



HIT Policy Committee Safety Task Force Transcript June 9, 2014

Presentation

Operator

Lines are bridged.

Michelle Consolazio, MPA – 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 Health IT Policy 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, MPA – 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, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jeanie. Jodi Daniel? Jon White? Marisa Wilson?

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

Here.

Michelle Consolazio, MPA – 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.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Paul Tang?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hey, Paul. Peggy Binzer?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hey, Peggy. Steve Stack?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Steve. Tejal Ghandi? Toby Samo? And are there any 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
This is Amy Helwig.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Amy. And with that, I’ll turn it back to you, David.

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

So, thanks so much, Michelle. I thought what we would do today is really review what we went through last week and then – and also go through some questions that are in some of the ONC materials. And then the plan in our next meeting, and probably at least one more beyond that, will be to get some input from other groups about issues that we should be considering in our recommendations. Could I have the next slide? And then the slide after that?

Okay. So, we had our first meeting, today we'll be reviewing last meeting, talking about next steps, going through some questions. On June 13, we will be arranging some presentations; I'll be asking you if you have other thoughts about people we should be soliciting, other than the ones that came up last time. We have a list of good suggestions. And then we have a couple of additional times scheduled before we have to report out to the Policy Committee. I'll note that the next to last meeting is the day before the July 8 meeting, so, that timeframe is relatively short. So, questions about that? Okay, next slide.

So the FDASIA charge was to develop a report that contains a proposed strategy and recommendations on an appropriate risk-based regulatory framework pertaining to health information technology. It's supposed to include mobile applications, to promote innovation, protect safety and avoid regulatory duplication. Next slide. And some of the things that the Safety Center is expected might do would be to promote the use of quality management principles to identify, adopt and adopt standards and best practices, to leverage conformity assessment tools and then – and to create an environment of learning and continual improvement. Next slide.

So the notion then is again that this would be a public/private entity. It would be created by ONC in collaboration with relevant agencies and other stakeholders. It would serve as a trusted convener of health IT stakeholders and as a forum for the exchange of ideas. It would also help promote HIT as an integral part of patient safety. And Jodi talked last time about the three E's, education, engagement and evidence. Next slide.

So our charge then was really to address key issues around the Safety Center, in particular to focus on the value proposition, governance, focus and function. And we spent some time talking about each of those four areas last time. Next slide. I attempted to try and summarize the discussion from last time. We pointed out that a number of other models exist, both in the airline industry, for example, with the NTSB and ARIAS and then within healthcare, for example the VA National HIT Safety Center.

The notion is we could learn from those values. I think there was consensus that people felt that participants in the Safety Center need to receive value, it'll be a voluntary thing. We don't have to have everybody participating to get value, but those who do agree to participate, have to get something sufficient from the Center. In addition, having some specific products will probably be very important, in terms of having people value the Center. And that could be an educational product, it could be something else. Next slide.

In terms of governance, I think there's consensus that this should be outside of ONC. It should have a clearly defined mission and priorities. A couple of people made the point last time that the first goal should be address new safety issues caused by HIT primarily as opposed to using health information technology to improve safety, which is another related issue, but a secondary one. That it also should leverage partnerships and avoid duplication, because there are already a number of groups in this space. Next slide.

Around focus, people felt that this should address all types of HIT and not just electronic health records. A number of people made the very important point that we need to consider the sociotechnical issues as well as just the technical. If you look at most things that have gone wrong, almost always there's a substantial sociotechnical component. People suggested that the Center should incorporate a variety of data streams, not just adverse events. So, for example, it should also include near misses and hazard reports. There was strong consensus that this should rely on evidence, when that's possible. Obviously the evidence in this area is sometimes somewhat limited. It clearly will have to include multiple disciplines and it should cover both broad trends, but also will have to respond, to some degree, to individual events. Next slide.

Okay, so, let me just ask people for comments about anything that I just went through, which was really a very brief summary of what was a rich discussion in our last meeting. And I could go around the call and just ask whether there's anything that stands out that we haven't brought up, could be other points that are important that we should – that we should include later on. Mary Beth, anything else?

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

No, I think you hit most of the points, David.

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

Okay. Jeanie, anything?

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

No, I think you – again; I felt that that was all covered in there.

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

Okay, good. Marisa?

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

No, I think you've covered everything.

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

Okay. Paul?

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

Um, I – so, I don't know whether we had the chance to talk about sort of the investi – so, we've got a data stream in and looking at it, did we talk about other functions like investigation or follow up and analysis and dissemination of best practices? Is that – should that have been up front or is that still yet to be discussed?

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

So, we did talk about that a little bit and for whatever – that’s a good point and we definitely have to say something about that. I think that’s something that we should probably talk about some more.

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

Um hmm.

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

There’s another slide set that I prepared for another reason, and there was a slide on that in the other slide set, and I don’t know why it’s not here, but it’s not. But I think that’s a very good point. Peggy?

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

I think great summary.

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

Okay. Steve? Okay, so let’s just go through some of these questions. The first one that ONC put to us is what should the governance structure and functions be?

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

I’m s – can I jump in? I’m sorry, I was on mute and so I said something that I thought was insightful, but it must not have been, you didn’t hear it because I was on mute.

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

Gotcha, we didn’t hear you. That’s great.

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

I apologize. I figured that out when you moved right on. The – is the sociotechnical bullet the one that’s intended to encompass the human factors element, sort of the human bandwidth, the interaction of the human component with the technology?

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

Yes.

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

Okay.

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

But we could certainly expand on that, because that’s absolutely critical.

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

Yeah, I just – I think it’s a big part of it, so – but otherwise, I think it’s a wonderful summary. Thank you.

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

Okay, great. Okay, so let’s talk about what the governance structure for the Safety Center might look like and – first of all.

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

Well I think you said, public/private, right.

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

Yup.

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

Certainly the – we need to represent the kinds of expertise that bear on the issues.

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

Yup.

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

So, this is Steve. I’m wondering, in addition to the governance structure though, and forgive me if I’m just having – here, how was this going to be stood up? Is this going to be something resourced by ONC, something that was a multiagency entity? You said public/private so, do we have a sense for how this would stand up and what it – apart from the governance, the oversight of it, how it would exist as an entity?

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

Yes, I don’t think we’ve talked about that on the call and I think that’s a very important question and a good one. I – my understanding from talking with Jodi is that it probably would be resourced by ONC.

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

Okay.

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

But we could make some comments about what we think.

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

Well, I think it plays into the – Dave, I think it plays – this is Steve again; I think it plays into the governance model a little bit. So if ONC were to have this and resource it, and then what you need is a governance body to help give oversight to the focus, the strategy, the purpose and the work, that sort of thing and then obviously ONC or whoever housed it would carry forth the work. It wouldn't be the governance structure that carried forth the actual work in many ways, then that changes the discussion, I guess, just for how would you compose a public/private thing. Much like this task force has ex-officio representatives from various agencies to help make sure that the public component is represented and then we try – I think it looks like we have a nice little diversity of private sector people here, I mean a structure not unlike this task force is one possible way to do it.

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

Great, I think it would be – there would be a number of people who would be doing this as their full-time job that it would be physically at some place that's separate from ONC.

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

Okay.

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

And that there'd be an ongoing budget for it, which would probably come through ONC. Amy, do you want to comment about that?

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

Yeah, I can comment to that. At this time, we submitted a request in the budget for operational funds to – for the Safety Center, and it would be operated in a separate process per contract or cooperative agreement, or something of that nature, but we fund an outside organization to do that.

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

Great. Okay.

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

Probably just another requirement, there would be certainly staff from within ONC that would be involved, but we would also expect it to be staffed separately, in terms of the main focus of operations.

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

Right. Yeah, I mean I think that there would have to be an advisory group that would – to go back to Steve's comment, that would be very much like this group that would advise the Safety Center, but that would include representatives from industry, it would be multi-stakeholder.

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

Yes, that's correct, in terms of a line of thinking – putting together an advisory group. Right now what we've done is we are finishing up a feasibility study with MITRE Corporation, where they're helping us explore different governance options and how that type of advisory council might function in the activities or the priorities.

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

This is Peggy Binzer. On funding, I'd really like to see, since this is a public/private partnership, I'd really like to see some private funding as well, whether it comes from industry, healthcare, healthcare foundations. It would really go to show the shared responsibility and to get better buy in for the Center.

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

Yeah, I – so this is David Bates again, I like that notion. Do you have a sense of which sorts of organizations might be willing to support it, or which specific entities?

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

We're starting to explore that notion with different groups and perhaps later in the phone calls we can share some of our findings.

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

Great. I also think that would be really helpful. The tricky thing is always establishing an ongoing revenue stream for things like this.

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

Absolutely and I do believe that government funding is necessary to keep this going and to keep it funded.

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

Great. Other thoughts about governance?

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

I feel bad, Dave, this is Steve, there's crickets a number of times – but no, it sounds reasonable, even an advisory group of some sort to help give oversight and then however ONC determined – defined its structure internally to support it and then fund it are other issues. So – but I think for right now it sounds like conceptually if no one's commenting, we've got some shared agreement.

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

Yup. Okay. Good. Well, let's – so, let's move on to the next of these questions. How can comparative user experiences with health IT be captured and made available to the HIT community and other members to promote learning.

Toby Samo, MD – Chief Medical Officer – Allscripts

I'm sorry, this is Toby Samo. I was on from the beginning, but had some technical difficulties, so I've heard the discussion. But can I just go back –

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

Sure.

Toby Samo, MD – Chief Medical Officer – Allscripts

– point for a second.

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

Yeah.

Toby Samo, MD – Chief Medical Officer – Allscripts

Maybe this is a grammar issue, but it says governance structure and function, so is that the structure and function of governance or more importantly and I don't know if we have really had the discussion or will, what is the function of the Health IT Safety Center? I mean we've listed that it is a convener in the discussion, but do we need some more detail as to what we expect the function of the Safet – of this Center to actually be.

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

So, we could certainly talk some more about that. The focus slide really, I thought, covered part of that, but let's – I think it would be good to spend some more time talking about function. And the other sort of list of functions was that it should have some educational activities, some engagement activities and some evidence related activities. What other – what are people's thoughts about what its main function should be?

Toby Samo, MD – Chief Medical Officer – Allscripts

So, I guess the question that I'll throw out to the group, and this is Toby again, is when you say that it's a convener, excuse me, that's very important, we need to have a place where a multi-disciplinary group of stakeholders can get together and address issues. But are we – is this entity only going to go be a place where you get together to discuss or does it have some sort of either influence or capabilities that enable it to either influence decisions or even better yet, to have some role in making certain decisions.

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

And can you play that – its Dave Bates, could you play that out a little farther, what sorts of decisions are you thinking about?

Toby Samo, MD – Chief Medical Officer – Allscripts

So, let's take the issue of clinical decision support, let's pick something simple, right.

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

Yeah.

Toby Samo, MD – Chief Medical Officer – Allscripts

So where is the line drawn on clinical decision support as to what should be considered under part of a medical device, and therefore FDA controlled? And where does the line sit to say that it sits under other auspices. So, will the Health Safety Center have the ability, I assume they would discuss it, but then what happens, what is the influence on this organization, of this organization and how can it actually play a role in some of that decision making process?

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

Right, so I think it would probably not make the decision, I would think it would certainly – because typically those decisions are made by the agencies themselves. Amy, do you want to comment about that?

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

Um, could you say that again, David, I actually was just – Jodi and I were just talking offline.

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

Right. So, Toby gave a good example around – we’re talking about what the functions of the – of this Center might be, and he asked the question, will it have the influence or capability to influence decisions or make decisions with an example being where should the line drawn about CDS with respect to what the FDA might control.

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

Um, that’s a – good question. I think what we envision for the – what we’ve been thinking about for the Health IT Safety Center is really that they would help identify best practices, help with dissemination of these practices, a lot of education around health IT implementation and how you operate health IT safely. In terms of specifically informing things such as where the line’s drawn with clinical decision support, in terms of I think what you’re saying, what should be regulated as a device or not –

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

Yeah.

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

– they may help weigh in but I don’t think that they in any way would make that decision. Jodi, do you have any thoughts on that?

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

Yeah, I'm sorry I joined a little bit late – this is Jodi Daniel. I agree with what Amy said. Obviously that is a regulatory decision that the FDA would make, that said, if there are areas of ambiguity that FDA hasn't weighed in on or if there are areas where safety risks are being raised and folks feel like more oversight is appropriate or things like that. I think that that kind of input from the field, from the experience from the data would be helpful in communicating with the regulators. But I don't – I think that FDA obviously would be the ones making that determination, at least as a final decision.

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

So David, this is Paul Tang. Maybe I'll enumerate the functions that might have been on your other – the other slide that isn't part of this deck, but I think the way I heard what you were saying, in terms of the functions of this Center, are one, as a convener, as you mentioned, of the multiple stakeholders involved. Two, as a data collector or aggregator, three as, and I'm trying to find a different word for this, but investigation; in other words, being able to follow up. This is all voluntary, in terms of gathering more data from some report, for example. Four, conducting some kind of analysis and then five, disseminating the learnings and best practices and potentially making recommendations, of course that are not binding on anybody, but based on the learnings that the Center develops through its analysis of the aggregated data, it may have recommendations. Does that enumerate the things that you were thinking about?

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

Yeah, I think that's most of them. So, somewhere in there we have to fit in the evidence evaluation, so that might be one more.

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

Right. Okay.

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

And also – this is Peggy Binzer, standards, what to report, how to report, taxonomy; some of the best practices may be standards for the industry on certain functionality that could be contributing to some events or hazards. In the near-miss area, it may be some standards to prevent a future event. But I see, particularly with the taxonomy issues and others a great role for the Center.

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

Yup, I –

Toby Samo, MD – Chief Medical Officer – Allscripts

Especially if the Center – this is Toby, especially if the Center – so first of all, that's a much better clarification, at least for me now. When – to add on to Peggy's comment, if we are going to be a data collector, which I think is extremely important as part of and perhaps managing that learning system that aggregates from multiple sources, we won't be able to do that and make the data really comparable unless we do have standards of taxonomy.

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

Well and – this is Mary Beth, I guess maybe, in listening to this discussion, would it be helpful for us to say what the Center is not. So to me, what I just heard in this conversation that I think brought this clearly to that focus is, it's not a regulatory or oversight, it's not a policy-making organization. Maybe those are the three things I just heard, but –

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

I think it's a learning – it's a learning organization.

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

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

So, I agree with what you just said, it's not either of those two, it doesn't make policy, it certainly doesn't enforce anything, doesn't have any authority.

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

So I guess the other question Peggy that you just raised, does it – standards or does it recommend – or – Because the standards one I think it's a little tricky, but I agree it would be helpful, but what would the role of the Center be to recommend that standards be set elsewhere or –

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

Yeah, that could – I'm just thinking about the information that the Center will be collecting, I think that they'd be not only helpful to define taxonomy and other things. But I think that they would be receiving information and I know that PSOs now are receiving information and help in defining other standards – and it kind of flows into the best practices. Best practices, it seems to me, is for providers and standards more for vendors and maybe I have this wrong, but maybe this is just in my own mind how I've separated things. But I see a lot of information really being collected for both and so it may be recommendations to standards to go to another body, just like the best practices. The Center isn't practicing medicine, so the best practices are for healthcare providers to evaluate and determine whether their systems – whether they should be adopting the best practices to improve the quality of patient care.

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

Right. I mean my train of thought is that it probably wouldn't be developing the standards itself but would be recommending that certain standards be developed and then promulgating their use.

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

Yeah, I think that's right.

Toby Samo, MD – Chief Medical Officer – Allscripts

Yeah, would tie in with best practices to say that this – using these standards for collecting patient safety reporting is what we’re considering to be best practices.

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

This is Amy from ONC. Just to kind of toss out some ideas for what we’re thinking and some of the work so far. What we – what ONC is doing this year, 2014, is we’re currently working using AHRQ’s common format, so their standards for reporting and analysis of data around health IT safety events. And we’re using that – this is a starting point and then looking at some initial data from specific patient safety reporting databases, being able to get an idea of how those might need to be changed going forward or where it looks like they’re getting the best detail. So certainly that’s what we’re thinking right now is sticking within – using the same common formats that are used for other patient safety data and analysis with the PSOs and within the federal government.

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

That’s helpful.

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

This is Steve, if I can – this is maybe a detail question but, how – PSOs operate under really strict rules for not breaching the confidentiality required to have the protection of just being non-discoverable. So how does – how would PSOs feed information into this kind of center?

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

I can take that one, David, if you’d like. This is Peggy Binzer from the Alliance for Quality Improvement and Patient Safety. Patient safety organizations under the Patient Safety and Quality Improvement Act of 2005, there are many, many ways that the PSOs can share good information. When the Act was passed, the privilege and confidentiality protections were intended to protect the very sensitive information, but, best practices and good information were intended to be disseminated throughout the healthcare system.

So, and I know that PSOs haven’t done a good job at disseminating best practices throughout the healthcare system, and part of that is because we have no revenue streams and so the best practices and aggregate data is really the only way that PSOs can be compensated for their work. We’re working on that, we’re working with National Patient Safety Foundation to really help us disseminate best practices, but be that as it may.

So, getting back to how the PSOs can work with the Patient Safety Center, PSOs can be – extend their protections to the Patient Safety Center and others. For example in convening, we can bring together groups of experts to talk about different issues and problems, identifying hazards, reviewing the data to develop best practices, all within a culture of safety and trust. And it can be done within the Act’s protection. Certainly names of providers cannot be disclosed, because that would be in violation of the Act. And so the confidentiality protections are there to allow us to share information about hazards and other things that could cause reputational harm, could cause malpractice lawsuits or other things, but allow folks to share that information without finger pointing and without fear of liability.

So, there are lots of ways that you can use patient safety organizations to share information, particularly aggregate information, trends, best practices, benchmarking and other information that can be very, very helpful. We found – the IOM in 1999 suggested that we need to allow healthcare providers and others in healthcare to talk to each other to solve some of these problems that are occurring repeatedly throughout the healthcare community. But because of fear of reputational harm or liability, folks aren't sharing that information, and we've found that that's very true that when you provide a culture of safety, then people are willing to – providers are willing to share information and share best practices as well. And also –

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

So David – I'm sorry.

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

So also, I'm sorry, go ahead.

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

– I'm sorry. So it's a wonderful description and I would think if our report is going to be in this element useful to the HIT Policy Committee, I think that perhaps – I just – we have a PSO for the group that I'm part of. But – and we use it robustly and for – it improved patient safety in quite a number of ways using it however, in the world I live in, it's hard for me to see – it's not like the FAA model, we use it internally across our organization. But I'm not familiar with and I don't have any oversight role that what – that there's any external reporting.

So some kind of candid assessment of what the likelihood is in the current reality of getting – of that being a good information source and/or if it's not currently a good information source, how it could be fostered and what the model is for that. We won't get into the details of that in this report, but I think if it's going to be useful to the Policy Committee, it would not be helpful just to say, collect information from PSOs – if that is, in fact, not happening in any way. Then you have to have another strategy or tactic that invest the time and effort necessary to foster that, because the FAA has a wonderful model for airline industry, at least it appears externally, but we really don't have that yet – for healthcare, I don't think.

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

Well and can I – this is Peggy Binzer again, can I comment on that? When I was a staffer at Counsel for the Senate Health Committee back in 2000 when Senator Firth and Senator Kennedy started working on the Patient Safety and Quality Improvement Act. And the edict that we were given from the Senate Health Committee was develop an NTSB model for healthcare, recognizing all the different systems that were used in healthcare and that the – you just couldn't have one system throughout healthcare. And so we brought together 126 healthcare provider groups to talk about how to develop an NTSB model for healthcare and the Patient Safety and Quality Improvement Act was the output of that – those discussions, so to provide protections to healthcare to allow the conversations on safety to improve the quality of patient care.

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

That's hel – this is Paul Tang, that's helpful history. The tr – one of the issues we have right now is there are, oh I don't know, 90 PSOs, there's only one NTSB. And NTSB was the model that – the IOM Safety – EHR Safety Study, that was the model, and a lot of people point to it, that seemed the most successful. The challenge was, how to get the amount of money and the – NTSB is authorized by Congress, it's not a federal agency, but it's an independent organization without any enforcement activity. That – there's a lot of attributes of that that would work here, if we just didn't have the money. So I think what's nice is that this HIT Safety Center that ONC is proposing, I think we can hopefully build a lot of what's in the NTSB model in a voluntary world. The trouble is also the funding, again.

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

And we, on the side of the PSOs, we're – want to foster that because in order to act as an NTSB board, it seems to me we'd need legislation to do that to –

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

(Indiscernible)

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

– provide the confidentiality protection. So if we're going to be leveraging current organizations that have different value proposition aspects to contribute to the mission of the HIT Safety Center, then PSOs could contribute to the confidentiality piece to that. I recognize that we haven't been good disseminators of information, but certainly with funding and an edict, a voluntary edict, that, I think, will change.

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

Is there a patient safety organization collaborative that would allow multiple of you to get together and contribute – one, we need to aggregate data instead of spread it out, have the same formats, etcetera. And the ability to analyze a much bigger data set than any one currently has – that kind of function, is there a collaborative where we can at least get some major players to participate in a way that you describe?

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

Yes, we're actually – AQIPS, the Alliance for Quality Improvement and Patient Safety is actually working on such a collaborative and also a code of conduct for our members to attest that they will be sharing information, data and best practices. Again, the issue here is that PSOs are not government entities and they don't have any funding, other than what they can generate from their innovative programs. So, with sufficient funding for the work that they've done, as well as credit, because a lot of these organizations are doing really amazing work and developing innovative programs and really good best practices. And so they also need to get credit for what they've done as well. So yes, there certainly is an avenue to make all of this happen, and so I just think that patient safety organizations can be part of the solution, I don't think the total solution, however.

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

So –

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

Paul, this is Amy Helwig from ONC. Just another point on the ways to aggregate. The original Patient Safety and Quality Improvement Act did call for a network of patient safety databases or the NTSB and that is established by the Agency for – AHRQ or the Agency for Healthcare Research and Quality and they can receive from any PSO as well as outside organizations. So it's been designated as an aggregator and they use the – AHRQs common format so that you'd have the same data elements when you do that aggregate analysis.

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

Is it working?

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

So what was the question?

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

Is that data aggregation working, the network of PSOs and use of common format in a way that can be analyzed?

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

Yes it is and we might be – AHRQ might want to comment, maybe at a future meeting, in terms of their status. It is currently including data from patient safety organizations. I think Peggy pointed out some obstacles, in terms of funding and the PSOs that it's not as easy as one might think to be able to submit data, but is up and has begun to receive some initial data.

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

Hey Paul, it's John White.

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

Hey, John.

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

Hey listen, so Amy is far and away more the expert on Patient Safety Organizations than I am, I'll just add two things. One, I'm happy to get the folks from AHRQ that can comment on the aggregation capabilities at a later date, if you want. But two, even though we don't provide funding for them, we do convene the patient safety organizations on a regular basis, so, happy to try to facilitate through that avenue as well.

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

Thanks – .

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

So David, this is Steve. So I didn't – I opened a big can worms, I guess, but we won't solve this, obviously. But I do think perhaps when you look at your agendas for our information presentations, perhaps some distilled facet of this, at least to inform the input to the Policy Committee about where more work needs to be done to make sure if we rely on this, it's a valid – no, no, it's valid, but a reliable or an effective source of information. Because I think a lot of pe – a lot of organizations created PSOs principally for the liability protections that allowed them then to share things very robustly internally, without the fear of litigation. So, I would suspect there are quite a few of them that are not really overly excited about the external reporting part of it, because that's probably not the principal reason they created it. But I don't know the universe like Peggy and Jon maybe do, and so if I'm wrong, I'm happy to be corrected.

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

Yeah I think initially your assessment is correct, initially patient safety organizations started in those states such as Florida, where Amendment 7 had passed in 2004 and taken away peer privileges and that folks recognized that we needed to put peer protections back to allow providers to be informed about how to do a better job. And so that's where PSOs started, but I think if you see one PSO you've seen one PSO. We have many PSOs that are focused on very innovative programs, doing a lot of peer-to-peer work, and not set up for protections, per se, because they're all set up to improve quality; otherwise you're not in compliance with the Act. But there are many PSOs that are focusing now on collecting data related to HIT events and contributions and near misses, I don't think all of them are, but we do have a good handful.

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 –

Toby Samo, MD – Chief Medical Officer – Allscripts

Yeah, this is Toby. I would just actually bring the conversation around a little bit. Clearly the data that's being collected by the PSOs is important, but we have to remember that's not the only data that's out there. And so we have to make sure that we create a structure where multiple different stakeholders can feel safe in supplying, let's call it de-identified data. And by de-identified I don't just mean patient and provider, but again from the vendor perspective, if we want to aggregate data from multiple different vendors, and we have a lot of data, there has to be some safe place to be able to put that. I don't think we're going to make a decision on how to do that, but that may be a point that we want to make to the committee that that could be an important role of the Center.

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

Thank you Toby, this is Jeanie Scott from Veterans Health and I wanted to bring that conversation around because we've put so much emphasis on the PSOs and I wanted to go back to, it was slide 9, is that the first goal should be addressing safety issues with HIT. And if – I think it was Steve who said, a recommendation going to is it July 9 that this has to come out for, or July 8, is that part of what we have to still do is develop a strategy for the various sources of information that would – that the Safety Center would have to need – that it would have to develop strategies for sources of information and allow a safe haven for all those different sources. They could be coming through from PSOs, they could be coming from a vendor community, they could be coming from a user community, they could be coming from yet to be defined communities of interest that the Safety Center would have to work towards.

And that's yet to be defined and that might – that would still have to be developed is that strategy, I like the way that Steve put that, is that we still, coming out of this, would have to develop that strategy for the sources of information. There's not just one source, there could be multiple sources and together that would help develop how do we better have health IT safety.

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

Thank you –

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

In my particular organization, as I mentioned, we come – we get from many different sources, we get from technology, we get from social, we get from the medical centers, we get from our PSO, and we have to put it all together.

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

Thank you – this is Steve, thank you, you said that so much better than I think I did at the front, so thank you. And the other thing, we have this technology that is collecting information in a quantity and a volume and a precision we never did before. And so the Safety Centers could play a really useful role if it can help suggest how we can structure this in such a way that maybe we do get some component of like an FAA system and we can make really robust use of that data in a non-punitive, supportive way for improving quality. I mean that would be a massive contribution to healthcare improvement.

Toby Samo, MD – Chief Medical Officer – Allscripts

Here, here.

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

So, were you thinking that the systems themselves could help with that?

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

You mean like the software itself, the EHRs and things like that?

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

Yes, yeah.

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

Well maybe, so that would be a whole other line of discussion. I'm fearful; I'm not going to suggest any more discussions because it takes too much time, but that would be a whole other line of interesting exploration for the Center, would be what roles could the EHRs play in that? But apart from that, which would be one discussion, it's just, if people want to report things, I'm having this problem, I'm having this challenge or we had this great success doing this. I think we need to have some way to collect that in a way that does not expose the good doer to some kind of secondary harm that comes back to them as a result.

Toby Samo, MD – Chief Medical Officer – Allscripts

So, I don't have data to support this, but my guess is that the vendors have significantly amount more information than the PSOs and other entities do about HIT related hazards and near-misses and the events because when something happens, the vendor hears about it. And so, to be able to bring that data in in a manner that makes it safe and protected and aggregate that from multiple different products into a single de-identified database would be very powerful.

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

This is Dave; I have let the discussion run here a bit. Steve thanks for bringing this up because it was something that I wanted to get to eventually, that is to say, what exactly can PSOs do and what can they not do? I also agree with the points that have been made about getting the other sources of data in, and that's something we should definitely include, too. I agree with Jeanie, we'll need strategies for all those various areas. And I think it would – I've been a little hazy as to exactly how much aggregation is going on at AHRQ – in places like AHRQ and AQIPS and what are the constraints that they're under, and that's something we clearly need to learn a little more about. Someone else had a comment.

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

This is Paul, I was just going to piggyback on, I forgot who the last person was talking about the vendors having a lot of data and clearly the end users have a ton of data, which a lot of times they do pass on to vendors. And I think one of the problems is, it doesn't have a place to go where people can make it their day job to figure out – make sense of this and see how it can be made better and distribute that. So each one of us, on the provider side and vendor sides, are learning one at a time all over, that's the regretful part.

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

Steve, this is Amy from ONC, just an – that the group might want to consider. So I mentioned AHRQs common formats and they actually do have a sample report of sample data for what an aggregate report of health IT related events would look like, in terms of looking at how it would look coming out of the network of patient safety databases. And ONC this year, using our fiscal 2013 dollars, we were able to commission some initial aggregate analysis and the contractor will be wrapping up that work in the next several months. So that, I think, may be very interesting work that the FACA might want to consider when we have that available. But the sample report is – we can just circulate that to the group afterwards, just so they can get an idea, a snapshot of what an – report using AHRQs common format data would look like.

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

That would be really helpful. Paul.

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

Great. Yeah. Okay, let me just go on to the next question on the slide with the italics, which is slide, I think 11. Actually, it might be a different slide on the webinar, but it’s how can comparative user experiences with health IT be captured and made available to the community – the health IT community and other members of the public?

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

This is Paul Tang; I think this is a key part that would be helpful. It’s almost like opendata.gov in a sense of having, whether it’s researchers or individual organizations or PSOs to have access to this comparative information. A lot of it may be text and hard to parse, but it’s just so important I’m not sure it’s even effectively used within one vendor’s user community, even though we hear each other saying the same thing, having someone again, as their day job, trying to parse through all of this. And just having a resource where we could get this user experience in a transparent way would be wonderful.

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

Another angle on this would be that it would be very helpful to have some sort of consumer reports or assessment of how the vendors do, based on some normalized measures. And the – one potential role for the Safety Center would be to gather some experiences like that; it could also be done by somebody entirely different.

Toby Samo, MD – Chief Medical Officer – Allscripts

So, if you’re going to start identifying specific vendors and saying, this vendor had this many errors, had this many events, then I’m pretty sure that you won’t get many vendors that are going to start supplying information from their own databases.

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

Right, I mean I’m thinking of actually not asking vendors to do it, I think it is important to identify vendors and vendors have actively resisted being compared to each other in any sort of identified way. When I buy a car, I can get information about how the other cars perform in terms of user experiences, but right now, it’s hard to do that around vendors. Now, it might be that the Safety Center doesn’t have any role with that. I’m not interested in comparing error reports, actually, it would be more things like, how does a vendor score from the human factors perspective, that kind of thing.

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 and one way to kind of look at this question here, too is, when we take the user experience, is the full aspect of it, human factors is one part, usability, the common thing, but also to think about what was the organizational model, what was your implementation plan? What was your workforce? A facility like me also did – here were challenges that we had. So when we talk about a comparable user experience, we're not just looking at it from usability and a product, but also a process perspective.

And that's where I can kind of see how this question can also go is, I'm in this community and I'm of this type of facility and this type of a medical practice, and so you can actually do those types of comparisons and I'm using this type of a product, agnostic of name. And being able to capture that type of thing and so you do some comparisons that way. So, if we used the car analogy, I'm a family of 6 kids and I'm looking to buy a minivan and I put myself in a sedan and it didn't work for me, oh, well let's go and look for a minivan and that's going to better fit my model and be a safer experience for me. So, that's how I can kind of see that type of a question being where the Health IT Safety Center can help match putting people into better environments.

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

Um, this is Paul Tang...

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

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

David, I was just going to piggyback on your comment. I think it actually goes beyond cars now a days, again with healthdata.gov and hospital compare, etcetera, I think we are definitely getting more and more transparency around providers, whether they're hospitals or physicians or – health plans, more data is becoming available to do compare and we're getting better and better at what's meaningful. So I think it's only natural that that's extended to the critical systems that we need to deliver the care.

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

Yup. Somebody else was going to jump in, was it Mary Beth, maybe?

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

Yeah, David, it was me. Thanks. I agree that we need to try to sort out how we get comparative user experience for our systems. I just think – when I think about a car analogy, it's pretty straightforward, there's not a lot of configurability to a car, right, other than colors and some of the optional features. I think the biggest challenge related to that item for us is really when you put an EHR into a complicated system that has interfaces and configurability and lots of different customizations, if you will, it really becomes difficult to compare apples to apples. So, I think we would have to take a step up and figure out a framework that would enable us to do that in a way that makes sense and makes it useful for both the end users as well as others. So, I don't think we have had a good way to do that today, with a few minor examples that are out there, but, we should set our sights on solving that challenge. I just don't think I know what the answer is.

Toby Samo, MD – Chief Medical Officer – Allscripts

Toby –

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

This is Paul –

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

Okay.

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

To respond to Mary Beth, I think that’s absolutely right. We did point out about the sociotechnical ecosystem this lies in; I think you’re definitely right that we need to figure out how to sort through that. I’m not sure that prevents us from starting to report. Again, it goes back to the hospitals and providers, clearly they have their own, whether it’s the social deter – they have all kinds of things that impact a score, so I think our challenge is, how do we design the score so that its most meaningful to people? And how do we educate the user base, whoever’s going to use this information, to know how to sort through all this. Because you’re going to have to recognize everything from the products that come out of vendors to the people who implement it and to use it, so yes, I think we need to start providing more and more data so people – everybody can learn. And I think vendors can learn a little bit, too, out of this process, right.

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

Absolutely.

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

You know, when I saw this question, I really wasn’t thinking about report carding, but more, we had a discussion last week at an HIT summit about who was responsible for what information. As we get patient engaged more and more, we’re giving them more and more responsibility and so, when we look at user experiences, I tend to think of the patient as well. And for example, when we prescribe a drug, we expect the patient to take a look at the pill and make sure it’s the right drug, but are they responsible for other things as well, beyond that and if they are we need to educate them. Just to have everyone understand what we believe folks should be responsible in healthcare, whether it’s the vendor, the provider or the patient.

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

Other thoughts about this? Okay, another area that came up in the FDASIA group was there was strong feeling that it would be helpful if we had an approach that enabled a listing of health IT products. And the question that ONC framed here was, how can the private sector help facilitate the development of a non-governmental process for listing these products? I actually am not sure that it has to be non-governmental, I didn’t write these questions. But maybe it could be non-governmental, maybe it could be governmental. One big barrier in terms of addressing issues that are related to HIT has been that there is really no listing of products, which is publically available.

Toby Samo, MD – Chief Medical Officer – Allscripts

So can you define a little bit what you mean by listing, I mean is it just well here are all the ambulatory EHRs that are available, here are all the enterprise EHRs, here are the laboratory information systems, or is it something more detailed?

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

It would really be that, I mean, there would probably be some versioning, because you’d want to be saying, okay, I have version 2.7 of your product.

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

David, are you saying listing also who has those products, so a particular prod –

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

No. Yeah, so just a central listing that these are the products that are available.

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

I mean it does exist to some extent today, on the ONC website for certified EHRs, right. If you go to the CHPL website, you can see which EHRs are certified in which category for Meaningful Use. So, at least a microcosm of it exists today.

Toby Samo, MD – Chief Medical Officer – Allscripts

I mean and here are listings by certain organizations like CAP, American College of Pathologists does a listing of all the laboratory information systems and various other entities do things similar. I mean I don’t have any objection to centralizing it, I guess my – I’m just trying to understand what that list will do and what the value of it is.

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

Right, I mean – I think the notion is that the value would be you could say you were using system “X” when you had problem “Y.”

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

The other – so this is Steve, gosh, I don’t have any opposition certainly, I mean, I would love to have information and transparency, but I am – what I’m kind of thinking is, some of that would be difficult without lots and lots of detail. Because you could have vendor A installed on three different platforms, running on two different operating systems with 100 different applications in the ecosystem across the different installs. And so unless there’s a clear trend, so identifying a trend, I guess, would be helpful. But I mean there’s just so much level of de – so even saying I’m on version 10 versus version 11, I would imagine, and the vendors here on the call could correct me if I’m wrong, but a version 11 install in health system “A,” “B” or “C” or doctor’s office “D,” “E” or “F” could be very different in their complexities or the issues at play. Is that fair, if any vendor can comment?

Toby Samo, MD – Chief Medical Officer – Allscripts

Yeah, this is Toby, absolutely. Plus, you have different clients that are on different versions so; one client may be on 5.5 and another one’s on 6.0 and another one’s on 6.1, so there’s a lot of complexity.

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

That's where, I don't want to shut anything down, I think – that's one of the challenges with what the work product we're going to do in just three calls is that, we can get a lot of this on the table. And then we're going to have to level it when we do the report for the Policy Committee for at what level we identify, these are some of the things that need to be worked on and these are the big areas that we have agreement. But, I would say, to the extent we can find common trends and themes, like, it is a problem for the user that there's this kind of variation across different installs of the same technology or different technologies, different vendors or there's a problem when the hardware is installed in such a way it interferes with interaction with the patients. Or – I'm making stuff up, but to the extent we can find specific use cases that are – where there are problems that are maybe more generally applicable across the different ones, I think that may be the highest bang for the buck as opposed to an overly precise focus on any kind of single install or vendor. And I'm not saying you're suggesting that, I'm just saying we have to level what this kind of Center can do, too.

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

Okay. Let me move on to the next one, which is, I'm actually going to skip the one that's after this because it doesn't seem like a useful question to me, but I'll go to the one which is, what continued or expanded role, if any, should the certification program play in safety related surveillance?

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

So this is – since no one jumped in, this is Steve. So let me be provocative here. I think there's a lot of focus at ONC about certification and so I'm sure that Michelle and the ONC team could help feedback into us. Perhaps having someone, I don't know if it's Doug Fridsma who's working on this and Jacob has a role obviously, I think, in this. But perhaps that could be useful, some update from them in the list of people you have address us about where certification is going. Because I know that they're busily at work trying to make that a more simplified, more streamlined, perhaps more rational process so that hopefully they focus on less things, but things that are more centrally important. So that vendors can actually comply and do it at a pace that's reasonable and so that the users can have more of an assurance on certain key domains that the systems are much more, I hate to use interoperability because that's such an overused term, but, interoperable and functional. But in a smaller number, but perhaps far more impactful domains. And I probably misrepresented the work ONC is doing, but I know that they're busily at work at it.

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

So, the way I would answer this is, the only role that I can see would be if the certification program looked to see if products basically could – had key safety related capabilities. And I don't know if there's a certification criterion like that right now, but it doesn't seem to me like there's a big overlap between certification and the Safety Center, unless I'm missing things.

W

(Indiscernible)

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

David, this is Paul. This is Paul Tang, a couple of things that might be useful, one is this button to push where you want to capture the – so at one point we had problem with performance and they always ask, well, what were you doing, etcetera. And so developed a one button push and it would capture all of the parameters, what screen were you on, all the software parameters so you could just annotate that and say, here's the problem that I had. Something like that might be very useful in terms of helping the safety report actually originate from the user and be useful to the vendor, where were you and what were you doing.

Another area, and it's one that certainly everyone, including ONC, has been working on is usability. I know we don't have a way to test it yet, but when that does become available, it could be really helpful and that clearly plays a role in safety related events.

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

This is Amy with ONC, just a couple of comments. I'm not the expert in this area, but I can at least fill in some of the questions. There is a criterion to use user-centered design as well as having a quality management system and on the CHPL, some of the products have now begun including results of their testing on user-centered design. And – so that one has to go into the individual reports to see those, but that is available and could be made more robust, perhaps, I don't know, I'm interested in your thoughts there.

And the other is just that the certified testing bodies or the ACBs, they do have a role right now in surveillance in that if they become aware of any safety issues surrounding the products that they're working on certifying, they're to keep track of those. And that was a program that was just initiated late last year. Just a little bit of background.

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

Great. Other thoughts?

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, may I have the liberty to almost phrase that question a little bit differently though, too?

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

Sure.

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

Is what role might the Health IT Safety Center play in its relationship with the certification program, so in what it learns to help feedback to the certification program as well. So that maybe things that the Health IT Safety Center begins to learn that it can feedback over to the certification program. So I think it's almost a two-way learning.

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

Yup.

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

So that as products are going through their certification program that there may be things identified that the Health IT Safety Center could hear about, but the Health IT Safety Center could be hearing about things that they could be feeding back over to the certification program.

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

I think that’s a better way of framing it, okay. Other thoughts about this?

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

This is Marisa Wilson. So, I’ve been listening to everyone’s – excuse me, comments related to safety and the standards, etcetera. And one thing that’s been sort of on my mind and – excuse me, I have a really bad head cold, is the role of customization across – individual organizations engage in. We need to figure out some way, when we develop this learning environment, of accounting for some of those customizations that are made because they have great impact on the processing and the workflows and the outcome. And I don’t – I know there is some gathering of that within the certification program, in terms of what functionality software can and cannot do, but then you’ve got this additional layer on top.

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

Um hmm. So, play that out a little further, what do you think the role of the Safety Center should be around that customization?

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

Well, I think if we get to a point where something can be reported, we have to have some ways of accounting for customization that was done to a particular entity’s application. Because whatever they did to it may only be applicable in that specific instance or it could be applicable across the board. So we have to have some way to capture that so it’s not always just the product, it’s version, a particular function, but what may have been done to that function in that particular organization. Excuse me.

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

Right, I mean, so I would go a little further even and suggest that one potential role for the Safety Center would be to – it’s clear that we need – it’s clear from my perspective that it would be helpful to have some post-implementation testing of systems because largely of the degree of customizations that organizations can make. This goes back to what Mary Beth said and we found that people often don’t even really know what they’ve implemented. So if they don’t do any post-implementation testing, they may totally miss that they have important safety issues. The example that’s been used most widely is around medication safety and the Leapfrog test, but we found that about half the lethal orders that we gave to organizations just went through with no challenge whatsoever, initially. And then organizations tightened that up after they got feedback about that. But I think that some sort of post-implementation testing would be helpful and this, the Safety Center, would be one entity that it could be organized through.

Toby Samo, MD – Chief Medical Officer – Allscripts

So – this is Toby, so there’s another example and in some ways it’s almost a combined approach and that’s the work that’s been done with the SAFER Guides. And the SAFER Guides really hold let’s call it the whole system accountable for safety.

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

Um hmm.

Toby Samo, MD – Chief Medical Officer – Allscripts

It certainly holds the vendor to make sure that they have a product that’s safe, but it also holds accountable, or at least by using the SAFER Guides, points out how the institutions have to play a role in maintaining vigilance over changes that they could make in the system that could impact safety as well. So I think there’s an opportunity for the Center to, again going back to the sociotechnical aspect of it, of using processes like that in order to ensure that there is some ongoing process to ensure safety, not just of the product, but of its implementation as well.

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

And Toby, the SAFER – did the SAFER Guides specify what sort of post-implementation testing should be done?

Toby Samo, MD – Chief Medical Officer – Allscripts

Yeah, and I mean it’s not specifically testing, but it’s more that there are processes in place, procedures and policies and processes, that ensure that there is vigilance about this. So, just as a vendor will have a QMS system process in place that the – I’m sorry, that the provider at whatever level, and it has to be different levels for hospitals as compared to the small physician practices, have a means of ensuring that these processes are monitored.

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

So this is Jeanie Scott, so it's going on that principle that you put in, for example, you test your – you put in your operating procedures and you test your design and your controls of those operating procedures. But then you also need to go through and you test the operations of it, so you set up your once a year – I configured my system to do this. And then once a year you go back through and you test that configuration, is the configuration still doing what I set it up to do a year ago or two years ago, it goes to that Leapfrog Study, did I test that configuration? Is it still picking up those order checks? And I can tell you it's a real life example that happened here in our organization that we had to go through and have people reconfigure things. But I think that's a key thing that this Safety Center can help with those types of practices. These are major systems and they may sit in a particular model, and it goes to that sociotechnical model, they may sit in particular practices, but we know that healthcare changes. A particular technical vendor product version "n.n" may work this year, five years from now as things change, there may need to be other changes and it's this testing of operations that the Health IT Center can be part of that process. They can say, is this still working and is it – how safe is it still in these operations? And that's that type of feedback that can be very, very beneficial.

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

Great. Other thoughts? Okay and then what role should government play in creating an environment of learning and continual improvement for health IT and the government, and particularly the Safety Center. This one seems sort of like a softball to me, I mean, we've already come up with lots of different roles that the Center should play.

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

This is Steve, I kind of think that's been the crux of this discussion so far.

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

Yeah.

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

I think it's major role that it played was creating the PSOs, because that's sort of enabling in terms of protection. We just need to get a cl – this whole collaborative together, both from a –

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

The thing I wonder – this is Steve, the thing I wonder is for something like this, so it's a Health IT, so emphasis on "I-T" Safety Center, but obviously I think there are a number who probably think expansively needs to be focused, because it doesn't have the resources to do the whole world. But, that has great implications for a Health Safety Center, in some ways, through – the means of IT, or the use of IT. So, it's not going to be like the FAA where you have a runway incursion or you have an accident and you have a team of people swoop in and investigate.

So they're not going to have – the Health IT Safety Center is not going to have an investigating team show up at your hospital to help do a root cause analysis and find the answers. So this is obviously different than that other model. But to the extent there are elements of that other model that enable a center like this to identify trends, identify things that have applicability across the whole system, to take seemingly small findings or minor annoyances or major risks at single institutions, but identify and to generalize what problem in the system needs to address it. To get a big bang for a small buck, it seems like that could be very useful. So I think the role of government in this is one, we try and design this in a way that follows kind of a principle of parsimony. Let's not try to take on the whole world, let's try to design it in such a way that it has a really positive big impact for a relatively small footprint. And I don't know if that's too general to even be helpful, but –

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

Steve, this is Paul Tang. You're – what you said actually triggered something, and maybe this is actually speaking in a – from a different perspective. I wonder if, a big role government can play, one, it offers the protection, which requires a law to the PSOs, but the other is, there does – this is a public good function we're talking about. So although we would like the governance to be public/private and the operation of whatever entities are involved to be public and private, there is a role for public funding, just like NTSB, for one.

And the other thing that came to mind was the Baldrige Award, which is funded by the government, I think from Commerce. And – but they do come in and I won't say to swoop down, but like Baldrige comes in to say look at what you did and learn from that and recognize it. It's very useful to have external view, particularly with the kinds of expertise needed to do this kind of exploration. And funding that from the government would be a useful public good. So maybe I'd almost say I don't know how much we can accomplish in a – with very short funding. We don't need enforcement but we do need the ability to go learn and I think that requires funding, so maybe that's a proposal for what government – a role that government can play in the Safety Center.

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

And I – an association of PSOs, I agree that funding is desperately needed. Another role that the government can play in the PSO world is one that the Joint Commission actually is playing a great role and providing a great service. Under the law, the Joint Commission can come into the culture of safety and work with the provider community to get to the next level in their RCA preparation and other safety issues. And they cannot, and they will not, take an accrediting action against the provider, but there is an expectation and a little bit of a stick that the provider needs to improve if they're not – if there is room for improvement. So, that's just another role that there is an avenue for accrediting bodies to participate in the culture of safety and assist in the analysis.

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

Well and I guess to piggyback – this is Mary Beth, I think the issue that has been alluded to, the protection – the confidentiality protection the PSO act...currently extend to the vendor community. So to the extent that we could remedy that, I think that would be tremendously helpful. I mean I think there are other work arounds to that situation, but that would be an extremely useful effort, from our perspective.

And then I think the other thing is we talk about the Center playing a role in dissemination, which I think is very important, but also perhaps in education in a meaningful way as well. I think it's one thing to have the Center send out an alert or a white paper about a certain set of issues and how you can resolve them. But to really have an education focus to whether it's by webinars or some way to really bring experts to the discussion and help the field really understand how you solve the problem quickly and effectively would also, perhaps, be something that we could do here.

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

I agree. Other thoughts? Okay, so groups that I think we would like to hear from, we'd like to hear from NTSB, perhaps from the VA Safety Center, also from a PSO group or two. We do have somewhat limited time, but other groups that people would especially like to hear from?

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

Well – so this is Steve, I wonder and I don't know how you'd do that – I mean if you could use a convener group like EHRA for the vendors or not. But I wonder if we wanted vendors to try to help be a source for some information, what they would identify as risks or barriers to them that might preclude that or where there could be opportunities. Because I think vendors are going to be in closest proximity to what are central themes or recurring problems as opposed to one-offs that are site specific. So that would be one thing.

There's – I'm just thinking out loud, I have a conflict in this because I'm on the Board for them, but convener groups like eHealth Initiative, is there any role in a group like that who convenes across all these different stakeholders? Because then you've got like retail chain pharmacies, you've got private payers, you've got provider groups, you've got patient groups, to maybe see – they didn't really give us enough time to get feedback from their side, it's such a short turn around. But if there are any insights to be offered there for what – where there's opportunity to get additional data sources or find ways to collaborate.

I mean, I think – the last thing I would say is, perhaps some perspective from the provider groups, because you're going to have really big challenges – really different challenges I mean, whether you're talking a smaller physician group versus a large institutional health system, for their ability to engage. I mean, even a group of say 20 physicians, which is not tiny, is not going to have bandwidth and much in the way of resources to report into this. But are there ways it can extract value or are there ways we can make it very easy for them to report without fear of reprisal or problems for participating in a learning health system in a non-punitive way.

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

Thank you. Other thoughts? Okay, so I think what I would like to do is wrap up a little early, unless anyone has other general comments or thoughts.

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

David, if I could just apologize to the group – this is Steve again. When these dates came out, I was able to clear my calendar for all the other dates, but I can't make this Friday. So, I'll have someone on the call listening on the webinar, taking great notes so I can participate in the rest of the calls that I'll be able to be present for.

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

Oh, that’s fine, we appreciate it. Okay, Michelle, could you go to public comment?

Public Comment

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

Sure. Operator, can you please open the lines?

Rebecca Armendariz – Project Coordinator - 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

Okay, well then let me just thank everybody, a really rich discussion today. I will go through and try and summarize it, but many, many useful points and discussions and I think we learned a lot, we’re making good progress. So, next – at the next session we will be hearing from some other groups. Thank you again.

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

Thank you.

Toby Samo, MD – Chief Medical Officer – Allscripts

Thank you.

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

Bye, bye.

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

Thank you.

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

Bye.

Public Comment Received

1. Slide 12/13: Third Question about listing. Also can go to KLAS and see how the various applications are ranks by the users. <http://www.klasresearch.com/>

2. Part one of comment (comment box very small): A reporting system is most welcome. But one must understand how limited it must be—almost diverting rather than helping. The reporting model from train wrecks and plane crashes (and even from near misses) fails for most of medicine. Here’s why: With airplane and NTSB-type problems we can see the results of mistakes. There’s a close call with another plane, or more often, bent metal and smoking debris. But in medication ordering errors, we don't know 98% of the errors because patients are old, sick, with 5 comorbid conditions and taking 12 other meds. Bad things happen when we do everything right and good things happen when we do everything wrong. It’s hard to see the results of most of our errors. More directly, if a clinician sees he/she has made or is making an error with the CPOE or EHR, or eMAR, they fix it. It’s only the unseen HIT-linked errors that reach the patient. [see part two]

3. Part two of comment: Ergo reporting in this format is problematic. And of the 2% of errors that are known, only some are reported for reasons too obvious to enumerate here. Medicine is messy and filled with uncertainties. Unlike NASA, we seldom have a smoldering wreck to examine and from which to learn. Thus, much (but not all) of these HIT safety reporting efforts are a self-delusion that provide a false sense of security and progress while the errors remain mostly unknown and largely unaddressed. These systems are largely a Potemkin village. Actually worse, unlike Potemkin villages that were clearly false fronts, here the builders have convinced themselves it's a viable solution. Caveat: my critique does not apply to certain types of “obvious” errors, like leaving hemostats in a patient or wrong patient surgeries. Again, I applaud your work on these reporting systems, but urge appreciation of their limitations: they will miss the vast majority of HIT-related errors.