



HIT Policy Committee Safety Task Force Transcript June 13, 2014

Presentation

Operator

All lines bridged with the public.

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

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

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

Here.

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

Good morning David. Jeanie 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 Lead – Office of the National Coordinator for Health Information Technology

Hi Jeanie. Jodi Daniel? Jon White?

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

Here.

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

Hi Jon.

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

Hi.

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

Marisa Wilson?

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

Here.

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

Good morning. Mary Beth Navarro-Sirio?

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

Here.

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

Hi Mary Beth.

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

Good morning.

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

Paul Tang?

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

Here.

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

Hi Paul. Peggy Binzer?

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

Here.

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

Hi Peggy. Steven Stack? Tejal Gandhi? Toby Samo?

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Here.

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

Hi Toby. And are there any ONC staff members on the line?

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

Ellen Makar.

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

This is Amy Helwig.

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

Hi Ellen and Amy. And with that I'll turn it back to you David.

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

So, thanks so much Michelle. This is the Safety Task Force and as part of the FDASIA recommendations one of the recommendations was that a Health IT Safety Center be set up and our group has been tasked with thinking about what that group might look like.

We’re asked to address a number of key issues around it including what the value proposition might be, what the governance should be, what’s its focus should be and what it’s function should be. And we’re in the process now of getting thoughts from other groups that are analogous and we’re very grateful to the group of presenters that we have today.

We have David Mayer from the National Transportation Safety Board, Bill Munier from AHRQ, Jeanie Scott from VHA who is also a member of our group and then Ronni Solomon from ECRI.

So, the way things will go today is we’ll hear from these individuals about their thoughts about what might be helpful to us and then we’ll have a chance to ask each of them questions. And with that I would like to hand things over to David.

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Good morning, did you want to start with me, David Mayer?

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

Yes.

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Fabulous. Well, I will go right ahead, I put together a little bit of a presentation, and look there it is on the screen, just to give you an introduction and a little bit of an overview to the National Transportation Safety Board, maybe I’ll just pause and just make sure you guys can hear me okay?

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

We can.

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Fabulous well we can just move right along then. I serve as the Managing Director, essentially the Chief Operating Officer, the Senior Career Official at the National Transportation Safety Board and if we just move onto the next slide it shows you that – I’ll just give you a little bit of an overview of our organization, the process that we use to approach transportation accident investigations and a key component of that process is what we call our “party process” and so I’ll spend a little time talking about that.

And sort of at the end I’ll make a few remarks about collaboration specifically with regard to aviation safety and make sure that you’re aware of some other activities that go on in aviation safety that are external to the NTSB.

So, the next slide begins to talk a little bit about the NTSB as an agency, I don’t know I think of the NTSB as a fairly young agency it’s been around, at least in name, since 1967, it was initially set up at the time that the Department of Transportation was created and the NTSB was initially set up as part of the Department of Transportation, it was supposed to be functionally independent but dependent on the Department of Transportation for certain shared services such as purchasing and human resources and whatnot.

That really didn't give the appropriate appearance of independence and consequently in 1974 the Independent Safety Board Act was passed that created the National Transportation Safety Board as a fully independent agency.

We are kind of known as the airplane crash people and of course that's true, however, we also have responsibilities for other modes of transportation, we do accident investigations involving railroad, marine, highway accidents as well as pipeline accidents, pipeline is not sometimes thought of as transportation by somebody outside the transportation community, but since its inception the DOT has had certain regulatory responsibilities for the nation's pipelines, they move commodities across state lines so they are engaged in interstate commerce just like the other modes of transportation, so for us pipeline is yet another mode of transportation.

We are a fairly simple organization in that we exist to investigate accidents, particularly major accidents and make recommendations about prevention.

The next slide shows a couple of other lesser known functions of the agency that I just thought might be interesting to mention. The NTSB has a small number of judges, administrative judges who hear appeals of certain DOT certificate holders. So, in other words if you are a pilot and the FAA takes action against you for allegedly violating a regulation or rule of piloting then if you disagree with that action you can bring it before one of NTSB's judges for the NTSB to rule on that issue.

We also conduct certain kinds of special studies about transportation safety, we tend to look at problems of a recurring nature or problems that we think a solution can be particularly informed by accident investigation work and publish studies based on that.

And since the middle 1990s we have also had a statutory responsibility to provide certain kinds of assistance to transportation accident victims and their families. They don't have status in our investigations but we try to make sure that every step of the way, particularly in a multi-fatality accident, that the family members are aware of our process and that as we move through the investigation they are aware of meetings or hearings, or document releases, news conferences and whatnot so that they are not taking aback by our process.

So, the next slide shows just our very simple organization chart, the NTSB is an organization of about 400 people mostly in Washington but also geographically spread out around the country. We're organized pretty simply, the NTSB is actually a board of five presidentially appointed board members that are shown across the top of that organization chart and we have an organizational structure that largely revolves around our five modes of transportation plus a research and engineering laboratory that provides technical support for our investigations. So, that's probably enough about our org chart.

The next slide shows a little bit about the independence of the National Transportation Safety Board, I mentioned the Independent Safety Board Act as 1974 that established the NTSB as independent, in other words we're not a part of any other federal entity, we're not a part of the Department of Transportation or a part of any larger department within the government.

We have no regulatory responsibilities. We do prescribe some basic regulations about how we conduct investigations and hearings and whatnot but we're not a transportation regulator per se, we're not like the Federal Aviation Administration or the Federal Highway Administration.

We do have statutory priority over other federal investigations that maybe conducted concurrently with our own work that provides a degree of what we think is important priority for safety investigations to ensure that our work can be conducted and not subordinated to other activities that might be surrounding an investigation.

And finally, we enjoy, to the extent possible in Washington, an important degree of political independence, in other words because we're not part of another federal entity our reports and even our budget requests are not subject to seeking the permission or review of larger departmental controls or other kinds of organizations.

And another important piece of political independence for the NTSB is that our five member board they serve staggered terms so they don't all come to an expiration at the same time and also there is a requirement that no more than three of our board members may be of the same political party as the president's political party that forces a degree of different viewpoints on our board. Transportation accident investigation is not a particularly political thing in the first place but this attempts to ensure that it doesn't become a political activity.

So, the next slide shows that the NTSB really has a safety focus our main product is our safety recommendations. We issue safety recommendations to the organizations that we believe can best implement solutions our only goal here is to improve transportation safety, we don't determine blame or liability in accidents we are simply trying to prevent a recurrence of accidents and to reduce, where accident do happen, the injury or the impact such as property damage or environmental damage. And we also evaluate and make recommendations about emergency response to major accidents as well.

There is no requirement that the recipient of our recommendations implement them, however, we do advocate for their implementation and we do a lot of tracking and follow up and we work with the organizations to whom we issue recommendations in an attempt to persuade them to take the action that we've asked them to do.

The next slide just shows our annual most wanted list of transportation safety improvements. I wasn't going to review any of these really specifically, but we do have a process whereby each year we announce a new essentially top ten list of most wanted safety improvements and that sort of sets our priorities for advocating for change and safety improvements throughout the year.

The next slide, since its Friday morning I thought I'd show you some pictures. This is what we call a Go Team en route to an accident, it's actually two separate pictures of two separate teams, but we often take federal government aircraft and fly to the scene of an accident so that we can put key staffers and investigators there as rapidly as possible.

The next slide just shows an NTSB accident investigator on the scene of one of last year's metro north commuter railroad accidents and obviously that's some of the wreckage from one of those collisions. And the next slide show some NTSB investigators on the scene of last summer's accident at Birmingham, Alabama of a UPS cargo airplane that crashed there.

And the next slide just shows some of the work that went on at that investigation site, at the top you can see investigators were covering some items from charred wreckage and those items are actually also seen below in the picture that was taken later in our laboratory, those are the recorders, the so called "black boxes" flight recorders and cockpit voice recorders, being removed from the wreckage and then brought to Washington for study and analysis in our laboratory.

So, just a few more minutes, really the next slide talks a little bit about our investigative process. We receive notification of accidents of course and organize very quickly a response that's appropriate to those accidents from our initial Tweets and press releases about going to the scene of an accident, which we've put out a couple even this morning already, we are very transparent about what we're doing and what we're finding in our investigations. In a high visibility accident we will speak with the media very frequently to keep the public aware of what we're doing.

On the scene we organize the investigation and we name parties to the investigation, in a moment I'll talk a little bit more about what that means. We conduct, for about a week or so, an onsite investigation of a major accident involving support from our laboratory back at headquarters or other facilities as necessary.

We conduct a fact finding investigation where we create a body of facts that we will make public once the record is complete and a technical review is held actually to ensure that the record is complete and after that we make those facts public, it can sometimes be thousands and thousands of pages of documents that we make available to the public on our website.

We may hold a hearing on an accident investigation which the members of our board convene and ask questions to various witnesses that are called, this is also part of the fact finding process and at the close of fact finding we independently write an accident report and conduct an analysis of the body of facts that we've collected and made public. And then we hold a public board meeting where our board members will deliberate and if all goes correctly adopt the report that the staff has prepared for them.

So, that's a little bit of an overview of the investigative process, the next slide talks about parties to an NTSB accident investigation. We actually are a bit of a public/private partnership when we conduct accident investigations because we name parties from those organizations whose employee's functions, activities or products were actually involved in the accident and who can provide qualified technical personnel to assist in the investigation.

So for instance in an aviation accident investigation we would typically look to the airline, the pilot's union, the manufacturer of the airplane and the manufacturer of its engine sometimes to become parties to our investigation and partner up with us as we collect the factual evidence that will be necessary for the NTSB to independently come to a conclusion about what happened and to make recommendations about how to prevent the accident from recurring.

Our party process is a little bit of an odd duck in government, I really don't know of too many other processes like that to protect it from becoming adversarial we don't permit claimants or insurers, or anyone in a legal position to join our investigation as a party, it really is a technical fact finding team.

The next slide just shows a few things about what our parties do, I think I described that they participate in the fact finding, we are looking to them because of their technical expertise. We share information among the investigative team as part of being a party to the NTSB's investigation parties agree that we will be, the NTSB, will be the official spokesperson for the accident with regard to the media so that we relieve them of that burden and of course they have access to the evidence that we're collecting in the course of the investigation.

Next slide, and I'm almost done here, the next slide just shows that the NTSB is not the only game in town when it comes to accident investigation particularly aviation accident investigation so I described our party process that we stand up and put into place every time that we conduct an investigation, but there are a variety of other partnerships essentially that have been in operation for quite some time that all work together to make aviation safe, one of them is the Aviation Safety Reporting System that activity has been around since the 1970s it provides a confidential reporting system that might be a bit analogous to a patient safety organization, essentially ASRS takes in reports from all aspects of the aviation safety system from pilots, air traffic controllers, mechanics and others, and provides alerts when their team detects safety issues and they may also provide aggregated statistical information that may be appropriate for helping keep aviation safe.

There is also CAST, the Commercial Aviation Safety Team, that's been around since the 1990s and it really is a very data driven focused public/private partnership there are a number of airlines and other organizations involved with the FAA in seeking out evidence and data upon which to base safety improvements, they tend to focus on specific important system-wide improvement or two at a time and collect data after making changes and improvements to the system they try to collect operational data and show the effect of the changes that they make.

Speaking of data, the last entity that I wanted to mention is ASIAs, the Aviation Safety Information Analysis and Sharing Program, that's operated by MITRE Corporation on behalf of the FAA it's also a fairly extensive public/private partnership that collects operational data near real-time data on commercial aviation activities in the United States, probably more than 90-95% of all commercial flights actually contribute data from recorders aboard the airplane to the ASIAs System and that data is used for real-time or near real-time analysis of the performance of the aviation system and searching for indicators of safety problems and are used to base safety improvements on what is truly big data for aviation safety.

So, I'll wind up on the next slide just kind of reviewing the goals for an NTSB investigation are to conduct our work in a cooperative, non-adversarial process so that we look a little different from say a criminal investigation.

We work to establish an agreed upon set of facts that we make public. Our parties may conduct an analysis of those facts, we will conduct an analysis to determine the cause of the accident, but we do that independently and we publish what we believe to be a fair balanced independent accident report that explains why the accident happened and how it can be prevented in the future.

So, that's really the end of my presentation the next slide just sort of closes it out with some contact information for me if you wanted to seek me out. So, I hope that's been helpful to you and thank you very much.

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

David, thanks so much that's extremely helpful. Let me just – I'll take the prerogative of the chair and ask you the first question. Can you tell us a little more about what the board does, that is to say, what proportion of their time do they spend with you, do they get paid for what they do?

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Oh, sure, that's a good question. Yes, our board is – our five board members, well currently we only have four board members because we are down by one temporarily, but they are fulltime paid positions. They are politically appointed with senate, presidentially appointed with senate confirmation and it definitely is a fulltime job. I know that is not intuitive to some people, however, we do have quite a flow of reports and products that requires their approval.

I looked on our dashboard this morning there are about 10 items pending board member review right now, later in the month they'll be meeting to deliberate the cause and adopt the report on the Asiana Flight 214 accident that occurred last summer in San Francisco, so that draft report is pending with them right now and they conduct a very extensive review of our docket, they take their work very seriously.

Another function that they play is, I had a slide a little while ago about our top 10 most wanted improvements in transportation safety, we divide that list up to advocacy areas per board members, so two times five is 10 and they actually – we design with their input a suite of advocacy activities whether that be attendance at conferences, meetings or other kinds of activities for each of the board members to play a very active role in advocating for transportation safety and change.

Also, I mentioned too the law judge function of the agency, if you are a pilot who's certificate was suspended or revoked by the FAA and you appealed to one of our judges your second step of appeal, if you wish to do it, if you weren't happy with the judges determination, would be an appeal to our full board so there is always a caseload of that going as well pending with our board members.

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

Great, so questions from the rest of the group?

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Yeah, this is Toby Samo, David thank you for the presentation. Just one question, do you investigate all accidents, transportation accidents and if not how to you prioritize which ones to investigate?

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

That's a really question. No we don't investigate everything, we simply couldn't. We have certain statutory jurisdiction that varies by mode of transportation so I won't review all of it, but in aviation for example, we are required to determine the probable cause of every aviation accident so there are obviously a very specific legal definition of what constitutes an accident and applying that definition we have about 1100 or 1200 aviation accidents every year, people sometimes think of airline accidents only however we also have responsibility for general aviation accidents and those can range from fender benders or I guess propeller benders all the way up to 2-4 person fatality accidents in general aviation.

We prioritize those based on either the severity of the accident and the extent to which we believe the scope – we prioritize them, we don't travel to every one of them, we delegate to the FAA the responsibility for collecting some factual information particularly on non-fatal accidents that we don't travel to and we try to set some priorities based on risk and our understanding of the circumstances of the accident.

There are some very common accident scenarios that we probably will choose not to travel on and if we are watching a particular kind of airplane for safety issues or suspected safety issues we may decide to travel on that. So, it's very much a real-time decision making process based on the severity and the circumstances.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Thank you.

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

I have a question, David?

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

Go, ahead?

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

Yeah, hi, it's Paul Tang, David thank you so much for the presentation, I've always been enamored by the NTSB process ever since sort of learning more about it in detail with another IOM safety committee, but the way I look at what you're talking about is the non-partisan fact finding activity that's not looking for blame, really it's primary mission is to prevent future accidents it's just I think everything we would like to have in the domain we're talking about as well.

When the IOM committee that was looking at this issue also came up and recommended, as you probably know, an NTSB-like model so our part is finding the money again.

You made a comment, so this is going to be only partially tongue-and-cheek, but you made a comment how you got to have pipelines under your jurisdiction because it carries another commodity, the packages, gosh, you know, data is becoming a commodity I'm wondering if we could talk you into covering our work because of its transport mechanism for data?

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Well, I certainly haven't thought of that connection. I definitely find pipeline accidents to be very, very interesting accidents because usually the cause of the accident is very remote from where the impact of the accident is actually felt. The cause of the accident maybe several states away or it may even be a US accident being controlled from a control center in Canada and it's these control centers that receive and process data from sensors and valves and pressure transducers throughout the pipelines that usually it's the human handling of that data that results in an accident as opposed to something that's right there at the accident site. So, they're always very, very interesting sorts of accidents.

We definitely make enormous use of data say from nonvolatile memory in GPS units or cell phones or whatnot that we may find at our accident sites, but so far congress hasn't given the NTSB any responsibilities with respect to interstate commerce involving data, I don't think that's been seen yet as transportation.

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

Well, here's a more related –

Tejal K. Ghandi, MD, MPH – President – National Patient Safety Foundation

I have a – go ahead?

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

Here's a more related question is you must give this same thought really to a number of folks who admire your model and want to implement some safety mechanism in their industry. What's the closest we can come up with that doesn't involve as much resources do you think?

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Well, I think some of the – I'm not sure if this is directly responsive, but I think some of the key attributes are stakeholder involvement, in other words, you know, if one were to conduct a review of an event then you certainly wouldn't want to do that in a vacuum, you would want to collect all of the relevant information by including people who have a stake in the outcome and making certain, that to the extent possible, that they understand that the fact finding or the investigative work is not punitive in nature and to try to eliminate the trappings of an adversarial proceeding from the activity to the extent possible, it may be a challenge in healthcare.

And I think – I really think a degree of independence is also critical, in other words, the entity that is going to write a report or prepare recommendations, or make a determination ought to be doing that without the control of special interest groups or a larger government agency just to make sure that you get good fair and balanced work. Maybe I'll stop there and see if I'm on a helpful track for you or not?

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

Well, thank you very much.

Tejal K. Ghandi, MD, MPH – President – National Patient Safety Foundation

This is Tejal Ghandi, I had a question for you and thanks for your presentation as well. You talked a lot about the public/private partnerships and a lot of the data that they collect as well and can you talk a little more about how those partnerships work and are you specifically just focused on individual incidents versus potentially doing a deeper dive into a collection of near misses that maybe are identified through one of those other sources?

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Oh, good question, let's see here. We definitely do the deeper dive stuff, we do them usually in the context of our special studies or special investigations, we for instance will be – we conduct a deeper dive into, I'm trying to think of a few that are public, one topic that we have done a variety of deeper dives is operator fatigue in commercial driving and that's certainly a hot topic again due to a high profile accident last weekend. We do that kind of work. We tend to base that on a handful of our own investigative work, investigations informed by whatever data sources might be available probably by other entities and other agencies.

So, for instance there are DOT databases on fatal accidents and other kinds of databases that we would use to try to add dimension to our own work and certainly, particularly in the ASIAs Program that's governed by, gosh essentially a board of directors that has a representative from each of the stakeholder organizations, so it's a fairly large board because essentially each airline is a stakeholder in addition to a variety of other private sector entities and they actually function to set the analysis priorities of the data system and to determine how best to put or to implement change based on the analytic work that they do.

On the other hand, you know, that's probably the extreme in terms of governance, ASRS, the Aviation Safety Reporting System, which I mentioned that functions as a confidential reporting program and is really become a model for other such programs around the world, that's not an NTSB activity its actually operated by a private sector contractor under contract to NASA, there are some historical reasons for why it's a NASA contract as opposed to an FAA contract, but it's essentially governed as a fairly simple acquisition effort on the part of the federal government.

I don't want to belittle it, it's of course an important and complicated contract, but in terms of government purchasing it essentially is a service being performed on behalf, by a contractor on behalf of a government subject to some very basic terms and provisions in a contract.

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

Okay, I'm just mindful of the time. This has been really terrific, thank you so much. Is Bill Munier on the line?

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

Yes, I am, I just –

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

Great, so David thank you again, it's extremely helpful and we might follow up with a question or two by e-mail.

David L. Mayer, MA, PhD – Managing Director – National Transportation Safety Board

Great.

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

Bill over to you.

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (AHRQ)

Okay, thank you very much I appreciate being invited to present to this group and I would say that it’s my understanding that there is an uneven body of knowledge represented in this group about patient safety organizations, common formats, our ability to aggregate data nationally about HIT, etcetera.

And so wanting to be helpful but not bore people that already know about it I tried to reduce this to a minimum and make it presentable. I actually went so far as to leave my name off the first slide so it’s definitely bare bones, but thank you for putting it on the title slide before.

So, anyway what I want to do is summarize what AHRQ is doing in this area working with ONC and for that matter with the FDA to try and shed some light onto HIT related risks. So, if we could move to the first or the second slide?

Basically, the Patient Safety and Quality Improvement Act of 2005 passed in 2005 to try and set the stage for improving the culture of safety by providing both privilege and confidentiality for deliberations regarding all of quality and safety in all settings in the United States wherever licensed practitioners operate.

So, that authorized AHRQ to set up patient safety organizations across the country to provide a safe haven, a safe table for doing quality and safety review recognizing that this was going to definitely help things at the local level where people could feel free to go ahead and dissect what went wrong and how they could improve quality at the same time we weren’t going to get any national learning unless we harmonized how people collected information and I think almost everybody is singing the harmonization song these days the problem is everyone is singing it and we aren’t getting there very fast.

But, anyway in this Act AHRQ was authorized to create common formats which were defined in the Act as common definitions and reporting formats indicating a knowledge, the reporting formats indicating a knowledge that we’re in a world of IT so that it shouldn’t just be definitions on paper it should also be reduced to common computer code.

And so AHRQ has been issuing common formats since September of 2008. It is too big a job to do common formats for all of quality and all of safety and I might add the Act is voluntary so we don’t have the right to compel anybody to use them so it’s a program of traction not compulsion.

But we decided we would begin in the area contemplated by “to err is human” which is that of patient safety and we would begin in hospitals. So, the common formats are most mature for the hospital setting although we do have an early version of them for nursing homes as well and we are looking forward to moving into the ambulatory setting in the next year or so.

In any case, we also became involved, particularly in 2010, when ONC began to get seriously involved in examining the safety of HIT and we worked with ONC and FDA to enhance what was already in the common formats to specifically look in greater depth about HIT related adverse events, specifically in our device module and it was, just as an interesting aside, when we were doing that enhanced module we started out doing something separate for HIT and it turned out to be in many ways very similar to what we already had for devices just a special type of device, so we ended up making it sort of a subroutine within the devices module to address IT specific items and we did that jointly with the FDA.

The Patient Safety Act also set up what's called a network of patient safety databases which is the national body that is able to aggregate information from all of the different PSOs that are collecting it and obviously we can't aggregate it in different forms so we're limited at the moment to aggregating what comes in with respect to the common formats. Next slide, please.

So, what are the common formats? They are a common language for patient safety event reporting. So, we start with a common language with English language definitions of what we're examining and we also standardize the rules for data collection which means we standardize the queries that are answered and the algorithms that drive them.

So, we are able to do standardize reports and present apples to apples if you will and again the common formats are not only authorized by statute but there is also – I today don't want to take the time to go through it, but there is a formal OMB approved process that we publish in the federal register which is collaborative involves all the major agencies, CDC, FDA, NIH, CMS, ONC, AHRQ, etcetera and gets public comments for the National Quality Forum and we've been following that process since 2008. Next slide, please. Okay and then hit the button once again? Yeah, just stop here for a second.

The common formats we believe are the only national patient safety reporting scheme that's designed to meet all of the following four goals which we think are important. The first one is very important, support local quality and safety improvement. So many national reporting schemes are built from the point-of-view of the entity receiving the data and they hopefully are helpful to that entity, but they may or may not be very helpful at the local level for a whole variety of reasons, sometimes that the local level never sees the data they just input it into some federal or state, or other agency and they don't get a report back. So, we designed the common formats to think they're living, the hospital formats, in a hospital with the major objectives supporting quality improvement in that institution. Next.

Oh, no, no not the whole next slide, there we go. We also – many adverse event reporting systems and surveillance systems just focus on a given area, we wanted to make sure that we contemplated harm from all causes, some of the OIG reports that you may be familiar with painted a picture of a very wide range of adverse events with more than 50% of them coming from kind of one off things that no one would have in their defined list of events so we wanted to make sure that we designed a system that could pick up harm from all causes, so just hit the button once there, yeah.

We are designed to allow comparisons over time and among different providers and then four, allow the end-user to collect information once and supply it to whomever needs it. This is a long-term goal, this obviously doesn't work unless everybody is driving off the common formats definitions, but we don't see any really good reason why one should define the same event differently depending on who is getting the data as opposed to the scientific value of the way it's defined and the information is collected and reported.

So, over time and this maybe many years away, but the goal is that, say hospitals will collect data in their own event reporting system, their own surveillance systems within the hospital it will be the information that they need to improve quality there which is the only place that quality will get improved is where it's being delivered and then that information can be used to report out to whatever agencies might need it, say the Joint Commission, the State, Food & Drug Administration, the PSO, etcetera, etcetera. So, next, just touch once more.

And this obviously would decrease the data collection burden right now there are all these institutional silos that are requesting data from the end-user and they're having to report the same thing in some cases two or three times and in different ways. This would not only improve science it would also improve productivity and allow quality and risk managers to spend more time actually improving care. Next slide.

The Patient Safety Act authorized creation of PSOs which in turn aggregate patient safety data to the network which I mentioned before. The network was designed, it's in the statute, to provide an interactive evidence-based management resource for providers, patient safety organizations and other entities, a national resource for quality improvement and research.

Also there are certain rules governing confidentiality of the data that must be followed. I think the NPSD is going to end up being a very valuable resource because it will provide nationwide data aggregated around common definitions and reporting formats.

The reason I say "will be" is that this again is a voluntary program and we've had – the NPSD will be receiving its first data at the end of this year the beginning of next year and you can say "well, didn't you say it was the Quality and Safety Improvement Act of 2005 why has it taken so long" and basically part of it is the voluntary nature but part of it also is that nobody does anything on paper today and if they did they couldn't export it to a national database so it requires software.

And there are legacy systems out there and it turns out that there are legacy systems that are employed by PSOs and they have clients that have different legacy systems, they're all writing maps, the maps are expensive, they're time consuming and they also by in large ruin the data so you end up getting, you're getting that isn't comparable, the common formats become uncommon formats and so we're working our way through that. We do see light at the end of the tunnel but it's taking a long time and the first information that's going to be useful I think is probably six or so months away from coming into the NPSD.

The other thing about the NPSD is that there are strict rules of confidentiality to protect the whole safe haven, safe harbor that's set up by PSOs and so there are some limits to what can be done and as we were working with ONC to talk about looking at HIT related adverse events from the NPSD we certainly can do that, but in terms of digging back down and identifying the source of those we aren't going to be able to do that so we have to find different ways to go about that.

And one of the things that's kind of interesting and people that are familiar with the Patient Safety Act and this whole thing, this history over a number of decades of the plaintiff's attorneys getting a hold of peer review information and so on and so forth we were wondering, this looks so ironclad when finally instead of state by state protections that disappear when data leave the state or even when the data leaves the walls of the hospital now we have ironclad national protections, it seemed like that would be pretty bulletproof and so I believe it is, but it's being challenged.

We've had a number of lawsuits already. We have a Walgreen's PSO that was sued by the Department of Health in the State of Illinois which wanted to see their quality data that suit was upheld and then it was appealed and it was upheld on appeal, we just won a case in, I say "we" the defendant's won a case in Kentucky protecting peer review data, but all of the safeguards that were set up by this law and sometimes – which may seem overbearing or difficult because for instance you can't just dip into the NPSD and see all the way down to the provider that submitted it, but there are reasons for that and the reasons are if the safe harbor is going to really stay safe it has to be bullet proof when people are suing to try and get a hold of this information for various reasons. Next slide.

So, I mentioned that in 2010 AHRQ, FDA and ONC collaborated to develop a special enhanced module to the common formats to address HIT related adverse events and since we've done that we've been working with PSOs, providers looking at the literature and what we're fairly sure of at this point is that many, if not most HIT related adverse events don't jump up and yell that they're an HIT related adverse event they present as something else, something malfunctioned, somebody puts and order in the wrong chart, a device malfunctions or whatever and they present as a different kind of patient safety event.

And when somebody does a root cause analysis or just even pokes around a little bit to find out what happened they find out that HIT may even have been the initiating or the primary cause, but it's either a contributing factor that's the primary cause but is masquerading as something else or it's a contributing factor among a number of things that are going wrong. So, getting at HIT related adverse events is not a simple business. Next slide.

And that brings us to the conclusion that if one were to set up say ONC's Patient Safety Center or any other HIT oriented adverse event system and just look for things that presented as HIT related adverse events you might miss the main meal basically.

So, it's important to look at HIT adverse events in the context of "all cause harm" so that one can see occasionally an HIT event is going to be so obvious that you're going to know what it is right away, but probably a majority of the time it is going to surface as a contributing factor to some other kind of adverse event. So, it's really, really important to look at HIT in the context of all of patient safety and even quality for that matter.

However, having said that it is really valuable to have available a focus of professional knowledge regarding the special and extremely complex nature of HIT risk. The risk from different products of electronic health records is very different. There are some things that are common, there are some things that are different depending on the product and people don't – there is no one person that understands all the products.

The nature of HIT risk is very complex. So, having a focus that actually understands that and is an expert about that I think is extremely helpful. And so for these reasons we think ONC with its Patient Safety Center and AHRQ with our PSOs and our Network of Patient Safety Databases make an ideal partnership for expanding the understanding of HIT risk and how to reduce it across the nation.

So, that's basically what I have to say in a nutshell this morning and I don't know in this format whether you have the ability or the desire to take questions but I'm certainly willing to answer any.

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

Thank you very much, Bill, this is David Bates, we do and I'll just ask you the first one. So, in the Network of Patient Safety Databases when the data does come in who will have access to it and review it?

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

Well, we have – the network which of course is a creation of the statute, there actually is a real entity which is Stanford at this point with a subcontractor of Westat which was the original NPSD. So, there actually is an entity out there that will be collecting the data and have access to it.

One of the curious, if you will, provisions of the statute was one might have thought that the statute would be written that data come in identifiable form and then get – made non-identifiable when at the NPSD because you certainly don't want the NPSD releasing identifiable information, but the statute states that the NPSD has to get data in non-identifiable form on the way in.

So, we actually have created an entity that is going to de-identify the data in a standardized way so that we don't lose that apples to apples interoperability and homogeneity of the data which is called the Privacy Protection Center. So, they will get the initial data from the PSOs, they will render it non-identifiable and pass it down to the NPSD.

Once it gets to the NPSD because it's non-identifiable, I mean, they obviously have to make sense out of it and aggregate it, but it will be – most of it will be publically available and if feasible, and if useful when we have enough data in there it is supposed to be available to researchers to look at for that interactive database as was stated. We also will publish ourselves in the National Healthcare Quality and Disparities Reports that AHRQ releases annually to congress and that actually is required in the Act.

So, it's kind of a long answer to your question but I mean, pretty much what comes into the NPSD is sooner or later going to be publically available and even available for study.

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

Other questions for Bill?

Tejal K. Ghandi, MD, MPH – President – National Patient Safety Foundation

This is Tejal Ghandi, can you comment a little bit about participation in the NPSD and sort of how AHRQ is working with the PSOs to try to get more data flowing into the NPSD?

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

Yes, we obviously – the interesting thing is that in order to get protections providers have to provide data to PSOs, the protections hinge on the submission of data to PSOs, but the submission of data from PSOs to the NPSD is also voluntary. One can imagine it could have been other but I think there was a predominate desire to get the protections out there and stimulate the maximum amount of review with the fewest amount of requirements which one can understand that.

But we are sort of at the mercy of the PSOs. Fortunately, most of the PSOs get into the business because they care about safety and quality. This isn't a big money maker for anybody so people that are becoming PSOs have a real interest in patient safety and most of them I think the vast majority of PSOs fully intend to report to the NPSD.

The holdup has been all of the issues that I've mentioned with software, expense, even when a PSO converts to the common formats it has to turn around and get all of its providers to agree convert and it cost money. So, it's been a long haul.

If you want to know what we're doing to encourage it we have annual meetings of PSOs, we have quarterly calls with PSOs and I'm sure the PSOs are sick of hearing me say "we really want you to send in your data." We do everything we possibly can to encourage the submission of data.

My own view of it is that it's going to continue to be hard, but it's about to get easier because once we begin to get aggregate data and provide it back to the PSOs they'll see tangible evidence of how that's actually helping them improve quality and they'll want to be part of the show and begin to see how they compare to other people. So, I do think it will – when we reach a critical mass it will have a certain amount of momentum but we're not at that point yet.

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

David, I have a question?

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

Go ahead?

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

Yeah, thanks Bill for really a helpful presentation and it was interesting to hear things like one way to make the data useful is make sure it's useful to the reporter. I guess the disconcerting part is that, like you say, it's almost 10 years later and we're almost just going to get some of the results and you talked a lot about the voluntary nature and that might be one of the things that held people back.

You also talked about even – was for common formats there is a lot of interesting things that can get lost in translation. So, what would your advice be, based on your experience now, with the PSOs and trying to get data into the database for the HIT Safety Center?

Do we rely just on the information coming in to the NPSD or is there something else we could do given your experience now?

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (AHRQ)

Well, my understanding of the direction and of course we have ONC, you know, as an integral part of this call, but my understanding where the ONC Patient Safety Center is going is that it's not itself going to aggregate data but it is going to be an expert about HIT related adverse events.

So, I would see our working jointly with them to make sure that we evolve the common formats to be ever more specific and sensitive in terms of picking up HIT related events using the NPSD but also using PSOs themselves even before the data come in because a number of the big PSOs really have very large databases of adverse events right now and I know ONC has been working directly with some of them. So, I would think the Patient Safety Center could as well.

We always have to be careful that we keep within the requirements of the confidentiality of the patient safety work product as it's called, but I think the safety center will use not just the information from the NPSD but information from what we know at AHRQ working with the PSO team, common formats team here at AHRQ, working with individual PSOs and then working with anyone else who is an expert in HIT related adverse events and certainly that's not limited to PSOs. I think that safety center should have tentacles all over the place.

I don't think it probably makes sense to have it try to collect data and I think that they have – anybody on the phone can correct me but I think that they're not going that root. Now there are a lot of complicated things if you try to become again a silo'd national database with just HIT related adverse events I think it probably isn't going to be a very productive exercise.

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

Very helpful Bill.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Bill, this is Toby. You know the common formats is, you know, a good means of collecting data that an event has occurred but from my knowledge of it doesn't yet have information about once an event has been evaluated to actually mark down what is the causality, something for instance that the hazard manager is making steps towards. Are there any plans to expand the common format or create a field within the National Patient Safety Database to accommodate that sort of data?

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

Yes and no. When we originally, with stars in our eyes, back in 2005 started the common formats we were going to make common formats, you can go back and see some of our original PowerPoint slides; we were going to do common formats for the four stages of the improvement cycle. The format as they exist now are basically formats about the first stage which is identifying the problems.

What happened is that it has proved such a heavy lift to get everybody on the same page for the formats and it turns out collecting information in a really careful way about patient safety is much more complex than I think many people realize.

When you have an event reporting system in a hospital and you just write free text into a field or even paper which a lot of them still are that's pretty easy but when you try to standardize it in a way that's thoughtful it's pretty complicated.

So, what I would say is in trying to do a good job and get people harmonized we have ended up spending our time on Stage 1. I would contemplate the fact that we might eventually get to the other stages it will be a competition between expanding the formats that harmonize data collection to other settings versus moving through the improvement cycle and that's actually a very interesting conversation, probably don't have time for it today but I think that hazard manager and other approaches like that I think have their own contributions to make and that we can work collaboratively with those things. But we do have an interest in it it's just we have to get job one done first and prove that's it's of value to the community.

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

This is Peggy Binzer, the comment was made that, you know, the Act was passed in 2005 and in 10 years we're, you know, not as far as we'd like to be on the database. I think some clarification needs to be made in that the final rules didn't come out until very late in 2008 and PSOs weren't certified for the listing process or listing process until 2009 so we really have only been in existence for 3, 4, 5 years.

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

Yeah, Peggy, thank you, that's absolutely true, the final rule was effective on the 19th of January, 2009. We had provisionally listed a few PSOs before that but the actual final listing wasn't until 2009. So, we're not quite as far behind as it might seem.

The first beta formats were put up on the website in September of 2008 but we didn't have the technical specs for them until somewhat later. So, yeah, but it's – nobody is more frustrated by the pace than I am as you might imagine. I've certainly done everything in my power to move it along as quickly as possible.

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

Another piece on this Bill, PSOs do they have any type of federal funding or do they get paid for their best practices from the government should they be shared or even paid for any of the data that they collect at their own expense?

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

No PSOs there was no funding for PSOs in either the original Act or any subsequent appropriation that AHRQ's gotten. AHRQ has supported and we obviously run the program here and we support the Network of Patient Safety Databases and the Privacy Protection Center that de-identifies the data, but beyond that there is no support for PSOs.

So, between being voluntary and having no money in it I might – there are now 80 PSOs across the country, which is I think wonderful, there are also 55 PSOs that have been officially listed and then de-listed, most of them for reasons that they didn't have a viable business model. So, it's a tough world out there. If you want to be a PSO you've got to find a way to be self-sustaining it does not come from the government.

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

Okay, well, thank you so much Bill. I think now we'll move onto Jeanie.

William B. Munier, MD, MBA – Director, Center for Quality Improvement & Patient Safety – Agency for Healthcare Research and Quality (ARHQ)

Thanks, David.

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

Hi it's Jeanie, I'm sorry my phone locked on me. Can you hear me?

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

We can, yes.

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

Okay. So, we'll move right along into the next slide, it's been very interesting listening to the first two slides. We'll just go right ahead to the next slide.

What I wanted to do is just give a little bit of a background and maybe dispel a little bit of myth about VA's Health IT and then how that led into creating this very small program that we have over here in VHA called – the name of the program is called Informatics Patient Safety it's had a couple of different names along the way, but, it's role in Health IT safety.

So, just a little overview, some folks maybe familiar that we have VistA which is a suite of many different products across care settings, electronic health record, imaging, medication administration. It actually includes the personal health records, My HealthVet, it includes our data sharing and it also includes our administrative application. So, I wanted to include in there that our VistA system includes both the clinical and the administrative side. Move over to the next slide.

A little bit of a history of our EHR. We've been around since the 1970s, early 80s is when we started developing at the different modules, very much at the service level and these are the types of applications that we do look at, continue to look at for safety, our lab, our radiology, our inpatient pharmacy and several other packages.

As we've evolved through the 90s we've added on our computerized patient record system, CPRS, which includes CPOE plus things like note templates and consults and interfacility consults.

In the 2000s we added on our barcode medication administration. Recently we've been sharing with Indian Health Services our VistA imaging and most recently this past year we've been working with Indian Health Services to deploy our barcode medication administration. So, we'll move onto the next one.

In recognition on it, as you can see here, through the 30 years of experience the system has been recognized for the way it's transformed the way we deliver healthcare here not so much from a – well, from a technology perspective we're quite proud of it with how it's been used, particularly the Harvard University Innovations Award in that it's the way that we do business and it's very much integrated into our healthcare processes here. We'll move onto the next slide.

So, what I want to point out here is when we talk about our system and I think we've had this discussion, several times before, is when we talk about Health IT it includes many different components here, the CPRS which is out of CPOE but it's more than just the ordering part of it, it's the note, it's what gets put into our progress notes and our discharge summaries and our surgery notes, it's the encounter information and the coding that goes in there, it's the allergy information, which is different than the CPOE. It is the reports that come out that display, the reports that are coming in from the ancillary, what I would call from the ancillary applications. It's the imaging, it's the barcode medication administration, the personal health record and the exchange of data that we're doing with that and My HealtheVet. Moving onto the next slide.

Okay, and we've had these discussions also about, in CPRS, which is Computerized Patient Record System, some of the features that we start to look in here when we say how can these effect safety, the clinical decision support, we have clinical reminders if on that graphic that you see here in the middle section off to the right, I apologize for the size of this, if you have the slides you can look at them later, we have clinical reminders in there and there is, you know, GI screening and breast cancer screening, and not only the initial screenings but then when someone has that initial screening then there are findings of where they go further deeper into evaluation for further screening, diabetic screening and different complexity screening is in our clinical reminders.

We have other clinical decision support that's part of the CPOE as part of it. We also have remote data retrieval and how information gets exchanged back and forth which are all considerations that we look at as to both the accuracy, the latency, the transparency and how it all operates including usability through all of this and how it's used in the healthcare setting. Move onto the next slide.

BCMA, it virtually eliminated our errors at the point of administration. You can see the history of when it was evolved in the VA and how much we've used it in here. This is one of the areas that we do look at when we're looking at Health IT safety and BCMA not just the computerized patient record system its one of our areas and how these two systems integrate together, when we're looking at – or particularly if we see something that is a medication error we have to consider what are the interactions of the two systems. We'll move onto the next slide.

My HealtheVet, this is an area that we're beginning to look at particularly more how it interacts with the, as you can see on the slide here, refilling of prescriptions and the display of data there, and the interactions that are occurring between the personal health records and the electronic health records you know back at, I would say the brick and mortar areas, and the sharing of these health records and how that information and the different documents are prepared when you're exchanging information back and forth, and the standards that are used there. We'll move onto the next slide.

So, that was just a little bit of a history of the different parts that we look at. Those were all traditional products that VA is known for but one of the things in the area that I'm responsible for, I am the director of a small office and I'm going to tell you a very small office, as I listened to the last two presentations, we are a staff of 50, we traditionally have looked that internal development but what we were also having to look at is how these work with vendor products, the circle there about commercial products and how we're interfacing with mobile. So, we're really evolving a model of how many different types of products and processes make up what is Health IT. We'll go onto the next slide.

So, a little bit about our Health IT Safety Program. Our inception was somewhere around 2002, very informal, no access or law, or anything that set us up. We came about from a collaboration with our National Center for Patient Safety with our information technology system and it was noted that there was a need to look at these separately from the Health IT Help Desk but also separately from the patient safety event reporting.

So, there was a group that came together and very much ad hoc that decided to start tracking these and this was early 2002. In 2005 the first position was created and I think what was interesting about this point in 2005 anyone who has followed VA IT history at about that time, in 2006, is when there was a differentiation of IT separation in VA and a decision was made, as we talked about the governance of a Health IT Safety Center where it might be, we had a lot of discussions here where a Health IT Safety Center should be, should it be in the National Center for Patient Safety, should it be in our IT development shop, should it be here, should it be there?

And the decision was made was to keep it – we decided, as a organization, that it needed to be independent, I think we've had some of this all along, it needed to be independent of the manufacturer, it needed to be independent in the face of the general safety, but it needed to be able to collaborate between the two.

So, where this office sits through several different organizations is we sit within our policy and planning, within that we sit within the office of informatics and analytics, health informatics and then this program. So, we are a program, but what I wanted to point out here is that we sit in a collaborative role between different stakeholders. We sit within policy. We sit within the safety department and we also work collaboratively with our technology partners and then also with external partners as well.

So, the areas that we worked with is we look at events but we also look at concerns. We look at the software development lifecycle. The areas that we are working with particularly most recently is with the mobile area is looking early in the process as we're beginning to build products so before we build them can we build them so that they are safer for use, are we using best practices and giving guidance and not only is it, as I said, mentioned that we have a very small staff not that my staff is doing it, but that there are the appropriate roles and resources on those that are building the products and that they are using the processes during the development lifecycle and the testing processes, are there quality management systems that are being used and the deployment strategies.

So once something is built then is it ready for use, what's the best emphasis for when a facility wants to adopt something, do they have their resources available and are they prepared to make those change processes either in healthcare, in their healthcare process or are they ready for their infrastructure in there and in their implementation practices? And this also goes to after they have it in there what's that continuous monitoring of does the product still meet the needs?

And then, finally, in the last thing is reporting an analysis of close calls, this is an area that we work with, we do have a database where we receive in concerns and we analyze them. We have set up a structured format of receiving in the data and capturing it to field. We use a combination between a narrative, we do believe in the stories and we do maintain that narrative, but then we further granulate it down into trying to get specifics so that we can later go back through and see what patterns are across our reports that do come in. Next slide, please.

So, a little bit about how that all comes out then. I wanted to point out that so then we have the identification, the communication, so what has come out of this?

In one of the top two points that I have is medication ordering errors, well, what we've been able to do over the years is to see through pattern identification is seeing working with our national pharmacy and working with our IT department and also working with the safety center is that there was a design practice that would autofill and by changing that design practice we were able to minimize those types of things.

So, we were the area that was able to pull those pieces together, it wasn't being pulled out of the patient safety reports and from the IT perspective so that's the way the software was designed but we were able to work together and see the connection in there and bringing in human factors folks to see where people were making those mistakes.

The other area which I think I wanted to point out is it's not just with the clinical software but the patient identification what we called patient identification catastrophic edit, is this was an administrative part of the Health IT and in that area we have a set of users who make changes that then have a downstream effect which we talked about maybe a patient identification errors, you know, the medication goes to the wrong patient, well where might that be further upstream? And we found out that it was an administrative software.

Again, we were the area that was able to make those connections between all of the different types of modules that are in place and see how they were connecting there.

Two things that came out of this was not only was there a technical piece, but there was a procedure guidance or a policy so within the organization we helped the area that makes these policies, it was a VHA level handbook, so what I wanted to point out here is there is both technical and policy changes that a Health IT safety area could work with.

The third bullet down alerts, advisory and guidance documents these are areas that we work within. The first one is actually an alert that we produced most recently. I picked this one because this is about after the software, after the product had been out there for a while there was almost a, let's sit back and just let the software do it and it hadn't been maintained the mapping of terms and these happened to have been laboratory terms had not been continuously monitored.

So, this talked about quality management or continuous monitoring of the Health IT after implementation and what type of processes would need to be in place, this sort of speaks to where the SAFER guides are going for just something that we had detected and then we had to go through and send out an alert and have facilities then say, with this piece of software you need to go back and periodically make sure that this is up-to-date and actually, you know, put policies in place so that they have a continuous monitoring afterward.

We also worked on deployment strategies within other offices and understanding what needs to be in place in order to make sure that you can contain things as you move things along.

The most recent area that we've been asked to work within – I think this last one; this mobile App is developing an inspection and review process. Over our inception our first part of our role was reporting, receiving reports and being more of an investigator, receive the reports and analyze them and then give them feedback.

Within the last few years we have been recognized as an area that can help be preventive. So, when there was the notion of developing mobile Apps we're actually being called in now before products go out to give guidance beforehand and I see that as that tipping point of from a reporting to more of a prevention area.

So, I did put up here on the slide if anyone, you know, wants to look at it, is this is where we give a communication and the guidance it's not an alert, it's not a safety alert, it's more of an educational component and it was at a particular symposium where this was presented as both a poster and a paper, and, you know, educating the community not just internal to us but the external community. Next slide.

And then what I want to point out also is our educational awareness across multiple domains of interest, so in the – I always have to say short time period that we've been around, officially less than 10 years and the short amount of people, the different areas that we have touched upon, we have spoken to risk managers, we have been at the National Patient Safety Foundation so reaching out to the patient safety community to make awareness there.

We have reached out to the Human Factors and Ergonomics Society, so reaching out to the usability and the design of those common practices. We have also been working with the commercial vendors so not only internally to our vendors but also we've had product vendors after we've had to reach out to them and say, hey, you know, there's something with your product and we need you to work on it. How do we build a safety reporting system and an identification system into our house, into our IT Help Desk? So, we've been influential to those external partners as well.

And I believe that is probably the last slide, yes, it is. I wanted to kind of give an overview of just even with the small set of resources and in the short amount of time the areas that we work on over here in our program.

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

Thank you so much Jeanie. Questions?

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

Jeanie, this is Peggy Binzer, you know I'm a great fan of your program I think you're doing excellent work. There are a number of issues that I think that you folks might have already had experience with that really cross every hospital policies and procedures or just best practices for unplanned downtime for example is one issue that every hospital will have to look at and it's something that AQUIPS and NPSF are considering taking a look at.

Also given that there are bills that have just passed in the house and the senate having VA patients possibly be able to use Non-VA hospitals, are you considering or would you participate in the HIT Safety Center and share some of the learnings that you have developed for the VA system?

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

I would have to say I think that would all depend on how the HIT Safety Center would set up as a governance structure and how that would all be set up and I think I would defer that to ONC. There are a couple of different models that have been put out there.

I was fascinated with the way David Mayer represents the NTSB. I think it is premature to answer that, but I think there is a need there for public/private input into the HIT Safety Center and there are many different agencies and healthcare that can give guidance to the HIT Safety Center.

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

As a follow up question, you talked a little bit about implementation and I’m wondering if the VA has any process for certifying implementation across your hospitals?

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

And I would say we don’t have a process for that and I think that’s where we talk about that difference between guidance and regulatory. We have worked in the past few years to recognize that implementation is very key to understanding risk.

We are, if not the largest, the second largest integrated healthcare system, I can never remember the numbers between us and the military health system. I think we are the largest. When things happen in the VA folks hear about it.

So, we have recognized, over the past few years, about really beginning more structured implementation even with known HIT products that have been in the care environment anyone can go and Google CPRS glitch, I believe it was 2009, it was an upgrade and we were lax in which we sent it out and had an upgrade, it was a small upgrade but now we have redefined how to do these types of upgrades.

So, you know, to that do we certify an implementation, no we don’t certify one but we take a more structured approach towards implementation. And each implementation is different, it does have to look at what is the scope of what’s happening and what is the change that will occur at the facility level to determine what is the degree that there needs to be the resources involved with it.

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

Great, other questions? Okay, well thank you so much Jeanie, let’s move onto Ronni Solomon from ECRI.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Good morning everybody, can you hear me okay?

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

We can.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Great. Well, I’m Ronni Solomon and I’m the Executive VP and General Counsel at ECRI Institute and I also have overall responsibility for many of our patient safety activities at ECRI Institute including ECRI Institute PSO. I did not send the committee, the Task Force, a slide deck today but I did send a lot of materials that I thought would be of high interest to you.

So, I sent you information about our partnership for promoting Health IT patient safety. I sent you a deep dive into Health IT related events that we did about a year or two ago. I sent you the ONC reports for safe conditions, I figured that you have it but just in case I sent it, we did that as a subcontractor to Westat and I think it's got some very good information on there on the kinds of Health IT related adverse events, near misses and hazards that we're seeing.

I also sent an advisory from the Patient Safety Authority of Pennsylvania that's got some great information where we worked as a contractor to that organization. And I sent you our top 10 tech hazards. So, I sent you a whole lot of information but I thought it would be appropriate for your Task Force.

I did not send you something that ECRI recently issued which is, our top 10 patient safety concerns and I'd be happy to follow up with that.

By way of background ECRI Institute is a private not-for-profit organization. We are independent so we're not owned by anyone. We have about 425 employees. Our mission is to improve the safety, quality and cost-effectiveness of healthcare.

For many activities we work as a science partner with the government so for example we work as an evidence-based practice center looking at the evidence of technology and looking at the evidence behind patient safety practices.

And we also work, you know, as a safety partner here in the Commonwealth of Pennsylvania. So, we work as a government contractor and subcontractor on many activities and engagements. Obviously, we have no regulatory authority and we view ourselves as a learning agency and in fact we have a motto about our work share, learn and protect.

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

Ronni, this is Michelle, I'm sorry, we're getting a little bit of an echo I just want to make sure that you have your computer speakers muted.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Oh, thank you, let me just make sure. Give me a second Michelle.

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

Okay.

Rebecca Armendariz – Project Coordinator – Altarum Institute

Ronni, you can click the green button at the top of the web meeting room to mute your speakers.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

I'm looking for that, okay got it.

Rebecca Armendariz – Project Coordinator – Altarum Institute

Great.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Okay, okay, now is it supposed to be green or not green?

Rebecca Armendariz – Project Coordinator – Altarum Institute

It's supposed to be not green.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Okay is that better now?

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

It does seem like it's a little better, thank you.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Okay, let me know if I need to adjust again. So, in terms of history we do have a long history in working with patient safety reporting systems and it goes back to about 1971 when we started a voluntary problem reporting program for medical problems, it was actually the pilot for a later FDA program and we call that our problem reporting program, it's still in effect and as a result of that program we issue hazard reports, so it's a very high touch program.

We do independent validation of all the reports that come in. We have laboratory for testing products. We have a large engineering staff. And like the NTSB since 1971 we've been investigating medical product problems. So, we actually go on site and do investigations, we do these mostly under contract with providers or provider organizations sometimes with others like medical examiners and in fact just recently David Mayer, who you heard from earlier, was one rotational assignment here at ECRI Institute, so we were sharing best practices about doing investigations and working on safety programs and we continue to work together.

Since 2003 ECRI has been the contractor for a statewide program in the Commonwealth of Pennsylvania that looks at adverse events and near misses, it's a mandatory program, it's very high volume so we get about a quarter of a million reports a year on that and we have a large team, multidisciplinary team that works on that.

And since 2008 we started a component PSO, ECRI Institute PSO, and through that PSO we work directly with many hospitals and provider organizations but we also work with many other PSOs so we're a, I guess, what you could call a super PSO where we aggregate and analyze data across many PSOs.

We've always focused, just because of our technology and engineering expertise here at ECRI, we've always focused very heavily on emerging technologies not just the unsafe parts but the innovation and the promise that they bring as well as the risk and the possible safety problems. And so because of that we really began to take a look at HIT related issues, oh, you know, a few years ago, maybe in about 2011 as those technologies began to really diffuse and roll out.

So, as a result we did things like our deep dive, which I sent you, and through the Pennsylvania contract we did an analysis of the many reports in that database. And as a result we for about the past year have been working on putting together what we think is a very exciting and hopefully will be a very valuable collaboration pulled apart for Health IT patient safety and that's a multi-stakeholder learning collaborative, it's been officially kicked off. We are beginning to get data so it's quite exciting.

And the purpose of the partnership is it's really pretty basic, it's to make healthcare safer by understanding and mitigating Health IT hazards and safety events. We have many provider organizations and vendor organizations and experts, in fact some of you on the Task Force are involved in this and we're very grateful.

ECRI is a convener but we're also participants. So, we are contributing our data that we get from ECRI Institute PSO on Health IT events. We're beginning to get information on HIT, we're not just beginning we've been getting it, but now through the partnership we're getting it at a deeper level.

So, the kinds of data that we're getting include what Bill Munier, what Dr. Munier, was referring to earlier, we're getting data through the common formats, standardized reports. We're also getting data through another standardized system called the Health IT Hazard Manager and ECRI was involved in beta testing that system a couple of years back under a subcontract with AHRQ, Abt Associates and Geisinger was also involved in that and now we've built that out of it and we've incorporated it into this partnership for Health IT safety.

So, we're now getting reports using the hazard manager which is a very deep ontology and taxonomy for collecting not just adverse events and near misses but hazards. We're getting things like Help Desk calls, reports of Help Desk calls I should say. We're getting alerts that hospitals share internally. We're getting root cause analysis. We're getting investigation reports. So, we're very heavily in the data collection stage and have analysts who weekly pull together and assess and analyze this information. So, we're starting on that journey.

What we're seeing is that there is still a lot to learn. Some people might say that, okay, we know a lot of things about Health IT safety so we know what to work on, you might already have an agenda. Others might say, that we need a continuous dream of robust reporting to stay on top of what's going on and on top of what's emerging and I guess personally I would fall into that later camp, I think that we need to have good reporting systems in place because they are one way to get that data.

But what we're also seeing is that we learn a lot not just through standardized reporting fields but through things like RCAs, through things like the narrative information that we get in our standardized reports.

So, as a PSO, as a portal PSO but also as a patient safety organization, you know, in small caps, you know, what ECRI has been doing 40 years, we find that we have to – we look across all of the events and problem reports that we get and we often have to ferret out what might be IT events.

A nurse on the floor may not report an event as an IT event they might report it as let's say a medication error or we might get a missed misdiagnosis and our team has to ferret through events to see if IT was a contributing factor and that's something that takes, you know, time, effort and talent.

So, we still, I think, have a lot to learn, we need to know what's going on. I think we need to spend a little bit more time looking at near misses and hazards because that's a proactive way of looking at things before harm occurs. We can find out what the modes of recovery are which is very valuable.

I think that it's so important to aggregate the data across multiple organizations, I think that provides value for provider organizations; it provides value for developers and for vendors. We have to look at usability issues I think that's going to be a big focus of ours for the next couple of years.

I can say a bit more about how this partnership will work it really is structured in three phases I'd say. So, we've got data collection which we've started with and which will be going on for quite a while. We have analysis. And what we think is innovative about this is that we've taken expert opinions and evidence into account and we've brought vendors in as collaborators on this project, on this collaborative and we think that that's a really important step.

So, AHRQ has published FAQs on how developers can participate in the Health IT safety world and we've followed up on that, so we have Health IT vendors that have come in as analytic contractors to our PSO so that we can really have a multi-stakeholder environment.

We have IT experts, human factors experts, implementation experts and we're going to collaboratively analyze the data looking for lessons. And then once these contributing factors are identified and once we begin to see trends and identify issues, and prioritize them we will reach out through the many professional societies and professional associations that have become a part of this so that we can disseminate. And engagement and dissemination are absolutely key so we need a lot of help with that.

I understand the challenges of setting up a Health IT safety center because there is just so much to accomplish and it really runs the gamut from engagement and shining a spotlight on things to analytics, to looking at the evidence to having the infrastructure and the tools, and the standardized systems, and then of course the dissemination and the ability to make change and sustain that change. So, it's a tall order. So, I guess those are the remarks that I had and I'd be happy to take some questions.

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

Thanks so much Ronni. Let me just ask you one thing, which is with the device work that you do how is de-identification managed? I mean, it seems like it would be very valuable to know exactly which device is involved, similarly, you know, with electronic records it's often valuable to know which record was being used.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Yeah, on the device side the programs that we've had for 40 years are confidential about the reporting provider and institution, unless that reporting provider or institution wants to be transparent. We do include product names and of course, you know, it's a somewhat different environment because you have FDA regulation and hazards and recalls. One of the things that we do is track hazards and recalls.

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

Thank you other questions for Ronni? Well, I'll ask you one other one. In the partnership work you talked about three stages were they data collection analysis and then dissemination?

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

Yes.

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

Okay.

Ronni P. Solomon, JD – Executive Vice President & General Counsel – ECRI Institute

And we are in phase one and phase two is overlapping.

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

Okay, any other questions from members of the committee? Okay well hearing none I just want to thank all the presenters from today this has been enormously helpful. In our next meeting we'll be hearing from several other groups and Michelle could we then go to public comment?

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee 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're 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 W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety – Brigham & Women's Hospital & Partners

So, thanks again to everyone and we'll be talking again soon.

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

Thanks, David, have a nice weekend everyone.

M

Bye-bye.

W

Bye-bye.

M

Bye.

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

Bye-bye.