the report, but the detailed outlines of how it might be structured and set up was not clear. And there are questions like, what should the governance structure be? What should the functions be of the center? How can it serve as a central point for a learning environment? How can it compliment some of the existing systems that are already there? How can it facilitate reporting? How – when issues are identified, how can it help organizations – so that is the very brief overview and we're going to have to come to a set of recommendations by July 7. So, this group has a short timeline. And, let me just ask Jodi, does that accurately summarize where we are?

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

Yes, it does. That's great. Did you want me to jump in and make some comments about the report and the meeting yesterday or –

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Sure, that would be great.

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

Okay. Thank you very much and really thrilled to have such a great group of folks here. So, we did – we put out the FDASIA Draft Report, and that's kind of an important piece, that it's draft. It was actually early April, we finally got it out, it was a little bit – than we hoped. But it's out for public comment right now and in – during that comment period, we also held a 3-day public meeting, which was May 13, 14 and 15, to get some more feedback. And then we had an entire day focused on the learning system and the Health IT Safety Center.

And I would encourage folks to, in this group, to focus on that area as opposed to the whole report, particularly in the tight timeframe we have and because a lot of the kind of line drawing of what's in what category with respect to FDA and – 5:06 can it be more within the purview of FDA to think through. And ONC is really focused a lot more on the learning system and how we address safety of health IT, as well as innovation in a pretty complex environment where the issues are impacted not only by the products themselves, which is where FDA primarily focuses, but also the use, the customization, the environment in which its implemented, all of that. So, we think that focusing on the learning and a Safety Center can be a really positive force for improving patient safety and the use of technology to improve patient safety.

So just a couple of things, and David highlighted some of these, but some of the things that came up when we talked about this at a town hall meeting were that there was – we needed more specificity on the center's goals and the charge, is this really a learning organization? Is this an enforcement organization? What sort of is the scope and the kind of guiding principles for a Safety Center? How does it – we heard a lot about the importance of it being non-punitive and confidentiality. We heard a lot about that people would come and participate in the Safety Center if they're getting something out of it that they can't get elsewhere, how do we think about the value to the different stakeholders that we would want to be engaged? We heard about the connection with patient safety more broadly and how do we make sure that when we're thinking about health IT as – the safety of health IT and the use of health IT to improve patient safety that we're thinking about it in the broader perspective of patient safety.

So there was – we talked about different models, the ASIAs model from the airline industry, the NTSB and there was an interesting discussion there. And one thing we may want to do is get our – once the transcript is ready, I'm not sure if it is yet, we can get a transcript of that meeting for folks who were not able to attend, so you can read the discussion that occurred during that session and get a flavor of some of the issues that were raised by the panelists that we had. But one concept that I heard that I wrote down during the meeting that I thought was interesting was thinking of the Health IT Safety Center as a convener of transformation. How do we convene folks to try to leverage health IT to transform patient safety more broadly, which I thought was an interesting concept?

So I think – we have only started to begun to think about what this Health IT Safety Center can be. We're very interested in your feedback. We are very interested in the panelist's feedback at the town hall meeting. And we're very interested in hearing what we get from our public comments. But, we have thought about this, I've talked about the three "E's," engagement, like how do we bring the right stakeholders to the table to have those dialogues that may not occur currently about best practices, about things that are working, things that aren't, risks and safety of health IT more broadly. So engagement, the second was evidence, how do we improve the knowledge from – and information that's available on health IT safety? We heard a lot at the public meeting that there's a lot of data out there, but the question is, how we can bring that data together to learn and to help change that data into evidence and then into improvement. And the third "E" is education. So if we actually know that there are practices that work well or that there are risks that folks should be aware of, whether – hoping that the Safety Center can serve as a mechanism for education for a broad group of stakeholders, so that there is more rapid learning. And therefore, better safety and better improvement leveraging health IT.

So, I think there's a lot of opportunity here and I think we really are looking for this task force to help us think about what are the principles that we should consider and – .9:42 our Safety Center? What are some of the key elements? Are there things we should stay away from? Are there things that are out there that we should build on as opposed to try to replicate? And how can we work collaboratively with some of the organizations already out there like patient safety organizations or other – the Joint Commission or others that are focused on patient safety more broadly? So, it's – I think it's going to be a challenge and I think it's also going to be a very exciting time to help get your input on how we can shape this in a way that really can both improve safety of health IT, but also leverage health IT to improve patient safety overall. And I will pause there and turn it back to David, or if folks have any questions, I'm happy to address them.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Great. So, and just one thing which Jodi alluded to, but didn't say explicitly, one thing that came up repeatedly that we think is going to be important is the ability to aggregate data from multiple PSOs, so, that's probably a function that the Center will need to have. But let me just open it up and let people ask questions at this point.

**P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)**

In the absence of other comments – this is Jon White. So, you all know that I care fairly deeply, as does AHRQ, about both the safety of health IT as well as general patient safety. And I think both are great aspirational goals to keep in mind. My opinion, and we can talk about it, is that the absolute must do mission of the Health IT Safety Center ought to be in sharing that health IT is safe and then beyond that, it's nice to be able to get to how you use health IT to improve patient safety more broadly. There are a lot of other resources that are focused on that as well, some at AHRQ and many other places, many leaders on the phone are working on that. So, I don't have a problem with both of those being in the purview, but I think that you've got to get job one done first and then you can focus on the rest. So that's my opinion, thanks.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Thank you, Jon.

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics - U.S. Department of Veterans Affairs**

Hi, this is Jeanie Scott and Jon, that's exactly one of the points when I was on the panel a few – I think it was about two weeks ago. The point that I brought up and I agree is that we need to have a very specific focus for the Health IT Safety Center is that it's a Health IT Safety Center and to focus on the safety of the health IT, of the product. And if we make that first and foremost focus and mission, then it will lead into the rest of it. So, I do agree with you and that was a point that I made first is, the rest of it can feed into it and I think we can learn we can get data from the PSOs. But I think we need to, on this Health IT Safety Center is, those three words, Health-I-T is what the mission of this should be, it's a Health IT Safety Center.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

So let me just comment that I think that the data from the PSOs will often be about issues with health IT that caused safety problems.

**Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology**

This is Amy Helwig from ONC; I've got a quick comment on that. Just wanting to echo Jon and also your comments, David, that AHRQ already funds the network of patient safety databases, which can aggregate from a – it's actually authorized in legislation to aggregate from all PSOs. And then it does have the added advantage that it is already gathering on all types of patient safety events because we know that health IT can be intricately a causal factor across many types of events, and not always showing up as a health IT factor alone. So, just wanted to kind of echo Jon's plug for some of the work already being done.

**Marisa Wilson, DNSc, MHSc, CPHIMS, RN-BC - Assistant Professor – Johns Hopkins University School of Nursing**

This is Marisa Wilson and I spend a lot of my time working through the sociotechnical model with my doctoral students who are responsible for creation, design and implementation of various health IT across different systems, ambulatory and acute and that kind of thing. I just personally want to make sure that when we talk safety, we are talking not just the technical glitches that may occur with software or hardware, but also the environmental use – the people use of the technology. Often what I see is technically things are working, but the way the process has been developed creates gaps in the – with the use of the health IT and communication pass-off or whatever. So, I think we have to be clear that it's not just technical issues, perhaps, but also the way things are being used, the way things are being implemented.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Okay –

**Margaret "Peggy" Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety**

This is Peggy Binzer from the Alliance for Quality Improvement. I'd like to build on that because we found that when we worked with clinicians in root cause analysis where we found a contribution for – from HIT, often times we find that the systems failures is other factors as well as HIT. So, it's very difficult to remove the clinical aspects given that the use of much of the HIT is a shared responsibility. So, limiting the Safety Center to only HIT, I think that we'll be focusing more on functionality and not on use and I think that most of the major issues I think we're seeing are in the shared responsibility area. And so I think that we need to consider that as well.

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

And this is Paul Tang and I was going to build on this last comment because one of the things that was discussed in the IOM committee as well is if you have safety reports going to PSOs, for example. I'm not sure we want to place the burden on the reporter to sort everything out, even if the HIT systems are involved. It's almost like a plane crash, the NTSB goes in and looks at everything from the mechanical to pilots to air traffic controller. And I wonder if we want to make sure not to narrow ourselves to things that are clearly, let's say a software bug versus things where the HIT system can both either contribute to an adverse outcome, or be part of the solution of discovering what near misses are participating in in the learning overall.

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

Hi, it's Jeanie Scott again; let me make it a little clearer. I guess what I want to say is the health IT system and how that – not just the product, but it's the system around it. And I agree with the other comments, it's part of all the sociotechnical parts that the Health IT Safety Center should be looking at, not just the product.

**Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation**

And this is Tejal Gandhi. I agree with that as well and I think this idea, we need to make sure the systems are safe first, before we kind of move on to then how we can optimize them. But I think they really go hand-in-hand because if we design it right initially so that the sociotechnical aspects are considered and we're really implementing optimally, etcetera, we're hopefully doing both, we're mitigating any of the unintended consequences while also optimizing all the benefits that we know we can achieve.

**Steven J. Stack, MD – Chairman – American Medical Association**

So this is Steve Stack. I'm going to go backwards in my three points based on the last comment. I agree with that except that there's no way to optimize all these things prospective and I know you didn't mean that, but – so I worked two 12 hour shifts in the emergency department the last couple of days and we just implemented tap and go with RFID badges to tap in. And the execution, separate from the vendors, is essential because we have providers being logged in to the wrong hospital, provider Dr. Smith being logged in as Dr. Jones. I mean there are all sorts of implementation and execution challenges. Clinicians who sit for an hour paralyzed, unable to provide clinical care because they can't document, chart enter orders, give medications because we have bar code scanning, but they're being logged in as the wrong clinician. So, I think that the technical aspect of this is really essential and there's a lot we can look into. And it's not just the EHRs themselves, or specific vendors or the deployment that's unique to each purchaser of a system. And then there are the EHRs themselves also, as a separate issue. So that was one point.

The next one is for PSO data, I think a number of you seem to be referencing data specifically by instance related to HIT itself. I'm part of a large group that has an enormous PHO with nearly 10,000 clinicians in it, and I'm not familiar that we track that specifically as much as focused on the actual clinical care and our medical decision-making. So, I'm not sure that every PSO is going to be attuned to this, so I think we want to focus on the technology.

And the third and the final thing is, I think the Safety Center has to have – it should be focused on health IT, but we should be clear on the front end that EHRs are not themselves all of health IT, they are only one instance of health IT and there's a lot of other health IT that's used. So it should be broad enough to encompass the true spectrum of health IT.

**Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation**

This is Mary Beth Navarro-Sirio. I guess I would piggyback on to what Steve just said and I guess one of the things I think is important that the Health IT Safety Center does for us overall is to help us pull together the disparate data that's out there. I don't think we really know a lot about where we need to focus our efforts to improve patient safety related HIT, there's not a lot of evidence or published information. So, I think one of the things that the Safety Center needs to do, perhaps as a priority, is to help us understand where we're best to focus our efforts and to pull together different data sources.

I mean I agree that I don't think that today we can get that information directly from the PSOs and the data that we're collecting and we hear a lot that folks don't necessarily want to have to report HIT separately from the way that they're reporting to their PSO today. I might have – I might give a patient the wrong dose of a medication, and that's what I report and the root cause might ultimately decide that it was a combination of things. So, it's really hard to disaggregate what's going on at the end-user perspective and we really need to get our hands around how we're going to identify and prioritize. And then I would agree that we need to look at the entire system, both the technical components of the EHR as well as the pieces that are more user – as well as things like configuration and interface and other things like training.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Great. So this has been a really – this is David Bates; this has been a really good discussion. I would agree with a lot of the points that have been made. When we look at doing primary data collection studies, we find that a lot of the issues are – actually most of them that result in harm are not just technical ones, they include things like what happened when a patient is transferred and the ball gets dropped. And Steve's point about EHRs only being part of things is clearly relevant, too. I've taken a lot of notes and I'll be going through later and trying to synthesize some of this. Other big areas that we think that we need to address?

**Steven J. Stack, MD – Chairman – American Medical Association**

Dave, if I could – this is Steve Stack if I could add one more thing.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Sure.

**Steven J. Stack, MD – Chairman – American Medical Association**

Clearly health IT done well is an essential part, a not without which part of improving healthcare in the country. It's safety, it's efficiency, it's value and cost savings. So, it's important that it's done well. So one thing I think, as we look at the implicit – the impact and implications of health IT could be, what is the human element's capacity for change? And notwithstanding the ability to flow map and design in an engineering way, how a system might work, once it's released into the live ecosystem if you will. Just what the human element's capacity is to absorb that change and how so many different health entities, hospitals, provider groups and practices, deploy things in such a heterogeneous way, even if it was designed prospectively, with what seemed to be clarity.

Because one of the concerns I think that clinicians have is the pace at which it's moving and the complexity with which we are asked to adopt it. So it's not, focus on these three tasks, have six months, accomplish them, and then move on. It's take these 40 tasks and do it all at the same time. I think the human element is really struggling, straining, and unable to keep up, both the people designing and implementing them in the health IT – and then also the clinicians trying to deliver care in using them. And I think that that's some task we should incorporate into our considerations.

**Toby Samo, MD – Chief Medical Officer – Allscripts**

Yeah, this is Toby Samo from Allscripts. I think we're all in agreement that this is a complex issue each time you have a patient safety issue or a hazard that comes up. And I think part of the discussion here brings up the importance of standardization, standardization of definitions what do we mean by a patient safety event? There's obviously been a lot of work with hazard managers and others to categorize it, but one of the other aspects in addition to all of us agreeing on definitions, is how do we implement so that we have a common evaluation process across all the venues, so whether or not that evaluation process is done by a PSO, done by the client in some of the larger organizations or done by the vendors. That we have some – that we have significant amount of standardization on how that information is defined and reported.

**Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation**

Toby, this is Mary Beth. I think that's a great point. I was talking to some folks yesterday at a very large academic institution that has been doing patient safety for a really long time. And I was talking to their patient safety folks, but they said that they don't even know where to begin to start to triage issues related to HIT and patient safety. And one of the suggestions they had was, is there some kind of algorithm that we could provide that was a standard estimate tool for, if an issue occurs, if you ask these 10 questions and it's a decision tree, then you could probably determine whether you need to flag a potential HIT safety event or not. But the frontline folks that are really trying to collect this information and understand what's happening really don't have any way to determine that, at this point.

**Marisa Wilson, DNSc, MHSc, CPHIMS, RN-BC - Assistant Professor – Johns Hopkins University School of Nursing**

Yes, this is Marisa Wilson and I have to agree with that. There's a lot of struggle with that definition. There's struggle in just using regular patient safety reporting systems with clinicians – excuse me, but with health IT safety, I think we need to be very clear and provide definition, provide example. So that when people – and provide, I think as Toby said, a method for evaluation, that provides some level of standardization so that we are all talking about the same thing.

**Toby Samo, MD – Chief Medical Officer – Allscripts**

So actually I'd like to, just a thought that comes to mind, so who should be doing these evaluations? Is this something that everybody should do, should a – let's say a large hospital that has an IT and has a risk department, an HIT department, should they be doing it? Or is this something that should be done by people with specific expertise in this area? And I'm sure that's not an either a yes or a now answer, but there may be certain levels of evaluation that are done in one location and another that requires expertise. Because I mean I know certainly within our organization we have a lot of experience of evaluating these events, but it took and it continues to take ongoing education and training of all those people involved, how to go ahead and evaluate that event.

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

This is Paul. I think it would benefit almost an organization of any size to have more or less an external group help – someone with the expertise and the objectivity. So, I don't know how you triage when to do that, maybe as this – let's say ONC operates the HIT Safety Center, they discern a trend or a concern and then they independently, whoever they either contract with or form – whatever group they form, goes to look into it further. And again, it's all set up in a non-punitive way, it's really to learn more and then make that information available. It's a lot like – if people aren't familiar with NTSB, so they only are investigatory, so they get the reports, they make the investigations, they make their conclusions and recommendations, but there's no power – there's no enforcement authority given to them, which is why that was part of the recommendations from the IOM. So –

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

So –

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

Go ahead.

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

This is Jeanie Scott, I'm from Veterans Health Administration, and I'm actually the Director of what is called Informatics Patient Safety. And in some ways, we are a microcosm of what ONC is trying to set up, that's what my program does is we – you might want to consider that we are like a Health IT Safety Center for VHA. We're a very small department over here in VHA, and we – that's...sort of what you're describing here is what we do. We are set up independently, outside of the PSO; we work with the National Center for Patient Safety. We're outside of the PSO, but we're also outside of the IT department and outside of the medical centers.

And we sort of work like the NTSB where we take different – we take reports in, we take them either from the safety events or from the IT, either outside vendors or our internal vendors, investigate them, provide recommendations and then work through, Toby as you mentioned, how do vendors determine what is something? And sometimes they don't quite know and so they may bring it to us and we help them evaluate it through a series of criteria. We've worked with a Safety Center, our National Center for Patient Safety, to help take what might be criteria for safety, but then sort of morph them into what – definitions that are more for health IT. So, I think that might help with how you work with a Health IT Safety Center. It kind of brings the product and safety and external all kind of together. And as, I think was that David Bates just talking there, like the NTSB, you're an external body that provides that consulting type of thing and brings it together and then disseminates it out.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Jeanie how – this is David Bates, that was actually Paul Tang who was talking.

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

Oh Paul, I'm sorry.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

It's okay. But how often do you do your investigations remotely versus doing on-site sorts of things? How do you decide – and how do you decide how significant something is, in terms of meriting an investigation?

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

Well we're – we don't necessarily do them on site and we have reports coming in to us. We're probably not, as I would say, what you would say a team that goes on-site like NTSB, an even occurs and go on there. I think we have a model that you can look at. We've been evolving over 10 years now, so we've gotten to the point now where we are looking at things more prospectively. We're getting things from our users that are saying, we think this might be unsafe. We are getting things from our programmers where the event has not occurred yet, but they're pointing out that we think these are unsafe. Ten years ago we were getting things where something had occurred, and we did it remotely, we looked at the product. There have been a couple of times where we've had to be on-site and had an RCA or that type of a thing and interviewed the folks and done walk arounds.

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

This is Paul Tang, this is a wonderful story because we're seeing the evolution and we've really gotten to the point of the culture of safety in a sense, because now you're looking at things prospectively, more importantly, peop – your staff and physicians are reporting things prospectively and that's sort of where we want to get to. But it takes – I think it takes some people, even if it's a small team, that thinks about that, thinks about the process and does the responsive actions that encourage people to report more and to think about it more. And I think that's what we're trying to put in – well, it would be nice to put into place for the whole country, because not everybody is the size of the VA – well, I guess nobody's the size of the VA.

The other advantage I guess you do have is you do – when you ask a question, then you do expect a response, that's one thing the NTSB does have the authority to do that, let's say ONC doesn't, but you have in your organization.

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

And you may have heard stories from the VA of safety alerts that have been out there in the public, go Google VA software glitch safety and you'll see them out there. We have had – ours are posted up if they're applicable to all they're posted up on the web. Some of them are kept internal because it's software that's – we have our own internal. But when it warrants, we do send notices out or we work with getting corrections out there. But I think it's – model.

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

One follow up –

**Steven J. Stack, MD – Chairman – American Medical Association**

I'm sorry this is Steve Stack –

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

– is it possible to get some kind of summary of your program, it's fascinating, and maybe something we could use as part of our feedback to ONC.

**Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs**

Yeah.

**Steven J. Stack, MD – Chairman – American Medical Association**

And to build on what she just said about the VA, one, where lessons have been learned over a decade to the extent a Safety Center can help disseminate some of those lessons learned and accelerate the learning curve for the rest of the health system, that could be very valuable. I'd like to emphasize though, how, as you mentioned in your journey with a single software program of VistA, and I don't want to make it overly simplistic, because I know it's not that simple. But, what the rest of us are facing in the community world is, I'm part of a health system that has I think around 80 facilities across the country. Some who are not even on electronic health records yet, others who have recently gone live in a continual stream of deployments with the regulations for say Meaningful Use changing on an 18-24 month schedule.

And what happens for us in the clinical realm is we have a call center in India, if we have an issue, we call, and it gets cataloged. We don't hear back. We have problems that go on for months without resolution and there's no – and it's all in the face of – had to lay off over 200 people because of economic strain, just in the market that I'm in, in the last two months. So, I think what we have to do is be focused and recognize that there are really serious constraints to how much these systems can take on. And I think that is one of the primary safety challenges we have with health IT now, is in our eagerness to want to take it all on at once, I think we've bitten off more than we can actually safely process. And this is Steve Stack, again.

**Toby Samo, MD – Chief Medical Officer – Allscripts**

Yeah, so this is Toby. So hearing of the VA experience in many ways it is another example of what we as the vendors see, depending on if you're dealing with a large client that has multiple hospitals, has an IT system that can go ahead and do their evaluation internally. Or if you're talking about an individual doctor's office or a small hospital that does not have those facilities or expertise. So at some point, there is a filter that comes across and eventually we get many, many calls about issues that come up that may or may not be related to our software. So I think the vendors, I know we do and we're certainly willing to share our experience, have a lot of experience in defining a process of how things are evaluated and we need to bring that expertise in as well as hopefully get some of the data from there.

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

This is Paul Tang. So I think this discussion has somewhat recapitulated the discussion both that IOM and the FDASIA Workgroup in the sense of, what's the problem to solve? And I think this is the problem to solve. We almost need a more centralized way of both getting all this data, analyzing it and then disseminating the lessons learned, because I think whether you're large or small, it's a challenge just to do it in your own house. So maybe we're ready to sort of move on in terms of how to – if there is going to be this National Health IT Safety Center, how would it look to benefit all of the stakeholders that were just mentioned.

**Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation**

This is Tejal Gandhi. I mean I think that dissemination piece is really important because we certainly don't want to have a Safety Center that's identifying potential best practices or implementation – both on the IT side, but also on the implementation side, for example. But then if that information doesn't get out to the right stakeholders, that would be, I think, a real shame because it seems now that often things are in pockets and people are constantly kind of making the same mistakes all over the place and learning and reinventing. And so I think that dissemination piece is going to be really important.

And then the other thing is, on the analysis side, I think there's going to need to be that analysis piece, but also identification of really what the best practice is. And that might not – there might not be research and data for that, it might require convening and consensus building and so on to really identify what the optimal solution is. But I think the ability to have that convening function is really important as well.

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

Sounds like we all think this thing is a good idea, the Safety Center.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Yeah, yeah. And so one thing I will do between now and the next time is to try and sort of organize some of the points that we've made. Our final output, I think, will be a series of PowerPoints, so I'll start working on part of what that will look like. And I think many of the points are starting to become clear and we probably have consensus on many of the issues. One thing I wonder about is, are there groups or entities that we want to hear from between now and then that will provide us helpful input? One obvious set would be some centers, which are already doing something like this. It might be useful, for example, to spend a session hearing from the NTSB and perhaps ASIAs and Jeanie's center, for example. Are there other groups that would fit – do people think that would be useful, A? And then B, are there other groups that we should include in that list?

**Margaret "Peggy" Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety**

I'd like to include some patient safety organizations to focus on the culture of safety and confidentiality and some of the work that they've been doing on HIT. I think that that would be very helpful and would build in to the conversation.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

So, who are you thinking of specifically?

**Margaret "Peggy" Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety**

Can I put together a list of patient safety organizations that have been working on HIT and send it in to folks?

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

You can, you can – why don't you just send it to me. I mean, recognize that we're not going to have the opportunity to hear from 12 different organizations because time is limited.

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

This is Jodi Daniel. I was wondering if I could suggest also, given the short time we have, one thing that might be helpful is we did have NTSB and a couple of PSOs represented on the panel that we had at the town hall meeting. And so if we can get the transcript, and I'll find out how long it'll take for us to get that, if we can get the transcript from that, it might give people some insight into their thinking about the patient Safety Center, without having to call all of them in. So – or we can identify areas where we wanted further information as a group, to help target that conversation so that, like you're saying David, given time, we don't have time for again, 12 different PSOs or 12 different organizations. So, that might help.

**Toby Samo, MD – Chief Medical Officer – Allscripts**

So this is Toby, just so that I understand the, what's the right word, the scope of this group I assume is not to define processes but rather, I guess, define what the role of the center should be –

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Correct, I mean –

**Toby Samo, MD – Chief Medical Officer – Allscripts**

– assumption. So therefore –

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

I think it's – yeah, go ahead.

**Toby Samo, MD – Chief Medical Officer – Allscripts**

Yeah, so therefore in terms of, I clearly want to get more educated about what all these other groups are doing, but I guess my as – therefore we should focus on bringing in groups that we might use as some examples of how this center might be structured rather than solving specific problems.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Yes, exactly. And I think we'd want to be thinking about things like, how important is it for the center to be able to do on-site evaluation? What sorts of analytic capabilities has it been useful for them to have in the background? And again, we would be making very broad recommendations about ho – what sources of data do they consider? In this instance, I – someone made the point that we need to look at multiple sources of data, I think it might have been Mary Beth, and I strongly agree with that. There's not any one source that will answer all the questions. So, it would be a number of sort of generic issues like that. I mean – are there other sets of people that – stakeholders that you think it would be useful to hear from?

**Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation**

David, this is Mary Beth. I guess one question I have for you and the group is are we contemplating enabling any patient reporting as part of the HIT Safety Center as well?

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

I don't think we've talked about, but that's a very interesting question and I think it's one we should make a comment about in the – I think we probably should. If you look at other areas, that has been useful, although if you look at what inputs the NTSB considers, for example, I don't think that they consider patient reporting.

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

I think they may consider it, but it's not very easy, none of its passengers knows about it.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Right. Jon, do you want to say a word about some of the work that you've sponsored?

**P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)**

Sure, I mean I don't want to take too long with it; we can get more into the depth of it later. Certainly in addition to the usual improving patient safety through health IT, we've got grant-setting opportunities out right now, special – notice the applications review for work to try to improve the safety of health IT. In addition to prospectively taking a look at health IT safety hazards through a project called Hazard Manager, we've supported it, actually David and some of his colleagues, to work on CPOE evaluation tools that's been in use for several years. So I think there's a lot – the bottom line is that there are a lot of good resources and I'll bring them to you all in more detail in future meetings, but I'm glad to be part of that conversation.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Okay. Are there other groups or people that you think we should be hearing from?

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

Another possibility is ECRI, I think they're a PSO but also they have some function in sort of looking at this, and maybe it's just covered under your PSO survey.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

They would definitely be another option. I'm not sure whether ECRI made a presentation at the –

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

They were part of the panel, David.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Yeah.

**Margaret "Peggy" Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety**

And let me add to that, this is Peggy Binzer from the Alliance for Quality Improvement and Patient Safety. We have multiple PSOs that are in partnership with different vendors as well, so ECRI is not the only PSO who's very active in this space. So, we have multiple folks who have a lot to contribute as well.

**Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation**

I also think – this is Tejal Gandhi, I also think it would be useful perhaps to hear from one or two of the vendors, in terms of how they review the events that they hear about, we've heard a little today, but in terms of how they review their events and prioritize and think about solutions and so on. Since they're probably the biggest in-basket for a lot of this knowledge right now.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Yeah, I agree, I was thinking that, too. Mary Beth, do you want to say a word about what you do and whether you think that would be useful?

**Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation**

Well sure, and I think all of the vendors do have a process for customers to report, they might call them different things, but support calls or glitches or potential issues, whether that's a phone process, online process, that come into a support desk. And I think all of us have ways of evaluating the severity of the potential incident that's been reported and then working with the customer to kind of triage through the steps of diagnosing and potentially fixing a problem. And then again, I'm speaking from my own experience, but believe most vendors do the same thing which is, if something is identified that could potentially impact other customers that's deemed a critical issue, then we would notify customers – a communication channel that they need to look at this or to potentially install a software patch or whatever the case may be. So, I think everybody's got a pretty solid process in place to kind of manage through those issues at this point.

I think the thing we don't know, on our side, a lot of the time is what happened in the workflow process or potentially the ultimate impact to the patient. Because I think many of you know that your organizations don't necessarily have a free flow of that information coming back to organizations where there's no confidentiality and protection. So, we often get just the initial incident and work with the customer to resolve the problem, perhaps without always knowing all the information related to work arounds or other potential causes or even the impact to the patient.

**Toby Samo, MD – Chief Medical Officer – Allscripts**

Yeah, this is Toby, I mean I'll echo what Mary Beth said. I mean we have a formal, corporate-wide process about how potential patient safety issues are evaluated, reported, documented. We have a five-step process, reporting, evaluation, communication, deployment and review. Again, whether or – at some point and whether or not it's – as we try to define what this center should be or if this is a discussion we get into depth within the center itself as to different methods of doing this evaluation. But we're happy to share that process.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Great.

**Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation**

I guess David the only other comment I would make related to that is I think that we strongly recommend that whatever processes we put in place for HIT safety reporting, we have to preserve the direct communication between the vendors and their customers. Obviously as a funnel for us to be able to really know what's going on and address issues quickly. So, we think that process should remain unchanged and then there should be another process that we're all feeding into as part of this as well.

**Steven J. Stack, MD – Chairman – American Medical Association**

Here, here.

**Marisa Wilson, DNSc, MHSc, CPHIMS, RN-BC - Assistant Professor – Johns Hopkins University School of Nursing**

And this is Marisa Wilson again and I know this sort of goes without saying, but just to make sure it's out there on the table, but having a way not only to just report, but to look at clusters, look at groupings and to send communication back out to end-user populations. I think we need to figure out a way to do that. Again, I have a lot of doctoral students, a lot of them; they're all over the country. They're all working on similar safety issues, they don't really have a singular place necessarily, unless they go to the evidence and do a synthesis, which they have to do, but there's not a central location where they can go and see what are optimal ways to do certain things. They're working on bar coding, they're working on alerting, they're working on all sorts of things, but it's across the country, very similar the issues they're tackling are very similar, but there's no sort of unifying body that provides guidance.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Great. Okay, so we're coming near the end of the hour and we want to retain time for public comment. So next steps, I'm going to go through our discussion today, also some of the summaries from the public meeting and produce a sort of a skeleton set of points that we've made, which we can talk about next time. We'll also start to organize sessions in which we can hear from other groups and if you have thoughts about specific groups we should hear from, please share them with me and with Michelle. Are there any other very last points before we go to public comment? Okay, so this has been a really good discussion. Michelle, can we go to public comment?

**Public Comment**

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sure. Operator, can we please open the lines?

**Rebecca Armendariz – Altarum Institute**

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press \*1. Or if you are listening via your telephone, you may press \*1 at this time to be entered into the queue. We have no comment at this time.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Great. Well, I just want to thank everybody again for serving on this group. I think we'll be able to provide some useful input and we will talk again soon.

**Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, David.

**David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners**

Thank you.

**Public Comment Received**

1. I would encourage soliciting comments from nursing staff and other clinicians