



HIT Policy Committee Certification Hearing Workgroup Discussion Transcript May 8, 2014

Presentation

Operator

All lines 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 Workgroup Discussion follow up from yesterday's Certification Hearing. There are members today present from the Certification and Adoption Workgroup on the Policy side, the Meaningful Use Workgroup on the Policy side and the Implementation Workgroup on the Standards side. This is a public call and there will be time for public comment in the room and on the phone at the end of the meeting.

As a reminder, please state your name before speaking as the meeting is being transcribed and recorded. For roll today let's start with people on the phone. Are there any Workgroup members on the phone?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Carl Dvorak here from the Certification and Adoption Workgroup.

Wes Rishel – Independent Consultant

Wes Rishel.

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC

George Hripcsak.

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

Good morning and thank you. And so we'll start going around the room with Mike Lardieri.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Yeah, hi, Mike Lardieri.

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

Charlene Underwood, Meaningful Use Workgroup.

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

John Travis, Implementation Workgroup.

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

Don Rucker, Certification and Adoption Workgroup.

Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman, Certification and Adoption, Meaningful Use and Policy Committee.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Larry Wolf, Certification and Adoption.

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

Paul Tang, Meaningful Use and 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, ONC.

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

John Derr, Certification and Adoption Workgroup and Standards Committee.

Joe Heyman, MD – Whittier IPA

Joe Heyman, Certification/Adoption and Meaningful Use.

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

Judy Murphy, ONC.

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

Steve Posnack, ONC.

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

Thank you everyone and thank you for coming back for a second day we really appreciate all of your feedback and taking the time to come and travel here today and again I want to thank all of the presenters that were here yesterday. And with that I'm going to turn it back to Paul.

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

Great, thank you, Michelle and also echo her thanks for everybody coming back and sleeping on some of the things that we heard yesterday.

I wanted to open up with just a couple of comments. One is this was a hearing about the certification process, the ONC certification process, not only did the panelists not disagree, I think they were in agreement that the purpose, the intent and the validity of the Meaningful Use objectives were good and so people were very supportive of that.

While the concern arose, about the effort and cost with complying with the documentation of meeting the Meaningful Use measures and so that's what we're here to address. We're trying to summarize what we heard as well as make concrete recommendations back to the HIT Policy Committee that would then go onto ONC.

Another sort of important distinction that came up and I think Alisa Ray's summary table was one of the – summarized it well, is the difference between certification programs and the intent. So, there's a difference between the certification of a complete EHR such as with CCHIT versus the MU certification.

So, the purpose of CCHIT actually which came out of the original Office of National Coordinator prior to HITECH was to give the market some kind of reassurance that one you had a complete EHR and two a little bit of reassurance that you were buying a product that was going to last.

So, that's what it was, it was really what I might call a market enabling certification, that was the way it was going to stimulate without the presence of incentive program, no HITECH, how were you going to stimulate the market, how were you going to make it a little bit safer and inform the market in terms of purchasing back then in 2010 or 2000, no, sorry, more like 2006, the mid 2000s.

The purpose of the Meaningful Use certification was to serve as a floor for programmatic needs such as the EHR, specifically for the EHR Incentive Program that was provided in the HITECH legislation. So, it's a bit more analogous to a condition of participation in the Meaningful Use Program than it is for certifying that this is going to be a comprehensive EHR. I'm avoiding the word "complete."

But that's one – so that's an important distinction because when people talk about whether it reassures the market or helps people select it only helps you select EHRs that are in compliance with the EHR Certification Program it does not guarantee that you have a comprehensive EHR that supports your clinical needs that may come up later on, but just wanted to make that distinction. So, I thought what we'd do – yes, Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, I appreciate that distinction. One sort of minor comment, when you talked about CCHIT there was another motivation for the CCHIT certification which was the Stark exception that fundamentally to get the Stark exception vendors had to get CCHIT certification and as I understand this situation is the ONC certification also gives them that Stark exception.

But the reason I say that is – I just want to say there was another motivation which I don't know if you could consider it a financial incentive, but at least for a vendor it's a financial incentive because it allowed them to sell to large organizations they might not otherwise be able to.

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

Thank you for that.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

This is Carl Dvorak – it was a significant contractual item and almost every contract we ever signed was a requirement to meet the then certification requirements that qualified someone for a Stark exemption to subsidize EMRs.

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

Well, thanks for that clarification it's very important. I think there was a little difference in the order. So, CCHIT Certification came first and then the Stark exemption piggybacked on that. Meaningful Use Certification was born out of –

Paul Egerman – Businessman/Software Entrepreneur

But it's a good financial incentive.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

There was – my sense is there really was programmatic coordination.

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

Yeah.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

That HHS went to HL7 and asked for a functional model for EHRs and went to CCHIT and said, you know, people created CCHIT and said –

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

Right, right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

We're going to need this –

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

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Can you like get it together so when we're ready you can be ready.

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

Good, thank you for that clarification.

Paul Egerman – Businessman/Software Entrepreneur

And they paid for it.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And they paid for it, yeah.

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

Yes. Okay, so what I thought we'd do is we have a number of folks, why don't we go around the table and give your top two takeaway messages, so your top two takeaway messages and then we'll go through sort of a clustering exercise after that and these are basically what you heard and then we'll go into recommendations based on these messages we heard. So, want to start, can I – go ahead?

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

I'll pass because I wasn't here yesterday.

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

Okay.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

So, I get out easy.

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

You get out easy, right.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Yeah, we had our national conference I just couldn't make it.

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

Thanks, Mike. Charlene?

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

Yeah I was actually briefing Mike so I'll tell you what I got –

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

Very, very good.

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

Again, listening yesterday it certainly is not for lack of trying to get this program to work that was one of my takeaways messages.

Then the second message was, as you look at doing any project there are three aspects to the project in terms of creating success, scope, timeframe, and resources. And what we heard yesterday is the scope was too large, that there are not enough resources and the timeframe is compressed.

So, when I look kind of going forward we have to do something short-term, near term, short-term/long-term we've got to look at those variables.

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

Excellent, thank you. John?

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

I'll probably pick some things that sound fairly technical, but having been through about 50 of these certifications it's where I live.

I think the first part, it might be a bit of a novel idea, but as part of the certification cycle when you have requirements that introduce medical code set changes, and it could be other specifications as well, you include in the criteria vendors to demonstrate the ability to map or convert legacy data where there has been a former standard and now there is a new standard and, you know, problem list is an example of that, family history looms to be an example of that. Those are probably not the only ones.

And then, I do agree with the commenters yesterday who spoke to the need to have built into the certification cycle more opportunity to do vetting of the tooling and the data sets for conformance testing. We have things borne out of our own experience we could give an example of that really indicated that's a good idea.

And I will toss one sidebar in there, I do think it would be of good consideration, as we look to where we are with Stage 2, to consider a probationary year for a new MU cycle where there is a hold harmless from payment adjustment, maybe from incentive payment as well, but definitely from payment adjustment to allow the market to have time to absorb all of the – that's in response to all of the upgrades, you know, give me time to take the code, get it into production, get into an adoptive mode and production before I attempt measurement. I think that really bears some serious consideration.

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

Can I ask you on your first point with the legacy codes, your proposal was to – what you heard was take that into consideration?

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

Take that into consideration as an outright requirement for certification because – and I have an eye on surveillance too, I think that we're in for a lot – for the potential of things being raised under surveillance that are really efforts and issues to try to help providers and hospitals convert all the forms of the legacy data to be able to meet the requirements of the go forward position. We act, from a certification and use stand-point, as if we're starting from a time zero we're not, it's Dr. Banas's testimony really.

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

Yeah, okay, thank you very much. I think your probation year maybe a way of sneaking in a delay, but –

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

Great.

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

But I'll just call it out. Don't?

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

Yes, somewhat similar I think the two things I heard was that there was a lot of what I would sort of call rework because of the tight cycles. In particular the thing I heard, sort of putting my programmer hat on, was that these data structures aren't like fully flushed out so people are doing lots and lots of iterations at the great expense to the country, you know, providers, vendors, everybody on stuff that isn't really ready yet.

And so I think there needs to be, besides somewhat longer timeframes, needs to be some additional vetting step. I think that the – like the NPRM process I don't think works well for highly technical sort of electronic connectivity things. I think there needs to be like – there needs to be actual, you know, whether you call a reference set or a just an actual code implementation of these things, that was one thing.

Then I think the other thing that sort of came through from what I thought was the uniformly well predisposed to ONC's mission group of folks was a lot of frustration and I think that the solution there is probably the scope of the things is just sort of getting too large for sort of the timeframe.

So, I think my recommendation would be to look at some of these areas and prune them out, you know, leave them for 2017 or, you know, as I look at things like the implantable device, some of the electronic transmission standards into things that don't have national receptors like health surveillance, maybe some of the things around clinical decision support, which hurts me painfully because that's what I did my, you know, graduate work in, I think these things need to be put on some kind of hold that the whole thing doesn't sink because of the political weight.

The specific challenge also is with ICD-10, I assure you when I talk with my colleagues, it's all one big jumble to them. They don't know, it's somebody in Washington, I mean that was – you know, very positive, otherwise favorable to these folks, so I think we're losing our political wind if we don't do something very specific and part of that would probably be holding off on 2015 until we get this sorted out, my thoughts.

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

Thank you. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yeah, it's Paul Egerman. My two things that I wrote down, it's actually similar to something Charlene said, is that – the first one is that I think people were just overwhelmed, you know, I mean overwhelmed in terms of the, you know, timeframes of magnitude, the complexity and perhaps that's causing – I certainly got that sense of what you said Don about frustration, people are very frustrated but overwhelmed is the way I wrote it down in my note.

And the second thing that I wrote is also similar to what you just said, Don, which is that too many things are immature that they're not ready for primetime. So, they find themselves with a moving target or things aren't working right so it's too much, too early. So, those are at least, to answer the question that you asked, Dr. Tang, those are my two takeaways. Now in terms of what should be done in response.

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

That will be the second phase.

Paul Egerman – Businessman/Software Entrepreneur

That's the second phase. So, I'm not going to answer that. I mean, I appreciate those comments but I think we should first come to some consensus about what the problems are before we come to a consensus about the solution.

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

And let me ask you a clarifying question on the too many things premature, do you think they are premature from a certification point-of-view or was the functionality too immature, do you think you heard?

Paul Egerman – Businessman/Software Entrepreneur

What I heard was it was immature across the board that sometimes the functionality was immature, a lot of times the standards themselves were immature in terms of for standards but also the testing process was immature and so you saw this a little bit in Alisa's testimony for example at the end where she says, lesson one things have to be fairly trained and then she talked about all the things that happened just after the 2014 stuff was published, you know, and that's not a good sign –

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

When you've got a lot of changes and updates going on and so the immaturity is – I would describe it as like equal opportunity immaturity, you know, it's sort of like there is immaturity everywhere.

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

I didn't get that sense from the testimony yesterday but did the challenges with the testing maturity reflect challenges with the underlying standards or was that almost – was there a separate additional –

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

Additional.

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

Issue from – that, you know, that as certification adoption folks we need to think about?

Paul Egerman – Businessman/Software Entrepreneur

Well, that's a good question because that may have been an intellectual leap that I made, but I sort of assumed that when you have change – one of the reasons why there may have been changes in the testing process was people were still sort flushing out the changes to the underlying standard and so that was one of the sources of that when they were actually using it. But, that might not be correct, but that was the sense that I had.

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

Yeah, in thinking about it last night I wasn't sure.

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

Okay, thank you. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess I have to resist my leaping to some conclusions. So, one of my takeaways was that while there are things that could be improved around the process and we heard a lot about more collaboration, Kaizen that kind of stuff about how we could collaborate better, that it wasn't the narrowly defined certification process that was the pain point it was the surrounding context.

So, we have Meaningful Use requirements that drive certification criteria and that linkage wasn't necessarily really as good as it could have been. And then we have certification criteria that, you know, drive testing and again that linkage might not have been as clean as it could have been and so the run-up, if you will, to the actual certification process needs to be addressed if we're going to fix certification because it's not that people couldn't show up for testing and it's not that the testers were unable to test them, I mean, there were issues with tests suites not being fully ready and fully operational, but those are like micro things.

So, I think, in my mind the bigger issue was around, so what's really the full context here in which the certification process is happening and that that's a bigger process that we should look at and the collaborative suggestions in many ways were trying to address that I thought.

To extend the discussion Jacob and I had about changing aircraft carriers and you have to remember that planes are taking off and landing while you're changing where aircraft carrier is that the aircraft carrier is not the only thing out there, right, it's part of a whole fleet of vessels and there may be other aircraft carriers.

And I think that part of the context was also like coordination with other HHS initiatives is really important both for – particularly on the provider's side because that's where sort of the crunch happens, right, we have this stream of things coming in from certification through ONC, but we also have ICD-10, for example, that wasn't coming through the certification process.

We have annual updates to payment process that requires new reporting requirements. So, all of that context stuff I think barrels in on – certification is the pain point but it's the context that's pushing the pain to that point.

The other thing I wanted to pick up on was my comment during the meeting about we're all early adopters. And one of the ways you mitigate risks, again this is a little bit of a solution piece, one of the ways you mitigate risk is with good sensing. So, what's actually happening.

So, I would say one of the things I heard was there weren't effective feedback loops during the early phases of this that might have signaled, hey, there's something that's really a problem here that's going to take more than just tough it out.

Fix the NIST stability issue, you know, if the server has a problem that could be fixed, right, but, if there is a problem of we've just got too many specs that we're trying to get test suites up for that's a more macro problem. So, that would be my other pieces, sort of the sensing point.

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

Good, thank you. One of my two are – piggybacks off what Larry just said – the expression by the panelists both during and afterwards were how much they liked hearing about all the other things that were going on and I would have to say a lot of this panel here also felt the same way.

So, in some sense it was everybody doing the jobs that they had to do without either looking at how you coordinate the test with each other or the cumulative effect on both the vendors and the providers. So, that was big takeaway for me and it goes all the way from the way the Meaningful Use objectives are set through the way that implementation is audited.

And the other one that I heard by multiple parties was really a call for narrowing – so one way to do it is to make the process better. Another way to do it is to make it more – limit the scope more, make it more focused and that addresses actually the three things that Charlene started out with. So, there was a call, people called out by name interoperability and CQM as a couple to focus on. Mike?

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

Yeah, so this dovetails exactly with that and perhaps is redundant, but certainly the certification focus on making our shared goals, because they are shared goals, easy to achieve and I would say as defined by time, effort, you know, frequency of need to do it, perceived value, etcetera, etcetera, but interoperability that's easy.

The current analogy is the interstate highways which are an easy way to get from one end of the country to the other without stopping except for gas may turn into paid toll roads which then you have to stop at every 100 miles to pay for.

But certainly, EPs and EHs with each other, with public health agencies, with registries and for CQM reporting would probably be the big four, and then the CQM measurement documentation reporting with face value, validity and feasibility to accomplish so certification focus to make that happen and just to add one that is supplemental to Paul's the call for useful usability to help support those goals and have certification support that.

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

Thank you. Let's see, John?

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

John Derr. I agree with everything everyone said. I also would like to point out that a lot of them wanted to get more cooperation by vendors and we're part of it, and workflow. And that it's really a, for patient better care than it is for just checking off boxes.

And on the partnership I'd just like to give you my own experience as I think it's justified. I've been involved with this since 2004 since President Bush did an executive order. When I took over the CIO position at Golden Living, which I don't know if you know, but we have 63,000 patients under our care at any one point in time. I knew that I had to get some type of interoperability and security and privacy.

So, I approached Mark Leavitt at CCHIT in order to do that and I then became a Commissioner and of course we were called long-term care and when I was at AHCA I always looked at the legislation and long-term care always synonymous with skilled living facilities and not home care, hospice care, LTACs, IRFs and assisted living, so, and I knew we had to have interoperability and I was always on Mark to say we have to have interoperability with us.

I formed an eclectic group of one person from each one of those different long-term things and that's where we came up with LTPAC as a name because you couldn't just say we were SNFs anymore. And then I formed a group which was headed up by a president of a vendor and they worked for eight weeks, this eclectic group, on how to do certification for all of the different providers within LTPAC, came up with something like 80 pages of Excel certification and they bought into it and as a result four of the big vendors actually got certification with CCHIT.

But, at the same time HITECH came out and we were not included in HITECH and so that confused everything, and secondly, at the same time MDS 3.0, which is the assessment for nursing homes, was the first major change in 10 years and it came out, as somebody said, the guide wasn't ready and we got it postponed, it was supposed to come out in 2005 and I think it actually came out in 2011 or something like that.

So, all these things they talked about yesterday was a factor and then also we got a whole bunch of more quality measures and that, but that was the team thing and they were all very supportive and if we hadn't had those two distractions I think we would have gotten a lot more types of things and of course most of the vendors now do SNFs, ALFs, home care and hospice, and have interoperability between those so that was my point.

And then I just wanted to – one of the things I worked a lot in quality and every time we talk about quality we're talking about quality that pertains to Meaningful Use and I have a slide in my speeches that has all these different quality programs that somebody mentioned yesterday and I call it piling on. We can't just use quality measurement generically because it just – when we do it, it gets confusing to some people I think that say, gee that must mean all quality measures, no, when we talk about it it's mostly in Meaningful Use.

And then I was at a meeting the day before yesterday at Brookings on assessments and we don't talk much about assessments but this was with six states that all their different agencies within states have no interoperability, no standardization of assessments and they need assessments for going into eligibility and then also longitudinal clinical care. Thanks.

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

Thanks a lot, John. Joe?

Joe Heyman, MD – Whittier IPA

Well, as usual I find myself disagreeing. First of all one thing that was really telling to me was Mark's comment, I forget somebody else made the same similar comment yesterday, as far as the end user is concerned there no difference between certification and Meaningful Use stuff, it's all the same thing.

And I would disagree with Larry that certification is the pain point. The pain point is on the end user. Now, physicians who are in large organizations where somebody else takes care of the problems for them may not recognize this, but for those who are in smaller practices the fact that – and that wasn't directed at you Paul, the fact that – the fact that –

Paul Egerman – Businessman/Software Entrepreneur

He meant Paul Tang.

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For the record.

Paul Egerman – Businessman/Software Entrepreneur

For the record.

Joe Heyman, MD – Whittier IPA

The fact that the certification process is so difficult is a big problem for the end user, especially those of us who are in smaller practices and the reason for that is because we have purchased a certified product which now will no longer be certified and forces us into purchasing another product because the first product cannot afford to go through the next phase of certification. So, I don't want to minimize how important this is.

And the second thing I would say is that I think there is a certain element of denial about the Meaningful Use Program on the part of those of us who are implementing the Meaningful Use Program. We think we know what's best for everybody, but, I would disagree a little bit with Paul's introduction about the ringing endorsement.

The ringing endorsement, I think, was for the program itself there is no question that Meaningful Use Program has gone a long way to causing people to adopt to take care of important technology needs, no question about it.

But, I didn't hear a ringing endorsement for the individual portions of the Meaningful Use Program for some of – as a matter of fact I heard the opposite for some of the measures. And, so I'm not going to say my first two things because other people said them, but I'll take advantage of this opportunity to say that I think it's really important to look at those measures at the very beginning to see how the implementation is going to be before they do the measure.

And any measure that causes somebody to hit a checkbox, any measure, even if it's to indicate that a patient doesn't fit into a category that is something that is interfering with the physician's workflow. So, that would be number one.

Number two is, I really think we should have listened very carefully to the AMA's testimony at the end of the process yesterday. That was really important testimony and it came on the back of a Rand Study which started out about physician satisfaction having nothing to do with information technology and after the first six practices that they started to interview they had to go back and redo the entire study because every one of those six practices talked about physician satisfaction being injured because of the use of information technology.

And lastly, I'll just say what I have said for the last two years and that is I was an early adopter. I had an EMR that I was using very meaningfully all by myself in a practice, all by myself and I was very happy with it until the Meaningful Use Program.

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

Okay. Let's see, Carl you're up?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Thanks, Paul. I had a couple of things. I think first, many of the issues that were discussed yesterday, at least to me, seemed more like symptoms than cause and I think the symptoms that I heard routinely throughout the day, the first of them was that the real impact of implementing and managing these regulations is likely an order of magnitude or more in their impact to both vendors, be they self-developed, traditional software vendors or even cloud-based vendors and software as a service people.

I think it was maybe an order of magnitude or more impactful than ONC understands and continues to put forward in their guidelines and I think dramatically more impactful to implementing customers be they small physician groups, solo practitioners or large health systems and I think that seemed like a bit of a drumbeat yesterday from the woman in, I think it was, I forget where she was, Presbyterian maybe, who felt lost to the CIO that testified as well. So, that's one big thing I think ONC right now at this moment in time is an order of magnitude or more off in understanding the real impact of this.

Two, I think the regulations really lack clarity and create a culture of fear in auditors taking back MU dollars or assessing penalties, I think we heard that culture of fear comment from several people and the uncertainty as to how to interpret these regulations and I think that's again a symptom we can come back to.

I think that the third symptom was the quality of the tools that are being put forward as saving people time which turn out to be just absolutely time sinks for folks trying to deal with getting things tested and the test data and the lack of quality in pretty much all things related to the testing tool sets.

I think the quality measures and Meaningful Use goals and the certification goals all seem to be running in three different silos and are not nearly as coordinated as people at the top levels of government presume that they are. And I think you heard yesterday throughout the testimony where these threads of these don't add up, they're not making sense in combination.

The next theme I heard was a constant theme of how do you actually measure if you need positive confirmation that a requirement was met, what creativity, what assumption and presumption can one build into the measurement as we populate numerators and denominators, how much latitude does a software developer have to assume that a physician reviewed the problem list simply because the audit log shows it was on the screen at some moment in time in front of them when they were logged on. How aggressive can we be in making assumptions as to what was complied with versus how deliberate does one have to be and force the press of a button or the check of the box, or some confirmation.

I think another thing that as we move beyond sort of symptoms –

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

So, Carl?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Yes?

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

Just to be fair I have to stop you at six, because –

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Okay.

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

We just had the top two.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

But, to the point of the cause I think I'll summarize it as I think our scope is larger than we understand. I don't think ONC has a real learning feedback loop. I don't see the feedback from the first three years really being fed back through something that creates a better outcome. It seems like it's getting worse not better and I tend to agree with the folks if this is the best we can execute then we should seriously look at narrowing scope rather than maintaining the current large scope or God forbid expanding it in this execution environment and I'll stop there.

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

All right, thank you, anybody else on the phone?

Wes Rishel – Independent Consultant

Wes Rishel.

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

George and Wes, go ahead?

Wes Rishel – Independent Consultant

This is Wes I only was able to hear part of the session yesterday, but I think that certification taken in the part of the entire loop where the certified versions have to be implemented and the time period it takes to rollout an implementation across the country or across a large, even across a large health system, we heard that we're trying to turn over the loop too frequently to meet all of the – to do a good job of certification requirements, to get them right the first time, to allow the vendors to react to what they learn implementing the initial requirement and then passing the certification test and then to roll it out.

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

Thank you. George?

George Hripcsak, MD, MS, FACMI – Department of Biomedical Informatics – Columbia University NYC

Hi, I guess a lot has been said so two things, yes they definitely said "too much and too fast." You know I wish I had – we had someone from a different field to come in and say how it goes elsewhere besides EHRs. I wish I had a context because it's hard to judge okay is this just what happens or are we off by, you know, 3 orders of magnitude in what we're trying to do? So, I wish I had that context.

The good news I heard is that Lorenzie's comments were basically saying that we can do a lot to make this better that wouldn't be that difficult to carry out. I mean, they want more help. So, that's a practical suggestion that could actually be implemented by ONC and CMS. Those were my two observations.

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

Great, thank you, anybody else on the phone, yeah?

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

Nancy Orvis as well.

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

Okay. Nancy?

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

Is she on mute?

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

Nancy, are you on mute? Okay, well if she comes back to use we'll include her. So, I'm trying to do an on the fly lumping and let me see if I get – fortunately, I mean there's a lot of similarity obviously.

So it starts out – I think Charlene had a good starter which is really, people are just overwhelmed by the amount and that there are multiple components. One is the scope of the program just Meaningful Use and I'll come back to the context.

Two is the compressed timeline now you understand that was given to us by congress, there is some interpretation there, but there is certainly no interpretation about the incentive part of the payment which of course drives a lot of the subsequent objectives and certification and the resources required to meet all of those and that's from everybody whether it's the vendors to develop the product, the users to implement them or the folks who designed the testing scripts, etcetera.

And then Larry's point about the surrounding context which was great and then Joe's point about it doesn't really matter who gave the context it's the context for everybody and that's pretty overwhelming. So, that's a big observation from yesterday.

The other comment it's a little bit like root cause, which is too many things were premature whether it's the standards or the potentially lack of clarity in the criteria, the testing or even the testing programs. And there is a perceived lack of a feedback mechanism.

So, clearly when you start something new, Larry referred to the early adopters, things aren't going to be right out of the gate, but the way you work at that and then become great is to have a nice and robust feedback loop that is both timely and has good input to the people who are designing each of the various components. So, that's something we could have benefited from.

Then, the talk about the lack of coordination and integration in the various components of the whole process and that's not just a criteria or the testing its really everything, as we said before, from the design of the Meaningful Use objectives, to be testable, all the way through the testing, the implementation and the audit and the backend. So, that kind of coordination would have been helpful.

And then going back to focus which can address a lot of, you know, scope, timeframe, resource and some of the things that came up were interoperability, usability and quality of products and the CQM. So, did I capture in categories the things that I heard? Joe?

Joe Heyman, MD – Whittier IPA

Yes you did, but I just wanted to –

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

The disagreement officer.

Joe Heyman, MD – Whittier IPA

But I just wanted to say that one of the things we heard yesterday about the feedback loop which I think was really important was that the NPRM process is not a good feedback loop for this kind of process. So, I mean –

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

So, it's clearly by design not timely enough to affect change quickly. So, that is a consequence of this being a part of a regulatory process.

Joe Heyman, MD – Whittier IPA

Right.

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

Yeah, thanks. Don?

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

I thought it was sort of an interesting sidebar takeaway that may be very, very important is crowding out of innovation. I mean, John Halamka's comment that he had not been able – you know, one of the most creative people on the planet, certainly in this space, hadn't been able to do a single innovative thing because of meeting I guess various things he had to meet with Meaningful Use I thought was – and we heard that from a lot of people but that was sort of maybe the most stunning point examples.

I think one of the metrics should be, you know, percentage of work effort in the vendor self-developers space, I don't know how you measure that, but, there has to be space. I think from a mechanical point-of-view for ONC there is this whole world of people doing Apps who – I mean, I sort of see they may just make all of classic HIT obsolete because you have one heavily unregulated space and then you have a heavily regulated space, you know, vast innovation, no innovation.

I mean, it's sort of we're setting up the innovator's dilemma I think unintentionally and so, I mean, it's sort of a philosophic issue, but at what point do people just say screw the 2% or the penalty and I'm going to use all of this flyweight stuff, I mean, it's right out of the Clayton Christensen and I heard that riff in the testimony. I mean, it's an interesting way of looking at it, but I think it, from ONC's point-of-view is a political issue, because those people have lots of, you know, visibility in the greater world.

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

Yeah, that's a fair point.

Paul Egerman – Businessman/Software Entrepreneur

Good comment. I suspect that the reason that there is less innovation is it's crowded out, you know, people are so busy doing these other things and so it still goes back to the scope of what is in the certification program that it just, you know, BIDMC and a lot of vendors are just running as fast as they can to keep up and that doesn't give them time to do anything else.

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

That's what Clay Christiansen says though, I would argue no, right, what Clay says is – which is what I think Don was starting to get to is in the context of legacy products selling to legacy customers, innovators will always come and bite at their ankles because that's what they can do, right, and it's not our job to protect the legacy vendors is it?

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

No –

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

Nor is it our job to –

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

No, I think you're right, Jacob, but all I'm saying is we've created an very artificial divide that exacerbates that, right, that's the point I'm trying to make is that where normally there's sort of a blend of stuff we have sort of created two absolutely separate camps, the compliance with certification camp and the, aren't complying with it, can't comply with it camp and that divide I think over time generates a lot of tension. That's what I was trying to get at, but, yeah.

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

I think –

Paul Egerman – Businessman/Software Entrepreneur

I have to say I view that a little bit differently. I mean, I resist it whenever anybody says – talks about somebody that they call a legacy vendor. This sort of implies that this vendor is sort of like an artifact that an archaeologist will find or has found, but there's another word for those vendors that you call legacy vendors and that word is operational.

Those are vendors who have operational EHR systems and there's a lot to be said for an operational EHR system. And the issue really should be viewed as how is ONC impacting what I would call the entire vendor landscape? Because it's not like there are two parts to the landscape. It's not like there is the old, tired vendors with old, tired technology and some new young people who are really going to take over the world with Apps that's not how it works.

There is a whole range of vendors with a whole range of applications and the certification process is impacting it and it's impacting it by making it much harder for smaller vendors and for startup companies to get into this space and so it's impacting it and when you look at organizations like what Marc Probst said and what John Halamka said those self-developed organizations have been the sources of a lot of innovation.

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

Okay, so the innovation topic is certainly one of the important things we want to consider. Let's make sure we stay on-topic with the certification process.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

I'd like to add to that though Paul if I could?

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

So, Carl, I've got some cards up in front, but –

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Oh, okay.

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

We'll keep track of you – there is a hand raising thing so everybody on the phone please do that and Michelle is really good about letting us know.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Okay.

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

So, Mike had his card up?

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

Yeah, so just a quick comment about maybe the root source of certification has to do with trying to ensure products that work and also, at some emotional level, a lack of trust in either the character or the competency of those who create products or those who might use those products in a way that is appropriate for Meaningful Use.

So, I think the one part I would add to the lack of coordination and integration is the clear call that I heard for collaborative coordination from various stakeholders as if everybody clearly trust each other and cannot move forward without the input of everyone else in order to get this right we would therefore never have to deal with the tension between certification and innovation if everyone in the room both valued that and knew that the only way to move forward to many of the points that have been made, including the ones I really resonate with Joe's, will get done.

So, I would just say that one of the recurring themes in lumping of issues needs to be around the issue of coordinated development that is highly collaborative between all the stakeholders.

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

Carl?

Carl D. Dvorak – Chief Operating Officer – Epic Systems

I was going to comment on the innovation thing. I think it's deeper than we understand right now and as one of the people who wears the chains and drags the cinderblocks of certification through life I watch ONC stand on the stage with West Venture Capital Funds people and to shuttle money to the smart medical record people in Boston and I do get a sense of disparity. I feel like some of us drag the cinderblocks by rule and others benefit from funding and contests, and participation with venture capitalists through ONCs work that it seems like there is a disparity and maybe it's a sense of guilt from ONC that they realize they're impacting innovation so they'll try to foster it in different areas, but I would certainly like to have that playing field leveled, it is a cinderblock and we're dragging it.

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

It's as if you were here, Carl. We can see you right here.

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

Carl, my dad's a psychiatrist, thank you for the assistance in diagnosing our condition of guilt and remorse.

Carl D. Dvorak – Chief Operating Officer – Epic Systems

Okay.

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

This is John, I'll say at the risk of piling on, I don't mean too, but I do want to call back part of the trough of that's made by the cinderblock is on the adoption side as well and this is echoing what Dr. Banas said, I think part of it needs to be judged – you know where Carl went, I almost was going to phrase, conspicuous highlight of anecdotal example of success for adopting innovation is not the rule of the day.

I think it takes measure where Dr. Banas was speaking of that as a practical matter the bandwidth of our client base also to adopt is part of that cycle and, you know, never mind that we might come up with innovative things, and I think I could speak for both Epic and Cerner, we are. I think there is part of the wane in the measure of how successful are our clients getting there to adopt it, they've got a rate limit that's probably even worse than ours in terms of taking new updates that are not related to the critical things that they're doing and that really was the highlight yesterday for me that part of the certification cycle was not just the vendor certification, it, again, is the adopted cycle and what that competes with.

And, you know, no one in this room had any tealeaf that would that would have predicted what congress did on ICD-10 but they just deferred our funds, so guess what, we all get to have the tea – the Army has been deployed, Putin has put them on the Ukrainian border, and they are going to remain there another year. We don't have another team to go put into place just because we were told that one maybe doesn't have to worry about doing end-to-end testing for another year. So, I think –

M

– foreign policy.

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

There you go, foreign policy, exactly, my brother-in-law is in the State Department I had dinner with him last night so maybe that's on my mind, but –

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

But that was an interesting –

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

Yeah, but, there is that effect, the deployed Army, you know, mobilization means war and when you tell that team to stand down we can't take them off the field. So, keep in mind the adoptive cycle and the impact there.

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

Good comments, I have Larry and then someone on the –

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

Nancy Orvis.

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

Then Nancy and then Charlene.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, maybe in some ways I will trigger a sensor to the earlier discussion about Stark exceptions and therefore we need a certification program. So, we have a legislative requirement that says we need certification and I believe the reason we have that requirement is the government spent billions of dollars and they want to know that the technology they were buying met some baseline.

And they didn't go into – a few things got into legislation about what that means, but a lot of things didn't and I think we should consider that we have that as a legislative requirement and that we don't necessarily overburden it and that some of the focus comments we had perhaps help address that as well, that's plenty.

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

Okay. Nancy you can either make a comment or we gave people a chance to state their top two takeaways from yesterday.

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

I wanted to talk about my top two takeaways too, because I heard – well, what I heard some of the pain of the providers and the vendors, and some of the – but I did hear a little bit of a disconnect too that other people talked about, between what was asked for in the Meaningful Use criteria and what got tested and the example that sticks in my mind is the six page patient education thing that came out with only a paragraph of patient education.

And, you know, from a provider' perspective, and I've worked in all of these, it's, wow, how many reams of paper do I have to pull out to keep – you know, I'm going to have these other expenses now because it just doesn't quite work the way it ought to and it impacts other parts of their budget. But, and I think there are very good comments about what we could do to make those work better.

I was heavily involved in certification testing for my providers on the first round and thought that it did a pretty good job and I think it was the confidence level for it. Even though we're in this – I mean, I think we're still five years into a long haul from CCHIT and what HITSP said and the last act we still have a long-term goal and I think we can't lose the fact that for a patient or an individual patient, or all of our patients, the quality of care they're going to get 20 years from now as they get older is heavily dependent on what is also happening – what is their history and can the doctors and physicians find out what is actually unique about that patient and they don't put them in the wrong bucket because they assume that they're like everybody else.

So, I think this is difficult thing we're doing, but, I think the payoff is tremendous. So, I'm going to stop at that but I said I'm encouraged that we're having these hearings. I think we will get a better way of doing certification out of this and I definitely learned a lot from all of the perspectives just to get to this point. Thanks.

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

Good, thank you, Nancy. Charlene?

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

I just wanted to add one more comment, this is relative to the feedback loop, in the documentation, in the testimony I think you saw the RAFT of letters that came from EHRA identifying issues with the problem and we were very aggressive, as a vendor community, to try and work with ONC and the other testing parties to try and get this to work, that was the focus, let's get this to work.

But, the other theme that I heard come out yesterday is not only is there a lack of – it wasn't that the feedback wasn't given, but the response was really challenging because of timeframe lots of reasons not because people didn't try.

But the other piece that came through as I listened to it is there is a lack of governance about the process. So, when you listen to, for instance, the testing bodies they all were kind of doing things differently and again, there's just fragmentation around all these different processes which add complexity and there are different interpretations.

So, again, I think you still come back to more of a root cause of scope and then multiple different streams and immaturity, you know, but the bottom line is it felt like, you know, yes there needs to be collaboration but there needs to be more than collaboration. There has got to be some governance over this to try and make some trade-offs in terms of how to guide this program forward and that has to be a collaborative process but it needs that component.

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

Good. Don?

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

Yeah, I thought part of the message I also heard was and part of the message for I think ONC to be empowered is in your discussions with CMS and the rest of Medicare because I think there's a lot of coordination issues on quality measures and whether, you know, if the Meaningful Use certification quality measures don't actually match up to the other quality measures.

And I think there's a broader thing, which again, to Joe's comment that providers lump in together which is the absolute chart bloat from these level 4 and 5 visit codes that make every one of these charts an unreadable nightmare for anybody who is taking care of sick patients.

So, I think I would see ONC as empowered from this information to sort of go back to CMS and the, you know, sort of with an HHS process and say, you know, from our public hearing we heard there are a lot of issues that really need to be solved on a sort of counterparty basis. So, I think that's part of this certification and adoption thing.

And I would say ONC should be empowered from what we heard yesterday to press harder on doing that. I'm sure the challenges are vast I can just imagine, but I think this is a data point that you guys should leverage in those discussions with CMS.

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

I think that's part of the importance of this hearing and giving the recommendations they can use as a data point. Lee, I'm sorry, I didn't see you?

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

Oh, no problem.

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

Lee is the acting director of this program.

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

Well and actually I really – I think Larry got to the original point before me, but in thinking about, you know, how we operate and how congress is viewing what we're doing going back to what John was mentioning about when ONC was created, it's a hugely bipartisan effort to get Health IT going across the country.

And, I think we've paid out now about \$22 billion in incentives and I'm sure the number is higher than that, but we don't have interoperability. And what's made this so bipartisan is there have been great promises over the years about the savings on the other side.

I am very concerned and there's great room for improvement here. But, I'm very concerned about innovation coming at the expense of interoperability. Because if we don't get interoperability in these systems and data flowing in a way that can actually save money congress is going to have fatigue with this topic and they're going to walk away from it. And I worked on the Hill for about five years and it worries me that we could be stepping on those first doorsteps of fatigue and disinterest in this topic.

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

Thanks, Lee. Uh-oh, Joe?

Joe Heyman, MD – Whittier IPA

So, at the last hearing I was accused of ranting about interoperability at the very end of the meeting, you will remember, and that's because I am the CMIO of a health information exchange which is very innovative and actually is very robust. As a matter fact I showed it to John yesterday. So, one of the most popular vendors, their cloud-based system, we have 16 practices on their cloud-based system, the charge to us for connecting to their cloud-based system for this group of 16 doctors is over \$50,000.00 to create the interface and then on top of that is \$75.00 a month to maintain the interface for each of those doctors. So it's \$75.00 per doctor.

This is not affordable even if it – and by the way it isn't an HL7 interface it's just exchanging C-CDAs. So, I just have to say that even if you create the interoperability if it's going to be that expensive to make a connection this is never going to work and this is one of the most popular vendors for small practices. So, I just want to get that on the table.

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

All right. Okay, let's – I think we're chomping at the bit to talk more about recommendations. Jacob yesterday talked about the carrier the aircraft carrier and you can't turn the thing very quickly. So, there actually does – nicely fit into two buckets I think. One is the process, it's a big bucket but it's the process and that can be looked at as more short-term.

And the other is the whole overwhelmed and there are multiple components of that and that's probably something that will take more time although we can make recommendations now that sort of help guide this ship in the future.

So, let me try these two huge buckets and they will nicely fit into more short-term and more directional kinds of recommendations. Yes Paul?

Paul Egerman – Businessman/Software Entrepreneur

I'm sorry, I didn't mean to interrupt you, were you pausing?

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

Well, it sounds like – it looks like you have a question that you have to get off your chest Paul Egerman.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, I mean, my issue is it's good to talk process and it's fine to talk about how long it takes to turn an aircraft carrier or something, but we've got to keep in mind where we are right now which is people are struggling to implement Stage 2, there is a 2015 NPRM where the comment period is finished, Stage 3 presumably regulations are being written for.

And so I'm trying to understand, well are we talking about a process that's going to be implemented in 2016 or 17, because it seems like there is a lot of stuff that is happening right now and shouldn't that be part of our discussion. Is there something that we could do immediately?

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

Well, yes, I think there is. So, one process, I think ONC isn't particularly happy with the current process and the way it's going now and would like to make changes quickly or at least propose changes very quickly and it's – this is one of the reasons we had this meeting planned with such short notice is to try to get information to them to feed into what they're thinking about now. So, it's not for 2017.

And the other thing is even if we talk about the broader issues in terms of direction it's not as if that can't have some influence or impact today but it's directed towards changing ship, because either – landing on the carrier or hearing all the people we heard from yesterday it's not as if they can have an abrupt change, they complained about little changes that happen even in the process of, you know, testing and certification. So, we can't change the ship in a major direction and expect there not to be fallouts.

So, that's my only caution is we want to have the input go to ONC and CMS as quickly as possible because it's likely to shape things as early as certification process for this year or what's being written for Meaningful Use Stage 3.

Paul Egerman – Businessman/Software Entrepreneur

And I just think that as part of our discussions I don't know if it's too late to make a recommendation but we ought to be making a recommendation about whether or not we want to pause or do something about Stage 3, if we want to pause or do something about that 2015 NPRM or even if there is something that should be considered about reducing the scope of Stage 2 to make it easier for people to qualify.

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

So, I think those three things are off the scope for today's discussion. So, Stage 2 isn't in this bailiwick for the certification process. Stage 3, as you know, the Policy Committee made a recommendation presumably the rulemaking is going on for an NPRM sometime this year and we will again, as a Policy Committee, react to that as well. So, we're trying to focus here on the certification process. Clearly, that is a pinch point and a pain point.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

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

And we've made comments on the others, yeah.

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

This is Jacob Reider, just to emphasize, where Paul is going, it doesn't invalidate what you're talking about Paul so I want to make sure that point is clear. But our purpose in having this hearing now today and the genesis of it, just to make sure we're all on the same page, is I think it was two Policy Committee meetings ago, Karen DeSalvo said in front of everybody there and the nation, Jacob Reider is going to fix certification and then the next day I got tweeted at by tons of people saying "are you done yet" literally, no kidding.

So, this is part of our internal ONC process looking at the details of the processes and the program itself. So, there is a context of 2015 you're right. There is a context of Stage 3 and what would be the 2017 certification you're right. But if those programs need to invoke a program, and I think Paul said it right, so the program is there to assure the public that the products do something consistently, reliably, etcetera.

And so if there is to be a program, and by the way there is, so I don't think we're calling into question whether there should be a program, what should be the scope of that program in terms of how we test things, how detailed we test them as this program accepts the certification requirements from regulations, so let's just assume that there will always be regulations that define functional criteria and we can argue about that in other contexts about what the scope of those criteria should be.

But given a set of criteria how does the program test products to that set of criteria and how can we take the current program, as it exists today, and evolve that program as quickly and yet as tentatively as we possibly can so that it meets the market need, doesn't put too much of a demand on folks who are trying to create products and yet, you know, as a buyer and for those on the phone I'm sitting next to Joe, Joe wants to know that his system works reliably he does and he wants it to be certified just like I want my car to be certified in the motor oil that I put in my car to be SAE certified there are things that we expect as a buying public and that's the context. I've talked too much.

Paul Egerman – Businessman/Software Entrepreneur

An observation, first these systems are a lot more complicated than your car, I mean, the technology in your car is simple compared to what is in these EHR systems. But if I'm also hearing you correctly all this discussion about limiting scope, possibly doing a pause that's not on the table for us. We're simply going to be talking about testing processes is that what I'm hearing?

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

Let me – so let me – two comments. One, don't – so I'm thinking about the global context of everything, all the program and what the HIT Policy Committee does, don't underestimate what we – the impact of what we say about certification is on the global program. So, I think there are important things to be made.

The other thing you just asked, which is I think that limiting the scope of certification, because it came out so loudly from the panelist, I think is in scope for today's discussion.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

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

And then I –

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

Yeah, I'll –

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

Okay. Mike?

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Yeah, thanks, Mike Lardieri, so, I guess, I didn't have the benefit of being here yesterday and hearing what people are talking about and going forward.

I just want to pick up what Jacob was talking about. If we're looking at products to do something and we want to do them consistently and reliably, in my mind I'm looking what's that one thing that's going to have the most impact that if we do it consistently and reliably it will have impact, and also be able to bring in providers who right now are not Meaningful Use providers, I mean, I'm behavioral health, so for the most part we're not included but we need to be included.

So, in my mind the one thing to do certification and ramp up step-by-step is all around interoperability and I think the issues you're talking about Joe about the pricing I'm not sure why do you need to do more than the C-CDA and maybe the C-CDA just needs to be more robust so you don't have those fees and we should just continue to ramp up in there and let everything else go slower.

And so if we're going to really focus it's really on sending the data around. If we don't send the data around than all of the rest of the stuff really doesn't matter and that's sort of my framework.

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

Okay. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I just want to verify an assumption that I think is correct that the aircraft carrier at this moment is actually in port, that the bulk of certification for Stage 2 has happened now I know that's unknown, right, and if we look at the numbers vendors continue to certify for Stage 1 maybe even as late as the 2014 edition stuff went into effect, right, so not 100% true, but in many ways I think very true.

The aircraft are not on board. They're not taking off and landing. They're at their home base on land somewhere and that this is actually an opportunity to think about retooling because the people that were talking about the issues with the certification process have been certified. And that the numbers in place that are yet to be certified are probably pretty small.

We have test processes that I have to believe have stabilized that we're not constantly changing things because that happened over the last 18 months. Okay, Jacob what –

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

Larry's looking over here so I guess I'll – so it's tricky because we often get advice from the Health IT developers, notice that I call them developers because vendors implies that they just sell things, they develop systems and as a recovering Health IT developer I always felt defensive when we were referred to as vendors.

So, yes the certification program is in a down slope, there are some vendors who continue to upgrade their products and those products pass through the program again and again, and again. We heard a little bit about that yesterday from Alisa and others.

I would – the ACB folks aren't telling us that it's all quiet. It's quieter and I agree with you that most of the products have passed through their first phase. But, I would argue that this doesn't ever return to port if we're going to continue to abuse our metaphor. It's a little bit quieter so this, you know, it would – there would have been a much worse time to do this. How about that?

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

Okay, so I want to manage time too, so Charlene is your card up or is that from before, okay and Mike?

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

So, I'm going to take a provider perspective. So, for me the main thing is to keep the main thing the main thing. So, I'm going to go Stephen Covey on you here for a second.

So, for from the provider perspective they need certification to make sure that in their very focused view they can achieve Meaningful Use that expectation that they, their practice managers have and that vague sense that they have that it really will do what it's supposed to do which is improve quality, safety, efficiency, cost, value, etcetera and help them anticipate and prepare for the healthcare reform the way we get paid in the future that helps us to stay in business and to help bring the necessary value to keep our systems afloat.

In the meantime, they need to make sure that the tool that they are now using to develop and deliver care is safe and effective itself so that they're not harming patients with tools that they intend to use to help make them healthier and safer.

And in the interoperability area I just have to describe the cognitive dissonance of interoperability, okay. So, I've been in emergency departments across the country using the same EMR that I use at my academic institution and ask the emergency physician do you want to connect to my EMR and they would say "no it's too much work" or there's the risk of, whether it's note bloat or other approaches, to be able to say, how do we get information that matters from the sea of information that doesn't matter and if we're going to focus on useful usability with interoperability it's the notion of finding what matters and how we do that.

So, I think we just want to be really careful to keep the main thing the main thing, ask ourselves a question if it doesn't really move the needle on those things do we really need it in certification to achieve our goals?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

But I think Mike those are really issues around intent of the bigger program. They're not a midstream change that would be of value.

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

Well, I would just say that it's really a good time to take a look at each one of those certification processes we've talked about, I won't enumerate them all, but just ask the question does this number one help a person meet Meaningful Use, number two, does it add to quality, safety, value, etcetera, etcetera and does it achieve not just the myth of what interoperability can offer but what the actual value of interoperability will be by people who choose to use it not simply receive a document that they then ignore.

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

Okay, so one thing – so my charge is to make sure we get an output, a usable output by the end of – by 12:00 o'clock and I would encourage us to not take advantage of this wonderful opportunity after hearing from a lot of folks yesterday to formulate a response and recommendations to ONC.

They've asked for it, they want it quickly. And I think we both owe it to them and it's in our best interest to make sure that we get those formulated above all. So, we're not going to talk about the policy of the program itself or Stage 2 but we have a lot of input to provide on certification. Don, you wanted to say something?

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

Yeah, one suggestion that I heard in bits and pieces yesterday was maybe for the certification to have that sort of – it required an optional component that would allow a lot of the structure that's already there to sort of be used as is without, you know, rewriting the world, rewriting every test script.

And whether it's I think the AMA comment yesterday or the comments, multiple comments about let's just focus on data liquidity and most of the data that's easy to get not like the cousin's family history and the, you know, transmittal quality measures and so maybe those are the mandatory and all the rest of it becomes optional then you can sort of work out in the special situations how those things actually could work in real life.

So, that might be an interesting way to leverage the work that's been done in a maximal way and yet sort of keep the political goodwill of the system. I think it worked out pretty well in Stage 1 to have optionality and I think it may be the simplest trick.

As I was listening to the aircraft carrier things I was a little concerned because as I was understanding it it's very hard for aircraft to take on and off at the same time and I think the Japanese aircraft carriers in the battle of midway actually all got sunk because that didn't actually work out for them. So, I think we want to be guarded in our aircraft carrier analogies and make sure that we don't get sunk so we may want to have scope that is limited.

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

Okay, so the limitation of scope right now is going to be the certification process. Let's, if it's okay with people I'd like to go into these two big buckets and drill down for recommendations and then we'll try to summarize them at the end. Remember our goal is to get this to ONC quickly. So, the first one, and –

Joe Heyman, MD – Whittier IPA

I have a question Paul?

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

Yes, please Joe?

Joe Heyman, MD – Whittier IPA

So, one of the things we heard yesterday, and I didn't bring it up because everybody else did, was the most important thing are the quality measures and the interoperability that was clearly a theme. But the fact of the matter is we can't narrow ourselves to just those two things. Is that correct?

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

No, so the two big buckets are one the coordinated integrated certification process, it is more short-term in a sense of it can give some advice that could have a more short-term impact. And the other was this being overwhelmed in the way that Charlene described it and that's where I would put both yours and Mike's comments.

Joe Heyman, MD – Whittier IPA

But, isn't it true though that for example the requirements to give a certain number of patient education things to a patient that still has to be certified even if we're going to narrow our focus on those two other things. Is that not right?

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

I think we can discuss that.

Joe Heyman, MD – Whittier IPA

Okay.

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

I think we can discuss it. So, I hear that and I heard that.

Joe Heyman, MD – Whittier IPA

Okay, all right.

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

So, let me – I'm just postponing just logistically, to try to get our short-term out first and then the longer-term, but it will happen.

So, the first one was the whole process and this had everything to do with the too many things are premature, the lack of coordination, the things not tested sufficiently, standards not – all of that stuff having to do from the process up to and including the, did we consider the process of certification when we actually recommended the Meaningful Use objective in the first place. So, all that's fair game and you heard one of the – a couple people propose this Kaizen, which is one of the ways you deal with this kind of the current state and the future state. But, so let me open that up for suggestions for recommendations on the process itself spoken broadly.

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

Don Rucker, I would just put in as maybe a compliment to the NPRM process that there be software that receives and sends the protocols that is part of that so that people can look not just at words but at code, because what we're certifying here electronically in the certification process is electronic interoperability and, you know, software and I think, that will, I think flush out many, many things and I think it would actually do it in a pretty fast time efficient so it would allow the rest of the process to move relatively expeditiously. Because I think it would tighten up the entire set of things that fall afterwards.

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

So, it's the software that –

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

Just a set of code that runs, that sends out the messages that are expected to be sent out, another set of code that receives the messages that are supposed to be received and what that will do is sort of force some clarity on what the data fields are and what the thing that is being asked for is.

It should be very simple on some level and if it's not then we catch all of these issues right at the root rather than propagating them through every vendor and every hospital and every practice which is what we're doing now.

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

And is this in the test environment? Is this in the test environment?

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

It's like almost – its pre the test-test environment but I could certainly see it as being used –

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

A reference implementation?

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

You could call it a reference implementation, sure, yeah.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Okay, go ahead Wes?

Wes Rishel – Independent Consultant

Yeah, I'm sorry I'm having technical difficulty raising my hand with the little guy here. I think that I have to weigh in on interoperability and that I can't emphasize too strongly the importance of having a level of precertification support that goes well above the testing that occurs during certification.

There is every reason to believe that the time spent in certification testing is bounded by budgetary issues. We can only afford to spend so much time in a certification test unless the charges to the vendors for the time of the testers get to be too much and we regularly face the strong possibility that two certified interoperable products will not actually interoperate. In fact we've seen that time and again.

I think we need to disabuse ourselves of the notion that certification testing will ever guarantee interoperability and look at other channels for achieving that.

I think because the Meaningful Use regulations now make it incumbent upon the customers of the vendors to actually interoperate the vendors are more willing, and let me say the developers out of courtesy to Jacob, are more willing to devote a portion of their budget to making things work with other vendors but somewhere, somehow that gap needs to be filled but we cannot expect it to be filled purely through certification.

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

Thank you. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess I'll pick up on the tail end of what you were saying Paul about Kaizen, that whether we do it – well, I think we should do it formally. I heard an almost uniform message in various flavors from the different panelists of the need to have active collaboration and that this kind of active interaction is likely to be more effective than writing letters and responding to NPRMs and that we should actually have the – get people together and have the discussions and it's probably not a one shot event and ONC has some experience with this around quality measure development that sounds like it's had some very good results, extend that process here.

And whether it turns up immediate things that could be done, tuning things that could be done to make the current process better for those who are still certifying to 2014 which to my oversimplified statement, I agree with Jacob we're not done.

And I think that we were hearing from vendors that if it were easy to put through stuff for certification, easy and not too expensive that they would be making additional enhancements to their products that today they're considering not making because the process is too onerous. So, small things could come out of that.

And I think it becomes a base for bigger changes in the future and it's also actionable. It lets people actually engage and addresses some of the concerns we've been hearing of I don't feel engaged, I don't feel like I'm being heard, I don't see the dialogue leading to something.

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

And what stakeholders would you bring together in the Kaizen?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I think there are sort of two tiers of stakeholders. So, there are the folks who are very close to the process, so there are the testing bodies and the certification bodies that I would have in there. There are the developers whose stuff is getting tested and there are the providers who are receiving this stuff and going, the actual test is whether I can use it and let's see how that pipeline is actually working.

And then I'd say that there is sort of the next scope out. There are the people who in the specifics of ONC and certification are creating the Meaningful Use Regs, so I'd extend to the people in HHS that are doing that.

I'd extend – we've talked about the surveillance piece so some of the how do we do surveillance and how does that work and so there is a part of that and clearly ONC should be involved as both the manager of the process and as part of creating the certification criteria, NIST as a creator of test tools.

I think it might be useful to comment about other things, other people who have had stuff certified. We had some comments from the certification bodies who do other testing everything from some things are on five year cycles and some things are on very short cycles it depends on the thing what the right cycle should be. So, it might be helpful to have a little outside opinion on that. Who haven't I talked about?

So, you know, to Joe's point, it might be nice to get people who are not so immersed in all of the details that can act as the sort of the sanity check of what are you actually going to deliver to me? I'm the guy who is using this, you know, whether it's at my peak performance time or my, I work too many hours today time and what did you just deliver to me? How am I supposed to use this? Maybe some of the people who do training as well.

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

Good. Don?

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

Don Rucker, one area we haven't talked about in this but I think is actually still part of it is the guidance that this whole process extends into the audit space, because, you know, so far Meaningful Use has all been sort of wine and roses in the sense, you know, we've given out \$22 billion but I think the thing that clinicians are now sort of donning and sort of – you know that sort of can I put it off until tomorrow kind of survival mode is, oh, my goodness now there are all of these audits coming and I took this money and now I'm going to be audited on stuff and I don't understand it. I mean, I know the endless listserv which Mike is a very strong participant in had all of this stuff on numerator denominator and what the meaning of 50% is and 51%.

And I think part of the Certification and Adoption Workgroup can be to provide clarity to the auditors on what that audit process would be and what sort of fair game, and what's not there because I think sort of what's gone before, in terms of challenges, is going to be amplified when, you know, the news comes out of audits.

I mean, because all of a sudden then it's just a very different political world in the practice space when people are worried about audits and, you know, I think, I mean, we saw what sort of happened to RAC in the, you know, SGR fix law. So, this stuff all has political consequences. I don't know how to phrase that but, you know, the tail end of –

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

Yes.

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

You know the very downstream of certification and adoption is auditing.

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

Is audit, right.

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

And we've never really talked about that, I don't believe, in any of our discussions.

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

I think that should be one of the folks involved in the Kaizen, yeah. Any other add-ons to – so the main recommendation here and was voiced by some of the panelists is a Kaizen to get everybody around in the same place so to document the current players and processes so that we can – in the current state, so we can look towards a future state and that's the entire certification supply chain from the objective setting through the audits really and everybody in between. Charlene?

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

Two points, and Jacob knows this well. Again, another component where there is going to be ongoing certification is around the CQMs, eCQMs because there are going to be versions coming out. So, it's going to be important that CMS is engaged in this process because that's where, as you know, there can be ongoing improvement of the tools, etcetera, etcetera. So, it is certainly an ongoing process.

The other message that we heard yesterday is the need for a roadmap so some predictability in the process. So, this would probably fall out of a Kaizen event but you could see, just like vendors have some regular update cadence, that if there is improvements I think there is a need for a robust feedback loop, an actionable feedback loop and a mechanism to get that plan so there is some transparency in what will be addressed or not, because, you know, as we heard from the private sector panel there are lots of great operational experience of getting this to work and starting to figure out what's working out there and what's not and there are going to be some revisions that come to that process some may be regulatory, some maybe not, but those are the kinds of things that need to be sorted out and managed.

So, that whole management infrastructure, governance infrastructure that leads to some predictability of, okay we're going to be putting out, you know, semi-annual technical improvement, technical correction documents or something like that, but some mechanism that gets that into place.

Now I expect that would be an output coming from the Kaizen but I think the need for predictability in the process and roadmap needs to be one of the goals.

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

Yeah, excellent, excellent. Mike?

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

Yeah and just to dovetail on that as well I think one of the key parts for me again with the end in mind approach but that notion of making sure there is a very clear definition early on of what does coordination means, what does integration mean, what does participatory decision making around this mean and how do we have a vehicle social networking or whatever the vehicle is to make sure that people are staying connected to the process that the questions that come out of this have answers and that people can at least see them and point to them whether they agree with them or not they understand how it was made and that everyone had a voice.

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

Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I continue to mull over your question Paul about who should come to the Kaizen. So, I think some other customers that are part of that ecosystem the HIEs, the HISPs now and public health as key recipients and participants in the information exchange that we want to facilitate.

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

Great. Okay, Mike?

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Just one thing with what Mike was saying about everybody participating. I think – I see a lot of listservs and things in social media there is no definitive answer. I mean, I get 10 different answers and I watched the HL7 stuff about the C-CDA go back and forth. I don't understand a lot of it. But it goes back and forth and these are all experts in it and they all differ.

So I think in the end in that social media thing there's got to be somebody or some entity that says, all right after all this we're going to do this and this is what everybody needs to then follow otherwise it just remain chaos.

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

Good, thanks. John?

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

This is John Derr. Did you include the non-incentivized people and the stakeholders and a group like behavioral and long-term post-acute care?

Just to carry a little bit onto the carrier part, because I was on one and I was in the destroyers and ships for 13 years in the active Navy and the inactive Navy and retired after 31 years. It takes a carrier at 5 degrees rudder about 10 miles of transfer to change course. But they can change course immediately if there is a threat and threats are – but they don't land planes at the same time because the carrier is on a big tilt and in today's carriers you can land and take off, especially helicopters and other types of things and then most of my life was on destroyers although I rode the enterprise for a week.

And we're the little vendors, because I was a vendor before I was a CIO. The little destroyers just sort of sit on the sideline and the main thing that holds this whole thing together is what we used to call NTDS system which we communicated digitally, this in 1960, '61, '63 we have to communicate between all – and then when we had a meeting the admirals didn't just tell us what to do. We all bought into this solution of how to, but prioritizing our threat we had – you know, aircraft out, called CAPS, is when some threat came in we prioritized that threat and we all worked together and communicated and that's what made the destroyer, the taskforce is what we called them and that's why the term taskforce in business came about and that.

And so I really like the CCHIT way of doing things. I thought that was a great model because everyone at the end of the day all bought into all of this certification and the testing, and all of the things that we talked about.

So, please include behavioral health and long-term post-acute care in this stakeholder's thing because interoperability between us is, because 40 and 60% of the people are transferred to nursing homes and home care and in Stage 2 tells the hospitals, as Larry and I know, we're being asked all the time now how are you transferring your care, ToC and that and how do you use project direct and that, so anyway that's my pitch

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

That's very helpful. Okay. Steve you get the last one?

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

I didn't expect to be immediately called on that. So, since everyone has been talking about having a party at our house, I do want to just make sure that we have reasonable expectations for how that would be logistically organized and when it would be appropriate for that type of party to occur.

There are other things that are in process right now that would need to be taken into consideration that could impact the scope and discussion of the party and what would need to be considered and parts of the gears that are all interconnected and when they would be able to be discussed.

So, I just wanted to make sure that, you know, there's not a – we're not going to have a party – there's not going to be an Evite next weekend for, you know, a Kaizen as you discussed and, you know, obviously this is something that the Workgroup can provide the Policy Committee needs to bring up at its next meeting and to be recommended to us then we would need to, you know, chew on it as a recommendation.

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

So, I guess I hear the signals, I'm trying to interpret and find out how to best – so you're – let's see here – if we go through – if we were – what we would be in the process of doing is recommending Kaizen with the following attributes and are you saying that would not be helpful or could you decompose what we're saying in our recommendation to be useful even if you can't have a Kaizen or are you saying really Kaizen would be off the table?

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

No, no, no I'm not saying that at all and I'm not trying to dissuade the – you know, if the group wants to recommend this –

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

As activity I think it's more along the lines that we need to look at it in the macro sense of all the things that are ongoing the coordination that is actually occurring with CMS on some of these issues already –

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

And where we could best fit this in at a point where it's going to be most impactful –

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

Yeah.

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

For us as part of the overall policy making process that we're already engaged in for many of the activities that got brought up.

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

Okay, that's fair.

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

And really since the Kaizen event party really never ends in terms of the PDCA process that has to be ongoing we need to figure out a way to keep the party going when people are at home which I am all about.

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

And, yeah, so there could be multiple phases of this and so the first thing that gets taken on could be, you know, smaller scope and specific to some of the immediate certification needs that we have as opposed to a broader exposition or exploration of the entire, you know, Meaningful Use Program product that has existed for the past four years and all the policy decisions that some of you have been part of that have been criticized today and in the past, you know, relative to the work that needs to go forward.

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

Okay. Jacob?

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

I'll just echo, Jacob Reider, I'll echo what Mike said. So, Kaizen for those who haven't participated in one is a snapshot it's one piece of a larger PDCA, Plan, Do, Check, Adjust, and that's just one, you know, kind of process improvement. I was going to say event, but it's really a process, right?

So, we don't want an event and I think I'm hearing the folks say Kaizen and I'm reading into it just like my patients say, I want Zithromax, well maybe you want Zithromax or maybe want to get better, right?

So, let's focus on what you all are asking for when you are saying we want a Kaizen and I think what you're asking for is a process by which we plan, do, check and adjust and one of the parts of that is to make sure that there is community engagement so that we look at the whole value stream together and together means representatives from different parts of the value stream those like Joe at the end and those like Carl at the beginning, and people like Steve at the regulatory beginning to say, okay, how does this thing flow-through, where is our waste, where can we find efficiencies.

Is that – I think that would be a very powerful statement to us that this would be what this group would be looking for.

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

I would push back a little in the sense of I don't know that we're asking just or at least the way I'm interpreting this, is not just for a PDCA kind of process. I think one of the values of the Kaizen, one you mentioned was getting all the players in the same room to even inform each other which was part of the benefit of yesterday, but the other is to get the data on the table, on the maps that say, right in front of you, what is actually going on and did we really mean for that to happen, because they arise by various and different programs, and tasks, orders, etcetera.

And that's probably one of the biggest learnings I get from Kaizen are those two things, one, really knowing what's going on and then having all the players see each other and that generally leads to cooperation. And that's actually a third output is cooperation about, oh, now I understand let me try to fix that for you because I didn't understand. So, it's a little bit more than around the edges. So, that's at least what I carried with that word. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I think it's relevant and we heard yesterday about different development cycles and we heard references to waterfall and I think regulatory process is inherently waterfall and that's not going to go away and the Kaizen and other agile scrum type things are meant to work within that framework as well as work on their own frameworks.

So, I think that there is, in my mind, sort of a dual message here of get together, find some things that can be done quickly, build the multi-participant trust and understanding, walk in someone else's shoes, do all those things that come from doing the Kaizen stuff together and hopefully see some short-term adjustments that can be made very small things that aren't going to have too many consequences, unintended consequences because they're small and we can test them and we can go "oh, that did have an unintended consequence, what do we want to do about it" outside of a waterfall regulatory multi-year cycle.

And so it's as much attitude and bringing the community together activity as it is a specific deliverable. And I expect that it will influence future waterfall process regulatory things. And so, to Steve's concern, Steve Posnack's concern of we're in the middle of several waterfalls right now.

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

Under the waterfall right now.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Under the waterfall, we're under several waterfalls right now that I think that maybe even a lightweight piece to start because there should be like a planning what we need to do to get this ready so it could be a lightweight thing that we begin to engage people, it might be a useful beginning that would then schedule a bigger thing. And we'd figure how do we actually make this useful long-term as well as a one-shot, it ought to deliver some real value by itself.

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

So, I think we need to come up with our recommendations and the rationale and it's up to Jacob and Steve to decide how to decompose it and how to fit it into their current priorities, etcetera. But we want to be true to what we heard and sort of as part of our recommendations. So let me summarize what I heard, vis-à-vis this Kaizen.

One, its motivation is really because right now it feels like a fragmented process. Some of the things are a bit premature whether it's a lack of clarity in the criteria, the standards, the testing, the tools and the lack of a feedback, a timely actionable feedback loop to continuously improve the process.

So, the purpose of Kaizen is to gather all the stakeholders together, understand and flush out and make visible to all the stakeholders the current state, have a collaboration which is part relationship building, what you just said, and describe the future state that doesn't have to happen all at once but it has the benefit of describing how you would streamline various pieces.

Of the stakeholders we we're thinking about are the folks directly involved with certification like the testers, the developers, the providers, HIE, public health, the Non-MU providers and the folks around the process like the ONC regulators, surveillance, NIST, other certifiers and the auditors.

That it include looking at the process of how CQM criteria – criteria related to CQM are also developed, tested and audited, and as one of the outputs a roadmap that helps improve the predictability and ability for everyone involved to plan, and overarching there's a governance and a feedback, and pilot component to it.

So, I tried to pull in all the things that were said but yet it's along the – it's under the concept of a Kaizen which is – the value stream mapping, understanding what's going on now so that we can really fully appreciate it and get out the waste and streamline it, streamline the process but mainly streamline the burden on everybody. Did that capture it? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Yes, I actually wanted to comment on one piece of what you said which is the roadmap piece. I mean, certainly nobody would disagree with the concept of the roadmap. But I am concerned about how practical that is for ONC to actually do.

And I would point out that we've had roadmaps. I mean, Stage 2 was originally supposed to be about information exchange but then it got transformed into advanced clinical processes. We used to have this swoosh diagram that Stage 3 was supposed to be about outcomes now it's about a lot of different things.

And in the time period when that occurred, if you look at the entire like five-year process we've gone through either three or four national coordinators depending on how you count the individuals and that perhaps is one of the reasons why there has been such dramatic change and so it's just an observation.

It's nice to say that we're going to do a roadmap. In some sense ONC I think has tried to do that, publish a roadmap in the past. The hard part is they haven't been able to complete it. I mean even a very minor example in the 2015 NPRM there is an observation that for coding family history the 2014 edition suggested SNMOED CT but since then a new HL7 concept has occurred and so that's the new one.

And so it's just an observation of just saying, yeah, do a roadmap sounds good and maybe the entire process sounds good but we really have to understand that we currently have a process where there seems to be not very much predictability.

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

Don?

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

I think the roadmap, whatever the roadmaps and the plans are I think also needs to have sort of another dimension which is the sort of the fallibility of the human mind and the processes, and the traction of this, you know, in sort of a usability sense almost a usability sense of regulation.

I mean, when I hear the family history stuff I cringe because as a clinician in an ER the family histories I get are none of this like exhaustive tree it's the people don't know who their family is or they – I mean, it's wrapped up in huge uncertainty and the assumption that you can make this electronic, which I think underpins a lot of the challenges with certification and adoption. So, I think whatever we have is there is some flexibility in how these things are applied and used, and measured and I think part of the numerator/denominator challenge is that.

So, I don't think having just a feature, function roadmap without some structure on the plasticity in the real world, and I don't know how you'd label that. I think we heard it mentioned yesterday is usability, maybe there's a usability component for regulations. But there's a whole dimension that I think is missing and I'm struggling for a name for that. But the family stuff just reminded me of that.

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

So, let me ask Charlene as she brought up the term roadmap. Is what Paul Egerman and Don are talking about a roadmap what you meant or what did you mean?

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

What I thought would fall out of it would be – and again I understand that we would love to see the broader perspective in terms of what's coming next from the program, but to some extent we're constrained from that conversation.

But at least it would be a prioritization of either what processes and/or what capabilities would be addressed in some sort of timeline. So, there would be a prioritization of here's the problem, here's how we're going to address them, a plan, maybe you call it a plan, but some mechanism so that we know what to count on and how to invest our resources.

So they would say, you know, because I know there is a capability to do technical corrections and in the 2015 edition there were some technical corrections but we don't know about that stuff and so we would like input into what that kind of stuff – that was kind of – I was thinking at the lower scale not the big scale at this point.

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

Okay, okay.

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

I would like the big scale but I thought that was kind of a little bit off the table.

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

Okay, sort of more a certification plan.

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

Yes.

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

A plan for the certification process. Okay, let me – I want to caution us we need to maintain for the bigger bucket that you all wanted to talk about so if we don't leave any time for that I think we'll be sorry. So, Mike?

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

Right, so actually to that point it sounds like you are asking for whether there is a group recommendation for a Kaizen event. My earlier comment was about I do agree that a Kaizen event for all the rationality you described is to be recommended as something I would strongly encourage but it's only a part of the overall ongoing process.

And my other supplemental point was just about it will be even more effective if it's part of an ongoing cycle of improvement and continued efficiency. So, I would like to see that be incorporated into the event how it would be sustainable over time, but I would certainly recommend to the rest of the group that we do move forward with that recommendation.

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

Okay. Joe?

Joe Heyman, MD – Whittier IPA

Well, just as an example of making decisions in a vacuum it just occurred to me we've spent months, I can't remember whether it's the certification one or the implementation one now, whichever one I'm on that did this, looking at long-term care and behavioral health and making recommendations about certification without ever knowing that the folks at that table, on the certification group, were overwhelmed.

I mean, we made these decisions without ever knowing that there was a problem with over – and I'm wondering about the capacity. I mean, I don't think those recommendations are worth anything without knowing that that system was going on – we were absolutely oblivious to it. So, I think that's a really good example of where the process is not working properly.

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

Mike?

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Again, I think, maybe I'm stepping into the area of overwhelm, but maybe and it was with what Don was saying, maybe we're counting too much. I know we need to count but I think we're counting too much and I'm sensitive to what both of you are saying about emergency room doctors getting a lot of information doesn't really mean anything, family history wouldn't, but, gee if somebody had a psychiatric history you'd want to know that, so that is important. And if you're in a different setting and you're an internist, family medicine things like that you do want to get that stuff over time.

So, I think we need to think in terms of making the information available to send, make it available to receive not necessarily count every instance that you have to get everything every time but make it so if you do capture it then it can follow along and then other people can receive it if they want to look at it they look at, in the right setting that it makes sense to look at or look for a certain piece like a suicide indicator or a psychiatric history piece you know where to look at you go there, you know, you disregard the rest.

But I think we need to maybe focus on that and count less so that people aren't so focused on putting something in so they're not so overwhelmed.

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

Okay. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, unrelated to the Kaizen event a suggestion that actually Paul Egerman mentioned yesterday and I had previously talked to some ONC folks about which is – and addresses Joe's point, of the Certification and Adoption Workgroup was set up prior to their being testing bodies and certification bodies and we should include representatives of those groups in the future incarnation of that Workgroup. So, it's a suggestion to enhance the existing and future Certification and Adoption Workgroup to represent a key stakeholder.

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

Okay, thanks. All right so I think we've heard actually much discussion and I think I'll interpret Mike's suggestion as a motion. Do we have a second to his motion? Which is – you want to restate it?

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

Yes that we recommend a formal Kaizen event as part – for all the rationale that Paul described earlier for the purpose of trying to improve the process and the goals that Jacob described yesterday, short-term tweaks we can make to the system, long-term enhancements and improvement, all the goals that we talked about earlier and with a follow on process that can allow the gains from the Kaizen event to have continuous improvement processes whether PDCA or other type approaches over time.

M

I'll second it.

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

Okay.

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

Any further discussion? All in favor?

Multiple

Aye.

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

And opposed or abstain? Okay, great. So, that recommendation will go forward to the Policy Committee which may choose to endorse it and go onto ONC and they can deal with the input in the context of everything else that's going on.

Okay, next major bucket is the whole feeling of being overwhelmed and this is what Charlene described as due to the scope, the timeframe, the resources, the surrounding context and making sure that we don't crowd out innovation. So, entertain recommendations on how to deal with that. Joe?

Joe Heyman, MD – Whittier IPA

Well, I'll just go back to the suggestion that we should confine ourselves as much as possible to interoperability and the quality measures and try to get away from the counting.

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

Security and privacy.

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

Okay, so, limit to interoperability, CQM and privacy and security. Okay. Mike?

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

So, to decrease the overwhelming nature of all test procedures, test data and test tools, i.e., test methods are fully and collaboratively developed, stable and ready for release simultaneous with final rules the program will be much less overwhelming.

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

So having the entire testing –

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

Test methods basically, yeah.

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

Methods and tools.

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

Yeah.

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

Available coincident with the final rule?

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

Right.

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

Okay.

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

It's a big lift but it's an important lift if we're going to succeed.

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

There just has to be more testing before we go primetime, I mean, that's what they were all saying, please don't just give us pieces and pieces, and then pieces of change, pieces and things like that.

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

They went all the way to the extreme.

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

Or even if it's not what the final – the implementation clock doesn't tick until that time however that's described.

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

Yeah, that's a friendly amendment timeframe. I mean it's going to be incremental but I think to Paul's point that will do the same thing.

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

Right, right, okay. Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, I guess I want to pick up on that inspiration of given the constraints around the regulatory process and how rules are written, I could imagine it would be really tough for ONC and CMS to say, okay we're going to bring in all these people to do all this development to then release with the rule, but I think the notion of an implementation clock includes time to do that so that its factored in. So, we used to talk about –

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

Right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

The 18 months as some magic number and maybe it needs to be twice 18 because it takes 18 months for the developers to do their thing and then 18 months for the providers to do their thing and so now we're talking about some months upfront to go from how do you turn the regulatory language into a test suite –

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

Right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And reference implementations and all that other stuff that would actually make it executable and would give developers a clear “this is the waterfall thing you're shooting for.”

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

Okay. John Travis?

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

To echo that the practical difficulty of it is that under the current model all of that is exposed to public comment and I'm thinking like Steve is that I just told you what was in the final rule without issuing the final rule if I release the test method to you for public comment that the final rule is supposed to be based on, you can't catch the chicken while it's trying to conceive the egg.

So, I think building in the timeline after that that's what we've all spoken of in the vendor community of have a vetting period that is defined as part of a cycle, our past cycles have not quite recognized that.

We've had public comment but I am here to tell you the test method does beget additional gaps. I mean, it's the practical very detailed way that you know you can conform and until you've had a chance to model that out you don't know your gap development is done. So, we need that period just simply to be its own part of the cycle.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Well, we have actually a gap. We have the time between NPRM and final rule.

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

Well, but my point being the final test procedure iteration would reveal what's in the final rule and that can't precede the final rule.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I understand.

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

Yeah.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

But I guess I'm thinking that –

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

We can work with iteration.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, there is a trial force.

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

Yeah we can work with iteration.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

NPRM is a trial force it's open for public comment and perhaps there's a way during the public comment cycle to do some more actual testing of the stuff.

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

Yes, I think we still would want to see the opportunity to preserve because there is a finished product that we finally respond to that really drives our final mock dry runs and preparation and I cannot name a cycle where we have not identified additional development off of an iterative process and, you know, obviously even beyond what supposedly was final that's been true from time to time with what we've seen.

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

Don?

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

Yeah, I think it may be helpful to have hard and set times that are minimum times for these intervals because I think otherwise they just sort of – so and I would suggest that it's not just the developer time but the customer time.

I mean, I know in our situation, you know, we're trying to put up a new building, you know, there are other practices, you know, there are internal things that, you know, I think all providers are trying to do and these short cycles just sort of do chaos because we're trying to do other things as well and they just absolutely collide in very expensive ways, right, so that means we are either just putting in crap that the doctors and nurses hate or we're hiring consultants at huge expense to try to do something.

And, you know, in big institutions, you know, most of that on some level is blamed on IT but a lot of it sort of comes back to ONC and, you know, I don't think that goodwill needs to be squandered.

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

Good. John?

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

A couple things, I've been mumbling back and forth with Lee yesterday and today on the Implementation Committee Workgroup at Standards we spend a lot of time on scenario testing and I don't know and it's never gone anywhere but it might come up and bite us in this whole thing so I think that should be one thing.

And then secondly, I don't know how we do this maybe and maybe it's the Secretary of Health and Human Services but somebody's got to work with – look at the big picture between what CMS asked us what to do.

I know our segment is highly Medicaid and Medicare regulatory our vendors are constantly making changes in the regulatory – much more than the hospitals are and somebody ought to look down from the 50,000 foot level and say stop this one here or this one, let this one have priority over this one and that and maybe it all has to come up to the Secretary.

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

Thank you. Steve?

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

So, the points that were raised earlier about kind of the sequence are important in terms of setting expectations and, you know, so there are those regulatory limitations. I think one question, you know, would be, I forgot who just raised it, whether or not participation at the proposed rule stage would be added value and for the developers that have already been through this a couple of cycles, you know, things change based on public comment people say, you've assumed that this would be easy to do or nontrivial and, you know, or a trivial thing to do and it is in fact the opposite and we take that into account and we try to, you know, recalibrate our approach, you know, where we can and that, you know, would affect a test procedure that would be based on a proposal if, you know, folks were to invest time. So, one it's a question of value in terms of time invested in the midst of the public comment cycle.

The other is and maybe this is, and I guess others can reflect whether or not you felt the same way, kind of a paradox I experienced yesterday where there is a desire for greater specificity and certainty but at the same time, you know, how that gets applied in a way that doesn't preclude approaches and workflows, and system designs that is flexible and that is innovative and that people can prove which adds subjectivity to a process that you'd otherwise want to be objective in some cases.

And so, I think if you all had feedback on where are the right areas to be objective and where are the right areas to be subjective because I feel like, and I would just express, you know, after the hearing here, feedback and input that we've received over the past in terms of disconnects between the test procedure and the certification criterion.

So, when I get asked to provide a regulatory interpretation and John knows this I start with the rule and the certification criterion and I ask myself what is the technical outcome expected by the certification criterion and a lot of times the test procedure articulates one way to get to that technical outcome and that's where I think we run into a lot of trouble with the test procedures because you need to test something, create an artificial over interpretation and then there is a criticism that we are limiting people's ability to meet the certification criterion.

And then that's where you would add, and I don't know that, you know, our certification body colleagues or testing labs would feel the same way, you add some subjectivity to their work where there is a little bit of dialogue between the developer and certification bodies saying, prove to me how you meet this because we have allowed for a greater range of flexibility. And so –

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

It's kind of what they're get paid for in a sense. I mean, isn't that like their job, you know, I mean, I understand that you have to have clarity as a law but I thought that was the whole point of the nested layer of certification was to achieve that?

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

Can I ask somebody who may have served on CCHIT how does CCHIT have more subjectivity in their testing?

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

This is John, I'll comment because I lived through their certifications as well, they are far more scenario driven and workflow driven they are not unit test. They really do a pretty good job and its 100% pass for the whole of all of it.

So, you know, when they certified ED systems they presented you, you started with triage, you did incoming med reconciliation, you did your note, you did the orders you place, you had shown the return lab, etcetera. If you failed one thing out of that you failed certification as a whole, you know, it wasn't, you know, unit testing or attribute testing of things that were in isolation.

So, good or bad, or indifferent that was a very whole test. It did not – remember also there wasn't a use component at all. So that certification program was to test the EHR so it could be eligible for donation under Stark and any kickback safe harbors.

Wes Rishel – Independent Consultant

Wes Rishel.

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

So, I think that you wind up with a little different objective that made an important difference. Here we're proving an exemplar for use. I agree with Steve's point and believe me I've used Steve's guidance aplenty just used an FAQ you wrote here just a moment ago to answer a question for a client. But, they – I've always viewed certification as proof of exemplar of capability to establish the basis the system had the whole of the capability.

We would still be there if we certified every particular means and that's where subjectivity gets in and we try to calm clients to understand it isn't about you do it exactly this way. We need to tell you reasonable ways to do it that's part of our job as our guidance to our own clients as long as we're making accurate representations about that capability is present in the basis of what we considered certified EHR.

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

Yeah, I mean to Don's question, I mean, yes there are certainly some areas today, I'm sure the developers can attest to it, there is some subjectivity to it, I think there are other areas where, you know, as we get into more technical discussions there is conformance assessment to particular standards, you know, the Consolidated CDA there are validation tools for those that produce more objective results.

There are others where you get to areas where, you know, we've adopted primarily functional certification criteria that don't have specific standards to it, eMAR would be an example where I know the test procedure has caused, you know Howard Hays from yesterday engaged with ISS, right, they have different ways and business processes in which some of those capability are implemented in the settings in which they're deployed and that raised questions for them as they were looking at the test procedure in isolation versus how they would deploy the system and how they would pass testing and whether or not they would be able to justify that their method met the perhaps prescriptive interpretation of a test procedure which was only one way to do a test.

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

Wes is on the phone.

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

Right. Wes.

Wes Rishel – Independent Consultant

Yeah, I don't think it would be reasonable to say that CCHIT was any more subjective than the current test procedures. It's particularly important when you have multiple competing ATBs that there not be an incentive to the ATB to be more flexible in subjectivity than another ATB.

Certainly, I think the process, the steps of going from the original set of requirements to the certification steps and then to the data that drove the certification steps was much more interactive and open than has been the case in a regulatory framework and in addition they beta tested the testing procedures to avoid problems come up during the head's down testing. But, I don't think it would be safe to say or to be reasonable to say they were more subjective.

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

Okay, what I want to remind us is the certification process per se was covered in our recommendation one and would be uncovered, so I want to make sure that we focus in on the overwhelmed part. So, I want ask Jacob if you wanted to make your comment now since you might have – okay, just take turns, okay, so let's stay away from the certification process itself and talk about the overwhelming piece and I think I had Michael Lardieri and then Mike and Joe.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Thanks, this is Mike Lardieri. Yeah, so on the overwhelming side I agree with Joe so we should focus on the interoperability first in there I lump privacy and security with that piece and also communicating with patients in that piece as well. And then the clinical quality measures and then I would go to fall to the third one would be what we're talking about with the certification process.

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

So, Mike?

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

So, Mike Zaroukian, yeah, the thing I heard yesterday that I think might be an interesting way of decreasing burden is to consider a demonstration project opportunity for certain current self-developers who are obviously not selling their products to anyone else they're living in the world their living in, but they could then conduct a limited natural experiment to test the feasibility of achieving Meaningful Use objectives and measures including those that are obviously certification dependent without the burden of actually having to go through the certification process themselves.

It would enable us to see what's actually required, what happens to innovation and usability when the self-developers are freed up from the burden of proving they meet all of the certificate requirements and instead can focus on meeting the measures including those that require the specific standards. One might even suggest that might be an option for certain commercial developers as part of a demonstration project.

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

So, are you saying demonstrate instead of comply with certification?

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

In other words if the main purpose of certification is to prove that you have the tools you need to achieve Meaningful Use and to move information around and all of our goals for improvement and reform, if we took the burden of certification away from certain parties with self-developers being the most obvious first place to experiment, but potentially others, and then seeing what happens to their ability to achieve Meaningful Use and to their ability to achieve the overall overarching goals including those that might be subsequent stages improved outcomes, health reform, etcetera.

Paul Egerman – Businessman/Software Entrepreneur

Can I just respond?

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

And we just relabel demonstration certification –

Paul Egerman – Businessman/Software Entrepreneur

Can I respond to that?

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

Yeah, let me ask that question though. I don't understand the difference between demonstration and certification except the number of letters.

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

Okay, so in other words they would be – I don't want to use the word "deemed" although it's almost leaking out, so the notion that says that they are being trusted, that their system is adequate for the purpose of Meaningful Use but they will still need to meet the Meaningful Use, so if they're not using Consolidated CDA, etcetera, etcetera they will fail.

But rather than having to go to an external entity to prove all of this through all of the scenarios etcetera, etcetera that they would be able to try to fly through that process without having to do that. And I see shaking heads so it's very interesting to –

Paul Egerman – Businessman/Software Entrepreneur

Let me respond.

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

Okay, sure.

Paul Egerman – Businessman/Software Entrepreneur

I mean, when we started the original certification discussions five years ago I was with Marc Probst Co-Chair of the Workgroup and we had some discussion about the self-development group organizations and we felt very strongly that there should be a level playing field and everybody should be treated exactly the same and that was felt that way as it related to the self-development people for two reasons.

One was a lot of these self-developed systems frequently somehow become commercial systems eventually but also it's not like it's like a zero or one you're either self-developed or you're a vendor supported. There are a lot of people who have some vendor stuff and some self-developed stuff and it's very hard to figure out like, you know, where that line is.

And so, I think the comments from the self-development people are very interesting in that those are individuals who have sort of like trying to satisfy a different, slightly different constituency in terms of, you know, being closer to physicians and patients perhaps than vendors although some vendors would argue that.

But, I really feel strongly – we've got to have a level playing field and there's another group which is the open-source vendors, the people who are trying to do things with the Vista product and the same thing there should be a level playing field and if certification doesn't work for the self-developed vendors then it doesn't work for small vendors or open source, or large vendors either. But, I don't think we should carve them out in any way.

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

May I respond? It's your call.

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

Yeah, okay.

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

So, I was going to say, so it could be a long discussion to go through the various nuances of that but the point I want to get to, just like my earlier point, was we need some way of trying to experiment, if you will, with a less prescriptive and maybe greater trust, less prescription, more opportunity for this process of focus to then allow us to detach ourselves from the requirement that you're actually demonstrating all of these things. So, whether it's through that mechanism or another is basically what I'm trying to get.

Paul Egerman – Businessman/Software Entrepreneur

It could be an experimental process.

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

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

I just would recommend carving out some group of people for special treatment. I mean, if whatever the experience is it should be available to every healthcare organization and/or every, you know, every developer. It shouldn't be somehow just, you know, these people are innovative we like them we're going to do something special for them.

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

Okay. Joe, Jacob, Don and Charlene.

Joe Heyman, MD – Whittier IPA

So, this is really just a practical thing about the overwhelming thing. I think that now that we realize that there was this incredible example of sort of very decreased waveband for all of this stuff that's being asked I think that we should specifically relook at certification for behavioral health, long-term care and the modular business proposal to do modular certification now instead of doing it the other way. We should look at all those three things in the context of their impact on the actual certification bodies because we never looked at it that way.

We never discussed whether that had any impact on the certification bodies and I think we really need to look at that before we start imposing a whole bunch of new responsibilities on certification bodies without having evaluated it in that context and if you wanted me to make a motion like that I would.

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

All right. Jacob?

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

A comment and then a question and there might be a yes/no answer and I encourage those of you around the table to nod or shake your heads and we will translate for those on the phone.

The comment is violent agreement with something that Paul Eggerman said little while ago that the systems are more complex than cars now automotive engineers might disagree with us. They are very complex.

I had a fascinating conversation with a guy at Department of Transportation. They are creating a certification program for cars to interoperate and by 2017 there will be regulations that require cars to interoperate to enhance safety, usability, efficiency, right, the parallels are actually quite remarkable.

So, I think it's interesting to think about how systems interoperating with each other providing decision support, right, because that's a lot what the car safety initiatives are around is helping us understand that the car 50 feet ahead of us just threw on their brakes really fast and our car can actually react faster than a human can especially if we are texting. So, that's violent agreement.

Self-developed systems are, as we've heard, innovative systems. We also saw that yesterday there was a self-developed system that exposed 6000 patients to the Internet. And so there is a regulatory context that goes beyond ours and yet ours, as we've talked about all day, dovetails those others and if one respects ours and has the proper safety and security protocols in place it's easier for folks to have confidence that the systems they're purchasing are going to protect them from a 4.8 million dollar fine. I think that's important for most purchasers and self-developers.

My question is, what if we were successful, Lee Stevens and his team are successful in evolving the certification processes to be more efficient, deliver value to the purchasing community and as a byproduct perhaps even makes it easier for Health IT developers to understand what's coming and to implement and what if that were to happen before, as I think I'm hearing consensus for, before the next wave of certification, right the 2017 Regs. Is that fair or is it unfair?

So, let's say there's a new Health IT developer who comes on the market six month from now and say the program is easier and you guys all took the hard test and they're going to get the test that's more efficient and are we going to get negative feedback from current Health IT developers who say, well we had the hard one make them do the hard one too. That's the question and that's yes or no.

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

If we were on call every other night then by – no, I think that's a little bit of this.

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

You know Jacob I'm concerned that doesn't – you know, to the complexity issue that's on the table a lot of these things no matter how they're certified have I think a whole issue of their ultimate clinical value. I think a lot of the line item things which individually sounds good, but if you're, as we are, asking that of every patient on every visit because that's really where the huge tension is.

So even if we had a perfect certification process on some alternate parallel universe I think there is still a huge issue that many of the – many if not most of the requirements sound good in isolation but don't work for every patient. I think that's the ultimate tension here and until we have a process where we pare back the complexity to recognize that patients are different and requiring stuff of every patient that is not needed by every patient is a huge – you know it's just a big central problem. I think that's where we need to cut back the complexity.

What we're hearing is maybe to interrupt that interoperability is one of the things that covers more patients and certainly in the brave new world of payment clinical quality measures will cover more patients. Many of the other requirements cover, as an actionable clinical thing, very few patients and so I think that has to be kept in mind.

And I think it's, you know, if we look more at the adoption part of certification and adoption rather than the certification part certification and adoption I haven't heard that we have a process in place other than sort of radically cutting back on some of these things which seems like a little bit of wasted effort and I'm not sure Kaizen does it, but I think we have to understand which of these things work for all patients and which work for some patients because there is not going to be happy adoption if you force something on every patient visit that only is relevant a small percentage of the time and that's sort of what we're doing, you know, whether it's immunizations or device implants.

Joe Heyman, MD – Whittier IPA

Patient education.

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

Well, yeah, I mean –

Joe Heyman, MD – Whittier IPA

Placing that on the burden on the EMR when there's much better education right on the web that you can get.

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

Yeah, yeah, I mean or you know additional complexity on things like medication list, allergy list, problem list, you know, the family history, you know, those things I think is where we sort of need to focus on the adoption part of it and the complexity.

And I think looking at whether it's applicable to every single patient might be a very good operational tool to address the complexity issue as you're sorting out, so I'll throw it out in that spirit which is beyond the quality of certification.

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

Okay. Charlene?

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

I just wanted to come back to the comment that's been made about the magnitude and the degree of magnitude because that's what I was really struggling with not only the degree of magnitude for the vendors but also the degree of magnitude that we heard from the providers yesterday and it feels like – I'll kind of go back to Jacob's point it's like a concentric circle.

If we could again, we need to probably improve the overall process but given that we're trying to focus there are some things we can probably do immediately to hone up and make the current process better, tighter.

Then you go to your next circle and then you look at the overall end-to-end Meaningful Use process and there are aspects of that we probably need to attack and I think, you know, that's another concentric, another component of it we need to think.

And then the broader piece, which I think is what makes this all overwhelming is that you put that in the context of everything else HHS is doing and when we look at our customers having to, you know, respond it's multiple moving parts and they're uncoordinated. So, you know, I've got to respond to my penalties, I've got to respond – if I'm trying to a shared savings and they got some measures here and there is no coordination among those respective pieces so it's really difficult.

And then we've got new regulatory frameworks coming out so with all of these moving parts, and I know ONC's right in the middle of it, it makes it really hard to come forward with value-based products for customers that tie the ends together because they're not tied together at the beginning.

So, again, I think we need to look at this holistically because we need to look at the holistic framework that HHS is driving and maybe we've got to take it bottom up to get there in terms of improving it, but it just worried me yesterday when I, you know, certainly heard Mari's testimony that the weight of this is so heavy that we might not get there and that's certainly not I think something any of us want to have happen. We know reimbursements, you know the rest of the story.

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

Right.

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

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

Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I feel like I can't be quiet about Joe's comments on the recommendations on voluntary certification for other providers because one of the clear messages we want to communicate with that is we want this to be fully aligned with the mainstream Meaningful Use certification program so that we're not looking for special certification criteria for these care settings. We want it to be the same certification criteria.

So, there could be an increase in volume going to the certification and attesting bodies because there are additional providers of software developers who want to get their stuff through the mill but we were hopefully not adding, with very few exceptions, any new certification criterion into the process.

And in general the things that we were adding were seen to be, in some ways, consistent and supportive with the bigger mission of the eQMs and privacy and security that's across all the providers.

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

Paul Egerman?

Joe Heyman, MD – Whittier IPA

But it's still adding volume, right?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

It does add volume.

Joe Heyman, MD – Whittier IPA

I mean, we never anticipated that there was a problem with volume and one of the things that we heard was there is. So, I'm just saying we ought to look at those recommendations in light of that issue that's all I'm saying. I just think to have made those kinds of decisions without having the input from the certification bodies is an example of what –

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yes, I agree with that.

Joe Heyman, MD – Whittier IPA

Is what part of the problem is.

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

Okay. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

I just wanted to respond to Jacob Reider who seemed to be asking a yes/no question and so my answer is no. I forgot the question though.

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

That's just your default, right?

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

That's okay it's on the public record.

Paul Egerman – Businessman/Software Entrepreneur

Usually I don't get in trouble with that one.

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

Okay.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

– all those old things are sunk costs they're history.

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

Yes.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, that's right it's not a problem if you make the test easier.

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

Okay. John Derr?

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

This is John Derr. Yeah, all we want is –

Paul Egerman – Businessman/Software Entrepreneur

That's not all everybody is asking for. They also would like to be tested a lot less frequently.

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

That's a different conversation for later.

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

All we really want at LTPAC, and I won't speak for Mike, is just interoperability and security and privacy period we don't want to add volume. But, here's one thing, Paul I mentioned to you a while back, there is very little Meaningful Use on the other end of receiving information and we will add volume to it because we do send people back to the emergency room, we don't want to, you know, but one of my fears with that whole re-hospitalization thing is we might not send somebody back that we should send somebody back, but it's that receiving part that's not much stated in Meaningful Use that might add volume to the whole thing.

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

Is there anybody on the phone that wanted to speak to this?

So, it's a good discussion I'm going to bring us back to how it was started because it is a significant departure from where we are which is to limit it in scope to interoperability, CQM and privacy and security. We did hear that and that's been echoed here.

One is to think about that and the significance and the pros and cons it's just like what Joe is saying, you know, if we don't consider the cons then we're still not going to do justice to the issue. So, let's think about is that – what are the implications, ramifications of limiting the certification, recommending that the certification be limited to those three things?

Wes Rishel – Independent Consultant

Wes Rishel.

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

Go ahead, Wes you just beat Joe to the punch.

Wes Rishel – Independent Consultant

Oh, I'm sorry, I just – I'm having Internet problems so I'm not able to tweak the little man.

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

Keep that private Wes.

Wes Rishel – Independent Consultant

Okay. I think the most important thing that we need to establish in any limit on certification is that post-hoc audit requirements couldn't take back something that was skipped in certification. In other words it couldn't be that auditors developed some set of requirements that said, well this vendor is going to be ruled out even though it wasn't the certified point.

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

Was that a comment or question? Was there a question in there Wes?

Wes Rishel – Independent Consultant

No, no it was a comment. I thought you were asking for comments –

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

Oh, no that's fair we just didn't –

Wes Rishel – Independent Consultant

Yeah.

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

We just didn't know whether we had to –

Wes Rishel – Independent Consultant

No, I just wanted to make it clear that there is any kind of loosening on certification sort of carries this implicit threat about auditors taking it back that we heard about and I wanted to make us consider that point as we went forward.

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

So, Joe, did you still have –

Joe Heyman, MD – Whittier IPA

Well, I was just going to – this was my question before about this. I mean, I think this is the right thing to do but my concern about it is one of the things that Mike said earlier which was, you know, part of the thing certification is supposed to do is to assure the customer that they can meet the Meaningful Use requirements and if we're only certifying this portion of the Meaningful Use requirements than it seems to me you can't do that without changing the actual requirements themselves, which frankly I overwhelmingly support.

I mean, I couldn't say more how important it seems to me to change those requirements and limit them to interoperability, to measurement, and to privacy and security. Those seem much more important to me than any of the other requirements and I would be strongly in favor of it but that's my concern.

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

Mike?

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

Yeah, so my point relates to that as well. So, the key issue though is how do we build a framework, if you will, whereby we can do sort of what we did for Meaningful Use at some point people trusted that we would be doing something more with the problem list and found out some other way through doing our usual work and our usual reporting that we must still be doing that, it would be great to be able to do the same kinds of things with some of the more utility-based, straightforward things that no vendor would undo now that they're doing it and would, as long as the certification criteria are reasonable not find it a heavy lift to just keep going. So, that notion of, if you will, retiring it and trusting that it's going to continue I think is a potential step forward.

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

Thank you Steve for raising your card because I was going call on you anyway.

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

So, I mean, this kind of echoes a question that you asked me yesterday, Paul, all right, where I think I heard from some of the panelists, for lack of a better word, having proxy certification criteria. So, transitions of care being one of them that does focus on interoperability, right, a lot of collected data gets pushed into that as a way to say, well, you know, obviously we're collecting problems because problems show up in the Consolidated CDA as an output of actions that occurred based on users.

You know that would require regulatory changes to have that type of structure it's not impossible. It could certainly be accomplished through a regulatory change. You'd have to think about that for Joe's comment how that affects upstream policy of if we're requiring – if Meaningful Use is a measure for providers to collect smoking status and we do away with the functional certification criterion for collecting smoking status in favor of a proxy output for like a Consolidated CDA includes smoking status the provider still would be measured on collecting smoking status unless you revisit the measure and get rid of the measure and that's a, you know, question that we're not here to answer right now, but I mean that's some of the upstream thinking that would need to be done.

Joe Heyman, MD – Whittier IPA

That's what I'm suggesting.

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

To get rid of it then correct?

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

Right, you were quick.

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

Okay.

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

Well, but I would take it the other way. So, whether it's Kyle or Charlene, or John, or others the notion that says, if I just keep doing my work and as long as I keep testing my measures and the vendor and I are both in agreement that this is working then I have every reason to believe, as I submit my reports that will work, I don't care if they were certified against it I know it works and I'm glad that they didn't have to go through the burden of reworking it and I will be all over them if it's not working.

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

Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess this proxy certification is in the air because that's what I want to talk about this notion that we have cascading evidence of something happened I can't produce the quality measure if I don't have the data. I can't produce the summary document if I don't have the data to summarize.

And so some of this got brought up in the Policy Committee discussions about MU and where things should be heading already and I think it's a very good notion to look at where we have cross linkages to rely on those to simplify what actually gets tested.

And to the point about being clear that what's happening is going to create dependencies on the bigger process, right, so if people say, all have to do is produce the care summary I can check that box. As a provider –

Joe Heyman, MD – Whittier IPA

No more checking boxes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right, sorry.

Joe Heyman, MD – Whittier IPA

No more checking boxes, okay.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I need another analogy. I can attest that I accomplished that requirement or I can – I don't even have to attest because the system is automatically calculating it for me.

I think that there is unfortunately a pattern of people get very myopic around what is required to meet a programmatic goal and so in discussions I've had with receiving, for example receiving Direct, people are much more focused on I want to make sure I can get my 10% and then in the future we'll figure out if this is improving transitions of care. But that in the future is very much – and they're thinking it's in the future just let me get through this one hurdle.

And in this case we're actually rolling it back and saying, no, no you can't produce a good care summary if you're not maintaining a problem list, if you're not getting good demographics, if you're not getting – I mean there are a bunch of things that need to happen for those other things to succeed.

And we shouldn't, in the whole scope of things, get people so focused on I just have to produce the care summary and do my QMs and I'm done. That they need to realize that those are complicated things and they're not just a point in time thing.

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

Okay. Mike?

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Yes, I guess I'm a little confused so trying to understand, so are we saying that we would hold the line on not going forward with and tweaking up anything except for interoperability, quality measures and privacy and security? Is that basically what we're saying?

Like going forward we'll just keep tweaking those, get those better and better until it's actually happening then maybe go back and even consider some of this other stuff, but just hold the line with everything else is that –

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

Well, I think the proposal was that we actually reduce certification to just those critical few and the trickle effect on the positive side, and that's one I want to make sure we also have considered the negative side, so trickle effect is – the problem we're trying to solve is it's overwhelming, the scope, dealing with it in a compressed timeline you crowd out the other stuff whether it's things you have to do like ICD-10 or innovation.

When you cram too much into a short period of time things get not done well and Don just said that or not done and one way to do it is to just not have as many things need to be done right now and that so it's really boiling certification down to the critical few. It does expose – so that's on the positive side.

On the negative side is sort of what Mike and Steve were talking about, well then the guarantee that we're trying to build into the system that when you have this system that you purchased will it produce the results you need in order to collect your money or avoid your penalties as a provider, we may be forgoing some of that unless you can somehow build it into these other composite measures.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

I just want to follow-up on that. I think, yeah, I want to do that but, you know, with our providers they don't have technology people that can help them figure this stuff out so what they buy they just have to know that it's able to do that somehow we have to say that and I'm not sure how we do both.

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

Yeah, so that's why it was here, but that's the cost. Don?

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

Yeah, I think on the positive side I think if you actually do some of the minimal stuff well like data liquidity I think you will actually achieve most of the other Meaningful Use goals just by solve and drag. I mean, to go from sea-based to land-based things, right, you know, the interstate highway system which we've used, right, the volumes predicted for transmission of cars in the interstate highway system are trivial compared to what's actually happened.

So, if we actually had these things there would be extraordinary demand for all of the other stuff that we're now sort of trying to do as one big bolus.

So, I think in part what we're saying is we actually want all these things, you know, the medication and the problem and all of this all of this stuff, but maybe the smarter better part of valor is to start with the connectivity first in a limited set, because if you actually successfully adopt those things the rest I am confident will flow. And I think we're seeing it as a zero-sum game when in fact I think it is not a zero-sum game at all.

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

So, going back to Jacob's question about is it fair. If there were this mythical 2016, I'll just make that a different number so people don't get confused, certification and it was only for these three –

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

How about 2020?

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

2020, then in theory we aren't going to have people – we aren't going to have developers have the easier track because they will have all – they will all already have been flushed out. So, fortunately we won't have to face the quandary you have about "oh, it's easier now" it would be, but vendors would no longer have to keep up with all of that. Did I get that right? Okay. Larry, were you –

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, so –

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

Paul, before we go to Larry, can we just note this meeting was originally supposed to end at 12:00 so we're going to try and end by 12:30 just to let the public know that we are going to extend it a little bit.

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

We're still going to end by 12:00.

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

Okay, we're going to try to end by 12:00.

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

Because people still have –

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay, so I'll be short with this comment. So, this is really more of a "what we've accomplished" so as an industry the amount of Health IT that's installed and operational in healthcare providers today is vastly different from what it was five years ago.

And in addition to hospitals and physician practices having systems we have a lot of evidence that there is actually much more physician participation in those systems than there used to be. Systems, health systems that had delayed doing CPOE for years because the physician piece was too hard of a leap are now doing it.

So, I think as we look forward about the things that are really critical we should acknowledge that we've really made a big change in behavior and that we shouldn't throw that away because, oh, we've already accomplished CPOE is done, it's not really done, the Stage 2 extends its use likely it gets further extended in Stage 3.

But we built a base that we can build on and we've seen evidence from the vendors that information exchange within their community of providers and across vendor communities of CDA documents is increasing rapidly.

And, so I think that we actually are seeing a shift and as we look ahead at the pain we've been through we need to solve today's problems and tomorrow's problems not yesterday's problems.

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

Which actually feeds into what I think I'm going to say. So, let me summarize where I think we are before having a motion which is that we would – and actually I'm going to ask for the cons again. That we would limit certification criteria and the testing, etcetera to interoperability, clinical quality measures and privacy and security.

Some of the things we've voiced about what would be the consequence of that, one is we would have a very different barrier to entry at that point in time, 2020, or whenever that is, but we think that's mitigated by the fact most of the vendors – all the vendors, in a sense, would have been through this and have to have that in their systems, which would mitigate some of the concern that you raise which is "gosh, do I really have something that's going to qualify me for Meaningful Use" and during that time would be the penalty phase or other programs that piggyback on Meaningful Use certification.

And so that's I think where we are and want to ask for one more time look at what are the potential downsides of that? It is a massive change to the current program.

Wes Rishel – Independent Consultant

Wes Rishel.

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

One of the – okay, what are the downsides to that and Mike Lardieri had his card up first.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

To clarify in my head for the downside, so if we're focusing on interoperability would we be adding the additional components that are necessary for behavioral health and long-term post-acute care into that interoperability package? We will?

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

Yeah, it's the same.

Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health

Okay.

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

And then Wes?

Wes Rishel – Independent Consultant

I just wanted to make the comment that the key to innovation in that situation is not to do all of the stuff that the other vendors have had to do. So, therefore have a cheaper product to bring to market. I think that's a concern that has to be measured but I don't think it rules out the assets being described.

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

Okay, thank you. Charlene?

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

My only comment was we just need to weave into there, and again I'm assuming that the process – the standards in this current stage were immature which caused a lot of issues not only in the rollout within the vendor community but also at the provider's side. So somehow that component if we're going to do that has to be accounted for.

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

Right. I think that's in our recommendation one.

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

Okay.

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

So, we don't get to do bad things with the good things either.

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

Yeah, so, wherever you've got them, yes.

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

All right. John?

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

John Derr, just a point of clarification we got an NPRM out there for other types of things that are going on for 15 and 17 and what's the timing of something like this? Are we really – because everyone was asking for something, expectations were for a meeting. So, are we going to turn our aircraft carrier on a 5 degree thing or are we going to make a sharp turn?

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

Yeah.

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

Or we don't have any control over it?

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

We don't have any control over that, but we also, in the spirit of everything that was discussed, described yesterday we can't possibly do that to them. One, it's sort of not possible in the regulatory timeframe and the other is it wouldn't be fair. So, this is forward-looking, date TBD. Mike?

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

Yeah, so just to clarify the caveat that I think you were mentioning about vendors who've been in this space for a while went through the process of complete certification, if you will, in other words for every measure every functionality who therefore are now at a higher trust level, if you will, and can focus on some of the areas we've talked about.

The contrary to that would be new entrants to the market where there probably does indeed, because of their newness, need to be a more rigorous process for those developers.

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

Okay, how did the summary sound to you that I gave you? Okay, someone want to move that?

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

So moved.

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

Seconded.

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

Okay and other further discussion? Okay, all in favor?

Multiple

Aye.

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

Opposed? Or Abstained? And how about on the phone?

Wes Rishel – Independent Consultant

In favor.

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

And that's Wes?

Wes Rishel – Independent Consultant

That's right.

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

And did we lose Carl and George?

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

And Nancy.

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

And Nancy. Okay, okay, well, thank you let's see, so to summarize we have two major conclusions they're made up of many component parts but they're all based on what we heard yesterday.

One is that we really do take a very holistic and end-to-end look at the process of certification from the objectives, Meaningful Use objectives that motivate it through the definition of the testing and the way things are tested and certified to the auditing at the end of the process looking for how can we create a more streamlined, more coordinated and more timely process as well as have ongoing feedback so that it can be continuously improved, at least in the regulatory environment.

Our second major motion was that we look at – we try to address the feeling of being overwhelmed by everybody in the process, the accreditors, the vendors, developers and the providers and look for ways that – and our primary method there of dealing with everybody being overwhelmed is to look at the scope and that also obviously helps with timeline and resources actually.

And that we limit the scope to things that are causing a lot of the pain now from a moving forward in advanced care models as well as dealing with all of the other programs that are going on and that's a focus on interoperability which we know Dr. DeSalvo is highlighting clinical quality measures as really an entrée to the future and privacy and security which has to be maintained and there was another breach just yesterday, at least a penalty phase was announced yesterday.

So that's where we end up and I think those are two very potent recommendations. Dr. Reider is that – okay, Larry?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess the question, because it occurred frequently in the discussion yesterday and it came up today of another way – another element of the “overwhelm” is the frequency and I don't think we have an answer on the frequency.

But I feel like we should look at methods to address the frequency and that could be both more and less frequent as appropriate because we've heard some anecdotal examples from other industries of certain things make sense to have frequent updates to and other things get left alone for 5 to 10 years.

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

Okay, my guess it that would come up in recommendations one, in other words –

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah.

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

Probably the Kaizen.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right.

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

Okay, thank you so much both for yesterday and you're sleeping on it and for your thoughts today in generating these two recommendations and we'll go to public comment.

Public Comment

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

If there's anyone in the room who would like to make a public comment, please come up to the table. As a reminder public comment is limited to three minutes and while those in the room who may want to make a public comment come up, we'll 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.

Mari Savickis – Assistant Director, Medical Affairs - American Medical Association

Okay, Mari Savickis, American Medical Association and again, I apologize, I'm going to read so I make sure I don't forget anything. I kind of prefer doing this off the cuff but got a lot of technical pieces here.

The AMA supports the use of Kaizen to address the concerns that have been raised over the past two days and we hope that practicing physicians and end users of EHRs will be included in this process.

We also agree that ONC should be – require vendors to perform scenario-based testing prior to certification to ensure the exception handling capabilities of their products.

A method for post certification testing should also be established allowing for ONCs certification to be used as a baseline benchmark. Although not required EHR vendors should also have the opportunity to continually test their products post certification and receive de-identified testing reports comparing their product to other high scoring EHR technologies.

The AMA supports the use of formative and summative testing in the design of EHRs. We believe the approach outlined by one of the SHARPC grantees, the MedStar Institute for Innovation, MedStar Health Research Institute is an appropriate and reasonable course of action to pursue, they're an ONC contractor, they have proposed that for safety enhanced design vendors should have two options to demonstrate UCD process.

For those vendors who do not already have a rigorous summative testing process they should be allowed to attest their UCD process and provide the summative testing results. However, ONC should set minimum guidelines such as guidelines on sample size and type of participant doing so could help avoid challenges with vendors providing varying levels of detail and would bring more consistency to the process.

For vendors with a rigorous UCD process in place they should be able to use the byproducts of their process to meet the SCD requirements and can opt to demonstrate the process as opposed to providing summative test results. This would include evidence of formative testing amongst other things.

We are concerned however that after hearing all of the concerns raised by numerous panelists yesterday not just with the Certification Program but also with Meaningful Use that this group is unwilling to make a recommendation on making the integral problem more manageable for physicians.

We understand the focus of the group is on certification, but two issues cannot be divorced. Even if the Certification Program is refocused to concentrate on quality measures, privacy security and interoperability and using Kaizen, all things that we support, it will take time to make these changes.

The products for 2014 are either in the market today, will be delivered or won't be delivered at all. So, physicians are left with the products out there now and the vendors must support these. The way to keep physicians from dropping out today or keeping them from making a decision to not participate is to make the program criteria more flexible.

Keep in mind that about 40% of EPs have never participated and of the other 60% 20% have dropped out. We fear that unless we change the course we are headed that we are going to create a parallel market. The one where providers participate in Meaningful Use with certified systems and those who peel off and seek higher performing systems. This cannot possibly be good for the long-term goal of data exchange and getting patients more connected to their health information.

Again, we strongly urge you not to divorce the issue of what will be required of physicians from what is being required of vendors. You cannot refocus certification today and believe that satisfaction will improve tomorrow.

We appreciate this opportunity to comment however all the testing in the world will not ensure the Meaningful Use Program provides value to physicians and patients. Only flexibility in the program now will provide the much relief to the end-user, the physician, who these programs are negatively affecting.

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

Sorry, Mari, your time is up.

Mari Savickis – Assistant Director, Medical Affairs - American Medical Association

Will you cede three minutes to me, Jeff, or one minute?

Jeffrey Smith – Director of Public Policy – College of Healthcare Information Management Executives

Yes.

Mari Savickis – Assistant Director, Medical Affairs – American Medical Association

Thank you. Having a recommendation from this body will send a strong message that these changes are needed. The AMA is spending a lot of time devote the EHR usability issue as several vendors around this table know we are deeply engaged with the vendor community.

We are in fact convening or have convened a set of industry experts to help us work through this issue. We are committed to this and we're plugging away at it. A change in Certification and Meaningful Use Program though is critical to addressing these changes. Thank you for ceding me 30 seconds.

Jeffrey Smith – Director of Public Policy – College of Healthcare Information Management Executives

Your very welcome, okay, okay, okay, hello, my name is Jeff Smith I'm with the College of Healthcare Information Management Executives otherwise known as CHIME. First of all I appreciate the opportunity to comment and I really appreciate the fact that you all are gathered around to talk about this really important issue.

One of the things that I struggle with is trying to understand how ONC measures success for the Certification Program and what process through which it understands what is and is not working. I hope that this is part of that process but I actually hope that a whole lot more is being done to try and understand if success is being met or not.

For the vast majority of providers certification is a requirement of Meaningful Use and nothing more. It does not provide assurance of interoperability. It does not pretend better usability or quality and may I be so bold as to suggest it says very little of security, it is a requirement of Meaningful Use.

So, the near-term and long-term suggested view that Charlene put out there, I would suggest that ONC focus its certification only on Stage 3 Meaningful Use requirements whatever those end up being. This means no 2015 edition and a much more teased out 2017 edition. This could include an incubation period or a gap year for broad vendor provider beta testing.

Beyond 2017 I would suggest that ONC dedicate more resources towards building a Certification Program focused on much more foundational elements of Health IT such as data integrity for patient safety, quality measurements and security components. Thank you.

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

I had a big faux pas, Marc Probst wrote in, so Marc had to go back to do his day job so he did submit some comments and I promised to read it so if you don't mind I'll read them now.

So, he had two, divided into tactical and strategic. So, tactical is the short-term tweaks build a certification body input into the policy development steps. We talked about that actually to bring that into the deliberations on the front end.

The second thing about the tactical is to remove future certification requirements for self developed EHR products, Marc of which is one, and maybe step up the MU attestation audit efforts for these organizations. So, if you don't have them certified.

The strategic points he made were one, redefine the purpose of certification and he says that the data to certification to help advise the selection and procurement is diminishing, those people have gotten EHRs.

Second point, delays or focus certification on the primary objective, interoperability, data sharing and privacy and security, so I think he'll be pleased with our recommendation.

And thirdly, develop a comprehensive data liquidity strategy that although the various HIE organizations do have different areas to focus this is confusing and remains redundant. From a comprehensive strategy standards can be defined and then policy Regs and finally certification criteria, for me, for Marc, MU Stage 3 should focus only on the strategy of interoperability, data sharing and privacy and security which would also push out the date for MU 3.

So, I think he would be pleased with the recommendations we came up with except we didn't talk about pushing out the date of MU 3 which we're not.

Okay, thanks again to all the folks here who participated with us in the hearing and this debriefing and I want to extend also thanks to all of the presenters yesterday it was a very informative day. So, thank you and we'll be presenting this to the Policy Committee next time. Good travels.

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

Thank you everyone.

Public Comment Received

1. I want to reiterate that interchange of data in a reusable format that can avoid duplicative or harmful additional care IS a priority.
2. VA is also facing an internal problem of deciding whether to pursue maneuvering thrusters vs. the warp drive of interoperability and EHR. I have been making the point that we should focus on highly clinically relevant, high-payback things. We should focus on things for interoperability, for example, that can be re-used in clinical decision support.
3. We in VA are trying to certify but have very limited resources. Unlike Dr. Halamka, we cannot easily divert resources from other projects (often congressionally mandated and unmovable) into MU.
- 4.
5. So getting a better focus would be helpful. The certification is "too broad" and requires too many ergs right now.
- 6.
7. I am especially concerned about the need to develop and certify quality measures for the alternate settings of care. Are the eQMs ready for development by vendors, are the ATLS ready to certify these additional measures. This is an example of the scope being too big, the resources too few and the timeframe too compressed. Also, are there mature eQMs in this space if the development and certification could occur?
- 8.
9. The gap between the NPRM & Final Rule is not a gap that can be used for true development of the final product. Only the final rule can truly be used for the final programming to the specifications that the final rule provides. It is a good idea to have a gap for final development of the tools, test scripts and then testing and implementation before the reporting periods start.
- 10.
11. This is David Tao, ICSA Labs. You've done an excellent job summarizing and categorizing the main themes from the hearing. Being overwhelmed and lack of usability were two key themes yesterday. But I haven't heard discussion today of the impact from the way the regulations are written and published. Ginny Lorenzi and others said it was very hard to digest the regulations and multiple associated documents. I believe that lack of formatting and large amounts of indirection in the regs are a factor. Cross-references to paragraphs and sections can't be found by a normal search, because full section numbers, such as § 170.207(b)(3). are not a single string, or the reference may be to an external document. I recommend that someone be engaged to create a "user friendly" publication version of the regs, containing the same text with hyperlinks added, spelled out section numbers, external references pulled into the document, and more readable formatting. While it would take effort to produce, it need only be done once, and would be small in comparison to the many thousands of hours saved for readers of the regs, since so much of the program flows from them. Thank you.

