



HIT Policy Committee Certification Hearing Transcript May 7, 2014

Attendance

The following Workgroup members were present:

- Carl Dvorak
- Paul Egerman
- Jennie Harvell
- Joseph Heyman
- George Hripcsak
- David Kates
- Michael Lincoln
- Nancy Orvis
- Marc Probst
- Donald Rucker
- Paul Tang
- John Travis
- Charlene Underwood
- Larry Wolf
- Michael Zaroukian

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a Certification Hearing sponsored by members of the Implementation Workgroup on the Health IT Standards side and from the Health IT Policy Committee side it's also sponsored by the Certification and Adoption Workgroup, and some members of our Meaningful Use Workgroup. We are going to go around the room to do roll call today. Let's start with David Kates.

David Kates – Senior Vice President, Clinical Strategy – NaviNet

David Kates; I'm on the Implementation Workgroup.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Charlene Underwood from Siemens I'm on the Meaningful Use Workgroup.

John Travis, FHFMA, CPA – Senior Director & Solution Strategist, Regulatory Compliance – Cerner Corporation

John Travis, Cerner, I'm on the Implementation Workgroup.

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

Don Rucker, Ohio State, Certification and Adoption Workgroup.

Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman, Certification and Adoption Workgroup and Policy Committee.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Larry Wolf, Certification and Adoption Workgroup.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Marc Probst on the Certification and Adoption Workgroup.

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

Paul Tang, Meaningful Use and Policy Committee.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Mike Zaroukian, Meaningful Use Workgroup.

Lee Stevens – Policy Director, State Health Information Exchange Program – Office of the National Coordinator for Health Information Technology

Lee Stevens, Interim Director of Certification at ONC.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

John Derr, Adoption and Certification Workgroup and Standards Committee.

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Jacob Reider, ONC.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

Judy Murphy, ONC.

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

Thank you everyone, just a few more administrative things. I'll remind you a few times today, but when you do speak if you could please state your name before speaking as the meeting is being transcribed and recorded.

Also for our panelists I'll remind you and you'll see it throughout the day, but if you could please keep to the five-minute testimony we'd greatly appreciate it. I hate having to cut you off, but I will. There will be a five minute time clock counting down for you so you'll be able to see that as well. And with that I'm going to turn it over to Paul.

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

Yes, thank you Michelle and good morning. This is going to be a very informative hearing. It is a topic that's important to all of us whether you're ONC, CMS, vendors or providers it affects all of us and it is one of these programs that we'd like to get right.

Meaningful Use has been extremely successful at least in my opinion we've gone from 0 to 60 sort of from the provider point-of-view and maybe close to 90% on the hospital side. And one of the prerequisites is that you must use a certified EHR and therein maybe lies the rub.

The goal for certification, I think we all we would agree with, one to have a minimum amount of functionality, this is a floor not a comprehensive definition, but a floor, minimum amount of functionality that would help us achieve the goals we have, the mission we have for advanced care models.

We need to follow common standards so that we can exchange health information with each other. One of the ways we try to assure that is by having test scripts and that is maybe where we are getting into some trouble because in starting up a new program there are a lot of things that you learn but the positive thing here is that we want to learn how to improve the program going forward.

So embedded in a test script sometimes it looks like and sometimes it actually is a specific way of doing a specific job and in a specific workflow and that's partly I think unintentional but it trickles down and then it ends up affecting everything down to the provider's workflow which causes a lot of angst.

What we'd like to do – and sometimes the other part is sometimes the documentation or the proof that you've done something is actually either more onerous or more costly than actually doing the functionality or using the software.

So our purpose of this hearing is to be forward-looking. We need to understand where things are working and where there are challenges and we're asking all of the panelists to help point us in the direction for how would we improve the program so that it accomplishes the things that we need in order to work in the new care model and also importantly to be interoperable so that we can exchange health information in a meaningful way. So, that's sort of the focus and that's sort of the approach and perspective we'd like everyone to take and we've given that out in our questions and we look forward to everybody's contribution to that objective. Let me turn it over to Mike Zaroukian for further comment.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Yeah, so good morning and again I'd just like to add my thanks and appreciation for everyone joining or participating. Thanks particularly to those who will be providing testimony today, very thoughtful comments shared in advance.

I think we're going to hear a lot of themes that will at times recur and that's important to hear. It's also then important also to make sure that we're focusing on some of the great suggestions and solutions that are proposed and so, again, thanks for bringing your experience, your expertise and your suggestions to the meeting.

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

Just a word about our process. We're actually – ONC is so anxious and intent on listening to the feedback and want to act very quickly, meaning this year, that we had this hearing and some of you know that you got asked to participate in the hearing on short notice.

So, we had this hearing this month but we're actually going to have a debriefing tomorrow morning so that we can get our recommendations out very quickly so it can go to ONC very quickly and they can act on it or at least look at it and review it as input to their process.

So with that I think we'll get started with Lee Stevens who is part of ONC and I think the Interim Head of the Certification Program who will give us an update on their current thinking and part of their request for input from this larger group. And anybody else in ONC want to make a comment?

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

I'm sorry, I'll remember someday; there are folks on the phone that I forgot to mention.

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

Yes.

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

Maybe we could just have them name themselves. I saw Michael Lincoln and Jennie Harvell, George Hripcsak. Is there anyone else on the phone?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Yes, Carl Dvorak joined from the Certification and Adoption Workgroup.

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

Okay, thank you, sorry about that.

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

Okay, on worries. Okay, Lee?

Lee Stevens – Policy Director, State Health Information Exchange Program – Office of the National Coordinator for Health Information Technology

Thank you. I wanted to give a brief overview of the Certification Program and a few key definitions. So, we use so many acronyms it might help to understand a little bit more about what we're talking about.

So first I wanted to take you through the certification process and there is an ONC sequence and a CMS sequence. When a developer creates an EHR there is typically an intention to meet certification criteria. The developer submits the EHR to an ATL, which is an Accredited Testing Laboratory, that actually does the testing for the criteria and they generate a test report.

The developer then submits the test report and other documentation to a certification body. So, ACB is an accredited certification body and the ACB issues the certificate for the scope of the capabilities that have been tested.

The next phase is that the ACB will then submit the certified EHR products to ONC and we will list them on the CHPL which is the certified list of technology that meets certification criteria. We are constantly in the process of updating the CHPL and creating new functionality.

Really the permanent certification program now is really only about a year and a half old. We had a temporary program going prior to October of 2012 and we are now looking at how we step back find out what's working and where we want to go in the future with the program. So, the CHPL is a part of the improvements we are making.

The next part of the process is the CMS sequence and this is really where the eligible provider, the eligible hospital or the critical access hospital selects a certified product from the CHPL that can then be used to demonstrate Meaningful Use and that generates a CMS EHR ID for the selected product.

The provider then submits that certification ID to CMS as a part of MU attestation and CMS validates as part of the process. This is really – I have to thank Steve Posnack for putting this together in such a concise way. It's a lengthy process but we've managed to get it all on one slide.

The test method definition here is another critical component. When we think about testing and certification program you might hear us refer to a test method and that actually is three-parts that equal a test method, that's the test procedure or the test script, that's the test data and the test tool.

The tools are mostly at NIST, the National Institute for Standards and Technology, we work with them frequently to assess how the tools are working. We have launched – we will have a total of 10 tools this year and I think one that will probably come up for discussion today is something like the EHR randomizer that's a relatively new way of testing and we've been working very hard to improve that process as well.

So, with that I just wanted to sort of lay this groundwork so when you hear ACB, ATL, CHPL test method have little context. Thank you.

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

Thanks, Lee. Any questions of Lee?

Okay. Our first panel is one made up of providers and HIE organizations and Mike Zaroukian is going to moderate that.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, thank you. We a total of six panelists who are joining us virtually and so Michelle can we confirm that our first two are here? Great, so that's great. So, just by way of background I'm a primary care provider, I'm a CMIO at a health system, academician at Michigan State University, so I'm living in the same world that the first panel is living is as well as some work in the other spaces.

So, thank you first and foremost from the provider and HIE sector for coming to present and we're going to start with Ginny Lorenzi. Ginny you may go ahead?

Virginia (Ginny) Lorenzi, MS – Manager, HIT Standards & Collaborations – New York Presbyterian Hospital

Hi, this is Virginia Lorenzi or Ginny, thank you for the opportunity to testify today. I want to note that my opinions are my own but are not necessarily those of my employer. And speaking of employment I'm employed at New York Presbyterian Hospital and have been implementing HIT for 20 years there and over the last few years I've been implementing regulated HIT and making Meaningful Use of it.

New York Presbyterian Hospital seems to really like health information technology we have a whole lot of it and we've been really busy preparing to attest for Stage 2 in the fall and we're using a component approach which means we have multiple certified products and we also are doing some self-certification.

So you had asked me a few questions for my preparation and the first is what I like and this is no secret but I'm a big HIT standards advocate so I'm so excited to see standards being built into EHRs at doctor's offices and hospitals across the country. I believe it's transformative with respect to interoperability and information reuse.

Another thing I really like is, as being someone who is participating in the certification program, I find that it offers support to those going through the process. There are implementation guides, there are tools, there are forums and there are handholding certification organizations you know, like IPSA and Drummond, and before CCHIT that are so helpful and provide real-time interactive guidance on the certification regulation and process all the way through.

You also asked me about quality and I'm going to say something very positive here in just the fact that I've noticed a great improvement in quality from the 2011 process to 2014. I'm very impressed, for example, how much more rigorous the testing got with CQMs.

And then of course the most fun question was challenges and I want to quote or paraphrase the Institute of Medicine's report, The Health IT and Patient Safety Building Safer Systems for Better Care, that was published in 2012.

In that report they talk about how this vendor system is part of the equation but the other part of the equation, where I've been living for 20 years, is implementing that system and that report goes ahead and tells how, you know, based on how you implement a system it could improve quality and safety or it could pose serious risks to patients and I know you guys really care about this, you have a whole section on your website devoted to HIT patient safety giving me advice on how to write EHR contracts and determine how to integrate EHR around workflows and how to reduce unintended consequences of these EHRs we put it into provider's sites.

So, but my problem is with certification it's like you get the football halfway down the field and there I am on the football field alone. We don't get any of that interactive handholding and detailed question and answering that the vendors get. We are left in the dark and unclear how to implement our systems in our unique environments to meet the Meaningful Use requirements. All you good work is in vain if implementers with certified HIT don't get better support.

So, for question four, so how would I design a certification program that would achieve benefit and minimize burden on participants? Well, I guess what I would try to do is maybe not do so much but what I did choose to do I'd see it through. I'd find a way to help with the whole process with EHR development through provider implementation all the way to Meaningful Use and that's my testimony. Thank you.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you, questions or comments from the group? We have time for a few.

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

You might want to go through everybody and then –

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, will be happy to do that. Okay, so thank you for those comments. I neglected, on page two, to make sure that everyone who is participating today understands the four questions that the provider and HIE speakers would be talking about, so the first was assuming we could design an ideal program what is the benefit of certification program from the perspective of your organization and how does the certification program help you, and what are you looking for in a certification program.

The second was, currently certification indicates that certain capabilities exist in an EHR and would certification ever indicate a level of quality per se? What are the challenges you have experienced with the current certification program and of course how would you design a certification program that would achieve the benefits you seek while minimizing the burdens to the participants?

So, again, thank you for that. Our second speaker is Chad Jensen from LaTouche Pediatrics?

Chad Jensen, MBA – Executive Office Manager – LaTouche Pediatrics, LLC

Thank you for allowing me to participate today. I'm Chad Jensen from LaTouche Pediatrics in Anchorage, Alaska. It's nice an early here this morning.

The certification program is a major benefit and helps us by allowing us to have a level of confidence that the EHR will meet certain level of guidelines and shows that the vendor has a level of commitment to meeting those standards and is committed to meeting Meaningful Use for us. And as a business every dollar we spend on EHR is extremely valuable.

And the certification helps indicate if we are spending our money on a quality product that is going to give us value and this helps us assure we keep the healthcare costs down by only spending money on a product that's going to meet the standards and at least have some indications that they are going to be around for a while. But in the end it allows us to ride the highest quality of patient care while keeping costs down and our end goal ultimately is to give the highest quality care so the certification program helps us by showing that if we use this product it's going to give these benefits to provide that high quality care.

But what we're really looking for is that the certification not only ensure us that EHR will meet those standards but also indicate a quality of meeting those standards and for me I believe that this is the major piece and challenge that is missing from the current certification program. While the EHR product may meet the certification program there are some components of the workflow within the product that does not work in any setting and while I understand that it's going to work fantastic in some settings, it's not going to work in other settings.

But there are other components I've seen within some products where it just doesn't work at all. So, for example, here are a couple that I've run into, some of my challenges, printing inside the EHR there is a requirement that you have to be able to provide third-party education out of the EHR product as well as the education print out six pages for a paragraph's worth of education and the vendors are saying, well it meets the measure, it's not a major issue for them to fix because they've already moved on.

So, I think that this is, for me, part of where that quality to only make it part way, like the previous panelists said, if you get to the 50 yard line and sort of stop. So, I think having that quality is really important.

And then testing more, for our Direct secure messaging it does do it, but it just doesn't work for the State of Alaska or some other states that have certain statutes. So while I think that the IT portion is there, the testing out in the real world isn't necessarily there on multiple standards within certification and I think that that's the biggest challenge and I would encourage that the quality become an indication of quality on a scale for meeting measures is introduced and as such I would actually redesign it, the current certification program so that it actually puts more burden on the vendors not less.

I know that there's a feeling of a lot of burden but I think that what's happening now is that there just – the burden is just to get the check box and not to get to that end goal of providing a quality product all the time while many times it does, but not all the time and so I think I would like to see something where I could say, hey they met really high marks in all of these area, but for these certain areas they didn't. And so for me that would be the major thing I would change about this current standard and certification program. Thank you for allowing me to share and that's all I have for those questions.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you very much. Okay. We'll now move on then to John Berneike of Utah Healthcare Institute. John, thank you for coming.

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

Thanks, Mike. John Berneike, Family Physician at St. Mark's Family Medicine in Salt Lake City. I actually have an IT background, Mike, did my undergraduate and computer engineering at Michigan State many years ago. But I think I'm here today representing the small independent private practice sounds like our previous speaker was in a similar situation.

You know all of us here we obviously know there's been a big paradigm shift in what we expect EHRs to do, you know, going from electronic SOAP note generators and data repositories to all the new functionality we're looking for in terms of chronic disease management, preventative care management, population health management, care coordination and transition of care, exchange and interoperability is a huge issue and patient engagement like education and self-management.

These new functions that we're asking EHRs to do require a lot of new implementation by the EHR vendors that had previously not been there. Some of the issues that I struggle with are the reporting, tracking registry and analytics functionality within the EHR and that's a lot of the same issues that come up in terms of the Meaningful Use certification.

I also think that it's important and I know ONC can't do anything independently in this regard, but I think it's extremely important that you continue to work with the other organizations within Health and Human Services for coding, billing, payment reform, you know, we're still stuck in a world where coding, billing and payment depends on how we document a visit and that's still back in the paper world and that needs to change if we're going to effectively use what could be done with EHR technology.

I also think that it's great that ONC is serving kinds of as the de facto standards organization for EHR technology, you know, the rapid pace of Health IT adoption that we're looking for in the system-wide changes that we're trying to effect, you know, that is beyond the capabilities and scope of any individual software vendor and so there has to be some outside influences to help drive the functionality and the changes and the standards, and definitions that we're looking for.

Like the two previous speakers said the human factors or usability issues are a huge part of the problem and as the previous speaker said, you know, the certification process currently is kind of geared towards the vendor checking the boxes to say "yes the functionality can be met" but it doesn't talk about how it can be met, you know, how easy is it, how effective is it for the end user. And so I would like to see, you know, the certification program definitely include some type of quality measurement and quality being measured in terms of the human factors end user usability pieces of it.

I think another benefit of the certification process for me, as a small practice, most small practices probably do not have the skills or the resources to do a thorough vendor evaluation on their own and they can use the certification process kind of as a surrogate for that so that we have the confidence to make a good choice based on, you know, the vendors meeting the certification criteria and even possibly, you know, if again in an ideal world if it would include quality measures as opposed to just quantitative that would go a long way to helping the small providers make good choices for EHR products.

Challenges that I've had include, again I mentioned it before, but the interoperability and exchange issues continue to be a burden even though the vendors have presumably met the requirements. Implementing it is another thing at the end user level.

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

Thirty seconds.

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

Okay, thanks, last comment, in terms of minimizing the burden, again, as a provider I'm less concerned with the burden of the vendors for certification. What I am more concerned with is the burden on myself as the end user to use the product and I think that has to be a major shift in the certification process. Thanks.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you. Okay, our next speaker is Dr. Colin Banas from Virginia Commonwealth University. Good morning.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Good morning, thank you Mike. Members of the committee thank you for allowing me to participate today. I'm Colin Banas from Virginia Commonwealth University here in two capacities, one as an internal medicine physician, and a big believer in the benefits of Health IT, and the second as the CMIO for VCU Medical Center in Richmond, Virginia.

So, let me first start by saying that I am thankful for the framework that Meaningful Use has brought to the landscape of healthcare and by proxy thankful for the oversight and contribution of the ONC in this landscape. I do, however, have some opinions on how to make it more facile, flexible and less burdensome for patients, providers and vendors.

To be fair my experience with the certification program has been limited. Most of the knowledge and perception of the program is painted through the eyes of my vendor. We have indeed contemplating modular self-certification in the past but ultimately did not pursue.

The reasons, number one we've incurred great cost already in our current vendor-based solution and of course VCU is not alone in this practice. We rely so heavily on vendor certification and processes that it often locks us into non-value added requirements simply to satisfy the report that demonstrates compliance with the attestation measure.

The second reason for not seeking self-certification is that research had revealed a prohibitive expense in terms of man hours and dollars, a timeline taking months and an excessive test burden to achieve certification. In short it appears something that is best left to the vendors and large custom institutions seeking certification for an entire EHR. It does not appear to be friendly for users who have a need for singular modular certification performed for unique solutions or workflows, whether these are legitimate reasons to avoid participation remains to be seen.

Perhaps we can learn as much from leaders and expertise in this room as the committee hopes to learn from VCU. It is important to note that whether these suppositions are true or not it is the perception of my colleagues that this is so. If nothing else I would suggest better clarity and education around the certification process, specifically in the instance of the one off phenomenon I have described.

It is also my belief that there is continued confusion regarding the blurred lines between a certified technology and how one uses it to achieve attestation. In examples in my written testimony one can see how certification drives the manner of adoption for attestation in an unintended way.

The biggest challenge with the current certification is that there is no guarantee that the certified EHR product will result in a clinician's ability to meet MU requirements especially for veteran users of this technology with years of pre-existing customization and concrete workflows. As the adage goes, if you've seen one EHR installed you've seen one EHR install.

I also want to point out that very often meeting the measures outlined in MU can require data and input from certified systems such as disparate billing, registration and scheduling that the certification process does not and most likely cannot take into account all of these variables.

Providers often feel obligated to rip and replace these ancillary systems at great cost simply to plug into the workflow which was certified against by their vendor. To quote Dr. DeSalvo, EHRs are like giant battleships with a variety of functions and customization that have been layered on over years and a one-size-fits-all approach simply cannot work for every clinician that shares a particular vendor-based EHR in this country. It is difficult to turn a battleship on a dime and I believe this very truism is why the certification program exists, I just wish it was more simple.

VCU has a number of examples where the health system already meets the intent of the measure but our certified technology was approved for said function in a different manner. It would be impossible to estimate the amount of research and development hours devoted to re-adjusting clinical workflows and code in order to be able to satisfy a report which was achieved in the vendor certified workflow and technology even though we are clearly satisfying the clinical intent of the measure. I cannot stress this enough. It is fear that drives this process for clients, fear of audit, fear of penalty and fear of vendor abandonment should a client choose to forge a different path.

The tenure of the MU program has started to shift, the exuberance over the prospect of new technology to benefit our patients is slowly eroding to a state of fear, fear of being penalized for failure to comply and at times it feels as though VCU is being penalized for being an early adopter of EHR technology.

A simple look at the collaborative web space that a vendor offers clients reveals that we are not alone in our frustration and in fact a new phenomenon has emerged as a byproduct of MU and certification which I title "Code Chasing."

Clinicians and hospitals are forced to load and test code at an unprecedented pace and even a best intention code can introduce a different problem elsewhere in the system forcing the client to choose between the lesser of two evils. I am not sure it is fair to place blame on the vendors in instances like this, I believe it is a direct correlation with the changes of certification and attestation requirements and the litany of “ah ha” moments that occur as real users attempt to use these technologies. I see I’m out of time so I will save the rest for Q&A.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you. All right. So, our next speaker is Dr. Howard Hays from the Indian Health Service. Welcome, thank you for joining us.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

Good morning, thank you very much for the invitation to participate here. My name is Howard Hays I’m a family physician by training and I’m also, for three years now, the Acting Chief Information Officer for the Indian Health Service, a federal agency that provides healthcare on Indian reservations across the country and in that role I function both as a vendor and as a provider because we supply a certified EHR to our users across the country.

I will try to constrain my comments on this panel to the provider perspective but inevitably some vendor stuff will probably leak into it. The first thing that I would say is what they said, the committee is correct that you’re going to hear themes and I agree with the comments of the people who have spoken before me.

With respect to the first question about does certification do? From my stand-point a certification program basically offers assurance that an EHR product meets some basic objective functional requirements and as a starting point for the shopping list for a hospital or practice, they check the certification off and then they begin to compare products on functionality, life cycle, costs, supportability, configurability that sort of thing. So, it’s the starting point.

On the other hand an ideal program could also serve to help doing like to like comparisons between products and help the consumer know that the product does what the vendor says it would do for all the value adds that the vendor is trying to sell you the product are you actually getting a real value, a real functionality here or is it vaporware. So, helping people to compare products on like functionality would be helpful.

The certification program should not be so prescriptive that they force all the EHR systems to do the same thing they’re more useful if they help the customer’s distinguish the capable systems from those that aren’t capable.

The challenges, a lot of reflecting the same challenges, functions that add to the workflow, add time to the encounter but don’t really add value to the encounter and our main one was the requirement to provide clinical summaries in Stage 1.

Requirements to adopt and unrealistic timeframe, just there is so many – it’s easy to write you’re going to use Direct for this, but the adoption and on boarding with that is much more complicated than it looks on paper.

Requirement to implement incomplete standards, standards that are still draft standards for trial use or haven’t been fully vetted in the marketplace but are required for implementation and similarly requirements that have hidden costs or added costs beyond the cost of getting the EHR “oh, we’ve got to join an HIE now and what’s that going to cost us.”

Inability for users to configure the system to their business workflow because there is a certification constraint, if you do that it's no longer a certified EHR. And inability for the vendors to be responsive to the user enhancement request because they're totally focused on certification "sorry we can't do that now" and that's my mantra to my users I can't do anything you're asking me to do right now because I'm focused on certification.

And any requirements that limit the vendor's ability to innovate and I'm speaking as a user here. I want to see innovative products but if they have to go to this standard that's certification then I'm not seeing it grow where it could grow.

With respect to the question about certification and quality, certified software does not equal quality software. Certification only means that the developer could make it past the test scripts. I think ugly software can often do the job quite well and very slick looking software can easily force inefficient workflows or workarounds that are time consuming and risky to patient safety.

I think the user centered design is an important part of certification but it's going to be hard to do that for every piece of the certified product so, you know, they pick the high risk ones for 2014.

Also, I don't think the quality is just about the user facing interfaces and the usability functions, it's about the data, is the data accessible and usable for analytics, how easy is that data to get to because there is a wealth of data in the back end of the system that the users need to be able to get to and does that add cost.

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

Thirty seconds.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

Yes, Ma'am, with respect to making certification work I think you need to find a balance between the essential functions that need to be present in an EHR and then allowing for innovative capabilities that allow vendors to distinguish themselves in the marketplace.

It might be worthwhile to consider levels of certification, sort of a bronze, gold, platinum kind of thing to where the bronze is what's necessary for Meaningful Use but then the certification can be allowed to compare and I have more but not a whole lot more, so thank you very much.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you, okay; our last speaker for this segment is Cletis Earle from CHIME, thank you very much for coming Sir.

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke's Cornwall Hospital

Thank you and good morning. I'm addressing the committee and I would like to thank the committee for allowing me to speak but addressing it from a different perspective. I am the CIO of a Health System in Hudson Valley New York.

What I like about the certification process is, you know, in our region we've been diligently working towards the Triple Aim and figuring out how we're going to address healthcare from a perspective of population management.

We understand that we no longer can survive as a small system, which we are, and we have to actually communicate and work with other care providers in our community, physicians, you know, sub-acute care facilities and by having the Meaningful Use in these standards it has allowed us to have a platform for sharing that information across the continuum allowing us to actually get in front of the initiatives that we see as far as care coordination and working together collaboratively with a lot of our stakeholders and again provide better care outside of the four walls.

From a quality perspective what the certification piece I think addresses and sometimes misses is that it requires EMR, you know, systems to push in at times frivolous data and, you know, you've heard that same theme throughout, at times there is information in our systems that in essence don't necessarily reflect truly what the physician basically wants to do taking care of a patient and that provides a problem and I think from a perspective of how do we address that we do need to deal with issues such as cut and paste and actively figure out how that's going to be addressed moving forward because that does create huge quality issues as we deal with patient care.

Some of the challenges, you know, I see from the certification process is the certification it's not establishing reliable code, you know, from our vendors, you know, time and time again we are held to some standards as far as trying to attest to the Meaningful Use Stage 2 that we have to actually wait for our vendors to catch up.

There are many pieces that I don't know if some of you are aware of, but vendors are behind the eight ball when it comes to providing code. What I mean by that is when there are changes there is a significant amount of patches that the provider has to do to, you know, make those changes occur.

As an example when we had to go for Meaningful Use Stage 2 we actually had over 10,000 different codes, you know, patches that we had to go for and then in a matter of a few months later or a month later we had to do another revision to that of about 6,000 to 8,000 codes, patches and those are resources that we don't have and I'm pretty sure I speak for many of us that we don't have those types of resources to accommodate such changes.

The regional extension centers and the HIEs are also challenges, you know, as we are required to connect via CCD and other methods we're finding many complications with doing that so much that, you know, I have rallied the troops of other CIOs in the state to basically, of common platform EMR systems, to basically go and force the hands of our vendors and our regional extension centers to basically allow them to work together collaboratively because they have other vendors that they have to deal with and other challenges, so that's a big issue for us.

So, in essence from a CIO perspective I can't imagine how other states are dealing with some of the challenges they have various EMR systems it's very tough. It doesn't seem like anybody has enough resources to deal with the various changes to certification.

How to achieve it, I believe that if we focus more on usability and not allowing the interpretation of the standards which is you could go from site to site whether it's physician practice or healthcare system everybody has a different interpretation from state to state, there are different interpretations. I believe that we need to figure out a different methodology of how we address that.

Also we need to understand that early adopters should not be penalized as you've heard in other common themes. It seems as if, you know, when we – we are all early adopters, we're making changes and our vendors are making changes at the last minute and that it requires us to, you know, change it and dedicate resources to accommodate those changes, it's very difficult. Thank you very much.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you. Okay, Michelle?

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

Before we open up to questions, I just want to remind folks on the Workgroup if you could state your name before you ask your question and to our panelists if you could state your name when you go to answer your questions, and for the Workgroup members on the phone if you could use the hand raising feature and I will put you in the queue for your questions as well.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay. Questions or comments? Paul?

Paul Eggerman – Businessman/Software Entrepreneur

Great, as soon as they get this microphone working, great, thank you very much these are great presentations and I really appreciate the effort everybody put into this and I noticed going through the Bios that Chad is calling in from Anchorage, Alaska and so I want to give you a special thank you Chad for your dedication because I suspect it's several hours earlier in Anchorage, Alaska and I really appreciate your dedication.

So, I have a couple of questions, but first for Chad and for John. You've talked about quality, certification quality and I'd like to make sure I understand what you mean when you talk about the quality of the software because it can mean a lot of different things. It can mean that the software just has bugs or it's just the software is hard to use or that the software is just not useful to you or, you know, it's just not effective for you.

So could you just, first with you Chad, could you explain when you talk about quality what you meant by the word quality?

Chad Jensen, MBA – Executive Office Manager – LaTouche Pediatrics, LLC

Sure, I think for quality for me would be stability of the product, does the product – does CDS constantly go down, when you do try to go do education type material do you have to wait 30 seconds for it to pull it up and it's not – you know, a user side issue but whoever is pulling the data from the vendor's side.

So, I think those types of qualities, mostly usability not so much – I think workflow could be a challenge to do but if you have to do 10 clicks to get to something I don't think that that's quality, but if you have to go to another screen, you know, that you may not go to all the time, I think that would be more acceptable.

But more time to take something to do I think would be a good quality measure, do you have to do anything, do you have to wait a significant amount of time and I would say that even 30 seconds to wait for something is a significant amount of time within a practice when you have a patient sitting there waiting and you're trying to pull up anything as simple as patient education or the system being so unstable that you can't even count on the CDS alerts because it's down again this week so the alerts aren't being cleared and the providers end up getting alert fatigue and not even using those certified portions of the product any longer. So, I think those are clear indicators of a poor quality within a product.

Paul Eggerman – Businessman/Software Entrepreneur

Great and John could you also?

John A. Berneike, MD – Clinical Director & Family Physician St. Mark’s Family Medicine - Utah HealthCare Institute

Yeah, similar to what Chad said, you know, when I talk about quality again I’m talking about the human factor’s usability point-of-view is it easy to achieve the intended result through efficient, effective workflow.

And again I think we also need to remember, you know, what is the goal of Meaningful Use, again from a provider point-of-view it’s not just to check the boxes on our end as providers so that we can get our Meaningful Use payment, it’s to achieve, you know, higher-quality, safer more cost-effective healthcare and, you know, having a tool that helps us do that effectively, efficiently with a workflow that, you know, fits the workflow of interacting with a patient, you know, so the patient is involved, engaged and the patient is ultimately getting the best healthcare as efficiently as possible and that’s what I mean by quality.

Paul Egerman – Businessman/Software Entrepreneur

That’s great.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

So, to jump in on this and maybe to the vendor defense a little bit and I’m not sure what the best form for this is, but I feel like the vendors often get stuck having to not only provide the function but then prove the function and in the proving of the function is actually what often diminishes the quality.

So a great example is I can use InfoButton technology in my vendor to provide patient education right from, you know, a beautiful HTML webpage type thing and it’s very slick but in order to get credit I have to launch a different form and record it in two different spots and then sign the form so that when the functional report goes and does it’s magic in the background it gives me numerators and denominators.

So, I feel like the over reliance and insistence on numerators and denominators might actually be a hindrance to the quality of the products that we are trying to implement.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Don Rucker?

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

Yeah, I have a question on functionality for Mr. Earle and Dr. Banas. So, sort of coming from the scope of function Mr. Earle you mentioned you 10,000 pieces of code and I was just curious if you had sort of a sense of – because I think the number of regulations, while large, is nowhere near 10,000, I think it’s maybe two orders of line item magnitudes less, so I wanted to get into that.

And then for Dr. Banas you sort of implied there was whole bunch of functionality that was sort of – you wanted to build on your own, maybe I misinterpreted that, and I was just curious about that sort of scope of function as we look at what to certify and adopt.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Mr. Earle?

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke’s Cornwall Hospital

Yes, again, yeah that's amazing, you know, the number, it doesn't basically equal to what you guys have, you know, composed but in essence there are so many variables associated in, you know, some of these systems it requires a significant amount of manpower and testing out. There are so many nuances associated to that.

So unfortunately, it is what it is, you know, as far as the different systems. I can't – and again, I know you said you're speaking on behalf of a vendor perspective at some point, I can't defend that because you have that variability in system design and some of the challenges associated with that, but I could just reassure you that the amount of work it takes to basically validate those systems and those processes, they're real and they're very painful to do that.

And again, in a sense when it can be changed month over month because a certified testing code didn't necessarily work in a real practical manner we actually are at the tail end as a result paying for those challenges and the work associated.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Dr. Banas.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Colin Banas, VCU, Richmond, Virginia. So, the innovation question or what you were sort of gleaning from the testimony. So, I have two perspectives, one, I absolutely believe regulatory reform has stifled innovation in the space of informatics, right, wrong or indifferent that's my opinion. I used to do a lot of really fun things as CMIO at VCU and I haven't been able to do those in about four years.

Number two when you were talking about custom workflows or when I was testifying to that, actually what I was alluding to is a perfect example in my written testimony. We have a standalone PAC system, I built a link into it from our vendor, 100% of the time you can see radiology images from within the EMR vendor, however, what the vendor certified to prove it is something that they – you know, a distribution license that they sell that satisfies the report because it writes out to a certain table, etcetera, etcetera, etcetera.

I do it 100% of the time. I have no doubt about it. I cannot provide the numerators and denominators requested by the program unless I buy the distribution license, which I have no clinical need for, or I go through self-attestation, which quite frankly I don't know enough about it but when we looked into it in the past it scares the heck out of me.

I don't have the people, I don't have the time and it's a lot of – in terms of dollars I'm talking about man dollars, man hours and dollars. So, I'm stuck and we do it. You know I almost want to call up someone and say remote into my system and I'll show you how we do this. Okay, done.

So, I think that's – that also gets back to my over reliance on “yes/no” or excuse me numerator/denominator attestations when I think you could provide some flexibility in the “yes/no” space.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Larry Wolf you had a question next?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yes, thank you. So, Larry Wolf and I guess I was impressed with the sense that all of you are early adopters and in fact we may have created a whole nation of every healthcare provider is now an early adopter.

So, I wonder if I could sort of speak to some of the challenges of the rate of change that you've seen since the MU Program started and how that compares with how you saw your systems in the past? And where do you think we should be going with that?

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

This is Howard Hays from Indian Health Service I'll speak a little bit to that. The Indian Health Service has been running an EHR since 2005 and we have used Health IT long before that as well. And so we were an early – we consider ourselves an early adopter and Meaningful Users, in fact before the Meaningful Use Incentive Programs came out.

What we saw as the real positive from that was that those facilities that had only adopted the EHR in part of the practice one clinic or something like that because of the availability of the Meaningful Use incentives it drove them to be more full adopters and so the meaningfulness of their use of EHRs actually increased.

And so I think it's been an extremely important program for us in driving the more complete usage of the EHR rather than having places where some parts of the practice use the EHR and others are still on charts and that sort of thing.

And so, I'm a fan although, as my testimony indicates, there are definite risks and issues that have come along with that in terms of – and to go to what Mr. Earle said, in our system it's 38 patches or 38 application upgrades that have to be implemented and even that number is daunting for the sites that have to implement those and absorb the risks that those patches might interfere with some of the workflow configurations that they've made.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you. Marc Probst?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Yes, Marc Probst and thank you, very good testimony, appreciate it. A couple of things came to mind as you were talking and you can react to these or ignore them I suppose.

You know, you all talked about assurance, that you'd like to see certification act as a level of insurance, assurance not insurance, and it brought to mind a couple of things, one is kind of the depth of certification. So, I've heard everything from workflow to, you know, user interface, to the actual code itself does that code have quality and I'd love some of your perception on how deep should certification go? I mean should it go down to that level of where someone is actually testing that code and how useful it is?

And then the other question I had was the purpose of certification. So, I've heard themes throughout of, again of assurance, but then I've almost heard class like, let us know, you know, which is the better product in our given circumstance and, you know, I may have heard that incorrectly but I would just love your reaction on those two things.

So, the depth, how deep should certification, in your minds, go to be useful and then secondly kind of the purpose of certification as opposed to a class or something like that?

John A. Berneike, MD – Clinical Director & Family Physician St. Mark’s Family Medicine - Utah HealthCare Institute

Yeah, John Berneike, I don’t think certification needs to address the quality of the code. I think that’s a realm that is currently being addressed between the users and the vendors currently and, you know, that’s an issue that was addressed long before Meaningful Use came out and just like any software product, not just EHR products, you know, a vendor has to provide high quality software to have a market.

I think in terms of, you know, the goal of certification, again, my closing remark I think sums it up, that certification ought to be about the burden on the end user for taking care of patients and less about the vendor checking a box saying that they can achieve this functionality.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you. Paul?

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

Thanks, Mike. I have three questions, but one is for Steve Posnack, because that sets us up for the other questions. It’s commonly thought that the provider, in order to qualify for Meaningful Use, must use the product the way it was certified, a couple of you even mentioned that, to Steve Posnack, is that true, one of the key qualifications is that you must use a certified EHR, it doesn’t necessarily say you must use each function as certified by the vendor. So, that’s a question – that could really open up a lot of things if that assumption that we’re all operating is true or false.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

So, you got me?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Yeah.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

There is an FAQ that we worked on with CMS in the past that kind of clarified this point. I mean, to participate in the EHR Incentive Program, Meaningful Use of certified EHR technology, so let’s start there, and then the second level down is, you know, certification is a snapshot, it is a check of particular capabilities as the developer presents them for the purposes of testing. There are numerous different ways of demonstrating a capability’s performance and at times one of those ways is used to demonstrate for the purposes of testing and certification.

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

Right.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

So, the FAQ that CMS published was to say if there are alternative workflows that are designed into the system for this certified capability those alternative workflows could be used, but, you know, that also I think gets to – maybe I'll make my one point here, you know, the point that Colin made, the developers would be in the best position to say that some of those alternative workflows are the customization that is permitted of the product for alternative workflows could lead to additional burden on the provider to count for the purposes of a numerator/denominator type of situation.

And so, at times, in my experience, you know, feedback from the developers has been that they've gotten tested and certified, the workflow or workflows if they've chosen to demonstrate more than one, that are the easiest to make sure that they can process the counting and the utilization because that's what providers need in order to attest.

But there is some flexibility there, you know, the certified product needs to be used because that's the purpose of the incentive program. But there is some flexibility there you can't use something that's, you know, not certified to generate an appropriate HL7 message for public health transmission. I mean, like that's where the separation would occur in terms of distinction. Does that help answer your question?

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

I think it does because I think that's probably not what the vast majority of provider believe or the vendors either believe or convince you to believe and I think that allows us some more flexibility as a provider, like Mike I'm a provider as well, to use the product and not rewrite our workflows just for the purpose of meeting Meaningful Use.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

But if it deviates you're left having to prove it.

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

Okay now that's where I was going to make another point. Speaking partly on behalf of the Meaningful Use Workgroup we've certainly heard the concern and feel the concern about usability. We certainly heard the concern about documenting your compliance with either the behavior or on the vendor's side the product. One might think that we could use the market and I think someone mentioned this sort of you really would like it to be – the certification process to include ability for you to compare vendors.

So, one possibility to invoke the market – we couldn't figure out a way to certified usability despite how hard we wanted to. So, but the market is pretty good as John just mentioned at doing that if we give providers/purchasers the ability to get access to that information.

So one possibility is as people go – as vendors go through the – developers go through the certification process and they get certified for objective "x" then maybe they publish exactly how they were certified and what's the workflow that was required that at least would give providers a chance to see "oh, this vendor implements this objective this way, this is the workflow required for this vendor to make the same" do you see what I'm saying?

That would invoke a market supplement to what provider and then vendors would be discouraged from saying "I'm just going to check the box and get past" and no matter how much it cost on the point of the providers. Then at least that would expose that.

The other part of that is innovation could occur at the reporting as well. So, for example you may need to show that you do, the provider has to do “x” well a vendor can figure out that if you’ve done the following things then you really have done “x” without checking a specific box and that could be one of the ways the vendor demonstrates their innovation and their ability to reduce the workflow and the burden on the provider which you all mentioned. That could be exposed in this comparison sort of matrix on how did they fulfill a specific certification requirement. So, that was one question.

I have a follow-up question, but let me get your reaction to that?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

I guess the notion that market forces could somehow influence, I think we’re passed that right? I’m not going to jump to a new vendor, I can’t, so, you know, if Vendor B does it better it doesn’t matter I’m still with Vendor A guy unless something egregious happens. So, I mean, there are few institutions that are ripping and replacing, but for the most part I think the battlefield is done in the states, people got what they got.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Colin, this is Mike, so given your fear comment too, the follow-up to that would be is assuming that you found one of these innovative ways to do this with a vendor would you have the confidence and the courage to attempt to attest for do numerator/denominators for that measure if it’s not, if you will, the vendors preferred approach for doing that.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

I mean, I’m getting there, yeah, I mean, I don’t mind a paradigm where the transactional system allows for add-ons, built-ons, I think we’ve hear things like that suggested before. A lot of interesting stuff coming out of Boston in terms of innovation leveraging on top of an EMR and so if those things were, you know, suddenly, you know, certified and were able to magically produce numerators and denominators for these things, you know, I’m game, absolutely.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

John?

John A. Berneike, MD – Clinical Director & Family Physician St. Mark’s Family Medicine - Utah HealthCare Institute

Yeah, John Berneike, I agree with what Colin said about, you know, market forces, you know, we are a captive audience of our vendor. It’s too expensive, too difficult to change vendors because we don’t like the way they implement something.

But I think to address the question, you know, somehow we need to shift the emphasis not from the vendor figuring out how they’re going to get certified and then imposing that workflow on the user, but the vendors, you know, working with the users, the providers and saying “what is your workflow that you’re doing, what is efficient for you and let’s figure out how to, you know, measure, track, report on that given the workflow that you do” not vice versa, which seems to be what it is now.

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

So, I guess that's the – I understand there is a high switching cost so it's not like the people in front of us are going to switch their EHRs, but if this were transparent just how vendors are being qualifying or certified stages 1 and the future stages at least it starts becoming part of public record and there is a, just for Hawthorne effect, there is reason to look good.

There is a reason to show how well you've thought this through from a burden point-of-view on the part of – so I think there are some ancillary benefits despite the fact that you don't have a choice of vendors being more transparent just like we providers have a more than – you know, most patients can't choose because their employer chooses for them in terms of plan, but you still have the pride of wanting to show how well your performing.

The in the second part of my question, it's a different question, but you talk about pace and again, as a provider I certainly feel that, one question for ourselves is, is the pace of change needed to – for your business, for your healthcare practice or organization, to meet the new needs of the new payment system, the accountability, the accountable care arrangements, what we call it just to not make it ACO, is the pace needed to adequately perform under these new models? Is that driving the pace of change for our systems that support that or do you think only Meaningful Use is causing us to have to go as quickly as we are?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

They seem additive not synergistic so it's – I need a population health module that does registries, etcetera, etcetera, etcetera, oh, yeah and I have to go do 20 things for Meaningful Use. So, it's – I think you see a thoughtful plea to slow down, you know, Stage 2 took hiatus between 2 and 3. I can't speak very well to how slow the certification should lag, but, yeah there is definitely a disconnect, although I think the – I'm still very positive that the Meaningful Use framework and the way that things are laid out in sequence is actually a very good guideline for how this country should improve the care of patients using Health IT.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Cletis?

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke's Cornwall Hospital

Cletis Earle, St. Luke's Cornwall Hospital, going back to the previous question that you just mentioned, you know, you talk about things that should actually be publicized. I think what we should really think about from a certification perspective, going back to quality, is that maybe we should require these vendors or these entities to outline certified processes along quality specific measures like your HCAHPS, your sepsis, your readmissions, your falls, you know, making sure that these system are handling these problems that we're having across the country in a standardized process, these can actually happen.

There are quantified – you know, initiatives that everybody is working on but they're working on it in their silos. If we can actually address this as a whole, you know, we can actually now have something measurable and achievable from a certification perspective across the board.

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

Can I follow-up with one more?

Virginia (Ginny) Lorenzi, MS – Manager, HIT Standards & Collaborations – New York Presbyterian Hospital

Hi, this is Virginia Lorenzi.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Yes, hi, go ahead.

Virginia (Ginny) Lorenzi, MS – Manager, HIT Standards & Collaborations – New York Presbyterian Hospital

Hi, so a lot of what, is being said, is getting me emotional here. So, the world I live in is that world of fear and that gray that Steve described, the fact that he had to describe it after that FAQ was written years ago is because it's hard to believe that, it sounds like even if something is written down it's hard to believe it.

So, we spend so much time trying to feel are we safe doing things that seem maybe a little different than the exact thing that was written but we think it's the right thing, so many cycles get spent, people that I have worked with for years that are just so wonderful are cranky and upset and tense because of this and I don't think it's just about slowing down.

My experience at New York Presbyterian, we tend to be busy, we'll move fast but we just – we like to work as a team and have help and we just don't feel that there is that help when it comes to actually implementing it. What's the goal of what you guys are doing? The goal is Meaningful Use. So, if you just get to the point where we make the certification program the best it could possibly be, you've left us in the middle of the field we haven't gotten to the end.

The end goal is for us to be able to hopefully have this system be used meaningfully used and help patients and providers. I'm telling you it's really, really hard out here. It's really difficult and gray is really hard when someone is going to audit you and you don't know, you know, you want to make sure you get that incentive and you don't get penalized, it's a big deal.

And the other thing someone said early adopters, you know, we didn't sign up for an early adoption, we do that sometimes, but we didn't sign up for that. And it's also, you know, when you say early adopter well I'm an early adopter because I'm making the deadline. The deadline is I'd better start collecting data in July if it's my last possible time, you know, so it's kind of funny – I agree that I'm an early adopter, but it's kind of funny that you're putting – you're labeling us as that. I see it, I see the standards are buggy, the EHRs are buggy, our trying to interpret it is very difficult and then again I just don't have help. Thank you.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you, so this is Mike Zaroukian, I'm going to insert a question and then I think we'll move on. I think Michelle has a question on the phone as well. My question, especially for provider representation here that vendors also need to hear and are struggling with as well, is what I heard are recurrent themes of usability.

If we were to slow down in one area and maybe speed up in another maybe usability would be the area to speed up on while we're slowing down on others. Dr. Tang commented on the issue of the challenges that we faced in terms of trying to certify usability so to speak in some of the work that NIST is doing in that area. There is however a science to usability of course and principles and things that have been published in that regard so I'm curious from the panelists, from the provider group, what suggestions they may have if we were to focus further on usability and certification what would you advocate for? Dr. Hays?

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

I'm having – this is Howard Hays, I'm having a little trouble separating my developer hat from my user hat because from the usability stand-point the issue that we had as a developer was that we had a lot of legacy pieces in there that were part of the usability suite that we had to do and so we couldn't document that they were developed using certain standards and so what we did was we contracted with human factors people and had them basically go through all that testing and documenting and we showed that it met the usability requirements.

So, it is a challenge is you're not – if you're developing new software to meet a particular requirement I think you can meet those requirements in a fairly straightforward way because the standards for that have been published but if you're trying to sort of kluge or adapt an existing system it's a little bit harder to do that.

But I do think that from a provider stand-point usability is key and we haven't succeeded completely in that – well, I'm a user too, so I know we haven't succeeded completely in that and that is a goal that we need to continue to work with.

I don't know if that's helpful or not, but one thing though that leads me to is, I've always had kind of a little curiosity, I mean NIST being a very sort of structured process for testing it hasn't always seemed to fit in my brain with the clinical workflows around an EHR it's just the – and the testing bodies want to see a particular screenshot, a particular function of the screenshot and it doesn't really, as others were saying, it doesn't really allow for the intent of the rule to be met because that requires some subjective interpretation and actually some knowledge on the part of the testers of clinical business process which they don't always necessarily have.

So, somehow and I don't have a solution for it, making it so that the vendors have that flexibility to meet what the rule wants to be met without having to constrain themselves to a particular behavior and a particular screenshot and the result.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay. John?

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

Yeah, John Berneike, I don't think this comment directly addresses the question but I think it provides a framework that would be appropriate to keep in mind and that's that, u1k Meaningful Use is not the ultimate goal, Meaningful Use is not the end it is the means to an end and the end goal is high quality, cost-effective, efficient, safe patient care and in terms of, you know, that framework trying to address, well how do we measure quality.

Again, I think it has to be less about checking the box of the Stage of Meaningful Use that we're currently in and more about, you know, is it achieving the end objective and one additional related comment that I've made to folks at ONC in the past is that, you know, I think everybody in the room here certainly fully understands the end result or the end goal of Meaningful Use, but I think a lot of people don't and, you know, we've all heard the cliché, it's Meaningless Use because they don't understand the long-term goal of what we're trying to achieve and so I think doing a better job of advertising and, you know, selling what we're trying to achieve here would go a long way towards making sure people embrace Meaningful Use so that we can ultimately get where we want to be.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you, so the term I would sometimes put with that is useful usability or that portion of usability that actually means what you did was not only easy to do but it was worth doing. So, good point. Okay, let me move on, Michelle, did you have questions on the line?

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

Nancy Orvis had a question.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay.

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

Hi, thank you for your testimony today. I'm with DoD and as a provider a question I had and working and having places in 50 states, have any of you been able to work with either your region, your ACO or your local HIE to agree on what you're putting in your numerator and denominators for the quality measures?

There is some work that I have been talking to with people in Oklahoma where they've gotten all the providers and the insurers to use the same quality measures to report out which is seeming to make some things easier.

So I'm just curious whether – I know that you've been all worried about your own individual organizations but some of you have mentioned that you've been trying to talk regionally.

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke's Cornwall Hospital

This is Cletis Earle from St. Luke's Cornwall Hospital, we've been working collaboratively with our health associations in the state, the two of them, and they've been an intricate part of helping us established those guidelines for us, they are working through, you know, or working with the RECs and the HIEs as well, so we've found some success, we have a great support structure in our state from that perspective and we're very grateful for that.

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

Is it making it easier?

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke’s Cornwall Hospital

It makes it extremely easier, yes, it’s helpful but there are times and many initiatives that we look at when we try to still quantify what does this mean, we’re still perplexed and we have to go back or reach out to CMS so, you know, it just – try to figure out what that means, you know, I can go back to the biggest issue which is the patient engagement side that’s always been a nightmare and I think it will continue to be a nightmare when it comes to the portal but that’s something that, again, we just all try to figure out together collaboratively.

Nancy J. Orvis, MHA, CPHIMS – Director, Business Architecture & Interoperability – Department of Defense

Thank you.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, thank you, John Travis?

John Travis, FHFMA, CPA – Senior Director & Solution Strategist, Regulatory Compliance – Cerner Corporation

Yes, thank you, this is John Travis with Cerner, I’m playing a little bit off Dr. Tang’s perspective of the quality of the certification and thinking about where in particular there might have been gaps between certification and use to assure one particular dimension, very important to use, that I don’t think has been spoken to so far, but I know Dr. Banas in his written testimony I think did very well summarizing it.

There are points of change of code sets and this goes towards also, you know, a bit to Steve, the use where certification and use really are kind of compelled to be mutually supportive. There are code set standards that have to be reflected in use and really are part of the measurement requirement for use for which there may be data migration, data mapping requirements things of that nature that really sit outside certification, they’re not tested for – the software is tested for its ability to support the code set standard for where you’re going, it doesn’t test the ability of how you deal with legacy data and that data may be in narrative form, that data may be in prior code set form and use makes assumptions about that ability.

And I think that’s a part of what we’re seeing of some of the difficulty with Stage 2 but for any of you, if you can comment on maybe what would be an appropriate role for certification to do better on that kind of a point where there is a change in standard that brings with it either data migration or data mapping and how that might not be strictly speaking a burden placed on the use side of the program if you get what I mean. And anybody can answer that, but I know, Dr. Banas you spoke to it.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

So, I think what John is referring to is, in our instance is something called legacy problem list, so 11 years on Cerner for summaries and the primary care doctors, you know, they went to the problem list before we even told them to and they starting putting stuff in there, God Bless them, but, you know, it was free text, it was ICD-9, it was SNOMED International, I mean, the entire nomenclature was wide open.

So, then comes Stage 1 and says, you know, you have to have at least 1 thing on your problem list as SNOMED, okay, you know, we do some nifty stuff and we get things on there, but now one SNOMED can live with 11 free text, okay, no problem.

Here comes Stage 2 and says, when you create a CCD and you send it through the Ether and it has to land on the other side it can only be SNOMED. Whoa, time out. Because when you, you know, when we were run the script and say, well, what's the burden of our free text problem and our legacy database, it's 100,000 entries and even the greatest, you know, nomenclature mapping tools, it's like a 30% conversion rate, so now I'm faced with 70,000 free text entries that I'm going to have to go – ostensibly go touch because the presence of one of them might cause that CCD to fail on a measure that I'm already scared of.

So, you know, I don't know that anybody really could have seen that coming, I think it's very forward thinking to consider legacy data when you are contemplating Stage 3 and beyond. But, you know, when I made the comment being penalized for being an early adopter, I mean, there it is, right, I don't have people to go touch 70,000 entries, you know, and even the scripts provided by our vendor, which are, you know, very good, they're a work in process and that's someone that has to sit and babysit that and that's not something that I had planned for. So, you know, I think it's very progressive to consider legacy data in future certification going forward.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Paul?

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

Were you going to have to do that, Paul Tang, were you going to have to do that anyway if you wanted to leverage your data for clinical decision support and other things.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Well, so here's my take on it, the people, anyone who thinks the problem list in its current state is the paragon of the clinical history of that patient is deluding themselves. I mean, we are just now getting our feet wet, I mean we as an industry can't even decide what belongs on a problem list let alone within our own hospital, like it is still so esoteric what we think belongs on there, what a surgeon thinks belongs on there, who curates it, who is allowed to contribute to it, don't touch it, do touch it, can a nurse play – I mean, it's sort of all over the place.

So, you know, I think it would have been a lot easier to say, what Stage 1 did, let's start playing with the problem list, but you went from let's start playing with the problem list and codified format to that sucker better be accurate and it better be in every – you know, every entry better be in a certain nomenclature and this is what's flying through the Ether.

And, you know, something similar from the quality measures perspective. I actually have a lot more faith in the billing data, believe it or not, at least from a hospital perspective, than I would ever in the problem list in this day and age because the value of the problem list hasn't revealed itself to the providers and the patients yet, but it will.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

John?

John A. Berneike, MD – Clinical Director & Family Physician St. Mark’s Family Medicine - Utah HealthCare Institute

Agree with what Colin said and I think it touches on one of the comments I made, sorry John Berneike, it touches on one of the comments I made about, you know, the need for coding, billing, payment reform because for coding and billing we are still required to maintain or address past medical history and that is not necessarily the same as a problem list and what I personally do and what I try to do with all the providers in our clinic is to use the problem list as the past medical history, but again those are two unique distinct things that we need to address in order to get paid and it doesn’t address your direct question John about, you know, how do we migrate the data but it is part of the issue.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, thank you. I think the next question, Steve Posnack, I think?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

You have Carl on the phone.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

You want to do Carl first, okay. Carl Dvorak?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Hi, yeah, thank you, many of the panelists commented on the environment of fear and uncertainty and I was curious have any of the panel members been audited on Stage 1 and if so what was their experience with regard to the strictness and the structure of the audit process?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

This is Colin Banas, VCU has been prepayment and post-payment audited on both Medicaid and Medicare side. The Medicaid audit, at least for Stage 1, well that was AIU so that was sort of a check the box phenomenon to prove that your Medicaid numbers are accurate.

The Medicare attestation was scary but not as scary as we had thought it was going to be. So, that is a plus. I guess because no one had really gone through it before no one knew the level of documentation, you know, the binder, the magic binder in case they come knocking that you need to keep, but, you know, it went relatively smoothly all things considered. So, that was a plus.

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke’s Cornwall Hospital

I would like to completely go the opposite direction, this is Cletis Earle, we were again early adopters, it was painful, it was a painful process and the reason why it was so painful we realized the person auditing us didn’t know what, you know, they were doing. They didn’t know anything about the process so they were discovering it for the first time themselves.

They had no idea of some of the logistics associated to Meaningful Use and what that meant. So, about four times, four iterations of that, it went over a course of about five months or so, it was painful. So, we hope that that’s not the experience of anybody else and that’s just kind of learning pains from something that’s just newly established, for Stage 2, God help us, you know, that it’s not that bad.

Chad Jensen, MBA – Executive Office Manager – LaTouche Pediatrics, LLC

This is Chad Jensen –

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Yeah, John – sorry, go ahead Carl?

Chad Jensen, MBA – Executive Office Manager – LaTouche Pediatrics, LLC

We did this as well and it was pretty painless for us.

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

John Berneike, I was also audited by Medicaid and as an early adopter I think I've got an interesting relationship with our state Medicaid, you know, they frequently come to me for advice on how things should be. So, my – even though they were not fully informed yet on how the whole process should work it was a painless and actually helpful interaction that I had with Medicaid.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, this is Mike with a follow-up question for the group in that regard, is would you benefit as providers from additional guidance and a source of truth regarding the relationship between certification criteria and the audit process so that you can be more confident that the way your system is implemented fulfills both the certification criteria and how it's deployed for Meaningful Use?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

I think any of those guidelines would be helpful as the stages change. So, Stage 1 sort of behind us, we know what to expect, you know, maybe a new provider jumps in, but we've got it down. Stage 2 we have no idea, right, so you're starting over from your audit defense perspective so any of that would be very helpful.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, okay, thank you. Steve did you want to go ahead?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Sure, thanks and this is – I gave Paul a hard time in the beginning that I would just bring this up. I would say, as someone in the weeds, you know, and as the ONC support staff for the hearing today, one maybe point that I'd ask you all to keep in mind and one separation that I tend to make, and I think we've heard this from the panelists today, and maybe I'm oversimplifying, but there are really two types of complexity when these conversations occur.

One is related to the functional capability. So implementing a standard and implementation guide, implementing certain functionality, the depths and the breadths of the rigor of the certification criterion that's in scope for ONC.

Then there is another type of complexity which is the Meaningful Use measurement, the numerator/denominator and often the certification process or the criteria are criticized through that lens when that's not necessarily an in scope issue for the certification program, because the policy has already been set, we're kind of downstream in that respect where what needs to be measured, what counts for a certain measurement, how you interpret what words mean so that you can accurately account for what needs to be measured are all policy, you know, types of impact that are set at the Meaningful Use policy level.

And so, in a lot of cases where the utilization is an issue in terms of measuring it could be an instance where, and I doubt this is the case, that the developers can't figure out how to measure it in a more elegant way and maybe that they don't have the time vis-à-vis when they need to get certified to figure out an elegant way, as, you know, you described Paul with some more sophisticated algorithms, so the approach that's taken in some cases when they don't have the time to figure out what's meant and you don't have the time, as users, later to figure out what's meant is that we get in the checkbox scenario where there is some action based on the user's human intelligence that needs to occur in understanding the measure.

And so that was just one thing I guess I'd ask for everyone here to keep in mind, as well as future panelists, in your comments to try and make that distinction if they are the abilities to do so to say, this complexity comes out of a Meaningful Use measurement kind of policy decision that's flowed downstream into how the development efforts to occur.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

May I respond to that?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Sure.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

With respect, Steve, speaking from the user perspective it's all the same thing.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

I agree.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

Okay, it doesn't matter whether the policy came down from CMS or ONC, or the rules it's a program that from the user perspective they don't really care why they're having to do this or which agency told them why they're having to do this they're having to do it nonetheless.

And from a developer's stand-point, you know, even though ONC publishes the certification rules a developer can't get away with just reading the certification final rule and certifying they have to understand the Meaningful Use rules as well and that creates an additional requirement because there are functional requirements in the Meaningful Use rules that if you only look at the certification rule you will miss and some of those functional requirements are what Colin was saying is, you know, how do you count that – how do you – without making the user go to paper and count every time they reveal a problem list how are you going to – how is the software going to be able to enable those providers to attest and validate that they've met Meaningful Use requirements.

So, point taken Steve it is – it's not within your scope, but from the stand-point of the scope of the users it's all HHS.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

And I think you see that users are desperate for a forum and we think that a lot of the players are the same or at least might talk to each other, so, yeah, I mean, I even put that in my testimony, like I know this isn't the forum but I'm going to sneak it in there anyway.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, this is Mike Zaroukian, I'm actually going to jump in as a provider with maybe another example for the group's reaction to, but also to see if this helps drive home the point. So, there is this interesting thing called view, download and transmit that patients are involved in.

There is a certification thing that relates to view, download and transmit. There is a thing on the Meaningful Use rule side that says view, download or transmit and so users and it may or may seem obvious to anyone or everyone in the room, but there is a lot of both providers, maybe even vendors, who are confused about what you have to have in a certified product, what has to actually be deployed and working and then what the patients are actually doing with the system and then the viewing and transmitting of what that will actually count.

So, I think what I'm hearing in the plea is again both a sense of truth to that and clarity, and conciseness, but also the issue that says this really actually represents the group think of both the certification and the Meaningful Use component as reflected by CMS, ONC, etcetera. So everybody understands that's where it's coming from. Does that resonate with providers in terms of an approach?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

There are a lot of cycles spent on that very thing, is it and, is it or, how do we meet it, you know, and it's not really value added, right, I mean, what are we after an interactive portal, do you have one, do your patients participate in it, done.

So, that's what I'm talking about, I think they went a little crazy with the numerators and denominators and I realize that's not this group.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Sure, Jacob?

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Jacob Reider from ONC I just want to point out Colin that it's not necessarily an interactive portal and I think that's the point of both of the regulations it doesn't say you have to have a portal, it could be on the customer and the patients iPhone or their Google glass or it could be projected on the ceiling in their bathroom. We don't define how the end user is going to do it, in fact that was the whole point not to be prescriptive and to say it has to be a portal. So, there is nothing that says you have to have a portal I just want to make that crystal clear.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Yeah, you may not say that but I bet you everyone is accomplishing it with a portal and so wouldn't it have been better to have been prescriptive?

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

No, but again, that's my opinion.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, yeah, okay, we won't resolve that today.

Virginia (Ginny) Lorenzi, MS – Manager, HIT Standards & Collaborations – New York Presbyterian Hospital

So, this is Virginia –

Paul Egerman – Businessman/Software Entrepreneur

If you have something that has an “or” says download or transmit for a vendor an “or” becomes an “and” right?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

– certification.

Paul Egerman – Businessman/Software Entrepreneur

Yeah.

Virginia (Ginny) Lorenzi, MS – Manager, HIT Standards & Collaborations – New York Presbyterian Hospital

Oh, my goodness, this is Virginia.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Hi Virginia, go ahead.

Virginia (Ginny) Lorenzi, MS – Manager, HIT Standards & Collaborations – New York Presbyterian Hospital

Hi, I had so many nitpicky questions I could keep you guys going for 10 days and I know that rule in and out but every day it speaks to me differently. I find new things and I’m talking about the Meaningful Use regulation.

This is the thing, I learned a long time ago that if I said it’s not my job I was going to get fired and when it comes to the Help Desk philosophy at my hospital they don’t want to hear it’s a network problem, it’s an interface problem, it’s the EHR, they want to say, no Help Desk it’s your problem, it’s IT’s fault.

You know we all are in IT together so me as a user I say it’s the government, so if something is happening, if you’ve got – and also if you’ve got a great idea here you have to help us through to the end, it’s really hard to implement this.

If you put – I’m not a switch flipper if EHRs are turnkey and I can turn on the switch it would be fine but it’s not. So, I am trying to lift that lever and it’s really hard and I need help. That thing that you cannot – we cannot implement gray, I need “it is or it isn’t.” I really need that so you need to come and tell me and help me, it’s interactive, because you say, it depends, well I need – saying that tons of conversations are wasted at my hospital because we’re not sure, we’re not sure, I mean, it’s very anxious – before it’s horrible.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, thank you, Paul Egerman I think you’re next.

Paul Egerman – Businessman/Software Entrepreneur

Great, thanks, you know, this is a terrific discussion and I think we could take this group and talk all day with this group, as you talk I have more and more questions that I want to ask. I was very interested in the comments about the relationship between the clinical systems and the billing systems and especially your comment, Dr. Banas, about the problem list versus basically the diagnostic coding it's just an observation that a lot of population reporting is based on claims data currently from CMS and we're switching to a system of doing quality reporting population data off the problem list and off the EHR and we're going to get very different results when we do that it's just in the law of observation.

I have a few questions about the certification process. There was a discussion yesterday about some things in what's call the 2015 edition of certification where there is an idea of doing certification every year and there is also a proposal that certification could be used for practice transformation and for perhaps a sort of like looking at the edge of the envelope and pushing innovative new ideas, EHR ideas out into the world and what is your view of that? Should this be used for those purposes for practice transformation and to create a much – for EHR innovation?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Should certification be used for?

Paul Egerman – Businessman/Software Entrepreneur

That's right.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Eventually, you know, I think we're still laying the Legos right now and I think that's the plea for the slowing down and the focus on what we've got because we're still not done with it, but once these things are in place, yeah, you've actually set up a massive framework to innovate. So, while I express frustration that I haven't been able to innovate for the last four years I'm excited because I know it's coming. We've just got to get over this hump.

So, you know, if – depending on how MU stretches out and the certification body continues to exist I absolutely think that's an appropriate form.

Paul Egerman – Businessman/Software Entrepreneur

And explain what you mean by get over this hump? I don't understand that.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

I mean, right now we're still, you know, state level one order benefit from an EHR to me is sort of ubiquitous data, right? I have an EHR where I work and I can access it anywhere in the hospital, anywhere at home, anywhere in the country, I can interact with it as opposed to when I was a resident I had to go find the chart, right?

So, I can read it, I can interact with it, I can prescribe things, I can contribute to it and I think you get a lot of benefit just from that. So, if you take that analogy towards Meaningful Use Stages 1 and 2, Stage 1 was a lot of ground work and I actually still think Stage 2 is right? Prove that you can create a CCD, prove that you can connect, prove that you can interact. So, you know, I think we're not at that innovative stage yet. I think we have to finish what we've started with Stage 2.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, another way I might frame in my own organization, we spent probably a year or two with the issue of planning and implementation, then the next year, and this is in our own galaxy, okay, our own little galaxy of an organization, then the next year in go live and stabilization and then early optimization, and now we're starting to move into the intra-galactical transformation of care.

We then have this whole outside inter-galactical world of patients and other organizations and those other things that this will enable, but the whole nation is moving forward in a much more rapid pace than that and the question is whether you can stay in your own orbit while you're doing that. So, Charlene, you're next? Oh, I'm sorry.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

– the Meaningful Use, Charlene Underwood, the Meaningful Use Workgroup hat, one of the challenges, and Paul knows this, we have extensive discussions and we talked about the problem list a lot, has been one of our topic areas and when we talk about the problem list in the Meaningful Use Workgroup we recognize it as it is today, it's an immature entity, it's going to evolve, it's important to the future, we want to incent it.

And so we have this intent on the Meaningful Use Workgroup yet when it comes to execution I don't think it was ever the intent of the Meaningful Use Workgroup to put you in the situation that you got in where you can't be flexible in terms of moving to improve upon it to use it for all the great things we think it's going to lead to.

So, the challenge is how do we, with the certification process, close the gap such that the intent of what we're trying to accomplish actually is what gets certified to and I think that's really – you know, where is CMS in the room I would have to ask, because there is interpretation of, you know, kind of what we're trying to accomplish as it goes into standards that gets lost.

So, I don't know if you can respond to that, but I know each of you spoke to understanding the intent of the program which I think is really valuable and the need to communicate the intent of the program, but the challenge I think we're trying to get to is how do we then, you know, enable you to meet the intent through a certified product and how does that process really fill that gap and I think we've got – we've pulled out a couple, maybe we attest less strictly in those kinds of things, but any other ideas on that front?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

John?

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

Yeah, John Berneike, my comment was kind of more directed at Paul's question about, you know, innovation and, you know, moving forward but it also addresses your comment about, you know, where is CMS in the room and it goes back to what I said earlier that, you know, we do need all of the players within Health and Human Services working together because you're right that, you know, if CMS doesn't change the coding and billing requirements, you know, our hands are tied in terms of some of the things we could innovate with, in terms of documenting a visit and not just documenting a visit but how we provide care, you know, currently it's almost exclusively face-to-face visits.

You know I could be much more efficient if I could manage things, you know, by managing population health through patient registries, you know, with phone, with e-mail, but I can't run a business that way and so we CMS to recognize what you guys at ONC are trying to do and keep pace with it.

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke's Cornwall Hospital

Mr. Earle, to your point, I believe that yes we do, you know, slow down, attempt to slow down, you know, when it comes to certification and adoption for attesting. What happens is we have to realize a few years ago there was a claim that there was going to be a need of 50,000 IT healthcare workers in this country and we're there, we're at that point now that we just – vendors, hospitals, institutions don't have enough resources to keep up with these changes, you know in essence all of the requirements to make these things happen.

There is a really highly competitive nature from people jumping from institution to institution we just can't keep up. So, from that perspective, keeping that in mind, when you talk about certification, when you talk about all of these other things knowing that there are these underlying consequences to making all of these changes happen, all of these requirements happen.

To the other point, to Paul to your point that you mentioned earlier as we struggle to survive in New York State and across the country hospitals, you know, there is a significant amount of hospitals have closed or have merged in the state and I can tell you we can't wait.

So, in essence I'm a proponent, again, as I said earlier in my opening comment, I'm a proponent for Meaningful Use, I'm a proponent for certification it is allowing us to be where, you know, the – I look at this as the infancy state where the banking industry was 30 years ago before the debit card became, you know, you can go to any institution and get cash.

We're using innovation. We can't wait for things to establish. We're looking at population health, we're looking at working with vendors, working with states, tying in data as we conform to some of these Meaningful Use initiatives, tying them into services and being innovative from that perspective.

So everybody is going to have to think about doing things a little differently. I see some success in our area and I imagine other institutions will do the same using Meaningful Use and the certification standards that you've established as a baseline.

Paul Egerman – Businessman/Software Entrepreneur

That's a very helpful comment. This is Paul Egerman. It's a helpful comment. It's interesting, I almost get a sense that you view certification almost the way I used to view my kids when they were teenagers, I love them but they were driving me crazy and so it that accurate or is that not accurate, in other words, do you understand?

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke's Cornwall Hospital

I don't know if it's the program not the certification body, but, you know, you guys are inextricably linked so it's guilt by association I guess.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

Paul, this is Howard Hays, I can resonate with that a little bit. Again, as Cletis just said, I really think the Meaningful Use Program is important and you'll hear me speaking out of both sides of my mouth because I think it's important.

In general I don't like the idea of IT in itself driving business process change, the business process change should come from the business side but you have the visionary business process, people that, you know, say we need to do things differently in medical practice and then you've got the people that are only going to adopt it if – only going to change the way they practice if there are incentives or reasons, or economic reasons or whatever, to do that and so in our organization we have used IT to drive business process changes but it's got to be a balance, the IT can't be IT for IT sake it has to be intelligently thought out and then there's got to be some leverage to get the adoption to happen.

And you guys are dancing that really difficult dance between how hard do we push without making, you know, without crushing people and I have a lot of respect that you guys have been trying to do with this over the past several years and we're here to try to help that without necessarily having all of the answers.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

So, I wanted to go back to what Charlene was asking about the problem list and certification. And, you know, I guess it would be helpful for the providers or the institutions to understand what you envision the problem list being used for as one of the things that we ask our vendors to design against.

So, if you really intend on doing population management or, you know, better clinical quality measures from the problem list exclusively then, you know, that opens up a whole different set of attributes that you're going to want that problem list to have.

The second thing is, I think we as a nation need to decide how we define a problem list, who can contribute to it. So, you know, I was just writing down, I have a problem list, I have a diagnosis list, I have a procedure list, I have a past medical history list, some EMRs have a past surgical history list and then there is family history.

So, for me, as a provider, when I admit a patient with coronary artery disease, you know, the SNOMED entry might be CAD in whatever SNOMED term that is, but in the annotated display or the comment section I'm going to put something like, coronary artery disease, MI at age 45, status post stent, which eventual revision for a 4 vessel CABG 3 years later, that's like 8 things, right, but I don't want 8 things on my problem list I just want the one from a clinical perspective.

So, if you think the problem list is going to get to that granular level where you're going to be able to mine and sort of do all these fancy things with it I'm worried. So, from the inpatient perspective I still stand firm that they billing data is a source of truth on the inpatient side because it's attracted, it's coded, if I didn't document it and it didn't happen it didn't get coded.

On the outpatient side I see a much bigger problem because I don't think there is – you don't have reliability in the pro-fee or the E/M Code on the outpatient side with the degree of granularity that you do on the inpatient side for the DRG. So, I actually don't know how to solve that one.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

John, I think you were next.

John Travis, FHFMA, CPA – Senior Director & Solution Strategist, Regulatory Compliance – Cerner Corporation

Yeah, I'm building off Dr. Tang's comment about maybe part of the certification process needs to account for the workflows that a vendor assumes playing the measurement. The measurement test for, is the system sensitive to numerator and denominator increment and does it know the difference between negative qualification and positive qualification but it doesn't test how. So, there is no challenge to the algorithm by which that necessarily occurs.

I like the idea but my question is how might that become informative through the certification process? So, would that present value to you and do you think that at all should create a constraint on how to use the system, because to be honest vendors are not clairvoyant we will do our best to try to be of good faith about the workflows that we can slot things into.

Does this also indicate a need to slow down in terms of allowing vendors greater opportunity to take valid stock of what those workflows are, does that play in the measurement? So, where in the – I guess to summarize it, where in certification does Dr. Tang's idea live as an informative disclosure, I guess, that is part of certification and not after and how much should it be exemplar versus constraint on what actually then becomes use in measurement?

And if that doesn't make any sense I can elaborate further. In other words, you know, does it do you good for us to tell you how we measure as a disclosure of certification and then how would that have helped maybe improve the experience you've been through trying to get ready for Stage 2?

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Well, you do don't you, I mean, those diagrams that show sort of how it qualifies?

John Travis, FHFMA, CPA – Senior Director & Solution Strategist, Regulatory Compliance – Cerner Corporation

Every vendor does in terms of I think their own guidance but if those had been available earlier in the process as a fact of certification and not, you know, post certification, publication or – I'm thinking if vendors have that as part of their discipline to prepare for certification maybe that moves it up in the process.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

I – well, go ahead.

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

Sorry, John Berneike, I think what you're kind of getting at goes back to the vendors imposing a workflow upon the user rather than vice versa which is what I said before the vendors need to understand the workflows of the providers and implement according to the provider workflows not vice versa.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

That was sort of what I was going to get at was, I know Cerner is very – they tend to get a lot of client input, but maybe we need more, you know, if this is the measure that Cerner is trying to tackle let, you know, a bunch of clients kick it around and say, well this is how I would like it to do and see what filters out because it does feel very prescriptive like, this is how you are going to accomplish patient education, well that's not how we do it, we've been doing it for 10 years we use this and so –

John A. Berneike, MD – Clinical Director & Family Physician St. Mark’s Family Medicine - Utah HealthCare Institute

Or if you want to get Meaningful Use credit you’re going to do it this way.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Well, yeah.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

I would have said the same thing as far as getting more input but on the other hand as a vendor that takes time and you’ve got a lot of different customers out there with different ideas about what the workflow should be and so how do you reconcile those into a product that can actually meet the majority of those workflows.

John Travis, FHFMA, CPA – Senior Director & Solution Strategist, Regulatory Compliance – Cerner Corporation

Let me respectfully call it – it’s kind of a Paul Egerman observation while I’m asking the question, but I think my point here is that there’s a part of this lifecycle, certification, that is exactly this that we’re doing a lot in the breach after certification and trying to accommodate and finding out nothing turns the lights on and causes the roaches to run for the corners, so to speak, no disparagement meant at all, but just a bad metaphor, but you find out in the wash how people really are trying to do something only when you’re trying to work with them to accomplish it and that’s an unrecognized part of the certification process, but it is definitely built into the Meaningful Use cycle.

I offered the suggestion it’s almost like you need a probationary year for a Stage in Meaningful Use to allow a year to get used to it and then measure against it as opposed to leaping right into a measurement period. So, I say that’s a year.

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke’s Cornwall Hospital

Yeah, I think from a perspective, Colin mentioned earlier, that ship has sailed, you know, for the most part as far as where we are. There are so many – this is such a difficult piece for the vendor, just speaking on their behalf, there are so many different ways physicians practice and how they do, you know, they take care of patients it’s almost a Herculean event to try to come up with this kind of standard even after, even post certification. I don’t know how it’s done. I don’t have an answer.

I just know from our perspective from a, you know, hospital perspective some organizations don’t have the ability to, you know, rip out and replace, we just don’t have that financial capacity, the bigger organizations can do that. So, for the most part, and we’re now also talking about some of the providers, you know, those practices who don’t have that capacity. It’s a very difficult task. I don’t see how that’s actually going to be addressed. I don’t know if there is a definitive answer to that.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, so we have about 4 minutes left. I’m going to go with Don and then Marc.

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

Yeah, Don Rucker, OSU, I think the panelists struck me as being, besides obviously showing concern about specifics, very much pro-information technology and really, you know, the transformative potential here and in that spirit, if maybe, you know, for the folks here, if you could maybe give one or two things where you think Meaningful Use and the whole process most needs to change, whether it's let's say for the country or for your practice, the lowest bang for the buck, the highest sort of workload, you know, sort of hot spots if we're sitting here saying – you know, because it's a big policy, here are some areas that really we need to focus on for, you know, to get a better win.

So, you know, a couple of hotspots that really, maybe most lowest return on investment from sort of a national policy point-of-view, biggest bang if we rethink them. I certainly got the numerator and denominator one but some other ones maybe where you would say, hey this is really what we ought to focus on, you know, wherever that is in the stack of policy and regulation, and certification.

John A. Berneike, MD – Clinical Director & Family Physician St. Mark's Family Medicine - Utah HealthCare Institute

John Berneike, my big bottleneck has been the exchange standards, interoperability standards and because of the lack of the finalization of the standards the vendors ability to implement those interfaces, you know, in addition to being a small private practice I'm also on the board of Utah's HIE Organization and, you know, the HIE is ready to exchange data but the vendors aren't there in terms of the interface partly because the standards aren't done yet.

Colin Banas, MD, MSHA – Internal Medicine Hospitalist & Chief Medical Information Officer – Virginia Commonwealth University Health System

Yeah, I mean, I was going to suggest more flexibility in something just like that. So shouldn't participating in your state's HIE be adequate to get credit for all of these other view, download or excuse me transfer of care summary, etcetera where – you know, so in the Commonwealth of Virginia the ConnectVirginia Information Exchange, any provider can have web-based access, you know, you have to fill out a form, so that's out there, right, and so if VCU was to sign up with them and start contributing CCDs to it, then you could make the argument that anybody in the Commonwealth that we send our patients to could go on there and get that.

But that's not how the measure works, right, I actually have to get someone's Direct address, pray to God that HISP talks to this HISP and then calculate that they've actually received it, digest it, whatever the measure is, we're actually not even there yet we're still developing, when really a big bank for your buck would have been, hey, let's get everybody in these HIEs and start trading through the Ether rather than getting so granular with, you know, numerators and denominators.

Cletis Earle, MS – Vice President & Chief Information Officer – St. Luke's Cornwall Hospital

Again, I said it before look at – I think focus on quality, look at potential national standards of care from a quality perspective. I know those are curse words, you know, in the provider community but, you know, taking into account acuity and those particular factors and then help standardize certification around those things.

You speak to other people from other countries, I was speaking to somebody from Australia and New Zealand the other day it was very interesting and enlightening to see how they've addressed these issues because they're ahead of us when it comes to those initiatives. Again you just have to look at, again, curse word socialize, you know, in essence standards and then once you figure that out you can actually tackle the small problems and instead of boiling the ocean you have something more tangible to deal with.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

I think my comments would reflect the others as well and some things I said earlier. One is the issue about time, you know, allowing more time for people to implement and even the probationary kind of thing even between – I mean, because the difference between 2011 and 2014 certified EHR is a big difference and the implementation requirements are pretty significant for providers, even when the vendors can get it done.

The standards issue is important I think in pushing out immature standards and expecting them to be adopted when – and it takes a lot more time to actually develop to those and implement them.

The other thing we haven't really talked about because it's kind of more of a vendor issue but the clinical quality measures was just a mess as far as I was concerned.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

It was.

Howard Hays, MD, MSPH, ME – Acting, Chief Information Officer & Director – Indian Health Service Office of Information Technology

Yes, and trying to figure out how to write that logic and how to get those measures doable given that they come from all these different organizations and with different ideas about how you measure the same – what data they're going to use to measure the same concepts was really ugly and I think that needs to be really thought hard about.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Okay, thank you. We've reached the end of our allotted time. Michelle?

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

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Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Yes. Chad or Virginia do either of you have a comment?

Chad Jensen, MBA – Executive Office Manager – LaTouche Pediatrics, LLC

I don't, thank you very much for the opportunity though.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

Thank you, alrighty, so thanks to all of our panelists for coming today and presenting, and for fielding, and responding to questions and asking some, and thank you to the rest of the group as well.

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

Thank you Mike for moderating that panel. The next panel we're going to set up is for vendors and Larry Wolf is going to moderate that one.

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

If you could take your seats we're going to get started, please. I tried already.

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

Yeah.

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

If you could please take your seats so that we can get started, also, for Workgroup members there is a lunch menu, if you want to order lunch I'll just come around and grab that as we get started for the next session.

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

I mean, it was good yesterday we might as well try it again.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, I want to get out so I figure if I can get to eat and go for a walk.

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

It does turn out – it's an hour and a half so, I mean an hour.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

It's an hour.

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

Yeah.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So much better when you – all right, okay, well we have our panel. We're missing some of our –

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

Just get started, yeah.

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

Okay, so we're going to get started with panel two. I just want to make one note that John Halamka will be participating virtually and his timing might be a little off so it could be a bit disruptive for the panel, so I'm setting expectations now that he might have to come in during the discussion and give his testimony. So, just an FYI and with that I'll turn it back to Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, Larry Wolf with Kindred Healthcare. I have the pleasure of moderating this really great group of folks. I was very impressed with the Bios.

We have people who are not only here as vendors, your current role, but a lot of you have experience as providers, some of you are continuing as providers, some of you may be developers but inside a provider organization, folks who have had a lot of experience as well as in the certification process in many different ways.

So I hope that we get a chance to actually explore all of those perspectives that you guys bring here. Pretty much looking forward to what you have to say. So enough intro from me. Why don't we start with Mickey McGlynn.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

So, my name is Mickey McGlynn I'm with Siemens Healthcare and I'm the Chair of the Electronic Health Record Vendor Association for whom I'm speaking today. Thank you for giving us this opportunity to talk with you.

Recognizing that certification is intended to ensure that EHRs meet the standards and certification criteria to help providers achieve Meaningful Use we do understand how important certification is to our customers and thus to the vendor community in support of our customers.

And while the obvious benefit of such a program is to enable providers to meet the requirements of Meaningful Use and the growing number of programs or reimbursement models that may be based on the use of certification technology the real benefits of such a program should accrue –

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

Sorry, if you aren't speaking if you could please mute your line. I'll wait.

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

They need to turn off their computer speakers.

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

Please turn off your computer speakers if you are participating virtually. Thank you.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Okay, and while the obvious benefit of such a program is to enable providers to meet the requirements of the Meaningful Use and the growing program and the growing number of reimbursement models that might be based on the use of certified technology, the real benefits of such a program should accrue to the providers and the patients in the form of higher quality, more efficient care delivery.

From a vendor perspective though achieving certification is an important result, our primary goal is to produce high-quality software that meets a broader set of our customer's needs only some of which relate to Meaningful Use or those defined by the ONC certification program.

As currently defined the processes, deliverables and tools for certification, although very well intended, are not effectively enabling EHR suppliers to achieve this goal. Our concerns are well documented in various letters and meetings that we've had with ONC and CMS over the past few years. There is not time to go through all the specifics today called out in his letters, but we have included them as part of our submitted testimony and I would request that you read these letters. I'll call out a few of our concerns right now.

First, the full set of requirements is not provided with adequate time for development. The full set of requirements is based on the information in the final rules, both certification and Meaningful Use, the test scripts, the FAQs, the CMS specification sheets and is even impacted by the testing tools and testing data.

And as they do become available, we have many examples that show that these deliverables have added and changed the requirements that were defined in the initial certification rule, this causes a lot of waste as we try and reconcile all these documents and incorporate the new requirements into the software late, ultimately impacting the quality and usability of the software. In addition it causes delay and when certified software is available in the market.

Second, the certification criteria for the Meaningful Use objectives, the requirements for the reports that measure these objectives and the clinical quality measures are not aligned with each other and not necessarily aligned with clinical practice. We are very concerned that as more of the provider community comes to use the software the dissatisfaction will reflect negatively on EHR developers when in fact we're doing exactly what is required for certification.

Lastly, the testing tools and associated data are not properly tested before they are rolled for use in the vendor community.

We believe there are a number of opportunities to improve these issues and the certification broadly for all key stakeholders while also maintaining the integrity of the program. We have documented these recommendations to ONC in the letters I mentioned earlier. I will highlight a few right now.

First, all the materials that impact the requirements must be available much earlier. Ideally concurrent with the release of the final rules and remain stable or the timeline for the program needs to accommodate when the information is actually final. You can look at any good software development methodology and it will tell you that before you begin to develop the software a complete and stable set of requirements are needed and the developers must understand how the software is going to be tested and used in order to be successful.

Next reduce the overall complexity of the program. In recent meetings including vendors, ONC and CMS this program complexity was discussed at length and there appeared to be broad alignment then that the program is in fact, way too complex.

Lastly, we strongly recommend the use of a Kaizen process to support and effective review of the certification program considering our recommendations and experiences as well as those of all the stakeholders who are here today. This approach has been used in other HHS programs with good results.

The Kaizen process should be organized around all key elements of the certification program and process and focusing on reducing complexity, eliminating waste, improving productivity, realizing the value, and achieving sustained and continual improvement. Participation in Kaizen events requires a significant commitment from all involved, however, we strongly believe that the opportunity for improvement fully justifies the time and effort needed to prepare and participate in these events, the EHRA commits this time and effort now.

We recognize that certification does have a very important role to play in the Health IT industry and we really do look forward to working with all of you to enable us to achieve the desired goals in a way that is effective and efficient. Thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, so moving onto Sasha TerMaat.

Sasha TerMaat – Legislative Analyst – Epic Systems Corporation

Good morning, my name is Sasha TerMaat and I'm here from Epic, I appreciate this opportunity this morning to share with you my feedback and suggestions for the certification program.

You asked first about what the benefits of an ideal certification program would be. So, let's take one example certification criterion, I'm going to take clinical quality measures, and consider the potential benefits of an ideal program.

In an ideal state certification of clinical quality measures would first bring together all of the requirements for clinical quality measures as a function in a single source that could be used to inform the development.

Next, certification would assure a user that this particular EHR could capture all the data necessary for a particular quality measure. It would test the accuracy of the measure calculation and check the conformance of electronic file to standard format. And most importantly, certification would ultimately assure a hospital or physician that files generated by a certified EHR would be accepted by CMS for participation in the program.

But we're missing key elements of this ideal state today. Certification is not a single source for quality measurement requirements. In fact, months after certification criteria are finalized CMS has published clinical quality measurement requirements in their implementation guides that both directly conflict with certification as well as adding new development needs.

This discrepancy challenges the HIT developers, it confuses EHR users who don't understand why they can't submit files that were generated out of their certified EHR and it also causes CMS to have to spend additional effort on separate clinical quality measurement validation tools.

In addition the certification program requires development and testing of clinical quality measurement formats that can't actually be used for submission, this is true in the 2011 edition, and remains in the 2014 edition. For example, CMS does not accept the QRDA file for hospitals but this is part of the certification criteria. So certification requires the development of functionality with very limited utility.

An ideal certification program wouldn't require development of standards that can't be used and would align and define the requirements that will be used with sufficient lead time that they can be developed and implemented efficiently.

Your second question was about challenges. I'm worried that there is a disconnect on certification scope. Take one of the updated 2015 criteria as an example, ONC estimates that the updates to standards for lab ordering and sending labs electronically will take an average of 100 to 300 hours per EHR product developed and certified. Accounting for some certification listings to be inherited this estimates about one developer working on the project for 15 weeks.

In contrast, when the Electronic Health Record Association surveyed EHR developers of all types and development models they estimated on average that this same project would take about one developer for 93 weeks. It will be hard to select appropriate timelines with such a discrepancy between whether a project takes four months or closer to two years. This is not a unique example. ONC estimates for proposed 2015 criteria are consistently only 10% to 20% of what EHR developers estimate. The EHRA estimates are available on line for reference and I encourage careful review.

Your third question was what suggestions I have for the certification program. I echo the recommendations of other panelists that a thorough review of the Meaningful Use Program broadly and the certification process specifically would be valuable and I'd also be happy to participate and contribute. In these more detailed discussions I urge consideration of the following ideas.

First, I'd suggest narrowing the focus of certification to the highest priority criteria which I see as interoperability and clinical quality measurement. These are key goals for the next stage of the program and offer the greatest benefit if standardized across all EHRs.

Second, I think there is opportunity to consider more efficient testing models for certification such as asynchronous or off-line testing, change validation when a criterion differs only minimally rather than full regression testing and reuse of test data sets between certification. I look forward to this ongoing discussion and thank you for your consideration.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, amazing, you're even under your time. Good job. Okay Emily Richmond.

Emily Richmond, MPH – Senior Manager, Health Care Quality – PracticeFusion, Inc.

Hello, my name is Emily Richmond and I would like to thank the committee for the opportunity to speak on behalf of PracticeFusion a free, cloud-based ambulatory EHR and patient portal platform.

When considering the potential benefits of certification from the EHR vendor perspective we look to the technology industry where the most well-known example of the widespread adoption of standards is the Internet.

The Internet, as we know it today, was created because diverse stakeholders collaborated agreed upon protocols that would serve as a foundation for future innovation. With standards in place but implementation specifications left up to the market the user experience of the Internet was able to rapidly advance in response to user feedback allowing the growth of features that serve the needs of different audiences while remaining compatible across different products, platforms and areas.

The EHR certification program had the opportunity to provide similar benefits to the Health IT industry by selecting standards that could facilitate interoperability across EHR products, but unfortunately those benefits are often overshadowed by the challenges that exist.

Before I dive into the question about certification challenges I'd like to provide some background on how PracticeFusion develops software. PracticeFusion recognizes that the needs of the healthcare providers are very dynamic. As such we have chosen to utilize agile methodology and the scrum framework in our software development process.

Agile principles in the scrum framework are used by many software companies in order to execute on what is sometimes called rapid software development. However, PracticeFusion combines rapid development with a rapid release cycle in order to deliver small, incremental product changes to our customers approximately once every two weeks.

Despite this unique approach PracticeFusion still faced challenges during EHR certification because of our desire to balance the extremely large volume of work that was required to successfully certify with the need to continue delivering product features that were specifically requested by our customers without disrupting their clinical practice.

We want to highlight these challenges because although an agile development process like the one used at PracticeFusion may appear to eliminate some of the difficulties related to the certification timeline this is not necessarily the case.

By the time PracticeFusion began working towards 2014 certification the ONC had clarified many EHR developer questions through the use of sub-regulatory guidance. However, we were still faced with a huge volume of product changes and very specific implementation criteria that needed to be researched, analyzed, designed, developed and tested all before we could even begin preparing for the ATL certification test.

Had we started the process sooner we would have had to change course quickly and on multiple occasions, expending time and resources as updates to test methods and FAQs were released that altered the interpretation of certain requirements. These updates ultimately changed the acceptance criteria needed to develop the software.

Despite starting the process after clarifications have been made we still had to locate and analyze upwards of six different sources of information including test procedures, CMS specification sheets, standard documents and various FAQs before being able to determine, with some level of confidence, how the software would need to function so we could move forward with design and development.

We share these experiences with the committee because we feel that non-software developer stakeholders often underestimate the time and effort required to overcome the challenge of simply understanding what needs to be built in order to certify.

Another challenge that we faced was integrating the certification requirements into our product without compromising usability and our customer's ability to provide high-quality patient care. The current certification program challenges usability in two ways, one through dictating prescriptive functional requirements that allow little room for innovation and another by requiring that health care providers adapt large volumes of products and clinical workflow changes in a short amount of time.

While we understand that some prescriptiveness is necessary in order to support interoperability and that some feature additions are needed in order to support Meaningful Use we feel that certification is moving in a direction of incorporating higher volumes of requirements that do not serve either of these goals, which in the long run may have a negative impact on both providers and patients.

At PracticeFusion have seen a 60% increase in support cases related to dissatisfaction or confusion with Meaningful Use required features during the first quarter of 2014 compared to the same timeframe after the release of our 2011 certified product.

In our written statement submitted for this hearing PracticeFusion proposes several changes to the certification program including reducing the overall scope and complexity and incorporating the feedback and expertise of EHR developers early and often, and the creation of certification requirements and testing criteria. This will help ensure that the requirements are aligned with the capabilities of EHR technology and that the program is fostering the development of software that meets the true needs of healthcare providers not just EHR systems that can pass the test.

We are also supportive of the previous suggestions that the certification program be reviewed using the Kaizen approach. Through collaborative efforts that involve all relevant stakeholders we believe that the certification program can be optimized in a way that provides ongoing benefits to EHR companies, healthcare providers and patients. Thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, Emily. Joseph Geretz?

Joseph Geretz – Chief Software Architect – SRSsoft

Good morning my name is Joseph Geretz, I'm Chief Software Architect at SRSsoft. Thank you for providing me with this opportunity to supply input on the certification program.

Certification today is the capstone to Meaningful Use objectives and measures its purpose is stated on healthit.gov as follows; certification ensures that EHR technologies meet the standards and certification criteria to help providers and hospitals achieve Meaningful Use objectives and measures.

The program's total impact on vendors accrues from the complete set of objects, measures, standards and certification criteria. The bulk of the burden which is placed on vendors today can be traced to the vast and varied scope of the objects and measures upon which certification is ultimately based.

Since 2010 we have experienced a progression of development from one peak to the next without seeing any valleys. We have lost our capacity to innovate on anything above and beyond the mandates of Meaningful Use.

Since embarking upon this program we have been unable to devote resources to features which our customers are requesting. In essence, the program has become our product manager "all Meaningful Use all the time."

Our customers ultimately bear this burden in terms of higher costs and lost productivity as the program with its tight deadlines trumps our desire to focus on the ease of use and productivity.

I deliver my remarks on certification today with some degree of ambivalence. Narrowly focused evaluation of certification alone will yield some benefit but only to the certification process itself. A broader evaluation of the entire scope of Meaningful Use objectives and measures, together with the demands of certification requirements, is warranted. There is much to discuss on this subject and hopefully we will have that opportunity in the near future.

I will now address the three points which are specific to certification. Certification benefits, from the vendor perspective, the beneficial aspects of certification are those which align progressive policy with commercial interest. The convergence of commercial motivators with proper healthcare policy will be the most effective combination of factors to advance the cause of Healthcare IT via private industry.

The most beneficial aspects of certification are those which govern relationships between vendors and those which help to promote relationships with customers. These are A; certification of interoperability. This levels the market for all vendors. Interoperability barriers are removed so that any conformant EHR may be integrated within any healthcare community.

And B; certification of suitability certifies for the consumer which products will be suitable for a desired purpose. To the extent Meaningful Use remains attractive to our customers this certification adds value. We caution, however, that the long-term attraction of physicians to the Meaningful Use Program should not be taken for granted. Should this attraction wane this aspect of certification will cease to be of interest from our perspective.

Challenges we have experienced include assimilation of specifications from a wide range of sources, specifications which are out of sync with the state of the industry, in conflict with typical practice workflows or based on immature standards.

Additionally, we are challenged by requirements to interoperate with unregulated partners and certification utilities and testing tools which are defective or overly strict with respect to the requirements.

Our proposal for an enhanced certification process, we recommend a narrowly focused certification which places emphasis on those aspects of EHR technology which are the drivers for the most important items among the wide range of prescriptive criteria to which we must certify today. These are interoperability and quality measures. This concise set of criteria represents the convergence of progressive healthcare policy with commercial interests. With this framework in place vendors in cooperation with market forces will naturally produce their EHRs to the standard which will advance the cause of Healthcare IT.

We support the suggestion tendered by Mickey McGlynn on behalf of EHRA, as well as other panelists, for the initiation of a holistic Kaizen process to review the combined Meaningful Use and certification programs with an eye toward improvement. We would be happy to participate in such a process. Once again I thank this committee for providing me the opportunity to deliver this testimony today.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, Joseph. Sarah Corley?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Good morning I'm Dr. Sarah Corley Chief Medical Officer for NextGen Healthcare and a former CCHIT Commissioner.

As constraints on provider's time become more prevalent healthcare professionals are turning to technology driven solutions that can increase practice efficiencies and allow them to focus on delivering quality care to their patients.

A certification program can give providers the assurance that the software product will meet baseline standards for compliance with regulatory requirements as well as the functionality that stakeholders think is important in supporting improved care.

Meticulous testing of EHR products is critical to their optimal performance and to maintain the highest standards of patient safety possible. The current certification timelines and cycles do not allow time necessary to safely develop content focused on user workflows.

Given today's limited timelines EHR developers do not have all the necessary requirements available prior to beginning their work that means there is a rework and extensive wasted effort when late guidance is issued.

In addition to the 18 month time period that vendors require from the final release of all requirements, test scripts and testing tools to safely develop the software, there must be time for healthcare providers to thoroughly test the software and their unique environments, that process includes testing all interfaces and connected software, and devices, adjusting workflows and training their end uses.

Our clients generally require 12 to 18 months to complete this work after general release of the software before they're willing to introduce it into their production environment. To that end I recommend returning to the certification process that was followed in the CCHIT model which included key elements such as broad stakeholder participation an environmental scan of availability of functions, maturity of proposed standards and a published roadmap.

Extensive stakeholder input by clinicians, vendors, academicians, developers, payers and consultants is essential to ensure that the certification is relevant to those purchasing and using the products and services.

There should not be requirements this collect data that is not relevant to the care of the patient in that setting.

The certification process should include environmental scans to identify the current state and availability of key requirements and functionality.

Most importantly, a successful certification program must provide a forward-looking roadmap of certification requirements and clearly detailed additional criteria that vendors should expect in the future, that could continue to drive enhanced capabilities and standards compliance without releasing requirements prematurely.

With roadmap certification occurs with predictable timelines and requirements. This provides the opportunity through which vendors could develop QA and test their software to increase their certification preparedness and the end-users have the opportunity to plan for changes in their workflow.

In addition to predictable timelines test scripts need to be published well in advance and pilot testing of the test scripts and testing tools must be done before the final version is released to catch and address any potential problems.

The current program includes many requirements not relevant to large segments of the healthcare provider community. Certification requirements should be limited to the core that all physicians or hospitals must adhere to. If there is a need for additional requirements for certain types of healthcare providers, add-on items can be certified separately so that vendors who do not serve that market are not forced to develop software that their clients do not want or need.

There should be evidence of the utility of any given certification requirement. It's important to remove requirements for automatic numerator and denominator calculations for measures that require additional documentation that is not necessary for the provision of care. These measures should simply be attested to.

No matter what the approach for HIT product certification to truly be of value to interested parties those parties need clear knowledge of what the certification program intends to accomplish and its criteria need to match what the end user is expected to accomplish.

It should include only criteria that support the core needs of the regulatory program focusing on a more narrow set of truly important and achievable goals.

While our common goals are improving quality, increasing patient safety and expanding interoperability, I believe that this can be done with a much narrower range of certification requirements. I thank you for the opportunity to present today and I look forward to working with you to improve the certification process. Thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, Sarah. Marc Probst?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Great, my name is Marc Probst I'm the Chief Information Officer at Intermountain Healthcare. I'm not sure how I'm a vendor, but for those of you on the HIT Policy Committee you know that when Michelle asks you to do something you do it.

I'm pleased to respond to the three questions that have been posed. The first question assumes we could design an ideal certification program and asks, what is the benefit of having a certification program? Certification serves the validation function which according to the CMS website quote "gives assurance to purchasers that an EHR system or module offers the necessary technological capability, functionality and security to help providers meet the Meaningful Use criteria."

With respect to self-developed technology such as that which Intermountain is now seeking to have certified for 2014, I frankly see very little value in certification. Indeed if a system is self-developed for use by its organization with no intent to market the product it is difficult to find utility in the certification program.

As long as self-developed systems are one, not available to the market for purchase and two, able to meet Meaningful Use objectives, it seems an unnecessary expense to require the self-developed system to move through the certification process.

Indeed I believe that the Meaningful Use requirement to use a certified product should be significantly relaxed if not removed for self-developed systems.

The second question asks about the challenges experienced with the current certification program. From my perspective one of the greatest challenges with the certification program is the compressed timeframes.

The current regulatory pace between final rule publication and the beginning of compliance is unrealistic and does not match the reality of safe development. Clearly, there are very real patient safety implications when HIT development and implementation is rushed.

Supporting this view is an American Hospital Association survey of approximately 500 hospitals, the results of which were reported in the December 2013 and which found that the majority of hospitals had not yet received from their vendors all of the needed 2014 edition certified EHR components. Nearly half of the hospitals found that the majority of the technology received from vendors to date required additional software code upgrades to make the technology functional.

The majority of hospitals were missing modules that support objectives of Meaningful Use that are new in the 2014 edition certified EHRs and at the time of the survey 40% of hospitals were at risk of failing to meet Meaningful Use in fiscal 2014 if current timelines remain.

We know from experience that the 2014 certification in Stage 2 Meaningful Use requirements combined with ongoing payment and delivery system reforms are simply too much change all at once.

The third question asks, how to change the certification program to enhance its value while minimizing the burden of the participants. Requiring everyone to upgrade in 2014 regardless of their point on the Meaningful Use journey has created unnecessary pressure for vendors and providers and unnecessary costs for providers who are not at Stage 2 in 2014.

Going forward we should base the provider certification requirements on the provider's stage of Meaningful Use not the fiscal year.

Under the current certification framework software design is often limited to what is needed now and not with a mind to what future requirements may be. More importantly, the cycle of software development to meet specified functionalities tends to impede innovation. Developers are working so fast to meet the demands of Meaningful Use that little time remains for life and cost saving innovation.

The Meaningful Use Program is unfolding incrementally. Providers and vendors don't share long-term strategic view for the program. Sitting here today with the benefit of hindsight it would have been preferable to choose all of the standards required for interoperability and to have set forth a long-term strategic Meaningful Use plan focused more on outcomes and improved patient and population health than on specific functions.

While continuing to support the current momentum created by Meaningful Use I remain convinced that we must leverage all of the expertise in the federal government to develop a long-range plan and architecture for a national healthcare information technology infrastructure and outline the pathway to comprehensive use of meaningful standards to facilitate national interoperability.

If appropriate standards and exchange infrastructure were defined with explicit certification requirements and time given for appropriate implementation we could then focus on the Triple Aim of better healthcare, better health and lower costs.

I believe that innovation in HIT would skyrocket, cost for technology and access to knowledge would be significantly reduced and quality care across the country will improve. Thank you for the opportunity to present testimony. I look forward to continuing to work with all of you as we look forward to the realization of shared information technology infrastructure here in the United States.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, Marc. So, I'm guessing that John Halamka has not yet joined us on the phone is that correct? I'll take silence as a yes. So he may very well join us during our discussion period in which case we'll give him a chance to have his 5 minutes, but in advance of that are there questions from the Workgroup members? Okay Paul you were first up with a balanced card.

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

Right, well I want to thank the panel for really a very informative and well thought out testimony and really liked a lot of the recommendations and the concise way that you talked about some of the challenges and obviously they were very consistent themes.

I'm going to pick on and try to recite and summarize, pick on one of the recommendations that came up more than once is the Kaizen which has been used in HHS let's say around quality measures with good effect. Another example of long lifecycle, a lot of confusion and the delay causes impact throughout the healthcare system.

So in your Kaizen some of the things that you talked about one really thoroughly reviewed the lifecycle from Meaningful Use objectives to the measure, to the certification, to the testing and to the audits. It's really an integrated lifecycle that should be looked at in total, it's sort of what I heard as I put together the comments.

The other you eloquently talked about complexity. Part of the complexity is because you have to look in so many places to find it. So, if you had an integrated comprehensive source that, oh by the way was consistent with each other, and when that was complete that's when the timeline, the clock started that's I think what you're saying as well and then we allow some pre-defined time, we've been using 18 months and I'm not sure that's enough it sounds like for everything from development to the testing, to the implementation which we commonly ignore.

And the eliminate waste which is the primary reasons for the Kaizen – remembering the value that we're supposed to generate with the providers and their patients and consumers, and above all I think you've all talked about the realistic timeline so that we can produce quality products safely.

So have I captured the main themes that you talked about? What I tried to do is summarize what a number of you said, but I really like that idea of the Kaizen as a unifying way and of course it would include all the stakeholders in that whole lifecycle so that we can come up with a more efficient but far more effective way of getting from our intent, as Charlene was saying from the Meaningful Use objectives, all the way to what's delivered and used. Does that make sense? Have I caught your message?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I think that's a good summary of that particular area, the Kaizen recommendation.

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

Okay.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Yes.

Paul Egerman – Businessman/Software Entrepreneur

That's not the entire message.

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

It's not the entire message but I tried to combine –

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

No, I agree.

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

I tried to combine a lot of the messages in what the Kaizen would do.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, anything that particularly jumps out that you're saying the Kaizen piece doesn't get? Where would be missing things.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I think the Kaizen would bring to light a lot of the issues together. You know when I listened to what the providers said, you know, plenty of head nodding from the vendor community there. So, I think all the, you know, the stakeholders in the room hearing it understanding it and, you know, there are processes that we don't understand from the government, there are processes that we have that the government doesn't understand, providers, you know, all of that, having the discussion together I think is the best opportunity to get to the root causes of the problems so that we can then address them.

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

I mean, the other thing I heard was from the providers and from the script is really the intent behind Meaningful Use and what it brings out, you know, what – the infrastructure it's created has been good and as we've gotten – we've developed all of these, in some sense siloed processes and information sources, that when they come together a challenge for someone having to build products that fit them all is really quite burdensome and really sometimes hard to satisfy.

I think Sasha gave an example of where Meaningful Use requires one thing and then, oh, by the way CMS wants – it puts both the vendors and the providers in the middle. So it seems like nobody with ill intent has caused this to happen. But looking at the whole picture through – and Kaizen is just a tool, could be very useful to address some of the challenges in a program that's really well meaning.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I would just reiterate a point that the providers made to a comment that Steve made and I understand what is being said, but like the providers, the vendors think about the whole program and they really are treated very separately and the conflicts that creates and the conflicts the manifest themselves in the products to meet the certification criteria are serious and I think getting at that with all the whole program in the room will be important.

Joseph Geretz – Chief Software Architect – SRSoft

This is Joseph Geretz, I think your summation was excellent. In fact, you showed us all how we probably could have said what we said in 30 seconds. One detail I would add is the overwhelming amount of prescriptivity to the program and it gets back to your point that the intentions are well motivated and the outcome that we're looking for we share that, it's that when there is little time to accomplish a lot, all of this prescriptivity is getting in our way and if we could, through some sort of process, focus in on what are the key outcomes we're looking for we might be able to build a better process out of this.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So any other comments about Kaizen from the Workgroup members before we go onto some other questions? I've got one, so I guess it's the Chair's privilege there.

So Kaizen is often part of an iterative process whereas the regulations now are in a many year cycle, Kaizen says we're going to try this, we're going to – best thinking around the table but we're going to get experience from real life and then we're going to feed that back in.

So, do you have any thoughts about how we can get some real life experience into this cycle in a quick way that could inform the regulatory process which is not quick and is, you know, intended in some ways to put major stakes in the ground and then we have to live with those for a while?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

So, this is Mickey, just a quick comment is I mentioned that we have letters that we've sent. I mean, that's real feedback that was happening while we were developing it. We give examples and we make recommendations throughout. So lots of documentation exists and there is a lot more than that. We tried to put a set together that was readable in a short amount of time but that told the story. So we have plenty of real life examples and I can imagine that the providers do as well as a starting point.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess I was thinking though, so let's – we get everyone around the table, we take on stage "x" and say okay so that we're going to bash out the stuff maybe in some pre-regulatory boxing ring. And so then we get through that, you know, so a week or two weeks, or month goes by is that the kind of Kaizen event we're looking at here or how do we then find out?

So, it sounded good, everyone thought this was really good, but we go to build it and we still run into many of the issues you've been describing because a lot of things we can't think through sitting around a conference table. So, any thoughts about how to take the more iterative nature of Kaizen and sort of bring it into the regulatory process?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Well, this is Sarah Corley, I mean, we had a process that worked before Meaningful Use with CCHIT now there was no requirement for providers to adopt it, but that process went through stakeholder review and a number of public comment periods to refine those criterion before it was released along with the testing as well.

And I would say that we have two issues that are the problem right now the enormity of the requirements is just huge. It's not a single day certification it's not even a multi-day certification. In the case of adding the quality measures it can be a multi-month or multi-year certification process that's ongoing.

So I think that you really need, as you heard from all of the panelists, to narrow the focus to what's really important. Okay, we've gone over the hump on the adoption curve so that we have the bulk of providers now using health information technology. Let's look at what are really important to accomplish and let's narrow the focus to those.

And why do we have to certify, you know, and test on gender and preferred language and all of that. If that's in the interoperability requirements for the C-CDA, test our C-CDA's why do have that separate process of counting that people are doing that. You know you see that you have high compliance with the demographics, why do providers have to attest it?

Really, take a careful look at what we're doing and narrow it to what's going to achieve the outcomes that we all hope to accomplish which is going to be better healthcare, more efficient healthcare.

Joseph Geretz – Chief Software Architect – SRSoft

This is Joseph Geretz I would just add to that it's the same methodology with any data point that's maintained in our EHRs you just need to look at the quality measures and if the quality measures are being generated from the requisite data than obviously that EHR is able to maintain that data.

I'd also make the point that focus on quality measures would make the program highly customizable from the perspective of what type of practice is being targeted. You know you family practice, you have specialists they're all going to be, you know, practicing medicine differently, tracking data differently and working with different quality measures.

So the certification that shows that a certain EHR is delivering measures on certain scopes of quality that will tell customers which EHR is most suitable to their practice.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

So, this is Marc Probst. It seems to me that certification is a direct reflection on Meaningful Use that's why we did it and when we started with Meaningful Use we defined a lot of capabilities that we believed an EMR should do and that we would go ahead and certify that it would do those things and we created another problem because now we took and we've put that technology in the hands of a lot more people, there are lot more users and now a lot more people are understanding the basic problem that existed that we heard about probably in our first six months of the Policy Committee, I remember explicitly the conversation about data liquidity, that if you only did one thing as a Policy Committee was data liquidity you would solve huge problems in our country.

Well, we put that out there, everyone recognized it but we still allowed them to speak French and German, use AC and DC, and, you know, there weren't those standards in place and now we're trying to go back and retrofit it.

And I think, Larry, to do that in an iterative fashion, to retrofit without solving some of those fundamental basic problems it's going to just be a continuous cycle of whack-a-mole in trying to solve, you know, these individual issues that are coming out.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you. David Kates.

David Kates – Senior Vice President, Clinical Strategy – NaviNet

David Kates with the Advisory Board, Sir I may put you on the spot, but I wanted to key off of some of the comments that all the testifiers had indicated in terms of reducing complexity and scope and narrowing the focus of it and, I mean, if you reflect back to, and Marc you touched on this as well, reflect back to some of the original motivations for CCHIT and for the certification process it was somewhat paternalistic and recognizing that there was a wide variety of technologies available that could potentially be adopted as EMRs and the thought that, particularly in the ambulatory space, that there wasn't a sophisticated buyer and therefore there needed to be some baseline functionality and protect, you know, sort of a protective nature, paternalistic again, to making sure that the basic capabilities of an EMR were met for a purchaser who may not understand, you know, the nuance of what is an EMR at the time, you know, I think back 10 years ago.

I'm wondering, you know, given the focus – and also make the observation that the folks here on the panel are the more sophisticated, comprehensive EMR vendors but there are still, if you go through the CHPL, there are a large number vendors out there and I'm curious as to should we take recommendations to reduce the scope and complexity and focus on data liquidity, quality measures and the like, are those historical motivations for the certification process, have they gone away? Can those be deprecated and still address the original motivation for these activities?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah Corley. I think that we don't need to certify to basic functionality anymore, right? I think that users are more sophisticated, although with the increase in adoption with Meaningful Use we have a lot of providers who are not so willing who have adopted and that probably contributes to dissatisfaction.

But, I think we really should narrow the measures, take away the one thing, you know, you have to do vital signs, you'll have to do a growth chart, if you want to sell to that market you're going to have vital signs, you're going to have growth chart and really focus on what we want to do.

We want to improve quality which means we need to have already measures. So quality measures need to be eMeasures that are part of the normal workflow and not include such things as requiring an exclusion to identify the drug you would have selected if the patient was not allergic to the drug, which is a huge burden to providers or it results in you defaulting something in which is not meaningful to the people that want the data.

So really, you know, focus on what quality measures where we have poor performance in this country that are costing us money not a quality measure for every specialty, if that's not really a big component of the problems of health care in our society let's address where the costs are, where the morbidity is and where we're not delivering that care. Focus the quality measures on that and let's focus certification, if it's necessary in fact, on making sure that the products can report that to the appropriate people that are accepting the quality measures.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Yes, I mean I do think we can focus, I mean that's what I just said a minute ago, David, but –

David Kates – Senior Vice President, Clinical Strategy – NaviNet

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you. Oh, was there someone on the phone?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Yeah, this Carl and I had my hand raised. I had two comments.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay, go ahead Carl.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Two comments and then a question for possibly Marc and Paul. One thing I noticed I do worry that experience is all around us and that it seems like we sometimes pick and choose the feedback that supports our predispositions. So I don't know if Kaizen is the right approach, but I think there is a moment to step back and self-reflective little bit are we really absorbing the feedback for what it really is, everything from development estimate, inaccuracy to whether or not the regulatory process actually enhances usability or deters from usability and whether more would enhance or deter it further.

The second comment was with the, I think Brailer under the Thompson HHS administration was the first to publish a report that positive certification would lead to buyer security and would enhance EHR adoption and I think evidence shows that it really didn't what actually enhanced adoption where the stark exceptions allowing subsidies up to I think 85% for health systems at hospitals to extend EHR technology that marked an uptick.

And I think this certification isn't really enhancing adoption like that either it's likely the stimulus funding that's driving adoption. And the question I have is for Marc Probst. If an organization could somehow demonstrate Meaningful Use without certified software could we not eliminate certification for everyone who could demonstrate such Meaningful Use regardless of the origin of their software?

If it's practical to be a Meaningful User without certification then my sense if certification may simply be a boat anchor the world could do without because it is a very expensive boat anchor for all involved, right the government, the vendors and even the user community who have to go through forced upgrades, clock in what version they're on at what moment in time for which program. So, I would wonder if there was such a way could it one be extended to everyone and if it was practical to do it could we in fact eliminate certification entirely?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Well, Carl, this is Marc and thanks that's a great perspective and I think the answer to your question is yes and I was going back and looking at the definition from the CMS website of what certification was for and it was really to give assurance to purchases and I suppose if people have purchased and now they're within the cycle just like, you know, at Intermountain we are because we develop our own, although I think we have purchased one I've heard that, right? But, previously, yeah, I think that's a great point Carl and one worth reflecting on.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, Paul, jump in with your follow-up.

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

Yeah a follow-up on Carl's question, this is going to be a question for Steve again. I pulled up the HITECH legislation and I'm trying to see what was required in that and I'm not sure – I'm asking the question, I'm not sure that we – right now we said certify for every Meaningful Use objective I'm not sure that's actually required in HITECH. Is that true or no?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

No that would not be required that is the way in which the structure has been created in part the assurance is for a lot of the measures, even some of the ones that have been identified as capabilities that are generally part of products to begin with for normal purposes.

There is a measurement construct to it and so in part, there is a certification criterion to support the use toward that measurement in driving why there is a capability for certification to exist and in part there was a kind of lemon construct that providers weren't going to adopt lemons or unknowingly adopt lemons and one could argue for critics of the certification program that the certification program didn't stop that from happening, but the construct of having a limited set of certification criteria is that – that's permitted under statute you have to look at that in the bigger picture, as folks said before, in terms of how that supports Meaningful Use and what that means in terms of the incentives from a statutory perspective that congress set forward for providers to use products that were certified and, you know, then you get into a question of the scope of the certification which I think is where the policy tension lies.

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul Egerman, so to pick up on what you just said, Steve, you could potentially have a situation where you have certification say for interoperability only and then Meaningful Use on other items. So, you could say I have certification for interoperability which seems to be a lot of what people here are saying, but thinking about the last panel as some being needed to attest to Meaningful Use of access to radiology images they could do that a variety of different mechanisms but they would still have that Meaningful Use requirement.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Yeah, so, this will take folks way back to the HITECH Act itself. The statutory definition for certified EHR technology is one that is a construction. So, congress first created a definition called qualified EHR.

Paul Egerman – Businessman/Software Entrepreneur

Yes, I remember.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Which they posited particular capabilities that needed to exist, that needed to be certified in order for someone to have something that meets certified EHR technology definition. We, through the regulatory process, to implement that requirement created the base EHR definition to which we assigned, in some cases, one certification criterion for each of those statutory capabilities.

So, the statute said, for the qualified EHR definition there needs to be CPOE. We have a CPOE certification criterion, so that's kind of – parsimony is the right word there. They said clinical decision support, we have a single clinical decision support certification criterion. So, starting at the base EHR definition I guess which exists today that would be the – I'd say the bare bones minimum that someone would need to meet the statutory definition of certified EHR technology.

Paul Egerman – Businessman/Software Entrepreneur

Thanks.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, Paul, do you have some other questions?

Paul Egerman – Businessman/Software Entrepreneur

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I did a head shaking view for several speakers now so let's do it for real.

Paul Egerman – Businessman/Software Entrepreneur

Thank you very much Larry and also want to thank everybody it's been a terrific process and being a former vendor I know also that it's a considerable expense for you to be here and so I appreciate your presence. I actually have two questions, first I would like to ask another question of Marc Probst since you are a different – you're a developer but you're a little bit different than the vendors here in that you have to be responsive to literally thousands of physicians and I'm just curious to what extent does the Stage 2 criteria represent items that your physicians were asking for anyway? In other words does it fulfill needs that existed within your organization, to what extent does Stage 2 do that?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

There are components of Stage 2 that are actually incrementally beneficial to our clinicians. I'd say there is more in Meaningful Use Stage 2 that we've had to retrofit our systems and processes to accommodate so that we could certify and attest to it.

So, you know, the concept around has certification or this process inhibited innovation, yeah, there is no doubt. I mean, we spent energy on things that we just had to do differently so that we could certify the product.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

But, again, has it been beneficial? I think in aggregate, you know, maybe not so much at Intermountain Healthcare but for the community I live in and for the things that are happening in that community there has been a lot of benefit coming from the program.

Paul Egerman – Businessman/Software Entrepreneur

That's very helpful and the other question that is somewhat unrelated is in the prior panel the providers, a number of providers, talked about usability and were very concerned that somehow certification wasn't addressing usability or that was a problem with certified software and I'm curious to hear vendors reactions to that. I'm particularly curious to find out is there something about our process by adding additional complexity or by being overly prescriptive, or having a short timeframe that makes usability difficult?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

This is Sarah Corley, I will start. So, we've added a lot of things so you've heard about the clicks so we can count something. So, you say, well if you've thought about software development thoughtfully you could overcome that but, let's take patient education and you hit an InfoButton, all right so that doesn't mean you actually provided the patient education to them, you hit an InfoButton for patient education do we count that or not? That's one of those gray areas. So, you can say, yes we're going to count it, which is what my product does, hopefully that's okay, but you hear other products that are saying, no you have to say that you actually provided the patient the piece of education.

So, you know, you have – so if you take it literally to say you need to document that you actually educated the client it's going to be a click. The exclusions I mentioned that, you know, there is no physician in their right mind, and I'm a provider I still see patients one day a week, there's no way I need to take the time to document what medicine I would give you if you could take that medicine which you can't. I mean, it's crazy, but that's a quality measure requirement.

There are a number of quality requirements that would I think, you know, just be amazing if you consider them at the level of work that they provide, you know, for a user, breast-feeding in the hospital you're supposed to count not only how many times the mother breast-fed but when it started and when it finished. Do you think a new mother is going to track that, no, so you have the short timelines which mean you can't go out and work with your clients on analyzing their workflow to see where something should fit in so that's part of the problem. And then you have these other pieces of work that they have to add.

You know the tobacco use, I would venture to say that every vendor and developer here had tobacco documentation in their products but Stage 1 came along and we used these weird current some day smoker, current every day smoker. Well, I care about tobacco use I don't just care about smoking and no doctor I know of uses that terminology. So we had to put them in and because we had a short timeframe for Stage 1 you actually had to go in and you did your normal tobacco use and then you had to select one of those things.

Now for Stage 2 we had more time to say this is ludicrous and it's more elegant but I think that as long as you have the short development timelines and the quality measures coming out that usability is going to continue to be a concern and it's not because we wake up every day trying to think how we can add extra clicks to our client's work, which I have been accused of doing.

Joseph Geretz – Chief Software Architect – SRSsoft

And this is Joseph Geretz, if I could backup the question actually started off with are there things in certification that our customers are asking for and there are but that's not necessarily always a positive sign because when we talk about usability if we want to put in a feature that our customers are asking for we need the time to do it right for them.

So, for example, CPOE has been expanded now from just prescriptions to include lab ordering and our customers definitely, they're asking for it, they'd love to have CPOE and we are going to release a certified edition of CPOE but if you ask me if it's done to our level of usability and to our satisfaction, and to the satisfaction of our customers I would have to frankly say, no, given more time we would have spent much more time on it and produced something that's much more usable.

So, they've asked for it, it's in the Meaningful Use requirements and the certification requirements and we're going to deliver it so we're checking off all of tic marks but when it gets to our customers they're not going to be happy. So, if we're not producing the desired results we need to take a step back and, you know, see what we can change here.

Emily Richmond, MPH – Senior Manager, Health Care Quality – PracticeFusion, Inc.

This is Emily Richmond, so just one component to think about for usability is that a lot of this is being driven by the timeline so the expectation of the customer is that they have this product available to them in 2014 so they can meet certain deadlines for Meaningful Use.

And so as, you know, an EHR developer we create the product that meets the certification standard which is in some cases a very low bar in other cases a different kind of bar, so, you know, very prescriptive but, you know, high in that nature and then, you know, we recognize that because of time limitations usability has been compromised.

So we had to get a product out to them that met certification criteria and now we'd like to go back and perhaps make it more usable, but unfortunately because of the way the certification program works and also the new ongoing surveillance required for 2014 certified products we're forced to basically think about the cost and the time required to recertify a certain module and whether or not we actually improve it.

So, as I mentioned in my testimony we release product updates every two weeks so we have the ability to improve the product for our customers very frequently and we want to do that, but when we have to think about how can we get on the schedule for certification and how do we prepare for certification, how do we practice for it, what's the cost suddenly the desire to recertify trumps our desire to create a usable product or we recognize we just can't do that and we need to focus on something else. So, it just sort of, you know, contributes a lot of time and money, and effort to the process.

Paul Egerman – Businessman/Software Entrepreneur

So, I just want to make sure I understood that last part right. So, if you get feedback from customers and you sort of said if you did this and this differently it would be more usable, the certification process is an obstacle in terms of your ability to implement that because that makes it more difficult and more expensive to be responsive to that feedback.

Emily Richmond, MPH – Senior Manager, Health Care Quality – PracticeFusion, Inc.

Yeah and I think it's not just customer feedback. I mean when we designed and said, we need to be certified by this date so we can release to our customers by this date, we recognized that we could have done it just the way, you know, Joseph mentioned in two different ways, the way would meet certification or the ideal way and because of timeline and, you know, just the wave of the leading to, you know, the pressure to get this to our customers we had to pick, you know, way "A" which is not the way we would have done it if we had more freedom and more time to, you know, get the designs of our customers, do more intensive user research all of that had to be compromised because we didn't have a lot of time to even prepare the software.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

This is Mickey McGlynn I'd like to comment on the usability point as well. I mean, clearly usability is one of the top issues. Every meeting we're in with vendors and providers it comes up. So we know that, we recognize that.

To that end, you know, whenever it's discussed it seems to have a lot of different faces what one provider means by usability is different than another provider. So, at EHRA we are trying to tackle this to really get to the bottom of it because we know – we don't want to spend a lot of money and time solving a problem – you know, doing something in certification that doesn't necessarily solve the problem.

So, certainly, you know, lots of work to do here but we spent a lot of time with providers and, you know, had a session where we said, what do you mean by usability and it's a vast definition, you know, there are many things that impact it.

You know we had a situation where we had two providers using the exact same product, the exact same version, in the exact same setting and one provider talked about their top five usability issues and the other provider said "wow, I wouldn't have picked any of them, I would have picked these" right so it's not at all black and white. So we do need to tackle it together, recognize that but let's be pragmatic about how we do that.

I'll give a few specific examples to you question of how this program impacts it. One of the biggest things that came out in that session we had with the providers that causes usability issues is the lack of training and education for the providers who are about to use the system.

The providers who said we had adequate time, we took the time, we spent the money, we required the providers to do it were significantly happier than those that weren't. Okay, so when you look at the timelines, and you've heard from the providers, there's not enough time clearly an impact on certification.

Another direct example is we've talked a lot today about how the criteria come out at different times and late in the game. So an EHR developer has done the software, let's just say they've completed their work on the data capture requirements so where all the data is captured, out comes a new version of the quality measures late in the game, the product is well through the cycle, new data capture requirements. The screen has been validated, everything has been validated, what do you have to do, you need to go back in and find a way to capture that data element when you're well through the process.

So, unfortunately at times then you're creating usability issues, I've got to go to another screen, I have to fit it in a place where it doesn't exactly fit because it's the only place I have. Having known in the beginning you could have done the analysis holistically together and produced a high-quality point. So, there are two real examples where the program itself and the associated processes have a direct impact on usability.

Paul Egerman – Businessman/Software Entrepreneur

Very helpful.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Okay.

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you.

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

Larry, I just want to interrupt and let you know that John Halamka is on the line.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay, so John, you're squeezing under the wire, but welcome, go for it.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Thanks, so much.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

You've got five minutes.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Can you hear me now?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

We can hear you.

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good, well, I apologize for joining the session late but I'm sure others have given the preamble that as we look at the certification program we know we started with policy and those policies were turned into regulations, regulations turned into test procedures, test procedures turned into scripts and then data was generated, and tools were created so you had the combination of scripts, data and tools and my comment as a self-certifier will reflect on my experience and I hope to be very objective looking at the scripts, data and tools.

Let me start with tools, I certainly want to thank my friends at NIST who did a very significant amount of work in creating those tools and hosting them, but my experience in using those tools was that in each day that we went through our testing process for some portion of that day the tools were not available, error 404s, server down, tools not responsive.

There was even an incident where on a Sunday afternoon the tools actually were change from one server to another server and then a certificate mismatch problem occurred rendering the tools unusable. And then on Monday, unfortunately, Washington had a snowstorm and no one was able to deal with the tools being brought back up and then on Tuesday there was a conference that was scheduled that took many of the NIST folks out of the office so the tools were just simply not available from Sunday to Wednesday.

And the impact on our self-certification was that we had to reschedule our certification activities on multiple occasions because of unavailability of the tools as well as our developers were unable to meet their milestones because of instability and the unavailability of the tools.

So, I realize everyone was working as hard as they could on timeframes that were extraordinarily rapid but I would hope that as we go forward to the future that we recognize that this is truly a mission critical software set and both the tools need to be mature and the hosting of those tools needs to be at a 3-4 nines service level if we are going to depend on tight certification timelines and tool availability.

Next, as I reflect on the scripts, which really are a byproduct of the test procedures, during our certification, and we did both hospital certification and eligible professional certification, we had the experience that the test procedures themselves changed and I recognize that there is a need to iteratively improve these procedures but that should probably be done before they're launched as opposed to in the middle of a series of testing cycles because what we found was often our test lab was not quite clear what to test because the rules of testing was continuously changing and then our folks who prepared for responding to the script were often caught off guard because "oh, last week the nature of this test changed" and so, again, we found ourselves having to do additional testing sessions, having to go longer than time and having to be extremely agile because the test procedures themselves were not stable.

Our sense was that the test procedures were developed via a waterfall method that a lot of very smart people looked at the regulations and created test procedures but they didn't seem to have the benefit of being tested among clinicians, among IT professionals and then iteratively improve before release.

And so often we found that the procedures were not an effective test of the function, they may have lacked critical relevance or they may have looked at just portions of the workflow so the fact that one checked the box and was able to get through a set of procedures and scripts didn't actually imply that a clinician in practice could achieve the policy goal through the use of the application.

So we hope in the future that there is an opportunity for more agile method for the development of test procedures that follows the workflow of data from point of origin to point of use ensuring that a continuous process along the way enables a physician to meet policy goals.

We found that the burden of testing was immense. I have five people in my organization that deal with our clinical systems development and so I'm certain you probably have heard testimony from some of our larger EHR vendor partners and imagine if you, vendor partners, had to achieve Meaningful Use with five people.

I had to go through the exact same test procedures and the exact same scripts and the exact same testing tool as you do with five people. I had situations where five people were sitting in rooms for 20 hours at a time hand keying data from exhaustive data sets that tested every possible variation of a particular regulation with a set of test procedures that took a very significant number of hours and I especially think of the automated numerator and denominator test procedures, and the quality measure test procedures as just an immense consumption of resources to the point where it was very challenging for my organization to do anything but the Meaningful Use Stage 2 certification over the last year, well we did squeeze in ICD-10 just in case October 1, 2014 was going to happen.

We also found that the timeframe from the publication of the criteria to the expectation of having mature products was so abbreviated that usability suffered. So, we were able to achieve certification, we were able to get through every procedure but we weren't able to optimize workflow so we ended up with artifacts like pop-up screens or checkboxes that interrupted physician's workflow that if we had a little bit more time we could have implemented more elegantly.

So what you hope is that as we go to the future we have both scripts that are better aligned with workflow and an opportunity to optimize the usability experience so that the end result is that the physician is made more efficient rather than less efficient through advances in technology.

And then one final closing point, what I hope and I think others have probably said is that certification in the future is not an attempt to be exhaustively testing every single possible variation on data entry and results but instead focuses deeply on a few things like interoperability or quality measures.

I would tell you that my five folks who worked on this would have been thrilled to spend a few months really getting interoperability done well as opposed to hundreds of test procedures that focused on problem lists or allergies, or family history or other things. So, I applaud policy and the policy goals but would hope that certification in the future would be more narrowly focused. Those are the end of my remarks.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you, John. So, we're getting close to the end of this cycle, we've got a few folks, several folks actually with cards up so let's try and – I'll take them around the room. So, Don Rucker?

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

Yeah, Don Rucker, OSU, I think one of the questions around data liquidity is the issue of standard maturity and I know in the Workgroups this has come up I think a number of times on sort of which standards we think are mature enough that, you know, there's not an A and a B and a C version, as I think Marc mentioned, but just like an A version.

So, was looking to the panel to see if you were either willing to call out some standards as not quite ready yet or talk about some process that ONC and the certification process should have as a sort of internal testing of when a standard is ready for use in regulatory work?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And I'm certainly happy to start with that. Dixie Baker and I have, with Jon Perlin, recently written a paper for JAMIA which is in the process of revision that actually comes up with a quantitative method for evaluating standards maturity, readiness and adoption, and we did use that in our recent response to looking at some of the proposed Meaningful Use Stage 3 criteria and the standards that might apply, and so you'll see, Paul Tang has those documents, showing an actual rating on standards maturity.

With regard to the Meaningful Use Stage 2 standards certainly I would say the HL7 2.5.1 public health standards were quite mature. C-CDA was early, but, you know, I at least felt like we were able to execute that reasonably well. Things like QRDA 1 and 3 were quite immature and a real challenge.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Thanks, John.

Emily Richmond, MPH – Senior Manager, Health Care Quality – PracticeFusion, Inc.

This is Emily Richmond, so sort of a continuation of that point I think sometimes there is an appropriate reason for including less than mature standards part of it is to allow it to be used in the market and to learn from it. I think that the challenge becomes when before the opportunity to learn from it can really occur a future regulatory cycle will introduce a newer version of that same standard.

I think there has to be an opportunity when a less mature standard is used to really let it play out before the next version or even a completely different version of that standard is used and I think the 2015 certification proposals introduce a lot of different types of standards or new standards from the 2014 edition without really allowing us to see in the market and with our providers where are these current standards good, where they need to be changed and also recognizing the fact that we've already put in, as a vendor, a lot of time and resources to build that 2014 certified standard, let's see how it works and where it needs to be changed before we move on. And this is not even just for like a release one versus release two but also things like adding QRDA Category 2 in addition to 1 and 3 and things like that.

Joseph Geretz – Chief Software Architect – SRSoft

This is Joseph Geretz, a couple of examples, eMeasures were incredibly immature and the proof to that is that they are currently being rewritten to a new standard that's going to be completely backward incompatible. We spent a lot of effort dealing with all the problems actually to create an automated parser so that we would not have to repetitively write all of these different quality measure generators and, you know, a lot of that work is going to have to be discarded when the new standards come out.

Direct messaging also a relatively young standard, the difference being we see that standard is being built out forward. Again, there is nothing wrong per se with adopting immature standard at some point, you know, you just have to start the journey, but there has to be an acknowledgment that there is a certain – well there's a very high level of risk involved when beginning new development based on immature standards and that has to be accounted for in the timelines.

Sasha TerMaat – Legislative Analyst – Epic Systems Corporation

This is Sasha TerMaat, just as another resource the Electronic Health Record Association Standards and Interoperability Workgroup surveyed the membership about the standards that were part of Stage 2 and 2014 certification and Mickey and I couldn't remember off hand if that was ever finalized and published but certainly something that could be an excellent data point going forward.

There was a definite correlation between, I guess, the number of implementations before the standard was adopted, the piloted uses and the overall maturity of the standard and the time and effort that went into implementing it for Stage 2 as well as the satisfaction with the process of doing that.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

This is Marc Probst, we use standard as a very broad term. I mean, everything can be standard and it seems to me there is a hierarchy of standards and at each of those levels there are many mature standards. One of our big challenges is picking those standards. It seems to me as an industry we could accommodate that if we knew what they were and we had the timeframe to get to them and if we did we could create an infrastructure that would be very useful for the industry. So, I think there is a tone of mature standards, there's a lot of new ones that are coming out but we need to be working at some very basic levels of standards.

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

This is Michelle, I just want to note the time. There are a number of cards up and we only have a few minutes. So, we have to be very efficient or if the question doesn't need to be asked maybe we could move forward.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay, so, let's vote for efficiency, we'll go a few more minutes and see where we are. John Travis?

John Travis, FHFMA, CPA – Senior Director & Solution Strategist, Regulatory Compliance – Cerner Corporation

Yes, John Travis with Cerner, I'll try to make this quick. I think it was Emily that mentioned that surveillance kind of had a dampening effect on innovation. This could also be a question for Steve and any of the panelists.

How do you look at product updates in terms of triggering, retest versus say an inheritance claim and is that fear because you're making a material change to the software versus a minor enhancement? Where is that calculus or that balance that gets struck and is that something that needs better clarity out of the certification program so that fear isn't there or the line is clear?

Emily Richmond, MPH – Senior Manager, Health Care Quality – PracticeFusion, Inc.

Well, I think in our experience it hasn't necessarily prevented us from doing things it's just a component that we have to take into account but the important thing is where certification initially was prescriptive in how we had to do something we are thus required to ensure that actual function continues to occur in whatever we iterate on the future and maybe that wasn't what our customers wanted. Sometimes their feedback is "I don't want to do that this way" and we have to say "unfortunately, you're required to do it that way because that's what we are required to make you do to be a certified product."

So, we're limited in our ability to innovate when the test procedures are so prescriptive. So, the surveillance is just, you know, I there is a need for surveillance and obviously certain things and there is an appropriate time to recertify a product or a product change, but changing the user interface of how demographics are entered I have to go and negotiate with my ATL and explain to them why I don't think it should be recertified or why it should and it's just, it's a time and it's a cost that appears to be unnecessary from our point-of-view.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Great, can we move onto the next question?

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

This is Charlene Underwood and I'm going to moderate the panel from the private sector this afternoon so one of my questions is, again we've talked about, you know, the certification process itself and how to change it, but you've had experience with external sources of certification Surescripts, IHE those types of things. Are there any lessons learned from those experiences that would apply to your recommendations? I mean, we could go there and, you know, use those processes or, you know, is there something that we could build on in terms of some of the private-sector processes and work that are happening?

Joseph Geretz – Chief Software Architect – SRSsoft

I was just thinking about it trying to think, you know, why was that such a better experience for us? I mean, one of the things about the Surescripts certification is that it is much narrower in scope, you know, they're not concerned with this wide range of prescriptive scripts that are designed to test, you know, can I do this, can I do that. Sometimes that has nothing to do with writing prescriptions.

I mean, one that jumps into my head right now is we have to prove that we have the ability to generate a hash from the contents of a file, transmit the file across the line and show that if the file is changed it won't match the hash. There's a thing called SSL out there or HTTPS and most of us do business across the Internet with it, you see the little key icon go on in your browser that's how all that stuff works.

So, as vendors if we want to be able to be sending information securely we should just be using the standards that are out there not, you know, demonstrating our ability to do something that, I mean, can do it but it just doesn't add value to anything.

So, I mean, to bring it back to Surescripts certification is narrowly focused on exactly what they're trying to certify.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Great, I might cut it short and go to Mike.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, yeah, just very quickly your suggestions on improving communication and collaboration I heard comments from Mickey in her letter including the one from 2012 about issues, Sarah with the model perhaps from CCHIT that showed greater perhaps crowd sourcing in collaboration. Any specific suggestions that the group as a whole feels we should do to help bring this together?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I mean, I think as we said in the letter having a discussion early on into the criteria and how it could be, you know, what it means and what it means to the providers and vendors in the same room I think would help to get some of these things – of course with the rest of the stakeholders as well, would get to some of the challenges that we face.

And then, you know, I found today incredibly valuable things like in the things I've learned in the discussion we're having and as far as I can remember I think this is the first time there has been anything like that, which, you know, there is something to be said about that too so I would just say that, thanks.

Jennie Harvell PhD – Senior Policy Analyst – Department of Health & Human Services/ Office of Disability Aging & Long-Term Care Policy

And Paul, this is John with a very quick comment. I am both a provider and a software developer so I get to see both sides of this coin and when I read testimony such as “well certification doesn’t matter that’s just a burden on the vendor.” Well, actually any burden we create for any part of this ecosystem takes away resources that might be spent on innovation and usability.

So, what you hope is just as we tried to do with the Meaningful Use Stage 3 proposals that everything that we get, with regard to certification and testing, is evaluated as developer impact, provider workflow impact, standards maturity and then we refine before we implement burden on any of these stakeholder groups.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Great, let’s get Carl’s question. I assume that’s why the card is up?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Yeah, first a comment on the question about software changes, I think one of the things people don’t always understand is that the smallest of mistakes can often have a catastrophic impact. A little mistake like the heartbeat bleed virus, you know, opened up amazing vulnerabilities. So as we make software changes each and every one of them is critically important because if not done really, really well it could lead to a very bad outcome.

But, the question I had was for Marc and for John particularly. I know that EHRA has provided feedback, we’ve provided feedback ourselves to ONC that the estimates for development that they provide I think 2015 criteria was formally estimated at about 1.6 FTEs to accomplish everything from a development perspective and we’ve provided feedback that experience is showing it’s off by an order of magnitude or more.

So, the question I have for John and Marc is what is your specific experience with the actual requirement for the development and certification of your systems as compared to the ONC estimates is it different if you’re not a vendor?

John Halamka, MD, MS – Chief Information Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So I presume I’m the John you’re directing this toward, John is such a common name. We have basically taken our development shop off-line for a year and so the impact on Beth Israel Deaconess was to effectively trump our entire IT agenda. So I would call – I’ll have to review the exact estimates that were made ahead of time, but if such thing as the ICD-10 assessment says which said that it should cost Beth Israel Deaconess \$600,000.00 and it has so far cost me 6 million is any similar type relationship, yes, I would concur with your statement it was probably understated.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

By a factor of many.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I’ve got one final question and then we’ll wrap for lunch. So, there are other HHS requirements that your providers need to meet for reporting, for quality measures, for a lot of things and those things don’t have a certification program today, how well have those things worked? Have there been similar problems of short timelines and usability and, you know, all of that or no they work great and we should use them as a model?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

So, this is Sarah Corley, well I beg to differ, so PQRS if you're reporting as a vendor rather than claims-based are required to be certified and not only are they required to be certified they're required to be certified to the latest version. So, we certified in February of 2013 and we had to go back and recertify our quality measures to the June update, so, not I can't say that works better.

I'll say the CPCI, the Comprehensive Primary Care Initiative, has requirements for our end users that we're not notified of in advance. They don't work with vendors to see that they're not data elements already collected such as the requirement for the provider to estimate the patient's, you know, risk of likelihood of, you know, whatever it's a user-defined how unhealthy they are but that has to be a structured field which we didn't have. So, we don't find out about it until our end users say, hey I'm in this program and you need to put it in. So, I can't say that any of those are working well.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Well there are other examples of disconnected requirements. I don't want to minimize them. I actually want to broaden them.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

Yeah, there are many – many of the CMS programs require certification and then have another additional set of criteria that aren't certified to but are required to meet the program. So, it's much broader, it's much broader and the timelines overlaps, it's very challenging to even sort through and then as we go to roll them out the timelines overlap such that it's not necessarily going to work out, you know, what I mean where we're able to get the software with the requirements in the times for the programs.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

So, as one of the state programs, particularly state Medicaid programs have a lot of quality reporting things, same problem.

Sasha TerMaat – Legislative Analyst – Epic Systems Corporation

This is Sasha, I agree that quality measurement is a challenging area though when I think of a model of the Pioneer in Medicare Accountable Care Programs where they do shared savings in some of the, I think, less prescriptive areas there are things to learn from.

So, your accountable care organization will have many of the same goals of engaging patients, educating patients, investing on the outcomes of their health, but they're not nearly the degree of quibbling over did I click the InfoButton link or not and a certain number of times within a certain time range, because you're ultimately measured on the quality measurement piece which we agree we have to hash through as a priority.

So, I definitely agree with some of the quality measurement things as being a priority we do need to work on but I think that some of the programs with less prescriptiveness more flexibility for how things are accomplished can be a model for where no certification exists and there are better outcomes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Great, thank you.

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

Thank you everyone, we really appreciate you coming to testify today. For those who ordered lunch we actually are going to move it into another room because there were a number of people that ordered lunch so it's going to be around the corner and the room it is in is called Monroe and so thank you and we'll return back at 1:30.

M

Thank you Michelle.

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

If everyone could please take their seats we're going to get started in a moment. Larry? Okay, thank you everyone we're going to get started with panel three, Marc Probst is going to be our moderator for this panel. No?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Indeed I am Michelle. Do you want to say anything Paul before we –

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

Yeah, I mean, it's been such a very informative hearing so far and we've heard a lot about the requirements and the challenges of certification this morning. So there are a lot of constraints to solve within and so I hope this afternoon is going to be part of the problem-solving and you all are going to help us with some of the solutions or approaches to what we heard.

So there is a lot of – everybody recognizes the good intent and the usefulness of the program. Part of the requirements of administering this program is certification and how can we do certification what's been your experience and what's your forward-looking experience, and how can we do certification with the least amount of burden but still preserve the needs, the benefit side because people do want reassurance that when they buy this product it will do the following things that help them that is their customers.

So we're really looking forward to this panel and your information about that and your advice. I will turn it over to Marc.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay, thanks Paul and thanks to our panelists for being here. We're going to talk about the certification and accreditation bodies and a perspective on certification from them. Our panelists all – well not speaking I guess but answer questions is Alisa Ray is she on the phone?

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

She's right there.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Oh, not on the phone she's here in person even better, thanks Alisa. We have Amit, Kyle and Mark, so we appreciate you being here if you'll introduce yourselves as you start your testimony and let's go ahead and start with Amit.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Hello my name is Amit Trivedi and I manage the healthcare vertical at ICSA labs one of the ONC authorized certification bodies and NVLAP accredited Health IT test labs. So, good afternoon and thank you for the opportunity to share ICSA Lab's perspective on the certification program.

So, as a bit of background I helped launch one of the first voluntary national EHR certification programs with Alisa and CCHIT in 2006 and actively participated in the formation and authorization of two different ONC authorized testing and certification bodies.

I feel I have unique perspective on the accreditation process, the development of certification criteria and testing tools, and understanding the needs of the certification stakeholders, but that being said, I think my comments will seem to be in line with some of the previous testimony.

I've supplied some more detailed written testimony as well but I would like to touch upon the following points. So, first, it's important to recognize that the industry has faced a major transition, progressing through Stage 1 and at this time, before plunging forward, perhaps the industry needs some time to take stock of where we are given the current inventory of standards and newly implemented functionalities.

The ONC certification criterion requirements create a solid standards-based foundation to build upon and we should focus resources not solely on new functionality but concentrate on doing what everyone has just implemented and doing it better.

Customers of ICSA Labs, hundreds of hospitals, vendors and Health IT developers consistently remind us of their struggle to balance the design of products based on regulatory requirements versus developing to their customer needs.

There are number of differences between the 2011 edition and 2014 edition of certification criteria and they highlight a number of areas that are positive trends including a better emphasis and standards, and implementation guides, more use of conformance testing and tools over self-attestation.

But, there also are some areas that should be monitored to prevent requirements from becoming overly burdensome and those include verbose and complex test procedures that are at times left open to interpretation, test data procedures and tools that are constantly in flux, a lack of robust support for some of the testing tools and the increasing administrative burden around data collection requirements for ACBs that have questionable value at times for purchases and implementers.

So as far as challenges administering this program, the cost of doing business as an ACB or ATL is a tiny piece of the puzzle, but, as we are tasked with executing the program this is something that I think the committee should consider. Adding to the cost is surveillance requirements that target customers of certified product vendors, at times unstable test tools and changing test procedures.

I do have some potential suggestions to improve the program for all participants and to help keep cost down and to help support the testing labs and certification bodies as they administer the program. And first off it's critical to pilot test the new procedures and test tools prior to publication. It damages the credibility of the program if vendors are debugging unstable test tools after their deemed ready for use.

And pilot testing should include ample time to recruit participants, validate test procedures, validate test data and thoroughly test out the tools or the effort becomes a somewhat meaningless exercise. So, every time this produces test tools or test data are revised it adds to the overall cost on the industry including vendors, developers, the cert bodies, test labs and ONCs.

So we do have better tools for the 2014 edition than we did for the 2011 edition and we need even better testing tools going forward.

Another area is consistency between test labs. Pilot tests should be a venue for all ATLS and ACBs to observe testing. To understand the expected results, to learn how the test tools operate and then provide feedback to ONC, to date, this has never been done prior to publication of the certification test procedures.

So as far as changes to the program and hoping to enhance the program and its value to stakeholders, I feel that the program should focus on a higher share of certification criteria on interoperability and security testing. The certification program should help set a floor for the industry as the program spurred great work in the community in developing implementation guides, updating standards and converging on terminologies.

The testing tools need to be more automated to efficiently handle more test cases, reuse test data sets and employ more robust types of testing methodologies including negative testing and testing the security of products.

How EHR's handle various functionality should be left to developers to innovate on. What information EHRs should be consuming and providing should continue to be a focus of the certification criteria. Additionally, we –

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

I apologize but your time is up.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

My time is up, all right, thank you.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Thank you, Amit. Kyle Meadors are you on the phone from the Drummond Group?

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Yeah, can hear me?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

We can hear you well.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

All right I'll get started. You know as an ACB/ATL who was part of the program from the beginning and we've watched the change over time, my comments today are really more about how things started well with the 2011 edition and then as we moved into the 2014 we encountered some unintended or unforeseen consequences and so with the sensitivity to time here I'm really speaking more about from that perspective rather than just specific suggestions although I have a few brief points and then we can expand upon those in our discussion time.

You know one aspect that worked really well in 2011 edition but changed in 2014 was the timeframe. We've heard a lot of comments about that today and I thought maybe we should get some context of why that's relevant.

You know in the 2011 edition we opened up September 2010 and really remained open through almost the end of 2013. It was a one day test event. So, you had that 36 month one day event kind of approach.

You get to 2014 well the timeframe was really February 2013 so it's really going to be the end of September this year, so almost an 18 month time. And then the test event itself is probably a 2 to 3 day event. So you put those together and you've really reduced the testing timeframe by a factor of 5 and that's just for the test event not considering the development and prep time which really adds to that, which really is the bulk of where vendors spend their time with. So, there was just a lot to do in a little amount of time.

You one thing that also worked well in the beginning, and ONC should be applauded for, was really setting forth standards and test procedures for the entire industry. You know 2011 edition we had some good guidelines which were attainable for most vendors but, you know, as we got into the 2014 edition it really stepped up in terms of complexity.

And there were a lot of strong points about the 2014 edition test procedures, but I will say looking at it now in hindsight we probably went a little too far in terms of complexity. You know when I do my introductory call with vendors for those who certified in the 2011 edition I always make this following analogy at the very beginning, I say, 2011 edition is like high school English, 2014 edition is like a college graduate class on Shakespeare sonnets. We have just skipped undergraduate totally. You've made a huge step up, you're going to struggle, everyone struggles just be prepared for that.

You know one thing we also did well I think in the beginning, and it's kind of like that first point, was having a single point of authority that ONC could speak for in the industry. You know we've heard some comments about the value for, you know, Kaizen or some iterative approach for the test procedures but we also have heard comments about the test procedure should be stabilized before implementation and I agree we definitely need to make some changes to our approach and our rollout of test procedures.

But I will say there is a certain contradiction in those two perspectives. You know vendors will justifiably hold off their development if there are expected changes in the test procedures. But, you know, we can't truly stabilize the test procedures in terms of not getting it at all if you have an industry that is striving for innovation. New vendors, new products will come in they'll test, they'll bring new perspectives and those insights have to be recorded or fed back into the test procedures to clarify or explain methods of implementation.

You know we've talked a little bit about beta testing or pilot testing the test procedures now actually I do agree it's worth exploring. But I thought I should add that, you know, 2012, you know, we had draft test procedures out for 2014 edition and, you know, we actually went to several large vendors and inquired about beta testing but they just indicated to us they weren't ready. They were waiting for the final procedures to come out before going full force on the development.

So then you almost get into this chicken and egg dilemma, you know, why develop your product on draft test procedures when you can just wait it out and let someone else do it but if we don't have someone do it how are we ever going to get to our final test procedures. So it's just something to think about as we go forward.

You know here are a couple of suggestions I would like to make, we can expand upon those in our discussion time. Basically, some things to do different as we look ahead, one is to slow down. I think we've kind of talked about that but we do still need expected timeframes. I think vendors will respond to timeframes to get the development but we have to be fair to their resources. But, again we've got to give a deadline or people just naturally won't start that's just how we are. I don't think there is an exact science to this kind of balance more of an art but I think we need to make some adjustments moving forward.

We've heard some comments about this earlier and I kind of agree about working backwards in terms of start with these end goal criteria, the major ones, CQMs, IOP, view, download transmit, automated measures focus on those primarily and then maybe we can do a little more spot checking on the underlying criteria that feed into them and to let those criteria kind of bear the brunt of things.

And then a more collaborative test procedure lifecycle, different stakeholders, more end users, clinician feedback and just a more iterative approach I do think would help.

You know a major goal for any program is to enable a marketplace that's vibrant and robust both for small vendors and large vendors to encourage innovation. I believe ONC, especially in the beginning, enabled that type of marketplace. I also think we can do that again going forward. Thank you.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Mark?

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

Good afternoon, I want to take the time just to thank you for giving me this opportunity to share with everybody here. My name is Mark Shin I'm InfoGard COO and I've been part of the certification program since the temporary program back in 2010. It's encouraging to see the large-scale adoption of EHR technology within the community or within the last four years. And a good deal was stimulated by the incentive program but it couldn't have been done without the efforts of everyone that was involved.

But with rapid development it brings a risk of unexpected challenges only amplified due to the large number of participants. And I would like to take this opportunity just to briefly share with you three examples of what we experience within the program today.

From the inception of the program there have been two major editions with a third edition soon to be released. It seems like a common theme we did not collaborate on the content. But, that's three editions, significant editions within an extremely short period of time.

We've heard from the vendor community how that affects them, but it does affect us as an ATL and ACB as well. Such frequency is challenging for a test and certification body because as we conduct conformance-based testing it depends on consistency and repeatability.

At the moment the current release pattern requires our team to frequently readjust our processes and tools. It prevents consistency and repeatability. This reduces the quality of service and guidance we strive to provide to our vendor community and I'm not encouraging a stagnant program, however, introducing significant updates with such frequency breeds programmatic instability.

It becomes challenging and expensive for us as an ATL and ACB to develop new or to update existing processes and retrain our personnel to accommodate the new requirement. But we believe it also becomes challenging and expensive as we heard from the vendor community to understand design and develop to the new requirements and to do so with patient care and usability in mind.

Reducing the frequency of major updates while introducing trial and transition periods for minor revisions would lessen the burden on us as an ATL and ABC but we believe it will be beneficial for the program as a whole.

We've also found the application of the surveillance program to be challenging. Although the surveillance requirements are well intended the lack of guidance from ONC leads to inconsistent surveillance plans among us as ACBs and this is troubling.

Over the past two years we've found that the majority of EHR developers have claimed the inheritance provision resulting in significant implementation changes from the originally certified product. In one instance we found about 16 pages of high-level descriptions not a detailed description but one liners of what they've changed from the time we originally certified until the end. It makes it a very challenging landscape for us to effectively conduct surveillance.

And without reconstructing or re-conducting tests or introducing a programmatic mechanism to enforce configuration management for product version control our surveillance efforts will be ineffective. Efforts are needed in this front to devise a single, well defined surveillance plan that all ACBs can support and enforce.

And finally, the current program lacks a well-defined proper set of security controls, that's our background we've been conducting conformance-based testing for about 20 years, the majority of the programs we support have to do with security and cryptography.

And what we've seen in the 2011 edition as well as the 2014 is there our absences in proper security controls and it shouldn't be an afterthought. We shouldn't deflect it to another entity or organization to handle, or be undervalued.

Personal health information is a sensitive asset that requires well-thought-out protection measures. With the multiple high-profile breaches that have been reported in the media it would be naïve to think that EHR technology would be exempt.

EPHI should be considered a high-value PII, personal identifiable information, with intentional requirements to provide confidentiality, integrity and access control not only at the application level but the secrets used to protect that content and this should be done both at the target level and during transition. Thank you.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Thank you, Mark. Alisa, I know we were just going to ask you questions but did you have anything you wanted to say before we get into questions?

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Just my colleagues did a great job and I'm glad I can sit here and participate in the Q&A.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay, great.

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

And save my testimony for the next panel.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

I agree your colleagues did a good job and again, I think we're seeing some themes as we through each of these panels and the conversations we're having but thanks for your time and the detail you each put into your testimonies. So, do we have any questions from our group? Don?

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

Mark can you elaborate a little bit on what you see as the security issues that you just referenced?

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

Yeah, I think there characteristics that we've seen but I think the gentleman in the previous panel gave an example of the hashing mechanism, providing a mechanism that might enable somebody to use it. What we found is most folks will provide that capability there but in a practical workflow perspective it's not well integrated if at all.

There are mechanisms and tools out there that are available. There are numerous security standards that are proven and have been in play both in the federal space and the private space that can be leveraged so we don't want to re-create the wheel what we do want to do is make sure there is some sensitivity and some sense of accountability to make sure that we have a layered security approach that starts from the application, the EHR application, all the way through the system and to the end users.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Great. Paul Tang?

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

This may sound like a rhetorical question but I think I want to draw on your experience. So what shouldn't we certify? In a sense it's a little bit like you were just saying about the security that maybe it's there but people won't use it they'll use something else. What are you finding that people are most complaining about, i.e., the cost is high and it actually doesn't seem like it's providing much value in terms of what's the reassurance, what's the assurance that this certification will produce something of use to the end customer? And you might have an insight that we don't. I'm sure you do.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Well, I know one common complaint around some of the procedures is EHR vendors are often required to generate a document or transmit a document but on the flipside – or message or other information, but on the flipside the receiving entities aren't there or are able to connect. So connecting the ecosystem is important.

So if we're going to require folks to submit or send, or generate documents we should also ensure that there is someone to receive it that's one area. I'm not saying we shouldn't be testing it, it's just they should be in parallel.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Any other thoughts?

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

What are you talking about there?

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Say, you know, clinical quality measures has always been a big one, you know, the registries that can receive the quality information that's been an issue from stage – you know, 2011 and in 2014 it continued and, you know, arguably that's one of the most important facets of the program being able to measure quality so we understand why it's being done, it's tough to argue on the programs we have sometimes.

Another area might be those certification criteria that are overly subjective or possibly ones that are used for the transparency purpose like the quality management system criterion it's another good criteria in concept, it has some potential value for those folks who are looking at products who go far enough into the details of the test report to see how a vendor may have self-attested to using a quality management system, but at the end of the day the question is do you use a quality management system "yes" or "no." You pass either way.

And so we question sometimes the value of something like that. So I can see from a transparency standpoint it may be valuable information if you are selecting an EHR.

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

Other examples in the functional objective things that you certify?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

And Kyle, just jump in if you have thoughts.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Okay.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay.

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Another – Alisa Ray commenting, another question might be just are we – if it is a valuable function are we testing it in the most efficient way? So looking at Amit and others have talked, Kyle actually, mentioned how the amount of time actually spent hands-on testing and we know that's not the only cost but the actual time spent testing has evolved from a day for the 2011 program to now I think it's safe to say amongst all of us, 3-4 days or more.

So what really we get down to is our time – are we spending our time in the most highly prioritized areas? G1 and G2 are really, really important, because they align with Meaningful Use, right, those are the numerators and the automated measure calculation, but I think if you talked with us typically to go through all of them it's a half a day to a day's worth of testing for a well prepared vendor, a well prepared vendor that can get it right the first time, but we probably haven't seen a lot of those. But, again, it's sort of aligning efficiency and are working as smartly as we can.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

I would just like to speak to some changes going back, I kind of alluded to this but it's just the data entry which is – I mean, there's a lot of good things about that, but, you know, in 2011 we basically gave the suggestion you needed to give out a day, you know, allocation to enter all the data in advance. I mean, I think now it's probably more like anywhere between, you know, 250 to, you know, much more man hours depending on the complexity of the system.

And a lot of what Alisa mentioned is automated measures, CQMs, but you've got to factor in too that's for the day of the test. You also need to do your dry runs and your rehearsals to kind of prepare and kind of test those out so your loading that data in multiple times running it through, cleaning it out, coming back through and as we've tried to do some things to help, you know, we offer some iterative kind of iterative wave testing approach to kind of break it up the testing so it's not just such an intensive effort over a period of time in your development.

But, you know, when you do a test you know when we get done it's a two day event that's just the tip of the iceberg. I mean, I think that's really where the vendors struggle with and it's not so much necessarily thinking like this one criteria is totally useless or that one it's just all of them have – it's a sum of the parts all these little things that are added to it that you've got to check off and you've got to make sure of and when your pulling up over 44 criteria now that's just a lot of things to keep track of, it really tests your project management skills that you can keep everything, you know, well aligned – I know Emily Richmond is on from PracticeFusion she did a great job managing that, I was able to test their product, but, I mean that was by far her full-time job just getting ready for testing.

I don't think we want vendors to have a full-time job for someone to do testing, you know, I mean, maybe for a season but it needs to be moved on because they have others things to do to innovate and support their customers.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay, great. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you and I very much appreciate your testimony. It's interesting to talk to a certification body only because it's a group of people I don't normally talk to. One of the comments that we heard from the vendors was their concern about recertification when they make minor changes to something and they say, you know, if they get something out in the field and then they do something a little different perhaps based on like user feedback and they add another data element or make a minor change then they have to get it recertified and that by itself becomes like an obstacle to making the change but also adds expense.

Do you have any ideas about changing the process so that it would be possible for a vendor to make minor changes without getting we certified?

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Well, this is Kyle, I just want to make...well, I know, I mean, recently, I mean as in the last six months or whatever ONC had put out an FAQ kind of clarifying certain kind of like maintenance type, you know, patches, you know, can reissued without recertification. I mean, there have been some efforts there on that.

I think the one question I think if I could go specially – Emily mentioned it and again I have some personal relationship with her so I don't think she mind me sharing this, but, you know, in her case I think it's things of, okay, I've got to think about changes that need to be made to support my customers. Well, I can't just simply say, oh, I've got to rush that in there and put that in there I've also got to think about, okay I've also got to implement it and test it out and get it certified and I'm not quite 100% sure, because it is the decision of the, you know, ACB whether I'll have to get retested or not, I mean, I think that's something they kind of have to factor in.

It's not – and I think it's, you know, like Emily will try to give me some head's up or give us a head's up, hey Drummond Group this is what we think we're going to be doing. Do you have any idea, you think this needs to be retested or not.

I think it's just something that, you know, you have to kind of factor in. I'm not sure – if you're asking a way to improve it, I mean, I can't tell you, I mean, I think we've made the processes as well as we can if we're going to – because obviously the alternative is always let's just retest everything and we don't want to do that, we want to allow attestation, you know, information, you know, to be handled to get recertification.

Like I said I think overall it's really not been an issue 2014 because everyone has just gotten through the first round and only now are we starting to see the attestations come forward with people making updates and stuff after it's been a year or so, six months since the previous, you know, the initial certification.

Paul Egerman – Businessman/Software Entrepreneur

Are there any other comments? What I want to do is find – is there a way for people to make minor changes without going through recertification? Like to add another data element or they do something that's not just an error correction but based on user feedback they think it will improve workflow or something? Is there a way that they can make a minor change?

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Sure, Paul, Alisa Ray, I'll comment. This isn't new we've all dealt with versioning in all kinds of software and I think the FAQs from ONC have helped. I think it could probably be further protocolized but I believe we're all following pretty much the same things where we classify version changes into major or minor upgrades and we give some examples about what minor upgrades are with the risk of noncompliance or affecting compliance is low and you gave an example to about adding something to the screen or things like that.

So in those instances, I believe most of the ACBs allow just an attestation and you get your new listing on the CHPL with that new version number. So there is no retesting there, okay.

There should be some dialogue with the ACB to see if they accept maybe review release notes or things like that for support.

Minor changes require or excuse me major changes would of course have some type of testing. And others can say if they follow that kind of process but I think that summarizes what we do.

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

Yeah, that's very consistent with how we – this is Mark Shin from InfoGard, how we handle current – how we currently handle that situation. Improvements moving forward, it all depends on the assurance level that you're trying to achieve. You can go to either spectrum where you want – where you allow more flexibility within the vendor community so you continue to allow the attestation approach.

If you need more accountability for whatever reason and you want to put more controls over it then you may enforce a situation where it could be a combination of source code review to full testing or whatever it may be. So I think there are several ways to handle it but the way that Alisa described it is how we handle it as well.

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

And recognize there are wide variation in the vendor community with their development processes some may issue patches or things every week or two. We have other customers that may do two well-planned upgrades a year.

Paul Egerman – Businessman/Software Entrepreneur

So part of the feedback I heard was the need for this flexibility and what I'm hearing from you is think that flexibility already exists.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

I'd agree that it exists. One of the difficulties though maybe around the timing and then for a vendor to be able to gauge what the result will be when they make an update because, you know, what they're probably looking to avoid is any kind of retesting and the amount of time it would take, you know, have a new product added to the certified Health IT product list.

But even if there are no changes and there's just an update to the listing that even takes time. Whether it's creating new test reports, submitting information to ONC, getting the product approved to be put on the CHPL. So there is always that timing and a concern I think from the vendors in terms of how is this going to affect my release and when folks are actively in the attestation process.

Paul Egerman – Businessman/Software Entrepreneur

Great thank you.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Great. Mike?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

So, thank you as well. My question relates to a little bit of the impact, if we will, on clarity around how one testing lab or another may be interpreting rules whether you created the same kinds of things the providers and vendors were describing earlier in terms of having a sort of a clear source of truth and especially as we think about people who may be transitioning from one ACB, ATL to another, both the burden of that on those who are picking them up but also the burden to the vendors who are all transitioning from one together and whether that speaks to anything about how the certification process could be improved to make that easier for you?

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Sure, so this is Amit Trivedi. I think, you know, consistency among the test labs has always been a chief concern of all of us. You know every time we get together we try to address it in some way shape or form. ONC has also helpful in certain areas like the product update process that we described. The reason there is that consistency I think is because that was one of the first issues that we tackled.

On the flipside, and I think Mark mentioned this, is the surveillance guidance. We each submitted surveillance plans, waited for quite some time to hear feedback on what we submitted. I can't speak for the rest of the labs but I assumed what we were going to get back was a consolidated approach that all test labs or certification bodies would follow. But instead, I think, we all got blanket approvals that our plans were good.

And so my guess is there is some inconsistency there and that's something we'd probably like to resolve because at the end of the day we all want to be doing the same thing.

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Alisa, may I make a comment? Build on Amit's comments, I think there are probably areas that ONC could create some protocols without a whole lot of work to manage the program to assure more consistency amongst us.

Amit mentioned the update process and I think we've made good progress working together on that. He mentioned the surveillance process as another area. Perhaps even extending that to how gap certifications are granted might be another area I would suggest for consideration.

And again just, you know, some almost like forms or checklists, or protocol work from ONC would go a long way I think to making the community feel assured that we are consistent.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

This is Kyle and I would – just one comment to make, because I know we send a lot of questions to ONC, you know, for different issues and got clarification. I know there is one point we've raised is sometimes that information isn't always pushed back to the other labs, you know, maybe it gets reflected in a test procedure but you don't know the context or the discussion behind it.

Also, I think to add is, you know, as far as the discrepancies from labs it's not necessarily that the lab thinks that they are doing anything wrong or different, let's just say different, they're implementing a certain way and then moving forward. They wouldn't be privy to how another lab is, you know, interpreting that.

I think one thing that could be done, this is just – and I don't know if there is any other good way around this apart from just the manpower needed from ONC or somebody to kind of, if you will, on a – we have a regular basis to meet twice a week but it's more for basic program updates. There would almost be a need for engaging the ATLS on a regular basis saying all right let's walk through this criteria and talk to me about how you're doing this, what are your challenge points, what are you seeing, what do not allow and that's actually one of the biggest questions we as a lab always struggle with is not so much how you do this but what is not allowed. That's really where it gets tricky.

I mean, everyone – when you see a really classic clean, you know, clinical decision support implementation you're like, oh that's great, that's exactly what we had in mind. It's when you start seeing different interpretations from vendors and you have to decide is that within the realm? Is this what they allowed or not?

And I don't know of any other way apart from ONC, if you will, and I hate to put this on them because I know that requires manpower, but almost surveying kind of on a regular, how do you do this, how do you do this, how do you do this. Okay, I have three different answers here, obviously that's not going to work.

Let's get together, let's agree we're going to do it this way and these are almost non-test procedure type of statements of just simply not this, not this, not this, this is the emphasis we need to check on. I think that would help and again I know that's putting time and effort on other people's shoulders.

But again it is hard for us, you know, in our case, you know, we're running through these tests every week. And, you know, an issue comes up we don't necessarily – we have to make a decision. I mean, we can pause for a little bit to get maybe some clarification but we also kind of have a pretty good feel for things so we feel generally pretty confident in what we're doing.

We almost need a third-party, if you will, to come in and assess us and I want to make this one comment, I really – I don't want to make this sound poor in light of what, because I really think overall ONC has done a good job managing the program.

But I would just add since we did this back in September 2010 I think ONC has only observed two hours' worth of our testing personally for Drummond Group or sat in and watched us. I'm not expecting them to do it hours every week. But, I mean, for four years it's really only seen two hours' worth of actual live tests.

I think it would behoove the ONC team for however we want to pull that in when there is – this other kind of collaborative group who kind of feeds into test procedures, I don't know, but to kind of witness some of this, to kind of learn and observe because there things you see in a test environment that you can't see anywhere else.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay, thanks, Kyle.

Joe Heyman, MD – Whittier IPA

This is Joe Heyman. I wanted to ask, you know, at the very beginning of the session today Lee Stevens put a slide up that he proudly said that entire process on that one slide and it was a very linear thing that went from one corner to the bottom corner.

I'm just wondering would there be any value in changing that entire process so that for example you're at the very end of the process so that you are actually part of the beginning of the process? So that before they created a Meaningful Use requirement the actual certification body had some input into whether or not that was going to be a problem for certification? Before they did a Meaningful Use the vendors had some input into that requirement to say whether or not this was going to be an interference in workflow, etcetera?

It just seems to me that having that very linear process without getting input from the people at the end of the process, maybe I'm just crazy about this, but it just seems to me like it isn't such a great idea to do it that way. And I'm just wondering what you think about that or do you think it wouldn't make any difference?

Amit Trivedi – Program Healthcare Manager - ICSA Labs

I think – this is Amit Trivedi, I think we're always happy to be at the table and offer feedback and advice but at the same time I wouldn't say that there has been no input. I mean, we all actively engage in the public comments throughout the rulemaking process. We provide comments to the test procedures, the test data sets all throughout that. I think it's a question of how quickly and efficiently we can organize, you know, as a group all of those comments and, you know, have them reflected in the final published computer.

Joe Heyman, MD – Whittier IPA

I guess my concern is about unintended consequences from the very beginning of the process. When the process is first developing the criteria for Meaningful Use for example and now we're thinking about certifying things that don't even have to do with Meaningful Use. So, I'm just asking whether there should be some reorganization but it sounds to me like you don't think it's necessary.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Yeah, I think that's currently integrated in the process. I don't feel like we're not part of the draft reviews as an example. But, like I mentioned before, I think the fact that the frequency of these updates occur within a very short period of time. We've been testing 2014 edition applications since, what, April of last year and for us to be able to go through another review cycle while we're still working out the process kinks and even the question earlier about potential inconsistencies or what Kyle mentioned all that can be worked out if given the proper time. But if we see the releases every two years it makes it quite challenging both in a business perspective but also so as a testing and certification body it adds challenges.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Alisa?

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Alisa Ray, Joe, I'm getting ahead of my testimony but maybe little different than my colleagues here. I completely agree I can't emphasize more how much I agree with your comment. It's actually going to be part of my testimony in the next panel.

Begin with the end in mind it's more efficient. I think we heard others talk about having a view of where you want to end up in that path or workflow and make sure all of the interdependencies and all the pieces line up.

Also, a development process like that it's not waterfall or sequential. If you modify it to do things along the way you're going to cut time out and you're going to end up with a product that maybe needs less QA at the end. So, I couldn't support your insight more on how to improve the program.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Yeah and it seems to me, as I was listening to Joe and some of your comments, how could it enrich even backwards. So we might – you know, it may be helpful to the certification process to know more up front but how can it enrich, you know, enrich what we're trying to do up at the front. I was thinking the same thing Joe, so those are good comments. Paul?

Paul Eggerman – Businessman/Software Entrepreneur

I'd just say picking up on that, I mean one possibility would it be appropriate to have some of you as members of either the Certification and Adoption Workgroup or the Meaningful Use Workgroup, I mean the groups that are giving advice on these things that perhaps do you think you would have – is that something that you would be interested in participating in and do you think you'd be able to add value to our processes? I mean, the process is voluntary and it's to give advice which does not need to be accepted but it occasionally is.

And so – I'm sorry, I said that right it is frequently accepted but I think the discussions also are very helpful to the ONC staffs people because I think they see the reality of how people view things. So is that something that might be an entry into the process?

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Yes I would agree with that and, you know, we are asked, we do provide feedback but at the same time we provide our comments the same time everyone else does. I don't think the cert bodies or test lab comments are weighted any more than anyone else, but at the end of the day we will be executing these procedures. So any way we can help make them better I think we'd be up for it.

Paul Eggerman – Businessman/Software Entrepreneur

Because it's sort of interesting, as I look at it, I mean, your testimony, Alisa, which I guess will be the next panel is interesting to compare the CCHIT process with the ONC process. But in effect CCHIT ran the entire process in terms of making the decisions. It's not like you authoritatively or autocratically made the decisions but you managed the entire process as to what was to be certified and so we've gone from that to where we are now where there is almost no involvement from the testing organizations. It seems like there should be more.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Judy, before Alisa answers did you want to add to the question?

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

Just a comment to that, so we got together with NIST just last week and were having some of these kind of same conversations asking for suggestions and they said just exactly the same thing that you are saying but it was specifically around the testing tools instead of the testing process.

And what they were saying was that if you develop criteria and measures, and scripts with the endpoint in mind, i.e., the testing tool or the testing process that you design it differently. So, I really like where this conversation has been going because you keep that in mind.

It's kind of like when he set up your annual goals and you want to think about how you're going to measure those goals, right, if you keep the measurement in mind it helps you form the goal and I think the same thing applies here so those are really good comments.

And then after your comment maybe you guys could talk briefly about ANSI, you know, that really wasn't on the slide, the process, but what role do they play in consistency if any? Because I was thinking that one when you were talking about that before as well.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

So, Alisa, I think you were ready to say something?

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Yeah, I was just going to add on from the CCHIT experience we learned a lot but we also learned from our mistakes. We had to invent and create and this is one of the iterations we made. We started doing it in waterfall process with our volunteers.

We develop the criteria, we'd get comments on them, we'd save the development and the testing until the end and sometimes you'd be in a heap of hurt because things didn't work or they weren't testable or they would take three days to test and you knew you had, you know, a couple of hours to devote to that criteria. So, I think frontloading so that you're sort of rationalizing the test built along with your goals for the criteria would just be huge benefit to the program.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Thanks and on ANSI any thoughts, Judy's question on ANSI?

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

Well, this is Mark Shin from InfoGard, ANSI's primary role is to make sure that we comply against the 17065 requirements per their scheme. So unless they've got specific instructions from the scheme owners as to how we're supposed to implement certain controls they are going to entirely allow us to make decisions as to how we're going to meet certain things.

So for example, the surveillance requirements, I won't go into detail as to what we originally implemented which were extremely tight controls but that was based off of ANSI's, I wouldn't call recommendation, but influence and obviously we just can't use that mechanism any longer it just doesn't apply based on a real-world situation.

So, it's not a knock on ANSI in any way shape or form, but that's their role is to make sure that they ensure that we comply with the policies and procedures dictated in 17065.

Judy Murphy, RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology

– any kind of consistency, yeah.

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

No they actually state that they can't share.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

They'll often defer to the scheme holder would be ONC then.

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

My comment on ANSI is, as Mark noted, was assuring, making sure we're complying with guide 65 which is absolutely essential for the business and the work that we're all endeavoring to do. So I appreciate the value. I thought they're very professional, very good to work with, very fair but even.

But, as you've said here there's a partnership with ONC. I mean, that's why it's an ONC ACB, right? The ANSI accreditation wasn't enough to allow us to operate or be in business. It needed a final level of approval from ONC.

So in effect ANSI left a floor but in terms of a lot of operating policies or management discipline I think that's the partnership with ONC that's always been my view of it.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay, great. Lee?

Lee Stevens – Policy Director, State Health Information Exchange Program – Office of the National Coordinator for Health Information Technology

I wanted to sort of circling back to Joe's comment a moment ago. One of the things that in the few months that I've been acting in this role, clearly we need to think about surveillance and quality as a line in this program where we need someone who really leads that and is able to take input and most people in this room maybe familiar with the federal hiring process, it takes a really long time, it's very complicated.

But we're hoping that soon we'll have someone in a surveillance role that will be focused on quality as well. And in that process it won't just be sort of – it won't be a one-way street of us saying this is surveillance or this is quality.

But I think that the expertise that you bring to this and from the quality side what we can learn from outside of ONC will really help inform the way that we do it effectively particularly on this point about the surveillance being consistent across the board that's a really critical aspect and if that's something that works well for everyone I think that would be an effective approach. But we'll be taking a deeper dive into that hopefully very soon.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Steve?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Sure, so, I mean, I also just wanted to, I think, clarify and respond to Joe's comment about the slide. I mean, I think your point is fair Joe about the thinking. I'm not sure it's accurate to direct it at the slide per se, because the slide really is a sequential set of steps it's test, certify, submit, list and that is a linear process that just happens.

I mean, that's – really the slide is really meant to represent how one goes through the kind of certification factory as opposed to the questions of – which we often think about a lot and we've been trying to think about more and, you know, Doug Fridsma who is, you know, in charge of our Office of Science and Technology, especially at the standards level saying, do we have a plan to test this standard before we

Adopt it?

And a lot of that thinking, you know, to help advance some of the work that the ACBs need to do in the future so that we know we have a testable method for a particular Meaningful Use metric or something along those lines but, that I think is a point that is better directed at the overall process as opposed to the kind of linearity of the slide.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Joe, do you want to defend your picking on the slide?

Joe Heyman, MD – Whittier IPA

Well, the only reason – the way the slide was listed it had each entity as a separate box. So it certainly looked like it goes from one entity to another entity, to another entity, to the final entity. But I'm not asking to – I'm not asking the question to criticize the process. I'm asking the question if there might be a better process and it just seemed to me, from what I was hearing, sort of all along the way, that every entity that was listed in the box over there, it would have been good – it seemed to me and maybe I'm wrong and that's why I asked the question, it just seemed to me that they ought to all be involved in each step along the way instead of having each entity listed as a separate entity and it goes through an arrow, an arrow, an arrow, an arrow.

But if it's not happening that way that's fine and if it's better to do it the way it's being done that's fine too I'm just asking as a suggestion because it just seems to me that a lot of the issues that develop about this that are problems that are unforeseen problems that develop later in the process might not have developed if those people had input in the very beginning of the process at the same exact time that the measure was being developed or maybe at the next step or the next step, or the next step. That's the only reason I asked. I wasn't criticizing. I was just asking.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Oh, go ahead?

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

The slide was a depiction of how once the program is opened and launched and running its operation. But, Joe, your comments reflected the development before we got through that gate.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Yeah and I think conceptually we've had some pretty good conversation about that though as a good topic. Charlene?

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Charlene Underwood. So because of your background and experience and I kind of want to throw the doors open a little bit, we've got a surveillance process that we're going to be implementing, we know that if we test something as complex as software at any point in time the next day that test is invalid because we probably changed it in some way or form.

So we've got a process that might assure that we can achieve Meaningful Use but as we've discussed it doesn't really ensure quality and those kinds of things because just software is a very dynamic kind of tool and when it goes into customers it's different.

So based on your experience with certification, accreditation is there a better way? I mean, is there a better way just to say, okay we comply with ISO development standards or whatever it is that would get us through this certification gate, you know, coupling it with potentially surveillance, is there a better way based on your experience the field?

Amit Trivedi – Program Healthcare Manager - ICSA Labs

Well, I think as an industry we're moving away from attestation and so testing in some way, shape or form is probably always going to be necessary. Maybe how we do it like you suggested that may be something we would need to examine whether it's having, you know, more robust test tools that are continuously available that people can continuously test new versions to and then submit, you know, verification that, you know, the capabilities haven't been degraded, that may be one avenue instead of trying to pursue recertification after every update. But, you know, I think there are a number of things we could look at and a lot of it revolves around what kind of test tools we use.

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

Just to add to that, this is Mark Shin from InfoGard, the way that we view our certification body role is to ensure that the integrity of the product is maintained once it's certified. So, a lot has to do with the functionality of the product in itself and really the burden is on the vendor.

When you look at some of the things that were proposed for the surveillance effort they tried to push – some of the responsibility gets pushed to the end-user, the providers, once you roll it into that scheme it creates challenges not only for us regarding enforceability, but cost, accountability, liability if you want to call it that.

So, we support other programs that have a very similar model, FIPS 140-2 is one which is a cryptographic standard. We did the exact same thing there where we test the product for a specific set of requirements. But there is an entirely different set of process and an organization that does FISMA audits. They'll come to the federal space and actually verify that certain risk factors are being addressed but one of the things that they do is to ensure that you're using a FIPS certified product, which is more or less what one of the goals in our surveillance program is calling out for. Is the product out in the field being used in the manner that it was intended?

So putting the cert body in that position although it's something that we're working to try and figure out how to do effectively, that could be a role, but when you look at the Meaningful Use process there is an SRA, Security Risk Analysis, that's required and part of that effort could be the verification that products are being used not only in a meaningful way but the tools are being applied appropriately. So it depends how we want to address the situation.

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

I'd add a comment that Charlene your first question was – is the bang worth the buck sort of for the wkg1 the accreditation and I'm actually going to defer commenting on that because I mean, I think, no doubt we're better for having gone through it. But truth be told, we're really doing most of it before the formal survey anyway and I think you just have to look at other places in our healthcare industry, other accreditors or certifiers, or whatever whether they are operating under that type of oversight or overview. There are a lot of examples in our industry. So, I'll defer on that.

In terms of the question on surveillance, I think it's a great opportunity to learn in its purest form by definition, it's like is compliance still in effect, that's the duty part. But it's a great opportunity for this group and policymakers to inform strategies. So, at the simplest level we want to know more about what's happening at the implementation level, you know, are providers turning things off or on? You know there are efficient ways to gather that kind of information without necessarily going on site, right, but wouldn't that be tremendous value for guiding future directions of what this group wants to do?

And, again that would require coordinated some leadership and making sure we're all collecting the same information. There are other examples, but to me that's the opportunity with surveillance it could be turned into a really good thing.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Great. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thank you. So continuing this theme of what we can learn from other things that you're doing it sounds like you're involved, some of you are involved, in a variety of other testing programs. And one of the things that I've heard a lot today was about the frequency which we do things and your comment that every two years is too frequent.

So, can you give us some perspective on what you're seeing in other context, other industries what their refresh rate is like and what the upside or downside of that interval is between major changes?

Mark Shin - Chief Operations Officer – InfoGard Laboratories, Inc.

Well, the FIPS 140-2 Program their frequency is every 5 years now the last revision was about 10 years ago because they couldn't agree on the actual content. But their target is to revisit it every 5 years.

But intermittently within that period they look at the standard, they look at the requirements and based on either innovative technology or as time changes other priorities arise then they'll make minor alterations or suggestions they call it implementation guidance. But the frequency of actually doing a revamp is about 5 years.

Amit Trivedi – Program Healthcare Manager - ICSA Labs

This is Amit Trivedi from ICSA Labs, we administer another certification program in Health IT and that's the IHE USA Certification Program. We only recently started that with a pilot last year and this year a full certification program. But I think, when you look at a refresh or anything like that, one of our objectives off the bat was providing a roadmap and giving, you know, clear guidance to the industry.

Right now we're in the gathering feedback mode for establishing that roadmap for three or four years out. But I think that's important so the folks understand what the scope of the certification will be going forward, how many criteria are being added. And then again, you know, that's a big part of this program too, how much is being added to current requirements, what's being removed if anything? Because that significantly affects people's, you know, capacity to handle the refresh rate.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.

Yeah, this is Kyle, if I could just quickly add, because we do different, you know, programs and I'd say kind of what Amit said and kind of based on if things have changed and I was talking about earlier as more of an art or science. I mean, I have – there is one program we use, it's shorthand is called AS2 it's basically like Direct, it's Direct secure UDI over the Internet back and forth MDMs and it's the de facto standard for the retail industry, we've been doing it since 2000 and we test that full matrix test which is you'll see a slide later on, David Kibbe will show next week or next session, a full matrix we did twice a year, every 6 months and the vendors want that, they need that, they've accepted that, they see the value in that.

I've got another test I'll be doing next year in GDSN for data synchronization and our last major test was 2006 I believe. They just didn't need a major test between now and then, it just depended on the – it used to be that we did it every year and then they just – they got to a certain level of maturity they were able to stabilize things and so they went, you know, eight/nine years before a major update.

I think it really just depends on the – if things change we need to test them. I guess what we need to do is kind of limit the changes. I know that's kind of the effort for 2015 to try to have the more gentle slope and hopefully we can get into that, but I don't know that there is any – I mean, you've kind of got – like I said it's more of an art and a science you've got to put your finger in the area and kind of feel out what does the community need, what do vendors support and what's the change needed, you know, that we need to verify.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Great, great. I want to thank this excellent panel and I think we're right on time. Alisa you look like you had something you really wanted to say, no?

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

She can say it on my next panel.

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

She can say it – yeah.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

All right, all right, she can say it in the next panel. Well, I really appreciate the preparation, the candor that you gave us. I want to show my appreciation to this committee too for asking I think really good questions and I think there are a couple of activities we can take forward based on this discussion and look forward to future discussions. So thank you very much. It's yours Paul.

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

All right. And thank you Marc for ably leading that panel. Our final panel for today is labeled private sector representatives and it's really similar to what was asked at the last question. What other organizations can give us some advice on certification? How can we learn from others? It's just like the equivalent to how can you learn from other countries. How can you learn from other private entities? And we have Charlene Underwood is going to moderate that.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

–

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

Well, yeah –

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Okay, I want to thank our last panel and I know many of you from previous roles in the industry and I wanted to take a moment just to express my thanks to you for taking your time this afternoon. I know there is a lot of passion in terms of each of you in trying to get this work, especially in the areas that we've talked about today, interoperability and advancing the intent of the Meaningful Use Program. So I look forward to your testimony. So, with that I will turn it over to Alisa who will start the testimony. Thank you.

Alisa Ray, MHA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Thank you Charlene and thanks to the group and I'll try not to be redundant from previous comments. I'm Alisa Ray, I'm here as CCHIT's Executive Director and appreciate the opportunity today.

In terms of background I think it's useful to recap CCHIT is a nonprofit organization with a public mission of supporting the adoption of robust interoperable Health IT by providing educational resources to healthcare stakeholders that includes providers, developers and others.

Founded in 2004 in response to the ONC's Strategic Framework CCHIT competed for and was awarded a federal contract in 2005 to develop EHR certification criteria as well as the certification testing methodology. CCHIT received federal recognition in 2006 as a RCB and during the following three years over 250 ambulatory and inpatient EHR products were testified and certified.

In February 2009 congress acknowledged the value of certification in the language of the American Recovery and Reinvestment Act by offering a multiyear series of incentive payments to providers and hospitals for the Meaningful Use of certified EHR technology. As authorized by this law ONC developed new regulations requiring EHR certifying bodies and testing organizations to become accredited.

CCHIT was among the first to become NIST, NVLAP, and ANSI and ONC ACB accredited, all of those things and under the new regulations each certifying bodies did not have the opportunity to engage with stakeholders to develop and refine certification criteria, EHR testing organizations were no longer involved in developing or validating test procedures.

In January of 2014, this year, CCHIT determined that its mission would be best served by voluntarily withdrawing from the ONC HIT Certification Program and instead offering our talents in new ways. CCHIT's future plans include offering direct education and counsel to both providers and developers on the requirements for certified EHR technology and how to best satisfy those regulations as published by organizations and government.

With a more global focus and an alliance with HIMSS CCHIT will also develop new programs and guidance in achieving interoperability and supporting change in the way providers and patients around the world use IT to positively transform Health IT.

So the questions I was asked, I was asked to compare CCHIT's independently developed certification program with the ONC Certification Program. CCHIT was originally created with the mission of accelerating adoption as a private-sector collaborator to ONC contributing to the adoption component of the federal Health IT strategic plan and from 2005 to 2010 CCHIT worked in this capacity with an emphasis on engaging the community of provider, vendor, payer and government stakeholders to develop criteria and testing processes that establish the benchmark for that system.

Capabilities were also published for forward-looking roadmaps or future requirements two or three years out. This independent development process included a high degree of transparency during the frequent development phase supported by multiple rounds of public comment, a rigorous pilot testing of both criteria and testing methods and CCHIT's full certification also allowed a validation of successful provider implementations of EHR products at live sites.

CCHIT's work pioneered testing and certification methodologies which formed the basis of today's ONC program. This includes the use of remote testing methods via observation of capabilities or functions, open-source development of tools to encourage and validate interoperability, a volunteer expert juror program to witness and validate testing, and the first introduction of EHR usability testing.

You also asked me to give some comments on differences between the now ONC program and some of the original work. There is a table in my testimony that goes deep on that but for today I'll just give a couple of high-level comments around criteria development and the testing process development.

So, CCHIT developed criteria with volunteer subject matter expert panels. The panel composition represented a broad range of stakeholders, multiple public comment rounds were conducted so there was iteration at least three different cycles and forward-looking roadmaps were published at the same time which allowed the providers and the vendor community to plan their future and look at requirements.

Second, the test process followed a similar cycle. The testing method development was community-based by subject matter SMEs or volunteers moreover the test were thoroughly validated with public comment and public pilot testing process. And once they were finalized and launched they were never changed until the next cycle. Another difference today –

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

Sorry, Alisa, your time is up.

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

We believe the community views certification more as a technical compliance check associated with the administration of the incentives and less as an assurance mechanism for providers purchasing IT as when we originally started. Thank you.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

All right, Mariann, oh, David?

David Kibbe, MD, MBA – President & CEO - DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Yes.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

I just went out of sequence.

David Kibbe, MD, MBA – President & CEO - DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

We're often panelists –

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

We got it, we got it.

David Kibbe, MD, MBA – President & CEO - DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

We're often panelists but not –

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

We're flexible here.

David Kibbe, MD, MBA – President & CEO - DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

So thank you for inviting me to be here today. I'm speaking today as the President and CEO of DirectTrust and also as a family physician who passionately wants us to achieve some basic level of interoperability in 2014.

I've been asked to compare and contrast the accreditation program run by DirectTrust and EHNAC with the ONC Certification Programs and also to provide some feedback on our testing that might shed some light on the attesting and certification ONC does.

In February of 2013 DirectTrust in partnership with EHNAC established an accreditation and audit program for direct exchange service providers including HISPs, CAs and RAs. The purpose of the program was to set a single national benchmark for the assurance of privacy, security and trust, and identity controls practiced by known counterparties in direct exchange.

Accreditation and audit transparently signals a high level of achievement and practice of these controls thereby permitting voluntary reliance on accreditation and audit to create a network of scalable trust without the need for further one off legal contracts or single one-on-one connectivity arrangements.

There are now 52 organizations engaged in the process of accreditation 13 of whom have achieved full accreditation in all three programs for HISP, CA and RA and one is a CA/RA. Another 30 organizations are in candidate status for accreditation.

More important than these numbers are the real-world effects they are having. Of the accredited and candidate status HISPs 26 are not participants in the DirectTrust anchor certificate bundle. Distribution of this trust anchor bundle permits subscribers of these HISPs and all 50 states to send and receive Direct messages and attachments with one another. This network now serves over 5000 healthcare organizations and has provisioned over 200,000 Direct addresses in the past nine months. HISP to HISP interoperability testing is active and ongoing and I'll return to that in a moment.

DirectTrust accreditation program is voluntary and is not a requirement of the federal government for participation in the Meaningful Use Programs as is the case with ONC certification.

Another difference is that ONC is testing software for compliance with specific functions and specifications whereas DirectTrust and EHNAC are testing organizations who use software against a set of standards, policies and controls that taken together aim at assurances for privacy, security and trusted identity.

However, the ONC EHR Certification Program and the EHNAC DirectTrust Accreditation Programs have evolved a parallel and highly related relationship in the market for EHRs in 2014 and beyond. The major EHR vendors certified for the 2014 edition are also either themselves accredited HISPs or are relying on accredited HISPs to provide their customers with the Direct exchange services. This includes the popular EHR technology supplied by Allscripts, Athena Health, Cerner Corporation, CPSI, eMDs, EPIC, eClinicalWorks, GE Centricity, Greenway, McKesson, Meditech, NextGen, PracticeFusion, RelayHealth, Siemens and dozens of other EHR vendors serving smaller markets of providers and hospitals.

These parties direct capability along with over 25 state and regional HIEs operating accredited HISPs virtually guarantee the ability of the nation's healthcare providers to achieve widespread interoperability of IT systems via Direct in 2014.

The one slide that I brought for you today gives a snapshot of the DirectTrust network as of this week. And I just want to in the time I have, short time I have remaining would like to provide you with a little bit of insight.

First note that on the left-hand side there are 26 HISPs and across the top you have the same 26 HISPs. So that means that 26 HISPs are testing with the other remaining 25 which is a total of 650 HISP to HISP connections that are being connected.

All of the green connections indicate that both the sender and receiver were able to send and receive messages with one another. If it's yellow it means that there was some problem and the very few red squares indicate that there was a significant problem and was unable to affect the exchange. The white bars there show that in effect that they have not started testing yet and we are bringing in a new HISP into this network approximately one every week.

I don't have time to discuss any of the learnings that we've gotten from this extensive testing over the past four months, but our current learnings from this testing strongly suggest that ONC, NIST and DirectTrust members collaborate very quickly over the next 14 to 16 months in order to make it possible for better ONC certification and testing to be done so that the kinds of downstream problems that you're seeing here that we have to fix will be fixed earlier and we can handle more significant problems. And I look forward to working with you on those as time passes. Thank you very much.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Thank you, David. Chris?

Christopher Carr – Director Informatics – Radiological Society of North America (RSNA)

Thank you. Good afternoon. My name is Chris Carr I work for the Radiological Society of North America and I'm here in my role as a Secretary of the Board of Integrating Healthcare Enterprise or IHE USA. On behalf of IT I want to thank the committee for the opportunity to provide comment.

IT began in 1997 as an initiative to bring together healthcare professionals in industry to improve the interoperability of health IT systems. It now oversees committees in 11 clinical and operational domains, 24 national committees and over 650 member organizations.

IT promotes the use of standards like DICOM and W3C, and HL7 to address specific clinical needs by developing implementation guides called IHE profiles. IT also conducts a testing process for HIT developers to help them implement those profiles. That testing process culminates in annual events called IHE connect-a-thons and in vendor's self-attestation of the conformance of their product with IHE profiles.

In the last two years IHE has begun to expand its testing services to include a product certification program. With that background here are some of the elements that distinguish that program from the ONC program.

The IHE Certification Program grows out of an established peer-to-peer interoperability testing process with more than 15 years of experience and many hundreds of vendor systems tested. IHE profiles and the IHE testing process focus on interoperability and information exchange and avoid, as far as possible, prescribing system functional behavior or evaluating usability.

To support this testing we've developed a testing platform and an extensive suite of testing tools in collaboration with an international team of developers including the interoperability testing laboratory at NIST as well as other research organizations and commercial developers.

The IHE profiles on which testing is based go through a development cycle of at least 18 months and often through multiple development cycles. The profiles selected for certification testing have been selected based on the maturity of the specifications and tooling, as well as industry demand and clinical significance.

In establishing a certification program we are partnering with an accredited testing laboratory ICSA Labs to conduct a pilot program and establish a clear definition for an ongoing program. We worked with ICSA and consulted with a number of experts on conformance assessment and attestation to develop a certification framework based on industry standard approaches including ISO/IEC guide 65 and ISO 17025.

And through this process we have evaluated carefully the increased testing and administrative requirements for certification including product surveillance, which is a new area for IHE and its testing participants.

The certification program is actually a coordinated set of regionally implemented programs administered by IHE USA, IHE Europe and potentially other national IHE organizations.

The IT profiles on which these programs are based are international in scope and common across all the programs. And IHE is developing a schema to ensure uniformity and reciprocity in these programs.

The program is being implemented incrementally and the intent is to continue to grow it gradually over time and it is designed to be complementary with certification programs of ONC in the USA and similar national programs in other countries.

I'd point out patient care devices as one area of testing where we have focused initially and as an example of how IHE is able to provide detailed testing in an area that might be considered a niche within Health IT. IHE has developed a test specifications in others areas like public health data registries, diagnostic systems in radiology, lab, cardiology, pathology, eye care and others that will be added to our certification program over time.

So the experience we've gained through this progress leads to a couple of recommendations that mirror those provided by other commenters today. Ensure that test methods are developed with sufficient time and resources to provide quality, stability and detailed coverage. Focus on baseline functional requirements and especially testing standards-based interoperability. Leave room for innovation above the bar. Leverage complementary testing programs by other organizations like IHE including their ability to extend testing into specialty areas and continue to work with establish standards bodies, IHE, HL7, DICOM, etcetera, to develop and disseminate the standards that provide the foundation for certification criteria. Again, thank you for the opportunity to comment. I look forward to your questions.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Thank you, Chris. Jitin, Jitin?

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

You got it right.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Okay, thank you.

Jitin Asnaani, MBA – Director, Product Innovation - AthenaHealth

Hi, I'm Jitin Asnaani and I'm Director of Technology, Standards and Policy at AthenaHealth and I'm here in the capacity of one of the founding members of CommonWell. Thank you for this opportunity on behalf of everyone at CommonWell.

The CommonWell Health Alliance, as you may know, is an independent not-for-profit trade association devoted to the simple vision that health data should be available to individuals and providers regardless of where care occurs.

We believe that provider access to this data must be built into Health IT at a reasonable cost for use by a broad range of healthcare providers and the people that they serve. The alliance currently consists of 10 technology vendors who collectively represent more than 40% of the acute EHR and 20% of the ambulatory EHR markets.

The alliance plans to define and promote a national infrastructure with common standards and policy which today include identity management services to accurately identify patients as they transition through care facilities, record locator service to help providers locate and access their patient records regardless of where the encounter occurred, consent management services to deliver a patient authorized means to simplify management of data sharing, consents and authorizations and trusted data access to provide authentication and auditing to facilitate trusted data sharing.

Our certification process is administered by the CommonWell Health Alliance Services provider which certifies each of the edge EHR systems that connect to those core set of services. Our approach is to certify the actual service interfaces, actually much like Chris just described, where we focus on the API calls, performance service level, security requirements, IHE standards compliance, metadata, etcetera.

As CommonWell services are added or significantly change we require an update to the edge system depending on the complexity of those changes to the service implementations.

As a result of this approach, we expect updated certifications to be driven by the release of new API versions rather than the version of the edge system and in a moment you'll understand why that's a very big deal and how that is very different from the way it works for other types of certification today.

We do not plan to certify workflows off the edge systems but do plan to provide guidance and best practices to help drive value and usage of the CommonWell network.

Ostensibly, based on what I've said, you can see that the certification processes of the CommonWell Health Alliance and the ONC EHR certification program are both aimed at ensuring that HIT systems are built with out-of-the-box interoperability that enables providers to truly focus on providing the best of health care and that's to a large extent true but there are some very notable differences.

The most obvious difference of course is that our certification process is driven by private sector entity hence we're here. But that's endowed with strengths that are complimentary to the regulation driven approach.

For example, our certification focus can be more responsive as standards evolve and market expectations change. Also, because we provide the services that are actually used day-by-day we are positioned to rapidly address weaknesses in the standard specification criteria, especially when implementation guidance is poor or outdated in the first place, that never happens in standards.

And we can do so in an incremental and agile fashion and this strength is, you know, I called this out as one of our strengths but it's a strength not necessarily only unique to CommonWell, in fact a number of our alliance members have been empowered to do real-world Directed exchange due to the independent certification process introduced by our colleagues at DirectTrust. So, it's very much a complimentary set of strengths that we should think about as very complimentary to the work that we're doing at ONC and throughout our own certification processes.

Another notable difference is that the alliance is focused on certification of interoperability only and not on the functional behavior of individual vendor applications. It is our belief throughout that the greatest value is created by standardizing on interoperability and then letting vendors compete on how to best deliver the user's experience.

Through standing up and executing our certification process we have discovered interoperability issues that should be in the ONC's certification of radar. Most notably we have suggestions on the quality and processes surrounding the C-CDA content standard. Now, I know particularly in a forum such as this that probably sort of nitpicky and granular, but we highlight them here because ONC has been remarkably successful.

The C-CDA is fast becoming the core content packet for health information exchange nationwide beyond those just recommended or required for Meaningful Use. So in my submitted comments I have expounded in much more detail but over here I'll bring up a summary to free up the biggest issues surrounding the C-CDA where the ONC has the opportunity to continue furthering the cause of interoperability nationwide. Number one is that the ONC certification process itself needs to do much deeper testing of C-CDA's today.

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

I'm sorry, Jitin your time is up.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

Already? Oh, I'm sorry, okay – let me rush through it and I will hit the summary and I'll do that in 30 seconds if that's okay? I promise.

All right, so there is – today when we receive C-CDAs often they are unparsable just by the fact that they've been MU certified. C-CDAs can include a wealth of information or very little information and unless you have designed a system that's actually ready to understand whether you're getting historical or active data you could have a very poor user experience.

And so if you look at this and I've detailed other short comings in my expounded comments, in summary, the certification process used by the alliance has the advantage of nimbleness and focus on real-world actively used services and some of the issues we've encountered are major impediments not just for us but for the nation in general for other interoperability initiatives here at this table and beyond and there is an opportunity for ONC to be able to step in and provide that valued information. Thank you very much.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Thank you. Mariann?

Mariann Yeager, MBA – Executive Director – Healthway, Inc.

Well, thank you very much for giving me an opportunity to speak with you today about our experiences at Healthway, I'm Mariann Yeager, Healthway's Executive Director and CEO.

I wanted to focus today really on our experiences in running a highly automated testing program in support of eHealth Exchange that I think most of you are familiar with the eHealth Exchange that I think most of you are familiar with the eHealth Exchange, it is a large scale nationwide network that supports a variety of cases, treatment, care coordination, disability determination, quality reporting using those query retrieve as well as push or submission of data.

As many of you know this started as one of ONC's longest standing initiatives related to the NHIN or Nationwide Health Information Network and in October of 2012 Healthway assumed responsibility for supporting the eHealth Exchange including on boarding and testing and in anticipation of that we really took stock in trying to evaluate lessons learned since 2009 when production first started and use that as a basis to design, develop and launch a very rigorous efficient objective and repeatable testing program that was really geared to accomplish three things.

One was to support the trajectory of growth, to improve the efficiency of the process by leveraging automation in lieu of manual verification and to increase the level of assurance of interoperability by testing both conformance and focusing on verifying known interoperability issues. So, the idea was to really test once and exchange with many without subsequent configurations.

Healthway since partnered with AEGIS to leverage their deep domain expertise and automated test lab called the developers integration lab and its automated testing approaches reduce the amount of effort and time for testing from months to just a few weeks. We actually had one participant that who completed that ran the test in two hours and testing was completed in less than one week with tweaks and with a substantial reduction and level of effort resources and costs for testing.

We also recognize that there are added benefits of mitigating risks that interoperability issues will be introduced into production resulting in costly need to handle patches and upgrades, so it was a necessity really from that perspective.

With the new testing program in place we've doubled participation. There are now 51 organizations in production. We will double this number more than double this number this year. To give you a sense 23 organizations have already completed testing under the new program and have been approved for production and are in activation stage. Another 36 are quickly proceeding through the testing process using the automated self-service test lab and 45 others are in the process of preparing to apply to begin on boarding and so when we reach the milestone of 100 participants in production this year we will connect more than 1/3 of the countries hospitals and nearly 30% of the US population.

So one question was, how does this really relate to ONC's Certification Program. So, we sort of look at it pretty simply they are a bit different, have different objectives. ONC certification focuses on certifying products that are sold out of the box really focusing on conformance related to transport and content of course is many other rich features and functions related to Meaningful Use.

Healthway supports a testing program however for participants and products as configured or as implemented for production level interoperable exchange of health information. So, it's really a specific implementation level test not general certification of an unconfigured product.

In addition, our testing program is much deeper and much broader with respect to interoperability testing, so yes there is important conformity checking against underlying national and international standards profiles such as IHE and that is actually in addition to transporting content we also do that level of validation for message and security, it is highly granular. There are thousands of automated checks and verifiable conformance verification so that is certainly very distinctive.

We also focus on interoperability testing with five years of production under our belts. We know where the issues are. We have data to support that so we really focus on verifying that known interoperability issues, again, are validated.

For example, this includes negative tests where non-conformant behavior is simulated by other systems to assure that the systems under tests properly respond. So, again, the objective here is test once, exchange with many without additional configuration in testing which is very different from the ONC program which focuses on basic conformance and functionality.

We've recently launched a product testing program which will offset the amount of testing that participants need to complete essentially since it's ensuring that those capabilities are supported in production. The savings and efficiencies are substantial, it substantially lowers testing costs by about 70% and similarly with the test and by focusing, you know, really on the likely connectivity issues that a production system once it's been implemented and configured would need to address.

In terms of lessons learned and advice for ONC, we're really not a certification body we're simply providing testing to assure interoperability in a production environment. So there are really four key areas which we think might be beneficial to consider, one is maybe consider using a public-private sub-regulatory process –

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

Mariann, I'm sorry, your time is up so maybe you could go through those four very quickly?

Mariann Yeager, MBA – Executive Director – Healtheway, Inc.

Yeah.

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

Thank you.

Mariann Yeager, MBA – Executive Director – Healtheway, Inc.

Consider that as a more flexible approach to maintain the criteria, maintain a multiyear roadmap so there is sufficient visibility and time and notice for vendors to plan for that criteria and time to employ and upgrade systems.

We can't emphasize enough the importance of testing and piloting criteria test scripts and tools thoroughly and that may necessitate going through the process multiple times and finally ensuring that the standards and specifications required for certification are mature, piloted and drawing a sharp distinction between emerging standards that are really akin to R&D efforts from those which are broadly supported.

And I'll close by saying that, you know, HIE is no longer an experiment there is a large scale production that we have to be cognizant of making changes that might be disruptive and so please be mindful that the decisions that are made for this program have real bearing on real world exchange treating real patients every single day. Thank you.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Thank you Mariann. I'll open it up to questions from our committee? Okay, if there are no questions I'll start then. You all alluded to how your programs could be complimentary to ONC's efforts. So, on the broader scale, can you just drill down to that next level and explain what you mean there? A couple of you talked to that point. And maybe if we're going to improve upon the ONC Program and you had an ideal case of what it does what might that look like?

David Kibbe, MD, MBA – President & CEO - DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

I'd be glad to start. Direct as a protocol is a required standard in the ONC certification for 2014. So, for most of the EHR vendors for example who are in the market today they not only want their products to be certified and usable in terms of their direct capability but they want to mitigate the risk associated with their users, their customers using Direct as a means of sending messages and content out over the Internet.

So, I think that the complementarity is that while certification to the software capability is important it's not sufficient in order for Direct exchange to occur at scale across multiple different vendors, products and their subscriber bases. So, that's the complimentary parity.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Okay.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Yeah.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

I'll bring in a perspective that is actually complimentary to that complimentary perspective but it's not exactly the same.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

We've got a lot of dimensions with this program.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

Yeah, I know, it's good we're going to be filling out a 4 x 4 matrix.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

I know, I know.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

So, the point that I would bring is that, you know, one thing we've discovered is, you know, CommonWell, Healtheway, Direct, IHE actually and a number of others as well, right, there is a lot of work that's happening, a lot of good work with great intention happening around the country. ONC – there is this very funny comment, I think it was Farzad who made it several years ago, when he said that regulation can be a driver of innovation which the private sector went "sure" but the reality is in some ways it can be and this is where this group right here, other folks out there are really showing where the rubber hits the road where there's an opportunity for innovation.

And the places where we're attacking specific use cases in Healtheway's case or DirectTrust case, or CommonWell's case, or IHE's very specific individual use cases are the places where you let these types of organizations run because they can react quickly especially if they're new to the world and if they're enabling that, you know, interaction on that day. So we're not testing such that a group of people around the world can interoperate we're testing people who the next day are going to start interoperating and then we are continuously refining, continuously getting them engaged, continuously updating and recertifying them as we improve interoperation. But we're not catching a lot of other things which may be also important in terms of clinical decision support, other things which you really want to do but are just not part of what we all focus on.

So, the place where it's particularly complimentary is that even as we take out these focus areas and we are positioned to very quickly iterate on those focus areas faster than any government regulated timeline driven entity can we uncover lots of places where if there was broader mandate, if there was broader certification you would solve problems for a large set of us as well as other people who are trying to interoperate, you know, point-to-point. The C-CDA is an example we brought up.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Yes.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

I could also bring up the XCA. I know that David has run into, and certainly we've run into, as Athena Health as a vendor, DirectTrust, sorry not DirectTrust, Direct Project also has work that continues to be tightened up. So, these are things we bring up as an opportunity for ONC to continue making sure you don't just leave it as we've done C-CDA so that you can do transitions of care in this one circumstance, you know, now all the best to you when really people have said that, you know, we all have to implement – as vendors we all have to implement C-CDA and now we want to use it for everything so why don't you help us to use it for other things which are actually really important beyond the initial –

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

So, this goes back to the roadmap that you keep referencing, right?

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

That's right, that's right exactly.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Okay. Mariann, did you or –

Christopher Carr – Director Informatics – Radiological Society of North America (RSNA)

Sure, I would just echo a lot of what Jitin said with respect to IHE. I would add, as I mentioned in my comments, that IHE has the benefit of a great deal of breadth. So, in specialty areas, diagnostic technologies, etcetera, IHE convenes expert groups that are, you know, addressing issues that have not yet kind of come up on the roadmap on the horizon for ONC.

And innovation, you know, is I agree that regulation can spur innovation it can also stifle it obviously and I think the iterative process of IHE that there is a regular cycle of testing and development and that it's voluntary so that it differs, you know, you're not imposing a cookie-cutter on a whole sector of the industry allows it to be a source of innovation and I think you can see, you know, IHE specifications have become the underpinning for a lot of what ultimately become ONC regulations and I would hope that would continue to occur.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

Yes, just to – I didn't mean to leave out CCHIT from my example, this group of people has been working recently together, so it slipped my mind I'm so sorry.

Mariann Yeager, MBA – Executive Director – Healthway, Inc.

I agree with the comments mentioned and I would say another way in which our testing program is complimentary to ONCs is that we actually point to it and so if an organization is using a product that has been certified for instance for the Consolidated CDA or transport we don't have to repeat those duplicative tests and so to the extent that there is more of that functionality that we have implemented in the network in the certification program that just offsets the testing we would otherwise have to do.

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

I think I said mine earlier.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

I'd like to make one more comment, I think that with respect to DirectTrust and the testing we're doing in interoperability we are finding problems that the testing that ONC has done does not uncover. I think ONC has a tendency sometimes to put out a rule or put out a standard and say "we're done with it, it's fine, it's going to work." Well, as a matter of fact one of the questions that you might have is, what are the problems that we're discovering when we're testing a production level address going from one HISP to another HISP, to another production level address.

Over 90% of the problems are associated with various small interpretations and sometimes misinterpretation of the applicability statement itself. This is information that's going to have to come back to ONC to revise the applicability statement and the specifications and cleanup a number of areas that are gray where they ought to be black and white. If we don't do that it really puts the whole program of interoperability via Direct upon which much of Stage 2 Meaningful Use interoperability depends at risk. So, I think there is a feedback loop here we're discovering but we're not – we haven't really acknowledged it yet.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

So, I just – I know I've got questions but this is a clarification question. This is kind of real life development, right, we always know we roll out something and we've got to improve upon it yet with the regulatory process these technical – that feedback loop doesn't seem to be part of that process when we all know it's just real life. So, is there a process where that works?

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Don't look at me.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Well, Steve?

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Well, can you be a little more specific in terms of the type of feedback or the action that you might expect based on the feedback?

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

There could be a change to what actually gets tested, it could be improved upon.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Sure.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

There could be more specificity when it's broken. I mean, it's all the stuff that we as vendors do every time we roll out a product and we improve upon it until we kind of get it as best as it can be and it's never as best as it can be so it's just an ongoing –

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

So, this.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

So we would think there would be technical improvements too –

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

Yes.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Putting any standard in regulation is really tough.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

The testing part is probably the area where we have the greatest ability to innovate –

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Okay.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

For lack of a better word and overuse of that term now at this point. The test procedures themselves that are developed are sub-regulatory in nature one could go about testing in a variety of different ways, right? You could just negative testing, that could be ONC's approach for testing for certification criterion.

The test procedures themselves could be modified and have been modified as we heard from the ATLS and ACBs earlier and the developers earlier than them about the stability of those test procedures, right?

So, if there are quirks that come out of them I know that there were some instances with some of the public health implementation guides where corrections were made because there was a field that was ambiguous or something along those lines, there was just an error and we had to decide how to best test that or to ignore that one particular component of the implementation guide so that testing could continue. So, those types of tweaks can be made.

If it's a matter of the standard itself then that's a regulatory issue which begets more regulatory action to correct the original regulatory action that's caused pain. And that's, you know, at the level where I would say I get more involved based on my day job it's not impossible, you know, we've had instances where we've issued an interim final rule to address those issues, our preference is, you know, is to get those comments ahead of time, we've gotten some comments now with the 2015 edition NPRM proposal on the newest version of the Consolidated CDA that we had included for comment that were very helpful feedback oriented comments.

And other things in advance, you know, to Joe's point of people saying like "this isn't going to work right now." And so that's early on feedback that we've already, you know, been in the process of listening to. So, that's before we start the process.

But once we're at the end of the process and test procedures are being developed that's the area where changes can be made and a new test procedure can be developed to better test or accommodate different aspects that need to be addressed. Did I answer your question?

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Well, David, to clarify, which bucket are you talking to?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Well, one thing I'd point out is that of all the folks standing up here I think DirectTrust is the only body that's dealing with a federal standard. I mean, the Direct specification, the Direct applicability statement is a federal standard it's the private sector, the 127 organizations in DirectTrust, that are basically doing that testing on the standard.

So it does beg the question is who owns the standard going forward and how do we modify the standard going forward? When its IG there is a very well-known established and successful way in the private sector for doing it. DirectTrust members can't just make changes in the applicability statement even though we're discovering that there are some that need to be made, I'd be glad off-line to talk with some of you about them, it's not a lot, I mean, actually it's a very, very good standard. It works very, very well particularly when there is private sector willing to make it work as the collaboration that slide indicates there is, but nonetheless there's got to be some curation of the standard going forward and we really don't have a way to do that at this point.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Yeah, okay.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

I think Paul you were next.

Paul Eggerman – Businessman/Software Entrepreneur

Great, thanks. I'd say first, thank you to the panelists, this has been a great presentation and I very much appreciate your time. In stepping out during one of the breaks David Kibbe reminded me that we've been here before, in fact five years ago Marc Probst and I Chaired a hearing on certification for ONC and back then CCHIT was the primary and pretty much only certifying body, and back then the vendors were very concerned about a process that was expensive and they had some frustrations and recommended that we focus on interoperability.

And so we made all those changes and here we are five years later and we are hearing information that certification is expensive, we should focus on interoperability, but there is one thing that's different is instead of people criticizing CCHIT there are some nostalgia for your organization that is being expressed and so I do want to make that observation and it perhaps show this is a very hard thing to do to get it right.

And, you know, the comments that Charlene just asked about flexibility are very interesting. I read your testimony Alisa and your lesson number one says don't launch a program until all aspects are tested and ready and you write that very nicely in italics and, you know, these sentences that come after it where you say that many of the 2014 test methods have already undergone updates and revisions, so I don't quite understand what is happening because in some sense I'm hearing Charlene and people say they want revisions and I'm hearing from you Alisa there are too many revisions.

And something from the last group I heard, well we should only do these things like once every five years. So can you tell me, do you think things are going to fast or slow or should we step on the brakes, or the gas pedal?

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

My comments were on mid-cycle revisions and I think that's disruptive to the operation of the program. I think we heard that from John Halamka and others.

Paul Egerman – Businessman/Software Entrepreneur

What you mean by mid-cycle? What's mid-cycle?

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

So once the 2014 criteria are released assuring that it's a level playing field as opposed to a moving target for a vendor that tests in January as opposed to May.

Paul Egerman – Businessman/Software Entrepreneur

And so what did we do wrong that that occurs, that there are those mid-cycle – so there is not enough upfront testing before the stuff is –

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

Sure, yeah, I think just an overall QA of the different components just like any one does with any program you're building QA it, you do a dry run, do a beta, make sure things are there and operating. It's just I think a waste of folks time to have to fix something a month later because someone didn't eyeball a typo in a code, some of the changes were that simple, but other things have been more substantive and it had greater impact. It just – it's a better operating – I don't think anyone would argue with the QA process.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

If I could make another friendly comment here, you know, particularly given the comments you made about 2009, I think that, you know, just spending two years learning how difficult it is for one very small aspect of the 2014 edition, that is Direct exchange, to get up and running, you know, to lay the fiber so to speak is profound to me in terms of the whole range of items that are in the certification criteria.

I think that the vendors are having a really hard time getting all of those pieces in place. Some of them are choosing to do Direct extremely well, maybe they're not doing Direct something else so well, they may not be doing quality reporting, others are not doing Direct very well at all and this is beyond the HISP this is that last mile to the edge client, to the EHR and I think that that's the problem it's the unevenness with which Stage 1 Meaningful Use will be adopted and put into place within this whole fabric over the next 12 months is what we're going to see.

And I think you've heard a thread here today, which I would echo is if we could focus, you know, if you could pick two or three things that really appear to be important to the Meaningful Use trajectory rather than 15 or 20, or whatever the total is, it would probably lead to greater success.

Paul Egerman – Businessman/Software Entrepreneur

So, to look back at where we were five years ago, the two learnings that I'm hearing that we should be sure that we understand is one is what Alisa is saying, to make sure thoroughly test anything before we put it out there for certification and what you're saying, David is to understand it takes a long time to get something and do it through all of the vendor process and get all the deployment and get it out in the field, it takes much longer than expected.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

It takes as long as it takes. I think when you have a good collaboration between the private sector and the federal government with respect to what you want to get done it can be done. I think what the DirectTrust members have accomplished in two years is very, very significant. However, I also think that if you have too many things stacked on your plate not all of them get done equally well and that's the message I hear and combining those two ideas I think is important.

Paul Egerman – Businessman/Software Entrepreneur

Thank you.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

May I make an additional comment to that? I completely agree with the comment here, but I will add that having spent now a good bit of time running interoperability initiatives for both the government and in the private sector you can't QA some of these things to death before you release them otherwise you either never release them or you'll take years and years, and years and that's not in the interest of the healthcare system.

The point is not untaken, I mean, my own comments suggested that there is more that can be done for both QA and for testing that should be done and I like sort of the intent around focus, but we've not hit the middle ground yet. There is some middle ground that says that we won't be disrupted to the process of vendors being able to deploy their systems out and wearing my Athena Health hat I don't have to really worry about that because we're cloud-based, so all of our providers immediately get the latest system that we have.

But that doesn't mean we should wait three years before there is a really important update to an interoperability standard that can make a difference. I would argue that the MDN requirement in Direct projects we've learned not so long after Meaningful Use Stage 2 was even announced that this actually could be better – that might make a lot more sense for it to be required than optional, that should just be part of something that's required now rather than waiting until 2017, because that means that not until 2017 can we actually realistically think about sending labs over Direct that just cannot happen, because neither would CLIA allow it, neither would the labs allowed it until we get MDNs and the requisite other messages around failures up and running.

So, I do think there is some middle ground here, on the other hand a tweak for the sake of tweaks, a tweak so that an additional field could be added in a lab result message probably not worth the disruption it will cause and even then I say that even despite the fact that for us at Athena Health it will take us about an hour to do it and an hour to deploy it. Wow, apparently God agrees with me.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

All right, thank you, thank you.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

You have the disposition notification just for those who don't know.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

Yes, oh, yeah, sorry.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

It's okay.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

That's all right, sometimes I forget to take off my –

Paul Egerman – Businessman/Software Entrepreneur

We all do that.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

All right, Marc?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Yeah, you send a message and it should send you back an MDN that your message is being disposed.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

So, first I'm really appreciative of the testimony that each of you has given us and the information you've provided. I do find myself a little bit bewildered and not by you guys, but just by the situation in general.

I mean, if I went and certified with each one of you are we – do we have interoperability now? I mean as a country? Well, and it gets to so many levels of certification and because you have a group of interest you can get to a certification because you've gotten a small enough body that interested in solving a problem and they'll go through and they'll create their standard, which isn't, but they'll create one, and then you can have interchange between those organizations.

I'm just trying to figure out where is the certifier of certifiers and really in a data liquid environment, to all four of these organizations, by – well, you would exist, but would all four of the organizations exist?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Well all four organizations are doing different things.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Well, but that's not true data liquidity right because you're doing specific things that all need to be part of the healthcare economy.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

No I don't agree with that.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Okay.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

I would argue with you. I think Direct exchange is very, very simple e-mail plus attachments with a public key infrastructure overlaid for encryption and identity validation. eHealth Exchange is a much more complicated set of query capabilities, I think they're complimentary to one another and institutions will use both.

I think it's a historical accident the way that, you know, that DirectTrust came to be and eHealth Exchange came to be but actually I think they're cooperating very, very well with one another and of course IHE is the basis of the eHealth Exchange Protocol. So, as a matter of fact there is a lot more fabric here than – it's not just loose threads everywhere.

Alisa Ray, MHSA - Executive Director & Chief Executive Officer - Certification Counsel for Health Information Technology

I agree.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Yeah, weaving it was what was being challenged I think.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Yeah, well, and again, I'm a novice, right, I mean.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

No.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

But it feels like loose threads for the – you know, the providers in the industry.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Yes, I would agree entirely with that position.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

Yeah, I mean, I would add that's a sensible way to evolve though you want to evolve around use cases rather than some generalized notion around interoperability because that's the – the hard part's around technology are being solved, a lot of them are already solved.

There are harder questions around usage which is around user behavior, it's around getting value from actually trading data even if I had an open connection between a hospital and an ambulatory physician who doesn't do any referrals to the hospital. Will data flow? They won't there is no need to, there's no impedance to it and any little bit of work is work that's taken away from treating patients.

So, I think it makes sense as each of these threads are working independently some of us are actually finding overlaps, Healthway and CommonWell is realizing well actually there are some places maybe – it doesn't make sense for both of us to be doing the same thing let's try to figure out how to collaborate and bring it together.

David and I have been talking about how identities play into both of our networks may be there is something there where we should actually be thinking about putting these threads together and bring it to other identity threads which are actually being solved elsewhere as well.

But that's a very natural way for us to go and to evolve because at the end of the day we're going to figure it out. Healthway is going to figure out some things don't work and drop it and they'll go for other things. We're going to figure out the same thing. Along the way each of us is going to uncover elements that really should be more broadly based than just what we're doing and that comes to the point around, Paul's point, around how do bring this, sorry it wasn't Paul's point, somebody's point around let's bring this back into –

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Yes.

Jitin Asnaani, MBA – Director, Product Innovation – AthenaHealth

The loop of government, what's regulation, testing, certifying, standard's development both at the government and in conjunction with standard bodies. So, I think it's a natural way to evolve and the certifiers – certifiers I'm not sure that makes complete sense today maybe in the future but there certainly is that an opportunity to certify the common element that are going to bubble up from each of these very use case specific initiatives.

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Thank you.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Thank you. Don?

Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University Wexner Medical Center

Yeah, I had a question maybe starting with Chris, as I'm listening to the things today it seems to me in a lot of cases we haven't even built a single instance of sending and receiving software. So, we're talking about an interface in policy where we haven't actually built, you know, the plug in the socket yet and so we have a policy around how we'd like to build a plug and how we'd like to build a socket, but we haven't even built a single one.

And I'm curious whether you see that? I mean, I see the IHE profiles as something successful because that's been built out, it's sort of validated, it's been going on for 15 years I think or something on that timeframe and maybe part of the recommendation of the Workgroup is something on should there be some prototype transmission and reception software that is a minimum standard before we put it into policy and I don't know where the other people on the panel actually are in that process whether that code exists.

But, I'm just sort of hearing a lot of times, you know, like on spelling of names in fields where it's never been done, I mean, just skip the workflow around it, just the actual plug and socket we're not talking about the power network, you know, we're just talking about the connection and maybe Chris you could talk to that?

Christopher Carr – Director Informatics – Radiological Society of North America (RSNA)

Sure, so IHE there are many instances of IHE profiles just to air our dirty laundry that have never had a plug or socket built yet, some because they're new and some because, you know, there were misses and things that committees thought industry would like and in fact there just wasn't – it wasn't time for it.

But some of the really, most widely implemented profiles have benefited greatly from having reference implementations built early on, especially so that vendor developers could test their systems against those and I think probably the core ones, the radiology schedule workflow which was like the first profile that was built had a test simulator built that was highly successful and then the NIST set of tools around the cross enterprise document sharing, XDS profile, which is, you know, kind of up there, has been chugging along for many years and literally hundreds of vendors test against it every year.

I think it is a very healthy thing in many instances to have that kind of visible test harness and proof of concept in place and that's certainly something we are working toward with a broader array of profiles. So, I think it's definitely a healthy thing.

Charlene Underwood, MBA – Senior Director, Government & Industry Affairs – Siemens Medical

Any there any other questions? All right, well, I want to thank the panel. I certainly took away the need for – and I think the theme that came forward today is there is just a lot of learning that’s happening in the field that in collaboration, and I think we hoped that would come out of the conversation today, with the efforts on the federal level would really bring value to achieving the goals of the overall Meaningful Use Program as well as improving certification and, you know, certainly having you here today to testify I think validated that. So, again, I want to thank you for your time and for your participation. Paul?

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

All right, thank you, thanks to the Workgroup, the panel, thanks to all of the people who shed so much light on some of these subjects.

Our task for tomorrow morning is to assimilate this and come up with recommendations and the whole reason is ONC in their forward thinking and receptive mode wants to improve the certification process and the purpose of this hearing was for us to get this input and try to make some recommendations to ONC in a timely way because they would like to do it as soon as possible.

So, that’s why we’re meeting together tomorrow. We get to sleep on it. So please sleep on it and jot down some organizing things. We had lots of themes but I’m trying to come up, even myself, with how to organize it so that we can, one think about it, deliberate upon it and get some useful constructive recommendations to ONC. And Jacob?

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

Thanks, Paul. I guess I wanted to do what you’re doing which is to send the group home with some thoughts to consider over adult beverages or other things before tomorrow. And I want to emphasize what Paul just said, what would be most valuable to ONC are explicit recommendations I think in two domains.

The first domain, and I had an off-line conversation with Larry Wolf that I’ll now make transparent and put in the public record so that nobody thinks there are backdoor conversations, and Larry said to me, it’s like an aircraft carrier and there are planes that are landing and taking off right now.

So, I think as much as everybody in the ecosystem would like this, oh, echo, echo, would like this program to evolve tomorrow toward being better, stronger, faster, more agile, less waterfall and so on it’s a program that is functional and is doing what it’s doing today. And so we can’t move it tomorrow because those planes that are landing aren’t going to have a place to land.

And so it’s near-term what are the tweaks that might be appropriate that aren’t going to change this thing to cause even more damage and, you know, quoting Joe, cause unintended consequences. And then what are the longer-term opportunities for us to learn from where we’ve been. Nobody is pointing a finger at anybody and saying they were wrong. This is a program that has evolved over time and we can look back and say, okay what have we learned in N years since there was one thing, I’m looking at Alisa Ray for those following along at home, that CCHIT learned, what have the other activities with the other ACBs and the ATLS what have we learned over this amount of time?

And then how can we, looking forward to the future, cause this program to be perhaps a little bit more responsive, a little bit more agile and, you know, of course we heard things that said two different things, right, be faster, be more responsive, fix things when they're broken and find ways to fix them and yet, gosh, you know, other industries it's 5 years, you guys are doing things too fast. So, be faster, be slower at the same time and what are the tangible recommendations that the group has for us?

Because I would emphasize that we are very interested in making sure that this is a good program, it's the Goldie Locks we don't want this to be so onerous that it impedes the industries forward progress. We don't want to stop innovators from innovating. In fact we want innovators to have the flexibility to innovate.

Yesterday at the Policy Committee Hearing I was surprised to hear that, you know, folks want us to be more prescriptive in some ways, right, and even Colin said that earlier today "no tell us it has to be a portal" that surprised me.

We want folks to be able to create something that's the iPhone or the Android App instead of a portal and allow for innovation to occur and yet provide sufficient guidance so that there's not too much ambiguity, to David's point earlier, when people have to interpret things and then if it's interpretable then you can bet people will interpret it differently and therefore you won't have plug-and-play.

So, I spoke longer than I intended, but I really want to give folks the guiding or the guidance that we are very open to this set of recommendations and we really look forward to the conversation tomorrow.

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

So, was that, turn the battleship but not too fast?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System

But not turn it over.

Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

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

Well, another thing that Joe mentioned, I think one of the things we could have done with Meaningful Use is to also consider how something could be tested at design when we're trying to specify it. I worked for IBM decades ago and even in their integrated circuit package all the circuits inside had to be 98% testable from the outside interfaces and that's just the way it needs to be done. So thinking about if it's a good thing to do that's fine, if it's a good thing to do and it's testable that would make the –

Jacob Reider, MD – Acting Principal Deputy – Office of the National Coordinator for Health Information Technology

And that's now fairly standard software development process to incorporate test driven development into a set of operating principles and as Steve mentioned earlier that is what we're trying to do with standards. Quality measures, we are talking to the quality measure developers and looking to them to deliver test cases with their measures which we think will actually make the measures simpler because they're not – you know, if they have to develop the measure it might actually cause them to think twice about making the measure as complex as it is.

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

So, there are two kinds, one what could be – I mean, we've heard a number of actually concrete recommendations from the panel about what could tomorrow – we do this whole testing of test scripts and the testing tools and what could we think about going forward with HIT policies that, as an example, could be measured, assessed at the back end. So a lot of good food for thought and let's come tomorrow, prepared tomorrow to – I'll try to come up with some organizing scheme, but to organize our discussion so that we get concrete recommendations in the short and the longer term framework.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, are we also going to get some public this afternoon?

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

We will as soon as I shut up. So, now I'm done. So, let's open for public comment please.

Public Comment

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

Okay, if I could ask the panelist actually to step away, if there is anyone in the room who would like to make a public comment, public comment is limited to 3 minutes, and while we wait for anybody who is available in the room operator can you please open the lines?

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers please dial 1-877-705-6006 and press *1. If you are listening via your telephone you may press *1 at this time to be entered into the queue.

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

Go ahead, Mari.

Mari Savickis – Assistant Director, Medical Affairs – American Medical Association

I guess I'm a frequent flyer. Hi, everyone again. I'm Mari Savickis, American Medical Association, thanks for the opportunity to comment. I thank ONC for hosting the hearing today. Given the number of problems that are being experienced with the program, the Meaningful Use Program and the Certification Program, we are disappointed however that CMS is not at the table.

The two morning panels we have heard from today, the providers and the vendors point to a number of serious concerns that must be reconciled. I'm reading, because I want to make sure I get everything right here, I don't usually do this.

I'd like to walk back from the provider point-of-view and try to connect the dots on what we've heard today. Physicians are dissatisfied with their EHRs and the requirements in the Meaningful Use Program. I'd like to note though that the physicians see the program as a single program they don't see certification and Meaningful Use as two different things.

EHR is seen as cumbersome they add extra steps in their workflow, many of these steps are smattered across the EHR with little identification to how they provide value back to the care of the patients. So, why so much dissatisfaction?

As we've heard here today EHR vendors want to provide high-quality products to their customers and be agile enough to address changes and still innovate and provide innovative technology. The lack of a submission UCD process may be less of an issue of desire so much as a lack of time. Most of their time and attention is directed at meeting certification requirements that are too prescriptive and they limit innovation and Meaningful Use requirements that require equally excessive allocations of resources.

The AMA strongly agrees with several commenters who recommended that the focus should be more on a streamlined Meaningful Use and Certification Program that is focused on promoting meaningful data exchange, improving the ability to report clinical quality measures, areas which are mandated under HITECH and with the industry as a whole is experiencing serious challenges.

To realize this goal a less prescriptive approach must be taken so that 1/5 of the US economy can truly leverage innovative technologies. If you streamline the current program that is both Meaningful Use and certification then you open up the possibility for greater innovation, well established and well understood web technologies as suggested by a panelist and other industry experts, this will create more agility for vendors to develop better products and doctors to use them and we will be working together to achieve the Triple Aim.

In the meantime, however, unless we provide more flexibility to physicians and other healthcare providers to meet Meaningful Use they are going to drop out. We know that the data from CMS points to at least 20%, as I've stated in the past, and yesterday at the full committee it was noted that 54 providers, 50 eligible professionals, 4 hospitals had graduated to Stage 2.

So, we fear that if changes are not made now that the weight of the program could be – or the program could sink under its own weight. So, we strongly urge ONC and CMS to create the flexibility that we've been asking for which would be allowing physicians to meet 75% of the requirements to obtain an incentive and 50% in order to avoid a penalty. Thank you.

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

It looks like we have no other commenters at this time.

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

Okay, thank you.

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

Can I just say a few thank yous?

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

Yeah.

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

I want to thank Kim Wilson who helped me identify the speakers and helped me coordinate everyone, so thank you, Kim. And I personally want to thank all of the presenters today for sharing your feedback and your willingness to come speak for us.

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

Yeah, absolutely, this was very, very helpful. What time do we reconvene tomorrow?

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

Nine a.m. tomorrow.

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

Nine a.m. tomorrow. All right, see you all 9:00 o'clock. Thank you.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you, all.