HIT Standards Committee
Draft Transcript
April 22, 2015

Presentation

Operator
All lines are now bridged.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology
Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is a public meeting and there will be time for public comment before lunch and at the end of the meeting. As a reminder to those making public comment, it's limited to 3 minutes. As a reminder to those in the room, if you could please state your name before speaking, as this meeting is being transcribed and recorded. We'll just go around the room to take roll and we'll start with Sharon.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance
Sharon Terry, Genetic Alliance.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.
Kim Nolen, Pharmacy.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
Anne LeMaistre, Ascension.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Cris Ross, Mayo Clinic.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Liz Johnson, Tenet Healthcare.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Steve Posnack, ONC.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Jon White, ONC.

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

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Dixie Baker, Martin, Blanck & Associates.

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC
John Derr, long-term post-acute care.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Arien Malec, RelayHealth.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Andy Wiesenthal, Deloitte Consulting.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
David McCallie, Cerner.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Mike Lipinski, ONC.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
I know Lisa Gallagher is milling around somewhere because I saw her earlier. And on the phone is Marty Harris.

C. Martin Harris, MD, MBA – Chief Information Officer – Cleveland Clinic Foundation
Present.

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

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Leslie. Charles Romine?

Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology
Kevin Brady for Charles Romine.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kevin. And Lorraine Doo?

Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health & Human Services
Yup, present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Lorraine. Anyone else on the line?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Yes, hi, this is Jamie Ferguson.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Jamie. Okay, with that, I'll turn it over to you Jon.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
All right, good morning everybody. Thank you so much for…oh, that's exciting. So if you're on the line and not muted, please consider muting; thank you. So thank you so much for coming today I think we have a full agenda and it's pretty exciting. Normally I kind of just pass you off with some bon mots and move ahead, but I think I would like to, it's been…it turns out it's actually been a busy month. I kind of smile and say, oh, it hasn't been much of a month since the last time we met but it has been quite a month and here's what's happened.

You are well aware that we released not one, not two, but three proposed rules related to the incentive program, we are looking forward to your feedback and guidance on those. We related…ONC released an updated Privacy and Security of Electronic Health Information Guide, of which we are very proud. And finally, right before HIMSS last week, we released a report to Congress on Health Information Blocking and all these have been…well first, all of these represent a lot of really hard work by really talented people. So I first just want to tip my hat to the folks that I work with, and not me, it's the folks that I work with; they did a fantastic job and I think that there's been very robust response to these documents.

Of course HIMSS is always an exciting week and for those of you who were there; I hope you had a good time. We certainly felt like it was very productive from the ONC side. But you know, the last thing that I kind of want to point out is, while we were away at HIMSS, a piece of legislation passed that repealed the sustainable growth rate and replaced it with a couple of different things. And I just wanted to point out to you that those who were thinking about the future of what we do here at the Standards Committee, in terms of commenting on standards and certification and providing advice to the government should note that not only is EHR Incentive Program rolled up into a broader incentive program that's replacing the Sustainable Growth Rate; it's one of four pillars of that, as a matter of fact.

But beyond that incentive program, there are advanced payment models contained in there and in order to participate in those advanced payment models, you must use certified electronic…certified health IT. So for the next 10 years, the way we pay our providers under Medicare is going to incorporate not just the Incentive Program, but certified health IT.

So, it's…I've gone a little bit longer than I wanted but I just want to say that the fact that this was passed by Congress and signed by the President is a tremendous…it's tremendous executive sponsorship by our government of what we are doing here. And I hope you appropriately recognize that and feel inspired in the work that we do here on a regular basis. The future is so bright, I gotta wear shades. So, thank you very much for your time and attention and the work that you're going to do here today and in the months ahead and we look forward to engaging with you. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Wow, I didn't bring shades; very Matrix of you. Well, as you said, it's an exciting agenda; we will be together for many hours today and really advising to two pieces; we're going to hear, in detail, about the NPRM and we're going to review each of the subcommittees work on the interoperability roadmap. I want to encourage you, same sort of comments you made, government can do very positive things; it can reduce barriers, it can build enablers, it can create economic incentives, it can change culture, but it can also do harm. Harm through over-regulation, being too prescriptive, selecting technologies not ready for prime time. So, I think of this group as a Federal Advisory Committee, it's serving an important role in the checks and balances to highlight the enablers and to, in attempt to mitigate some of the risks quashing innovation and reducing the amount of burden.

We'll look at the NPRMs and we'll see comments on the NPRM Certification Rule in May. It is a very broad document. It contains many, many stakeholder inputs. And I think you can look at it and say I wonder, should we focus on a few things very deeply as opposed to a lot of broad goals superficially. And I think that's going to be a tension, I'll look forward to your comments, I'll look forward to the publics' comments, because as I talk to stakeholders in our industry, there is a sense that we are on the cusp of great change. And I would really hate to quash that great change.

As an example, this Argonaut Activity that several of us have participated in in 3 months, has produced a set of open source APIs for a total cost of $37,000 is the operating cost, per month, of that initiative. So hmm, change in industry, 3 months, $37,000 per month, that actually seems like there has been a change, there has been an incentive to move us forward and you don't want to squash those kinds of private sector activities. So, as we have our discussions today, I've read through all the materials, thought there was some really deep thinking about highlighting the goods, reducing the bad; let's just all go forward with that dictum that we all accepted in medicine of doing no harm, and look forward to the discussion.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Did you say dictum or victim?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Ah well. Oh and by the way, there will be several approvals along the way as we go through each of these reports, we will want your approval to forward them off to ONC.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Speaking of approvals, the minutes from the last meeting?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Indeed. I'm sure all of you have looked at those very fine minutes, are there any edits or changes recommended? Any objections to approving the minutes as written? Okay, none being heard, they are approved by consensus. Moving forward with our first presentation, Dawn will give us an overview of Medicaid Eligible Professionals progress towards Meaningful Use.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Thank you John. Okay, so I understand that everybody is very anxious to know about Stage 2 progress, and we will be getting to that next month. Most of the information I will be showing you next month will be around Medicare progress for 2014 and Stage 2, because the Medicaid providers are on a slightly different time frame, in terms of the data that we have and their MU progress, which is what I'm going to be talking about today.

So first I just want to show you some of the registration numbers. These data are through February, and you can see that there has not yet been a plateauing of registration, it's still pretty much going strong, the line just keeps going up. What you can see is on the left hand side bar are the estimated number of eligible professionals based on the estimates that came through in the Stage 2 rule. But what we actually see is that our Medicaid registrants, there are about 30,000 more Medicaid registered providers than was originally estimated so the additional number of providers that we actually have registered over the original estimate is mostly Medicaid professionals, which has a bearing on how we should set our expectations going forward.

So if you use registration as a marker as intent to participate, we see that there is still very strong interest going forward in the program. What we do know is that Medicaid providers are on a different kind of timeline; they don't have to…they have an…one more year before they can…will no longer…they can start in 2016 and still receive incentive payments and then the final year that they will…that they can be paid incentive payments is 2021, compared to Medicare that had to start in 2014 to receive incentive payments and the last year that they'll get incentive payments is 2016. So totally different timelines there.

So now I'm going to talk a little bit about Medicaid eligible professional's progress towards meaningful use. This first bar shows you, of the total providers who are registered with each of the different programs, their progress towards meaningful use. The dark blue line shows you the…how many have been…have achieved meaningful use, either been paid or attested. You can see, of the providers who registered with Medicare, 86% have achieved meaningful use. However, among the providers who have registered with Medicaid, only 30% have achieved meaningful use. About the same number have been paid through the Medicaid program, but a good portion of them are AIU paid and they haven't made that next step to meaningful use.

So Medicaid professionals are able to receive an incentive payment and then skip a subsequent year, as many subsequent years as they like. And then attest to meaningful use one year later, two years later, however many years they want to. So what you see here is, of the providers within the Medicaid

program who first attested to adopt, implement and upgrade, AIU, in 2011, 40% attested to meaningful use in the subsequent year, 2012. Another 20% attested in 2013, and then we're still collecting the data on 2014. So less than half attested to meaningful use in that first year after. The same thing is playing out for the 2012 attesters who first attested for adopt, implement and upgrade in 2012 and umm…we don't know what's going to happen with the providers who attested in 2013; we'll just have to see.

This slide you've seen before, but it just is…sort of emphasizes the difference in the timelines for the Medicare versus Medicaid providers. Medicare providers, if they don't want to miss out on incentive payment, have to attest in each year. So they have to attest in…if they started in 2011, they have to attest in 2012, 2013 and then in 2014, they are…they were scheduled for Stage 2 and the same thing with the 2012 cohort. So regardless of if they skip a year or not, they're still scheduled to attest to 2014…to Stage 2 in 2014, flex rule aside.

So the providers who attested in 2013 are scheduled for Stage 2 in 2015 and so on and so forth. They can't skip years like Medicaid providers can. So going back to Medicaid providers, what we see here is that of the universe of Medicaid registered providers that 176,000 providers, only 8% could have attested to Stage 2 in 2014. Really the only group that we're looking at who could have attested to Stage 2 in 2014 are those providers who received an AIU payment in 2011, because they had to do their two years of Stage 1 in 2012 and 2013. So that is of that cohort, which is 47,000, a little bit more than a quarter of those have actually attested to two years of Stage 1, so they would be eligible or scheduled to attest to Stage 2 in 2014. So a very small proportion of Medicaid providers would be coming in to do Stage 2 in 2014, assuming they don't take the flex rule option to do Stage 1.

Rolling back up to the universe of all registered providers, what we see on the left-hand side is, who is scheduled for what. So the left-hand pie chart is 546,000 providers who have registered with the program, 50% are Stage 1 for 2014, about 4 in 10 are scheduled for Stage 2 in 2014. But when you look at that 4 in 10 slice, and that's on the right-hand side, it's about 223,000 total providers, about 7% of those providers are Medicaid providers. So, the vast majority of providers who might be scheduled…or who are scheduled for Stage 2 are Medicare providers for 2014.

So this just sums up what I just said; the vast majority of providers who are at meaningful use are Medicare providers and those who could have attested to Stage 2 in 2014, would be also, the vast majority will be Medicare providers. And that is all I have. I can take any questions if anyone has some.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Questions? Comments? Wow, no controversy? Okay.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation and Analysis – Office of the National Coordinator for Health Information Technology
Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well thanks so much.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Thank you, Dawn. All right, gentlemen to the podium. So, after the update on the data, and thank you Dawn, we're moving on to a fairly substantive discussion, I think, discussion of the 2015 Certification Notice of Proposed Rulemaking. Presenting to you today are the Director of the Office of Standards and Technology, Steve Posnack and Mike, what is your official title? I don't know.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Division Director.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
What is it?

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Division Director Federal Policy…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
The Division Director…a Division Director in the Officer of Standards and Technology, Michael Lipinski. We are going to get a…all right, sorry. We're going to get a thorough…we're going to get a thorough detailed review of the NPRM…

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
…that he gets.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…and with time to ask questions and then Steve may have some additional items at the end of the discussion. So, with that, take it away.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Good morning; thank you Jon. So I'm going to ask that the Standards Committee also have no questions at the end of this, right? …I know, probably not. All right, so we're going to talk about particularly the ONC's proposed rule, which is the…we affectionately refer to it as the 2015 Edition Proposed Rule. I just want to say a few things about the rule itself before we dive in and that's that we understand it initially was, I think in double-space, 431 pages; but it is a legal document and actually, it's just few points is that it was set up the same as the 2014 edition. So we went through the criteria in exactly the same way as we did in the 2014 edition.

There are actually some additional adds in there that are supposed to help the stakeholders. So for instance, the Office of Federal Register has a new requirement that says, list out a summary of all standards that you're potentially proposing and give a link so you can have access to that standard. So there's a section in the rule that lists every standard that we…you know, that we're proposing in this

rule so that you can easily access it, find a quick summary on it and then if you want to dive in deep, there's a way now to get to that standard and look at it.

So I just wanted to mention a few things about the rule in terms of how it was structured and it's actually almost like two rules, so you have all the criteria and then you have all the changes that we're proposing for the certification Program. So that's a whole other section really of the rule itself where it talks about…and we'll talk about some of that here today like the transparency provisions, the surveillance provisions, some other provisions we have for our certification bodies related to like records retention and how they certify, so; just want to make those few points about the rule itself and how it was structured.

Okay, so let's dive in. So it's a pretty packed agenda, I guess I…it's I think it's 57 slides, but that is 374 pages less than the rule itself. So as you see on the agenda, we're going to try to focus, I'm going to go through some slides fairly quickly because we've given this presentation at HIMSS minus the one part on the slide about the analysis of all the certification criteria, and that's what I think we want to focus on here today with…using your expertise and so forth in terms of comments and questions. So point being is in that prior presentation, it took us about an hour, so I'm going to try to go through some of the other stuff a little quicker so that we can focus on those criteria and then also have plenty of time for questions.

Okay, so the big thing that we've been talking about in prior regulations and work of like our health IT Policy Committee and in stakeholder engagements is creating a more open and accessible certification program. So currently with our editions, they focused just on the EHR Incentive Program. And what we've done now, like I said, is try to make a more…with our proposal a more accessible certification program.

So a lot of simple, structural changes such as calling an EHR module now a health IT module and that's to try to give better, you know, more appropriate attribution to some of the things that are certified, such as a HISP, potentially a LIS, a laboratory information system. So that was a simple change; it actually doesn't change the definition at all. It's the same definition as what we had for an EHR module, so again, just about proper attribution. Do want to point out in our last rulemaking last year we no longer, and with this…starting with this edition, have complete EHR certification. So everything will be a health IT module that comes through our certification program.

And then the big point is to try to support the care continuum, delivery system reform, some other settings as noted on the slide, long term and post-acute care as well as behavioral health. So I'm not going to spend much time on here, but these are more of the little specifics in how we've like changed it structurally and also made it what we would call like program agnostic, so…and setting agnostic. So just a few things, you know, the CEHRT definition now, if you've had a chance to go through all the rules, is actually in the EHR Incentive Program Stage 3 Rule, it's defined there. We used to do that but now it goes with the program. Some other small things, we've gotten rid of like ambulatory, inpatient designation, things of that nature.

This is just a slide pointing out that our program has already been leveraged by other HHS programs, other federal agencies. So like there's a chronic care management, which requires the use of certified technology now in providing those services. The Department of Defense references certified technology in their procurement.

Okay, so let's talk a little bit about the goals of our proposed rule. Up here are some of the things, as I already mentioned before, you know, broader settings, better care, smart spending, healthier people, delivery system reform and then the ability to support, obviously, the nationwide health information structure through interoperability. Hmm,

M
Try clicking one more time.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Yeah. Okay, so there were actually four goals, not just one goal, broad goals that we talked about at the Health IT Policy Committee. They were interoperability, I think last time we lost access...

W
(Indiscernible)

M
Fewer things…

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Exactly. So the main broad goal were, that we talked about at the Health IT Policy Committee were interoperability, access, user market reliability some of us refer to as like consumer protection in some of our proposals and then supporting the care continuum. And so here we're actually going to talk a little more in depth about those different broad goals as more specific goals as we go through this. And as you can see on there, there is the goal of still supporting Stage 3 of the EHR Incentive Program and our criteria do that and so do our other proposals. But we'll go briefly through all these as I run down the slide deck.

So obviously, on the interoperability piece, standards adoption. So we believe we focused on the standards that needed to be, you know, needed to be updated, as well as new standards for interoperability for particular use cases that we thought would support interoperability. We're going to talk about a few main ones, such as our proposals for the base EHR definition, the common clinical data set which you've seen in the interoperability roadmap. But then there are also other use cases in here; there's obviously the public health and the lab interoperability; so if you didn't hear it the first time.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Bilateral asynchronous echo.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Yeah. So…okay, so the base EHR definition. For those of you who are familiar with our past rulemakings, which many of you are here, it comes out of the…what they call the qualified EHR in the HITECH Act. It specifies certain capabilities that it thinks…or the HITECH Act, I should say, specifies certain capabilities that it believes all providers should have in their EHR. And so we just renamed that the base EHR in our past rulemaking. And with the 2015 edition, we've identified some additional capabilities that I'll talk about.

So here it is, compared essentially to the 2014 edition base EHR, and what you see there in red are the new criteria that we've added to the base EHR definition; so you have smoking status, implantable device list, which is the ability to record change, access, unique device identifiers for a patient's implantable device. And then obviously the big one as well, application access to common clinical data set, the API. So, moving on.

Okay, so the common clinical data set; so this is the data that we think that should be moving always with each patient, whether it's having access…the patient having access to that data, the provider having access to that data or that access go…or excuse me, the data going with a patient in a transition of care. So what I just want to…obviously, as up on the slide, it aligns with the roadmap. And I want to point out what the red and the blue mean.

So the blue are data…data elements, data categories that we've had in the prior, which we called before the common MU data set. So we're changing that name, so even for the 2014 edition, we're going to call it the common clinical data set; and that's again, part of that process of making it a more open, accessible certification program that's agnostic to any other program. So calling it now the common clinical data set. And the blue is prior data categories that were now either changed or added a standard with it.

So just quickly, like sex now is, we've used the HL7 version 3 standard. Race and ethnicity, we still have the OMB standard, but we're also using PHINVADS for more granular recording. Preferred language we're actually changing that standard, based on our proposal, that is. And then vital signs is new, with associated vocabulary standards. Immunizations is new, again with associated vocabulary standard.

Aga…so unique device identifiers, as I mentioned, so it's in the base EHR definition, so providers have that ability to record it, access it, exchange it…excuse me, access it, change it. They also can parse it, based on our…the criterion, they would be able to, that is, what the technology…to that criterion. And also access it through the, what is it called, the global unique device identify…I probably butchered that, but it's the FDA database on that. So that's the functionality providers have. Having it in the common clinical data set means that that information will then go with a transition of care. It will also mean it would be accessible through, for instance, with an API. So we're making sure from a safety perspective that that information is both able to be recorded and then able to be exchanged.

And then the assessment and plan of treatment, the goals in healthcare…or health concerns, is really just a restatement of what we called before the care plan. It was to be more clear as to what we were asking for here and not to be confused with the actual care plan template, that's in Consolidated CDA. So it's just a little more specificity to provide clarity. All right, I'm not going to spend too much on the analogies for folks here; I think they get this. So we're just showing the analogy about like how the data itself can go into like…think of the consolidated CDA as a suitcase. And with like the next slide, so you can have like a single transition of care, the patient taking that suitcase or with like data portability or provider's trying to batch export a lot of patients' data, the Consolidated CDA and that common clinical data set can all move at once.

All right, so let's focus on some of the criteria that help improve interoperability and facilitate exchange. So, a few things to highlight with the transition of care criterion. So, as you know now, we're moving to the Consolidated CDA release 2.0; it…compared to release 1.1, obviously a little more…it's more constrained, a lot more clarity on like the vocabulary, the templates and so forth; so it's, in that respect a better version than 1.1. What else are we doing? So, we're going to test and certify to a health IT

module's ability to both create and receive release 1.1 and 2.0 and then be able to…so that would be able to like send back to a different provider both a patient's information according to release 1.1 and 2.0. We think that's like the most conservative approach to make sure that we…that that information gets there, but we're requesting comment on if there's a better way to do that. And then also make sure, by doing this, that if somebody's on a 2014 edition and is using release 1.1 and not 2.0, that that information can still go to them from somebody on 2015 edition product.

As you can see here, there's a lot more…testing to make sure the information is in the Consolidated CDA is accurate, that there aren't, you know, that they can detect errors, that is the health IT module in any process Consolidated CDA . Also to make sure they can do XCM processing, if that's how they got a message in, so they don't lose that information. And then the Edge Protocol, that's still our same approach as we had in release 2. And then we actually added in some patient matching data constraints as well, as part of our proposal.

So data portability; for the most part it's very similar to the 2014 edition. We've been more…we focused more on the user enabled capabilities, so like on the slide here, we focused on how it would be configured for like timeframe event and location. And obviously again focusing on that common clinical data set.

So the API; so, two things that…obviously we can have some discussion after the presentation, but I want to just emphasize is that…so it's in the base EHR definition, so that means providers have that capability, so that allows them to use, you know, to be able to take that patient data and use maybe a third-party vendor to do other aggregation analysis of their patient data, if they wanted to. So they have that capability. And then it's also in the VDT, which means then patient access is there. And we have, I think it will be actually, wait until I get to the next slide. So the other big point here is so the capability we propose, which I believe are on the next slide, are floor and so we're not trying to capture through certification every potential capability that you could have through the API.

So security; we're not actually…they're going to have to demonstrate their, I guess, their security structure, but we're not saying particularly what security features they have to have. Again, it's a proposal so, open for comment there. Obviously being able to identify the right patient. The data again is the common clinical data set and it's focused on just a, and this is always out of my area of expertise, but to be able to pull the data from a request and it's not necessarily the ability to be able to change, you know, update the data in the EHR, if that was what was coming through an App, that's not what we would be testing or certifying to.

And then the ability to either pull all that common clinical data set or just like the patient's med list or something of that nature. So, and then the documentation, which is a very important piece here. So this makes sure that all the technical implementation requirements are documented for…so for other developers, they're going to be able to see that. It also…we're also proposing that they include their terms of use, including any developer agreements, so that will be available to the public to see as well. And, very important request for comment here; so we're asking for any feedback on how we can even go further here that would make this a more open ecosystem related to the APIs, whether there should be more capabilities that we should test and certify to as well for certification.

So okay, quickly on patient safety; so there are a lot of proposals in this rule that we think promote or improve patient safety. I mentioned the patient matching as part of transition of care; I also mentioned already the unique device identifiers. I'll just quickly talk about the safety-enhanced design criterion,

which was something we proposed initially in the 2014 edition as well as the QMS were both in the 2014 edition and we said in those rulemakings that we would be taking…this was a first step, back then, and that we'd be looking to take the next step in future rulemakings. And that's what we're doing here.

So, safety-enhanced design; our proposals have more capabilities, expanded set of criteria in which we would require developers to apply safety-enhanced design to. It also is more specific as to the information that must be part of testing and certification and thus be available through our Certified Health IT Products List. So that was some compl…clarity provided in response to feedback.

And then on QMS, it makes me laugh sometimes when I say it, but…so, under the prior approach, you could show that you developed…you had a quality management system that was consistent with a recognized standard or you could show how you map to it. But you also could say you didn't use one, and you could still get through certification. But, it was a first step. So I need to…I personally, and everyone needs to remember that that was a first step on our path. And so this time, you can't do that. So now you actually have to show that you use a recognized quality management system, or your quality management system maps to a recognized system.

So, addressing health disparities; and again, based on stakeholder feedback, there are some proposals in here, in our rule, that address…that specifically address health disparities. And I mentioned, as part of the common clinical data set in race and ethnicity, we're looking at more granular recording of that data. We also have a criterion that starts to record now social, psychological and behavioral data. So it's a criterion that would test and certify a module to be able to re…again, those same capabilities, record, change, access this information.

Data Segmentation for Privacy, which can be in certain settings, particularly behavioral health setting, could be useful in exchanging data. And then I want to talk about like for instance, accessibility of health IT. So, this…there are a few different proposals in here but I'm going to focus on the one that actually we'll talk even more about later, would apply to any model that was certified. And that is simply, similar to the QMS, It says that instead of saying or proposing that a health IT module be certified to an accessibility standard, a recognized accessibility standard, we're saying, tell us whether you are, developer, are you certified and which ones, and just identify them.

And you don't have to be certified. Again, like in the prior approach with QMS, you can get through certification saying you're not certify…you're not…you do not use any accessibility standards or have not developed to them. And what we think we're doing with this approach here is we're going to rely on the market and the public who…and the consumers who care about this to determine and analyze that data. Because what's going to happen if a developer says that I don't use any of them, I don't, you know, I don't develop to accessibility standards.

Well that information is going to be on our Certified Health IT Products List. And as you've probably heard already from Steve or others, we're going to make that more of an open data file. So, people…the public will be able pull that data, they can analyze it and associations or stakeholders that care about that data can make that data in a different format and publicly available. And this goes for any of the certified capabilities; so we'll let the market drive how important that is and we're not going to put so much as, make someon…or make a developer be certified to a particular accessibility standard we think the market can drive things in this particular area.

So I just want to quickly point out something that we've done new this time, which is, make the test procedures for the criteria available now. So there's the links right there. The comment period actually extends about a month past the comment period of the proposed rule, so this is a good opportunity to give early input on the test procedures that go along with the proposed criteria.

So, talk a little bit about a few of the main proposals of the certification program. So this is that other part of the rule that I was talking about, if you wanted to split the rule up, this is the proposed changes for the Certification Program. So one of the big ones is the…a new approach to privacy and security. And so what this is doing here is it's saying, each…depending on what's in a health IT module presented for certification, it will have to be certified to certain privacy and security capabilities.

So the best example…or just one example, I guess, is I'll just use public health. So if a provider brought forth, oh, excuse me, a developer brought forth a module to be certified to the ability to trans…for transmission to immunization registries or syndromic surveillance, they would also have to be certified to the criterion for authentication and access, as well as the criterion for audit…auditing and audit reports, and, I believe, the encryption criteria as well. So we've identified those, we're looking for comment.

If we think that…if stakeholders think that there should be additional of the criteria that we have for privacy and security certification, if there are additional criteria that should apply in a certain instance, we're looking for that feedback. But we think this is a clearer approach for developers as to what they have to be certified to. If you remember way back in 2011, we had like this inapplicable or infeasible approach where a developer sometimes wou…we heard, at least through feedback, that they would just build it into the system, even if they didn't think it applied, because it was easier for certification. So what we've done here is we think we've provided that clarity for developers and efficiencies.

And then we've also, a big point is, we removed that responsibility from providers. So if you remember before, in the 2014 edition, privacy and security is just rolled up into that base EHR definition. And so it was just on the provider to make sure they had the right privacy and security capabilities in however they put together their certified health IT technology. They won't have to worry about that through this proposed approach.

So, surveillance of health IT; so the first point here, in-the-field surveillance can happen now. Certification bodies have the ability to do that now. What we've done with our approach is we've given them guidance of how to conduct that type of in-the-field surveillance. And so in-the-field what we mean is, obviously in a provider setting, a production setting so when it's tested in like a testing environment it hasn't been implemented yet. And so here we're looking to do surveillance of that product in an implemented setting to ensure that those certified capabilities continue to work. And it also provides some safety assurance to make sure as well that the technology is working as it was initially certified.

So there are two ways to look at this, and I'm not going to get into too much detail, but as to like all the different parameters we've laid out about randomized surveillance and so forth. But there's reactive and randomized. So reactive would be, if they're getting a lot of complaints then that's an indication they should maybe go look at that particular functionality with that vendor, in-the-field…through in-the-field surveillance. And then randomized is what we've tried to lay out some parameters as to like how much of the products that they certify that they should be looking to conduct in-the-field surveillance on and then in how many particular settings?

So transparency. So we have a current transparency requirement in our rule and, I'm just taking a quick look at time; so, we have a transparency requirement that says, you just have to…a developer has to put in all their communications, marketing materials, any additional cost related to attempting to achieve Meaningful Use. So essentially, public health example, do you need an interface to start reporting to the public health department; you would at least have to let your provider know about that.

What we've done now is we're saying, any additional types of cost to implement a certified capability, that has to be make known; also any potential limitations on a certified capability must also be publicly known in communications; and this is for current customers and future customers, this would apply if this was finalized about…I think our proposal is, and it's a proposal, but 90 days after a final rule; so that would have started applying to the 2014 edition products as well, not just future certification, the 2015 edition.

I think I've mentioned already, through other discussions of proposals of the open data of certified, CHPL as we like to refer to it, Certified Health IT Products List, so I won't spend much time here.

All right, so, let's talk about the actual criteria. So it's hard to see on this slide, because it was hard to get it all on one slide, right? So there are 68 criteria, but this is kind of how it breaks down, and I'm going to spend a couple of minutes on this slide explaining it to you. So, if you brought a product thr…in for certification under our proposed regimen and under the proposed criteria, you would start every product would have to get certified to QMS and that accessibility centered design. Then from there, there are conditional certification requirements.

So that first column I look at as mandatory certification requirements for any health IT module. Then there are conditional certification requirements. And there's going to be a slide after this that actually lays that out for a developer, when a conditional certification criteria would apply to their product. So developers that are listening or are in the room, take note of the next slide particularly, for the conditional certification requirements.

And so there again are the privacy and security criteria as well as the safety-enhanced design that's going to apply to certain criteria. And then the Consolidated CDA creation performance criterion, which I think we have a slide on and we'll talk a little bit more later.

So, next column over are all the criteria that support the EHR Incentive Program, so there are, I think, 37 there. But each individual provider is not going to need technology certified to all of these. And we'll have some slides and we'll talk about that. And in the last column are additional criteria that are available for certification and may support different use cases. I'm not going to talk to all of them, but like for instance I'll talk about like maybe the CQM filter criterion.

So we worked with CMS on that criterion and it's there and has functionalities that support group practice reporting, ACO reporting of quality measures. So, as you can see there's again about that…the open accessibility of the Certification Program, different use cases. We have criteria that have functionality and standards for interoperability to support those use cases proposed in this rule.

So the red; the red as you can see on the thing are all unchanged criteria from the 2014 edition which means you could use as a developer test results previously used to be certified for certification to the 2015 edition, obviously at the discretion of a certification body. And the blue is minimally revised. So there are only three up there and really every…all three of those criteria reference SNOMED and what

we're…only thing we've done here is we went and said set baselines at the most recent version of SNOMED for certification; so very minimal change. So after you take this all in, and you may need more time after this presentation to do that, and we're obviously always available for questions on that. But we think it's a helpful guide to how to approach the criteria, depending on what your goal is.

So, here's that slide I mentioned for developers; so this is those conditional certification. So if you're on the…starting from the column from the left, if you were going to bring a product in for certification for…to a functionality criteria that falls under one of these, you know, how we bucket our criteria, so we're like A is like all the clinical criteria, B is all the care coordination criteria and so on. If you brought a criterion, or excuse me, brought a module in for certification to a criterion that fell in that bucket, these would be the additional requirements that you would also have to meet to get through certification. So it's kind of like a developer cheat sheet for certification to the proposed 2015 edition.

All right; okay, so again, this is just a different slide of those unchanged criteria that you saw in that middle column that are associated with the M, excuse me, with the EHR Incentive Program Stage 3. And they would again all be eligible for gap certification. The QMS one obviously if you didn't use one before, quality management system, it's not going to be unchanged for you and so we've noted that there. And there are a few…and as you know, the IPPS rule published on Friday and it includes our C-3 criterion, which is the ability to report CQMs in a structured way. And the proposed standards that are included in that criterion are unchanged, compared to the 2014 edition. We are requesting comment on that, so it could change in the final rule, but for now it's unchanged. And these are the criteria that…in that column if you remember, the far right column I guess for me, of the available criteria, these are some of them that were also unchanged.

So I've already talked really about the privacy and security criteria, safety-enhanced design, the QMS one, so, we're going to move through some of these fairly quickly but I just wanted to show you like the delta between the 2014 edition and the 2015 edition. So again, going through these labs, with the LOI IG, which was part of our voluntary edition proposal before, but this is an updated version as well as the eDOS we're proposing there, the only…we changed the name of drug-drug/drug allergy interaction; we've added for CPOE to the end of it. But then the other proposal in there is the added interaction check response documentation. You'll also see this in CDS when we get to it.

Demographics, focusing on standards there, not really any new functionality; it's just focusing on the standards. And I think I have actually referenced all these standards when we talked about the base EHR definition and the common clinical data set.

So vital signs; we added some new vital signs to the vital signs criterion and then we proposed it all be encoded in LOINC and UCUM as well as additional metadata. And then there is actual optional certification criteria as well including new functionality that we've proposed related to…primarily to pediatric settings. As I mentioned, problem list just SNOMED change. Let me go through these very quick. CDC, just what I mentioned before as well as the Infobutton standards, they've been updated so we're obviously focusing on the most recent one.

Drug formulary is a fairly…a more revised change. So we broke it out based on preferred drug list and drug formulary. And then for drug formulary, we've added the NCPDP standard, but we're also taking comment on versions that are essentially available now. This version, version 3 is the one already referenced in part D program by CMS. And then we've added also additional functionality about auto checking to make sure you have the most recent information. Smoking status, again, just updating the

SNOMED code and it's any you can code, but we do want to…we do point out in the preamble that you have to be able to still map to those 8 for exchange that we've always had.

Family health history; we broke them apart so there's a separate Pedigree standard and criterion versus just the SNOMED one, and I'm going to talk a little more about what that means for the EHR Incentive Program, shortly. Again, Infobutton just on patient-specific education. We talked about transitions of care, we talked about data portability. So we…the clinical information reconciliation and incorporation, affectionately our own CIRI. We have the consol…excuse me, the CDA creation performance will apply to this one, so we're checking on that, the ability to create one after you incorporate that's accurate.

EPrescribing does have a few proposed revisions, more clarity as to what we're expecting there. VDT doesn't really change much, except for the API add. There is the…making the lab reports available consistent with the…it's not that recent anymore, the CLIA rule, patient access rule. And then we also emphasize the fact that these are all functionalities that the user, the patient, needs to be able to enable.

CQMs; again this is trying to create more user enabled functionality to make sure that's clear for the provider that they're going to have that functionality; it's not going to require additional training or having to contact a developer to be able to do some of this functionality.

So these are all the public health ones; I'm not going to go down through…I mean, immunizations we did make a proposal related to bidirectional. I want to empha…point that out at least. But then the rest are all just either updated standards or we're pointing to the standard that we know that's available for that particular use case and obviously the most recent version of it.

So labs; there's been a strong focus on harmonization and interoperability with labs and we're focusing on the most recent LRI IG. And then the automated numerator recording and the automated measure calculation criteria would be updated consistent with the final Stage 2, excuse me, Stage 3 objectives and measures.

So, these are some of the new criteria and there aren't that many. So the patient health information capture one, so here's a criteria where we thought we would give developers the opportunity to innovate. It's just a broad functionality that we're asking for here; it came out of like recommendations we got from the Health IT Policy Committee, I believe. And so it's got to have the availability to rep…record and…technology certified to this criterion, record and access patient health information documents.

And so what we were talking about there is like an advance directive, but it could be a care plan, a birth plan as well. But we…and then we do have another provision, to be able to take in electronically information from a patient and examples we give are like from a mobile device or so forth, but we're not setting any standards there for certification. So we just want to see the ability to get patient-generated health data in, but again, it's giving the opportunity for developers to innovate in how they meet that criterion.

Talked about the implantable device list; I talked about the API one. So the consolidated CDA creation performance one, I didn't talk too much about that, but it's essentially making sure for the criteria that it applied to, which is, if you go back to that developer slide, it tells you when it conditionally applies, making sure that they create a properly formatted Consolidated CDA. I talked about accessibility design.

These are some more, these are the new public health ones with the particular standards. We can, you know, obviously talk about some those if you like but, I don't need to say too much more here.

I talk about the…psychological and behavior data one. We also have the Health e…the work that came out of the Health eDecisions S&I work in that. So we propose two criteria there. We also have the care plan, if you just were going to get sort of subset for other settings, that this is consistent with the Consolidated CDA care plan. I briefly mentioned the Data Segmentation for Privacy; I did talk about the feature…filtering one; here you have some of the characteristics that you would have to be able to, as a developer, would your product be able to capture and filter on.

I mentioned the Health…and so then we have HPD for the provider directory. So eSMD; I'm not going to spend too much time on this. We worked closely with the CMS Office of Financial Management. There…it's all structured; we have various standards we point to, obviously the Consolidated CDA. There are additional standards that are referenced as well, but I'm not going to run through them. It's obviously not tied to the EHR Incentive Program, but available for certification.

All right, so quickly I want to talk about the EHR incentive use case. So these are just the eight objectives that have been proposed as part of Stage 3. So this is how you build and so I'm going to go through this slide very carefully for you and it goes back to that slide where we had…where we broke out the mandatory conditional certification, what aligned with MU.

So if you were going to build your, you know, as a provider, what do I need to participate in the EHR Incentive Program. And so you start with your product getting, you know, and you're working with your developer and their product gets certified. They have to do below that solid blue line always; so like you always have to do your mandatory certification, all these conditional certification requirements referenced on the slide, would apply to something that would have to be certified for…to be able to have a product that would support your attempt to achieve Meaningful Use.

And then there's the base EHR definition and why I have like the broken blue line dashes is because we, ONC, still define the base EHR definition, but it is referenced in the CEHRT definition, which CMS defines. So, to participate in the program you have to do the base obviously, because it's in the CEHRT definition or have those capabilities, I mean. But I also wanted to point out through that broken line that it's still ONC that defines the base EHR definition.

And then you build on top of that. So what's in the CEHRT definition beyond the base; well they're listed on this slide for you. So there's still…ONC no longer requires those meaningful use measurement calculations, I want to be clear about that, but from a policy perspective CMS believes that those capabilities are still important for providers to have and thus they are in the certified EHR technology definition.

And then they have additional capabilities there, as you can see, related to CQMs. And these are the criteria that you would need; that's the names that we've listed. And then you get up…and so for family health history, remember how there was Pedigree and then there was just recording family health history to SNOMED. So you can choose either one of those, whatever in your practice setting is most important to you…or would support your work or your practice, that's what you would get certified to. And you would only need one of those, not both.

And then, up above, it's hard to see on this slide but the dark, bolded criteria are the criteria that are already in the base EHR definition so once you have that capabilities, you're not going to obviously have to get certified to it again. But the ones in the white are the newer are, excuse me, the capabilities that you wouldn't have, having gotten all that other certification.

So, once you do all this, what's it look like? So this is what it looks like, and it's not…and so, I want to break it down. So the 2014 edition, you needed about 42 criteria if you were in the ambulatory setting, to support…this is minimally to support your attempt at Meaningful Use, you needed to have…you needed a product certified to 42 criteria. 2015 edition, it doesn't change, it's still 42 criteria; but of those 42 criteria, 45% of them are unchanged or minimally revised meaning if you had a product already certified to the 2014 edition, your developer can use those test results to get certified to the 2015 edition.

So, what I want to…what this emphasis is that other 55 is where we focused on interoperability; things like transitions of care, API, where we went to standards that we thought improved interoperability. So that's where we tried to put our focus on and then as you can see, almost half of it is unchanged coming from the 2014 edition. So we wanted developers to focus on that interoperability aspect, making that data be available and accessible by providers and patients.

And the one thing also I'll note here is, this doesn't even count for potential exclusions. So if you're in the ambulatory setting, take CPOE for example where we split that out into three criteria. You may not even need CPOE for say meds or diagnostic im…or however you want to split it out, depending on the specialty you are. If you're not…if you're going to maybe meet the exclusion, you're not going to see 100 patients, you wouldn't even have to have that capability, so you could only actually be certified to 39 criteria.

And I guess that's another point I'll make. So the 60% of the criteria, you would only…support Stage 3. And the other point about the additional criteria, it's not just additional criteria for use case; it's us also splitting out functionality or giving options and flexibility. So like I gave you the example of family health history; there are two criteria there, but that adds to the total, but it's really to give flexibility based on what you need. CPOE, another perfect example; used to be one criteria but now it's three to give that flexibility that providers and others and developers have asked for.

And this is just an example of how you would build to another setting. So it's just focusing on, you know, what would always be required for certification and then what else you may need for that partic…or want for that particular setting. Here's a behavioral health example and that's it.

So these are ways to comment. ONC has tried to facilitate the comment process. So, there are two links up on there that I want to identify for you, which is the Microsoft Word version of the rule. And that allows you to cut and paste. We know that like it's not as easily to use the Federal Register version of the rule, so we have a Word version and then we have comment template as well, which allows you to see all the criteria and proposals, tells you where you can find additional request for comment in the FR…the Federal Register version, but it helps you organize your comments and it also makes it easier honestly for us to go through those comments quickly, so we can get to a final rule faster.

All right, just some additional resources and question time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
I'm sure there are no comments of any kind. So Jon and I debated who would moderate the question and answer session and since I was not going to bias the jury in any way, he said, well okay, you can do it. So let us start with Leslie Kelly Hall whose sign went up first. Leslie, are you on the phone?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I am, sorry I was on mute. So, I have a couple of questions; one back to the VDT access in the open API recommendation. We are going to see a plethora of consumer applications wanting to join into this wonderful opportunity and they will be new to this world and often not a covered entity or an EHR that's typically using HIPAA constraints. And so you stated that we are not offering any sort of guidance, only a minimum security and connectivity guidance, could you expand a little bit on how you would see the…a consumer friendly application join our world and what kind of criteria they would need?

That's one question. Another question on your slide number 29, could you go back and define those titles yet one more time? I was not clear on the mandatory versus optional. And the third question on the accessibility issue, the market driving the accessibility; will there be any sort of accessibility guidance as optional or are we just going to stay silent on those? So, three questions. Thank you.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Want to take APIs first?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
No, I'll go first. While Mike's navigating the slides. So this is Steve Posnack; so Leslie on your first question, the application programming interface requirements apply to the data source and not necessarily to the…any application that would be accessing the data. And so the other thing I think we'd want to emphasize as well, as much as we would maybe prefer or like for certification to apply all of the soup to nuts components of things, certification is a baseline and so in certain cases, we go as far as we think is necessary for developers to functionally meet the certification criteria requirements. Or provide enough guidance in the certification criteria to set the parameters by which they'd be able to build on without the additional overhead of other certification requirements to get through the program.

So, In terms of the API functionality that we've built in, at least, and what we are interested in comment on, is whether or not we specified it enough for both the developers that will be providing the API, as well as from application developers that may be accessing the API, that there's enough guidance in the certification criterion for both to, I sat be happy, for lack of a better word. I'll turn it over to Mike.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Okay, so I'll start with, if I remember correctly, the first question which was on further clarification of the mandatory versus conditional certification. So I'm on slide 29. So that first column starting with criteria proposed as always required, so we've identified two criteria that any product brought forward for certification would always have to be certified to these criteria. So there's a QMS one which would have to show that they do quality management systems consistent with a recognized standard, either from a standards development organization or the federal government. And then there's the accessibility-centered design, which is very similar to QMS. And I think you asked a question related to that.

So there we've identified in preamble a list of recog…internationally recognized standards, also 508, that revolve around on health IT's accessibility for those with disabilities. And what we've proposed is you either say that you've developed to multiple ones, you can list every standard and for whatever functionality you've been certified to and that would be part of your testing results and part of what would go on the certified health IT data list or you can say you don't use one; and that would also go on the certified health IT list and be available for…to the public.

And we also have another criterion, I didn't spend much time on it and we'll call it an available or option criterion, so it's in that far column, it's sort of an accessibility technology compatibility. So a developer, if they want as like a market differentiator, can get certified to this criterion which would show whether they could use, you know, text-to-speech functionality with their product. And that information would also be on the certified…I'll just call it the CHPL, and then available again to the public. There is one proposal that would be required, so in VDT, we have WCAG, so I think that's Web Content…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Accessibility Guidelines.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
…Accessibility Guidelines, thank you Steve. And we have currently, I think it's Level A, so that has a particular requirement and we're asking for comment if we should move at this time now, which has been 3 years since our last proposal and actually would not be required of a developer and a provider to use all the way until 2018 for the EHR Incentive Program, if we should move to the next level there. So those are the…where we are on the accessibility. I'm not sure if that answered all your questions, Leslie, but, let me know.

Leslie Kelly Hall – Senior Vice President of Policy Healthwise
Yes thank you; I appreciate that.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Next Arien Malec.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Thank you. So first of all I want to applaud both of you for putting together the one-pager, I think it was incredibly helpful for those of us who were incredibly confused by the mapping between the CEHRT Rule and Stage 3 Meaningful Use. And as a friendly suggestion in the future, because of this complex mapping between certification and programs, it would be useful for you to collaborate with CMS and other programmatic organizations to create these kinds of one-page cheat sheets or summary cheat sheets in the future.

I've got a number of questions, actually one's occasioned by Leslie's question which is that as I read the application access or API requirement, it really is application acc…it's an EHR or a data holder side certification requirement. I'm not even sure how a mobile App or other App that only accesses data would even certify to that. So if you've got…if there's something in your heads about how you could do the reciprocal, I got confused by that. That's actually not my main question, but if it…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
So, that's not in scope.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, okay; that's what I thought, so…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
We're not…yeah, it's not focused on the App itself, it's on the…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So to Leslie's previous question, my understanding would be that it wouldn't be possible for an application to get certified, that only accesses data but doesn't provide data. So thanks for that.

The main question that I have is whether ONC, so the NwHIN Power Team created a set of standards readiness criteria or a standards readiness evaluation framework. In the last Standards Committee, Stan and I presented, and the Standards Committee approved, a transmittal that lists recommendations to ONC. Some of those recommendations included recommendations on how certification criteria, what are the readiness criteria for certification criteria that included the provision that certification criteria should be meaningfully production used before they're incorporated in certification criteria.

So first question and then maybe a follow up comment is does ONC have a formal process for evaluating proposed certification criteria to test whether they're ready for primetime and ready for inclusion in certification criteria? And, as I think Steve's smiling, I'm asking because I note a number of requirements or a number of certification criteria that to my knowledge have never been real world production tested in…outside of a Connect-A-Thon setting or testing setting. And I wonder about whether there is a process for including those. And if there are certification criteria that are included that have never been production tested, are there any suggested limits that ONC has in terms of how those certification criteria should be used in programs or programmatics.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
I'll take this one. You notice I was ominously quiet while Mike was presenting; this is a good professional development opportunity for him as well. So we do have a process internally that we go through that I think can always be improved so, any suggestions that people have that they think we have not necessarily considered. There are trade-offs involved in every decision that we've made with every proposal that we I think agonizingly go through during the internal deliberative process and in part its where we feel that the regulatory process and the certification criteria can help set a marker forward where something may not necessarily have gotten enough attention that we feel deserves some additional attention, and the regulation is a way to do that.

If there are those in this "available column" where we've determined that there's a proposal worthy of proposing for comment, we've proposed it. And so there are, in that respect, trade-offs that we've made in saying, well maybe something isn't as mature as we'd like it to be, but we believe that it was time to make a proposal and thus this is the opportunity for us to do that. In other cases, you know, we looked to see if there have been, even at a level of demonstration through Connect-A-Thons or like pilots, we evaluate that component, we look at the relative kind of implementation experience that we

may know about that exists in the field. And to the degree that the other component, as you and David have presented and as we've thought about more, there are other mission components that the federal government has that we need to take into consideration as well, in terms of supporting our other agencies' missions. And those other agency missions often intersect with what the market wants sometimes.

You know, eSMD is an interesting example. Those standards are relatively new; no one's going to argue that. CMS is looking to make the experience for providers in response to audit requests to submit clinical documentation easier and more structured and standardized, as opposed to either paper or PDF. And that's kind of their mission and so in support of their mission; these standards are kind of at the point where we had a choice of proposing them or not in this regulatory process, not knowing when our next regulation is going to be, proposing them for comment to see what the industry reaction would be.

So, that's not to say that some of them, you know, if we took a step back and said we're going to have an opportunity to infinitely regulate at any period of time, would we do choose to do them at some other time, you know, I think maybe we would have for some of them. But, this is the vehicle that we had available to us and if the comments that we get back as we've demonstrated in the past, tell us that it would, to John Halamka's do no harm point earlier, would have an adverse effect on the industry as opposed to a supportive or accelerant type of approach vis-a-vis a certification criterion, then that's something we'd take into serious consideration.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Quick follow up; as a friendly suggestion I think you're in the position of having a hammer and sometimes the problem is not a nail hammering problem. So in areas where ONC or other federal agencies believe that a certain area is ripe and ready for production pilot or production demonstration, it may not be wise to look at the regulatory mechanism as the mechanism to affect that. There may well be other policy tools and policy levers that ONC and those other federal agencies have available. I guess that would be friendly suggestion number one.

Friendly suggestion number two would be, I have a worry, maybe it's a paranoid worry, that someone will…if this…if a certain criterion gets through the final rule stage, someone will use the presence of that in a formally regulated…certification criteria to imply that that standard is ready for incorporation in other programmatics. And so to the extent that ONC wishes to use that tool, it might be useful to flag certain certification criteria in a draft or tentative or other level of marker that might indicate to other regulators that it's…may not be ready entirely for primetime.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology- Office of the National Coordinator for Health Information Technology
I think those are two valid appreciated, you know, friendly comments. The cynic on my one shoulder understands your vali…you know, your concern. Certainly when it comes to policy that's set through the Department, we have a roll and clear all those documents and so we have the opportunity to go back to our other colleagues and say, hey, you may want to rethink your approach here. But, if a state looked at our rules and decided to require something, they wouldn't necessarily check with us; so, I mean I understand that concern and we've heard that as we've talked to other commenters.

And that's something I think we would certainly appreciate as a part of public comment process, that yeah, yeah, yeah, we trust you guys, ONC, to help corral everybody that you have the control over, but there are a lot of other people that will just look at your list of criteria and think that they're good to go,

even though some of these that are in the available column, as they're adopted as certification criterion, if they're ultimately avail…ready to be certified against, could then evolve into a pilot demonstration mode and certification can help be that iterative approach. I think overall we are looking to have a more iterative approach with the industry and trying to find new ways to have either ideas of certification criteria or other elements that we think would provide…go through this kind of pilot and demonstration process.

One thing that we're looking to get to, and I think what I always go back to in terms of why we have certification for everything is, you know, market assurance, consistency and we're in this position, which is a little bit of paradox of kind of, and I know this…this is how I see it, so, I'm sorry if people don't get it, but regulating the future past. And that's kind of the hyphen as I describe it with attribution to the X-men title that kind of gave me that experience; but we're looking at standards that have been now developed in the past for applicability in the future.

And that's kind of my construct where we're looking at standards that have recently been published the past few years, that may not have been or may not be at the point of maturity that we'd like them to be, but we're looking to a compliance date somewhere years into the future; we have to make a decision now from a regulatory standpoint. And that's a little bit of the trade-off that we have, especially with supporting the EHR Incentive Program.

In other areas, thought, we can look to the market assurance that certification might be able to provide and that's where I think a point Arien made to me the other day, ideally and I think one of our goals going forward now with the administration of the certification program is to get to production level conformance…production-ready conformance. And that's something that we are still aspiring to with the testing processes that we have and the tools that are currently being developed.

The criterion that we've got in for Consolidated CDA performance is one of those updates where we're looking to get to production level conformance through the testing process. It's going to be in vitro still, right, and that's our below the line kind of limitation until we get into the either randomized or reactive surveillance that the certification bodies will be able to do, which will give us better assurance of how products are actually implemented in the field. And I feel like I've droned on far enough…so, thanks.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Jon White wanted to make a follow-up comment.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
So, just a brief one; I appreciate the tone of the questioning and the constructive comments, it really is, it's good and I…and so keep going along these lines. I think that everybody here recognizes that when there are criteria that are proposed in proposed rules; they're not plucked from thin air based on whimsy, right? There's a customer somewhere that wants some of these and Steve talks about the reasons for market assurance. I'm guessing that for some of these, you know, there's some where things might not be ready for primetime and we want to hear back from you about that.

There might be other places where your comments might be along the lines of, we can handle that in other ways, you know, the other John here said, maybe there are ways that the market can do this where we don't have to necessarily regulate. Constructive comments back to us would explain to us

how the market might be able to handle that or the industry might be able to handle that and how we, as the arbiters of some of this stuff, can trust but verify that it's going to happen to provide some of that assurance. So again, great discussion, keep along these lines and look forward to more rich discussion.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And so we have many people in the queue, is…now David; is this a friendly amendment to this discussion?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, it picks right up where Arien left off and I'm happy to start from fresh if you want to push me back in the queue, but it might save a few minutes if I can just reference the previous conversation and…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
With your permission…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And I just, first, I really like what you did with the API requirement, where you specified a functional set of goals but did not prematurely close on a formal specification or implementation guide. And I think that's an appropriate way to strongly indicate where you want us to go, but to realize that we don't have a concretely proven best way to get there, let the market figure it out which is why I'm dismayed to see some equally unproven things put into the optional category that are over-specified and yet are as equally unproven as the API goal.

And my question is basically why couldn't you specify those in functional modes in the same way that you did with the API? So for example, the Health eDecisions clinical decision support, to pick my favorite one, I mean, I think that is an unproven, inflexible approach that will yield, at some point, to much more appropriate approaches along the lines of what the API Workgroup has proposed with orchestration patterns and the like. And what I'm worried about now is if I were to go out to the CDS vendors and propose a pilot of some of these more FHIR-based approaches, they'd say no, they've telegraphed that they're going to require the Health eDecisions artifacts and…that would shut that innovation down because you prematurely specified an unproven approach.

I would say the same thing for DS4P and I would say it also for eSMD, although I understand that may be a different…there are different drivers there that are more complicated. So, just to reiterate, I love the notion of telegraphing the functional requirement, let the market figure it out and then come in with an appropriate clarification and standardization when the market's figured out what works.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Yeah, so I think that's the point at which we're at in terms of the public comment process. It's fair and appreciated in terms of you all's experience in terms of how your colleagues in the market react to what we may put in as a proposal. I think, you know, I go back to the precedent that we have already in terms of pulling back on things. So I would put this also in the broader context of what ONC is trying to accomplish with our certification program overall, in terms of being able to broadly support the care continuum, being able to broadly support other programmatic needs and other market needs. If the Standards Committee, as it takes a step back were to say, you know, first steps should be a functional

criterion and as the market weeds out what standard might be the best to meet that functional requirement. The next step for ONC in the future would be then to reference kind of version, you know, release 2 or a version 2 rulemaking that standard to provide that market consistency where there is some coalescence around a particular approach, or not. And so I think to the degree that we get comments back on the clinical decision support ones or DS4P, we'll have to weigh those with keeping it as it is, dialing it back and making it a functional criterion or ultimately, potentially not adopting it in final rule altogether.

And those are all the different trade-offs that we'll have consider as the comments come in and the different trajectories that would come out. And if, you know…I think that's probably where I'll end.

M
That's all I have to say about that.

John Halamka, MD, MS – Chie Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So let me just amplify what David has said, I mean, I actually of course as you might imagine, get a lot of back-channel communications from members of this committee, especially since we have many virtual folks and they would say, HPD, eSMD, Health eDecisions and DS4P as a cluster, all fall into this category where a functional description would be welcome, but prescriptive standard selection would not be. In effect you're at the point where as a society we haven't yet invented the Internet and so we're instantiating Morse code. Really? You know, the Internet's just around the corner.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Two years away.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well hey and next, Dixie and then of course I do recognize Wes, Eric Rose, Cris Ross, I think that's and Leslie has also come back? Okay, very good. So Dixie.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, this is…this topic was one of them I was going to bring up so, I appreciate your explanation of what the thought process you go through, Steve. I also…so I had a couple of comments about security. And I want to start by thanking you for listening to the Transport and Security Working Group and changing the way that security is certified. We really appreciate knowing that our recommendations are being listened to, so thank you.

I noticed in…so, my first comment is that I noticed in the chart that says the following sections must meet the following security criteria, table, whatever it was, that in the clinical area, data integrity is omitted. And I was wondering if that was on purpose, because it seems like such a…it seems like a mistake, quite frankly, because obviously all of us in healthcare know that data integrity is arguably even more important than privacy. It's extremely important; so I was wondering, number one was that intentional or is that just kind of a slip of the pen?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Well it's intentional because of the context in which the criterion has always been applied, which is for exchange. And so the integrity criterion is always applied in terms of hashing for the data that's been exchanged and not necessarily on local data integrity.

Dixie Baker, MS, PhD – Senior Partner, Martin Blanck & Associates
So you don't think integrity is important for exchanging clinical data?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
We do and so that's going to be tested part and parcel with when data is exchanged, the integrity criterion is applicable. For the kind of local functional criterion, like drug-drug, drug-allergy interaction checking, which is where that criterion is excluded, if I'm not mistaken, that criterion doesn't come into play. So it's the context and the applicability of the spe…the actual specific functional requirements that are included in the integrity certification criterion, not necessarily, as I understand your statements, the integrity construct as a whole. Does that make sense?

Dixie Baker, MS, PhD – Senior Partner, Martin Blanck & Associates
No, it doesn't; you know, that's like saying well we didn't include authentication because they thought…we thought they'd authenticate themselves when they were exchanging data anyway, for example. I think that's a critical mistake…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Well let me…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…because it's a safety issue, data integrity is a safety issue and I think that's a mistake.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Let me try and restate. Our integrity criterion for the past 5 years has always applied to data when it's exchanged.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm, right.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
That's the context in which the criterion…that we've scoped certification to apply the integrity functionality. That's not to disagree or say that your points are related to internal system data integrity aren't important, that's just not where we focused certification on, from before. So all we're doing is carrying forward the applicability of the integrity certification criterion to be specific to when data is transmitted, to ensure that that data's integrity remains intact.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Hmm. Okay, I understand what you're saying. Let me go to my second question; the Transport and Security Working Group weren't asked to respond to the security criteria for the API. So I just wanted to point out that we were…the Transport and Security Working Group did make a recommendation to the ONC about API security that included OAuth 2.0 for the authentication and authorization of Apps. And it included Open ID Connect for authentication of individuals. And I know that that was just put forth at our last meeting, so you guys didn't have that as input, but I wanted to give it to you now.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Thanks. Well, I mean, the group's certainly welcome to comment on if you have anything additional to comment. I think there is a balance that Arien and David have articulated in terms of in terms of how detailed we should have that certification criterion be. Certainly we could point out the predominantly used standards in the industry today for that type of requirement in the preamble if we wanted to give additional guidance. That's one approach that we've taken before in terms of not foreshadowing, other, you know, say 3 years from now there's something different people would be able to use for certification as opposed to locking them into, you know, all…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Okay, then forget the standards but authorization and authentication need to be there; authorization and authentication of applications especially, from a functional perspective.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
So it would be great if you guys could look at the specific security provision and…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Okay.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
…suggest alternative language that you think would…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Okay.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
…make that clearer.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
We will. We will. Okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Next Wes?

Wes Rishel – Independent Consultant
Thank you. I've got a couple of smaller questions that lead to the bigger ones, so think of it as cross-examination. Just so Mike gets his on-the-job training….about on-the-job training, remember that Thomas Edison said perspiration is more important than whatever else. The notice that the race and ethnicity specifications or specificity is deeper in the proposed rule; I just want to observe a couple of things.

One is that the biggest problem that we have in interoperability is when the party collecting the data doesn't need it but the party on the other end of the interface does. And I don't know who the customer is for more specific race and ethnicity, but I have the feeling it's analytics for policy and things like that. And this is a specific case of a generic problem that's really at the heart of a lot of the criticism from physicians about the Meaningful Use Program which is that, it's not my job to collect data, you know, and so forth.

I'd also note that anyone in the data entry capacity, whether it's a physician recording in the chart or a medical assistant, will add whatever specificity they need to get the job done, whether or not they have actual data to support that specificity. They're not going to fail to complete this chart, so those kinds of reactions at a minimum they need to be balanced against the implementation and training costs associated with them.

I have a question about the very laudable introduction of QMS into the, you know, taking it out of the, you can say, I don't use quality category. These requirements, do they go to the level that FDA goes to where they actually look at the output of the QMS and make some judgment about whether it was used properly or is it simply, did you use one? And if not, are those outputs transparently available? Can potential customers see the QMS outputs that we're describing?

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
That question…so, it's just they have to say, they don't…they have to say which ones they use, but it doesn't really, to my knowledge, go beyond that...

Wes Rishel – Independent Consultant
So there's no, and you know, we see a process of regulation over time and I'm not necessarily saying that we should be any more aggressive, I'm just trying to understand where we are. I was surprised to learn recently that ACBs currently have the requirement to record and make transparent publication of complaints. I'm very interested in the random and reactive surveillance. What I'm wondering is how will this be funded? Is it…right now the relationship between an ACB, I'm sorry, between a testing body and a vendor is very transactional; here's a new version, here's what we have to certify, blah, blah, blah. Here's how much it costs. Here's how much the vendor had to budget for activities around, and that's often much higher than the actual fee. Are the various bodies expected to increase their fees at those transaction points in order to fund the ongoing surveillance? Or is there another mechanism for covering that cost?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the N
Sure, so that's a good question. The certification bodies have their own business models and it's up to them if these rules are finalized as they are to execute a business model that they think works best for them and potentially their customers. So today they set their own rates, they have their own approaches for certification and testing costs if they do both of them and they do build in, as far as I'm

aware as a part of their contracts and the like, surveillance requirements. And how they choose to building whatever funding mechanism they may need, they would…they'd have the flexibility to do it all up front or to do it on the back end if someone was selected them, they would have to provide some additional resources to the certification body.

Wes Rishel – Independent Consultant
So as they compete for business, they can develop a business model that is relatively light on randomized surveillance and therefore charge less and be less of a bother to their clients, is that…?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
No, I mean, that wouldn't be able to…so with our proposal we set the parameters…

Wes Rishel – Independent Consultant
Okay, fine. Yeah.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
…which all certification bodies need to do randomized surveillance. So that would be the consistent baseline for all of them; they'd all kind of play by the same rules; how they want to execute their business around that is up to them.

Wes Rishel – Independent Consultant
Okay. Finally, I was…really appreciated your future-past construction there and want to point out that it extends one step further than the context where you were using it. And that is that we're talking about using standards in the future to transfer data that was collected in the past and at some point that means it wasn't connected…collected at the level of granularity or to the exact format that's required. We somehow need to be sure that we're not creating an impossible requirement in terms of transferring old data, maybe some exception of something like that because if we get to a just non-doable standard, then it will be just ignored, even though it's required. That's just a comment.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Yeah, I didn't want to pick up, hanks. I appreciate…I was trying to do my best to have a Rishelism. So, we should probably create that hashtag, right? The one thing on race and ethnicity, because there are a few points that have been just to touch on that real briefly, that's a product certification requirement only, the product needs to demonstrate that it can fully support that value set. The provider would then have the flexibility, working with his developer or what have you to choose whatever granularity that they want. Of if there's some other program requirement a state or whomever that wants to collect more additional detail, then at least the provider has the assurance that the product can have the support for all those detailed codes. But as far as our rule goes, we just say that this is what the product needs to minimally support. We don't make any distinction in terms of how the provider implements that or what the developer provides as a pick down list or some other thing.

Wes Rishel – Independent Consultant
I appreciate that, and that's an important distinction. Clearly one of the ways that certified interoperable products don't interoperate is by the various levels of implementation of the certified capabilities. And I pose that as just a conundrum, not…and I don't have a solution at hand today.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Yeah, so I mean at least for that one, the…and this is a specific instance where we may have addressed that, the product functionality also needs to be able to roll up to the top level OMB codes, and those would need to be transmitted at a consistent level, at least at that top-tier level, everybody's exchanging the same data.

Wes Rishel – Independent Consultant
Thanks.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…you know Steve, we are transmitting to Altarum with about a 20 minute delay, so we're actually creating the future in the past; just wanted to let you know.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yeah the guy with pitchforks and torches will be by later.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
The one other, you know, to Wes' point about the data collection, you know, surreal moments of life. I experience most of my healthcare vis-à-vis my kids and some of the data collection, as you noted Wes, is on the patient now. So when I go to the urgent care, I'm actually entering in the race and ethnicity and my smoking status and all those other things and I was like, I regulated that. So, a surreal moment, at times, turns the type of work; but I knew exactly where it was coming from, but that's another element where I think we're seeing how much of the data collection is at times, you know, at check-in or registration kiosk through some type of consumer-facing application that may not necessarily be on the provider anymore; they're meeting the data collection requirement.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Hi, can…yeah, sorry, I had to take myself off mute, can you hear me?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
We can, yes.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
I'll try to be brief, I know there are probably a lot of comments. So I had two very high level thoughts about what I heard this morning and what I've seen perusing the NPRM, the Cert NPRM. The first is to follow on to Arien's question, I was little surprised to hear I think it was Steve's response that a standard that ONC thought might be ready, wasn't quite sure, that they felt it was appropriate to put in the NPRM and get some feedback on it and that will help determine if it belongs in the final rule, which that concerns me a little bit.

The approach might be crudely summarized as run it up the flagpole and see who pukes. I think that an NPRM coming from a federal agency really should be that federal agency's…should reflect that federal agency's firm belief about what is appropriate to have in the final rule and, of course, the point is to, since nobody is perfect, to get input from a broader set of stakeholders and course correct. But it shouldn't be just, well, we think this might be ready, let's put it in there because that's how, at least in my opinion, that raises a very high risk of ending up with a reg that doesn't do what you want it to do.

And keep in mind that we're…that the Standards Committee is here to help you with that; so involving the Standards Committee at an earlier stage. I understand you may not be able to share drafts of NPRMs with us, that may not be kosher or legal, but if…you can come with specific questions, like is the HL7 Pedigree standard ready for primetime or has it and so on and so forth and the Standards Committee is here to help you with that. So, that's one bit of feedback.

The second is also kind of broad and a bit of a corollary and it has to do not with any individual proposed standard or criterion, it has to do with the totality of them. And I heard the figures that you mentioned about 45% of the criteria in the NPRM are…were already in a previous NPRM and to me, that doesn't sound like a lot. And I realize that it's not apples to apples, they're splitting and so on and so forth, and some criteria are easy to engineer technology around and some are difficult. But the idea that you'd have something on the order of 50% or greater of a reg that's new criteria is really concerning.

And the…there is a really strong current of opinion if you look at physician list serves and so on and so forth, that there is a certain, this is not how I would put it, but this is how people express it, tone deafness, on the part of policy makers about how much regulation is enough and in particular, how…what amount of certification criteria is enough. This is a concern to end-users, even though they're not the ones who would have to comply with the regulation, but it's because their vendors are…end up being hamstrung by the certification criteria and can't implement many of the new features, enhancements and so forth that their customers want because their entire R&D agenda is hijacked by the certification criteria.

So, I am interested for your thoughts on how do you know how much is enough? And when do you say, well geez, there are 20 things that are….we really would like certification criteria for, but you know, really only 15 might be appropriate for the reg. So I wanted to share my concern about that and invite you to respond.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

Sure, thanks. Well, and I think this chart is probably still up from slide 29. The criterion in the two left columns are criteria that I think arguably no one is going to disagree with necessarily, the privacy and security criteria being applicable to products and at least the quality management system as well as the other one that we've proposed that's new.

When you look into the certification criteria that are proposed to support the EHR Incentive Program and the base EHR definition, which is something that we've aligned with a statutory requirement; we've done that analysis and this is pretty close to the magic "P" word, parsimonious list of criteria that we can come up with to fulfill our statutory obligations and to support the EHR Incentive program.

And so to some degree, there's not necessarily any additional choices of getting rid of criteria that we can do with…absent other policy changes to say the EHR Incentive Program or the like. So, I think it's a

fair question and point, and it's a balance and a trade-off with the work that we do always to make sure that we're supportive of the industry.

The one other thing that we are working to do for developers vis-à-vis the kind of Kaizen lean work that we've already worked on in response to recommendations from our committees, as well as other work that we've done in terms of publishing the test procedures is, to do as much as we can now to take the guesswork out of developing systems for the final rule. And that's really a professional goal of ours with lessons learned in terms of past regulatory cycles that come final rule developers know what the need to do as soon as possible with as much guidance clarification as possible. And we're going need help from everyone around this table as well as in the developer community to get to that spot, but I'm confident that we can.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Sorry, John, can I just respond to that real quick?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh yes, and then Jodi has a friendly amendment, so please, go ahead with your response and then Jodi.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
So I wanted to gently push back on that and remind you that we're on your side, you know, the Standards Committee, we are here because we want the federal government's efforts in this area to be successful; so please keep in mind. The…but it sounds like what you just said is that there is nothing that could…there is nothing in the NPRM that could be removed without engendering a failure of ONC to fulfill its mission. And I just…I think there has to be some room. You don't necessarily need two different ways to record family history, how about start with one and maybe phase another in after a period of time. There has to be some…not everything here I think is do or die, I mean, if that were the case, then there wouldn't be a need for an NPRM other than to meet statutory requirements, right?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards a Technology – Office of the National Coordinator for Health Information Technology
So, and I guess I'll respond first and then let Jodi go. I didn't mean for you to interpret that there's nothing that we could do, your example on family health history is an appropriate one in that there is an or there, that's an example where we actually split the 2014 edition criterion into two criteria to allow for more flexibility for developers to choose a path in terms of continuing to pursue the SNOMED CT approach to recording family health history or to take the next step and also implement the HL7 Pedigree oriented approach.

So, that's…if that's an approach where yeah, we could get rid of the one that's (a)(15) listed there as family health history with Pedigree in a final rule, based on public comment and the like. There are other…all of the criteria in the available proposed column there could fall off the map if we were to get all the feedback and assessment of criteria that that's potential. But those are all trade-offs and assessments that we need to do when we go look at a final rule.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
Can you hear me? Okay, this is Jodi Daniel, I just wanted to add that particularly when you look at the right hand column but also throughout, the comment that we're just tossing things out to get feedback

and seeing if it's ripe I think is a bit of…is a bit inaccurate. For all of these things, everything that we've put in our regulation are based on stakeholder feedback that we heard about either standards or functionality that are ready or that are necessary for particular types of providers, particular settings, etcetera.

So we put things in our proposed rule, when we are getting some strong input support and where we're hearing some strong signals that some…a particular criteria is necessary and right for a national standard. And the…that said, we often…the reason we put it in a proposed rule is because we're looking for a broader stakeholder feedback; we may be basing that on more limited input, that's the whole point of a public comment period. So, you know, as Steve said, there is definitely flexibility when we move to the final rule on what we put forward and what we stick with in the final rule.

But everything that we've put in here is based on…is not just things that ONC pulled out of the air, but stuff that we have heard through our advi…through this committee, through the Policy Committee, through different listening sessions we've held, through different…the S&I Framework, for lots of different forums, through work with various stakeholders like the long-term post-acute care community or the behavioral health community as either critical, necessary or already in use.

And we do do evaluations, we have very in-depth and intense discussions about the policies and about whether something we believe is right to put in the proposed rule and to get broader feedback on. So, there is a very rigorous process in place that we do within ONC and across the Department. And I just want to stress that and this is sort of the last step in that process and it's the one where we're testing out to make sure that what we've heard really does make sense from a broader perspective.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Um hmm.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
And that's where the comment period fits in.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Thanks Jodi.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…Eric.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Very quick, just clarification, thank you Jodi, and Steven does that mean, maybe I misread the NPRM, does that mean as an EHR vendor I could get certified if I don't have the ability to create and incorporate family health history in accordance with the HL7 Pedigree, that it's an optional criterion for certification?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
That's…so, from a developer's persp…so this is a connection of the CMS rule and the ONC rule. The CMS certified EHR technology definition requires that providers have a product certified for family health

history to either the SNOMED CT version of family health history of the HL7 Pedigree. So as a developer, you have the choice of getting certified to one or the other…

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Okay, thank you.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
…and your customer...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Thank you, I didn't realize that.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…next is Cris Ross.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Thanks John. So, I hadn't…I just had a couple of things briefly. One was, I wasn't planning to say anything about this, except I wanted to say in response to Jodi's comment that everything in the rule has some sponsor for it; I totally get that and I'm sympathetic to your requirement.

I think there is a growing set of concern that we've reached the straw that breaks the camel's back problem and if there is a role for policy or standards to be able to help ONC differentiate between vital and nice to have, I think this is the time just because I don't think it's unknown to people around the room that our friends and colleagues are all saying enough. MU3 looks too big, we can't swallow it, help. And I don't know what technique would be most helpful to try and trim back to something that's achievable, but it feels like that's work that we need to be attentive to.

I have two real quick questions; one is, this is just maybe me being anal or interest in completion, but looking at the grid and the legend in the bottom left and I'm not sure what's meant by the items that are just plain black with a slightly gray background; you mark some of them are unchanged and some are minimally revised, but all those things in black look like they're longstanding. What should we infer by that?

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
I can take that. So those are the revised criteria…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
…and I think this is a perfect segue so that I can talk a little bit about…I know we've been hearing a lot of questions about why the criteria…looks more than 45% is a lot to us. So those are those ones that have been revised. And remember, we're starting, it's always been a building block, right, 2011 edition, 2014 edition, we look at that criteria again, what additional functionality…what standards have changed,

right? So a lot of it is keeping pace as well, right. So I just…those black ones are revised and I just want to point out some, just…and then they're in your slide, the deltas, but for instance like drug-drug, or excuse me, yeah, drug-drug, drug-allergy interaction checking and CDS.

CDS just has the Infobutton change and it's only…it already was in there, it's just saying…it's the newer implementation guide and then the newer implementation, or excuse me, newer version of Infobutton. And that's the same…and then the other thing that's been added, but it's asking the developer to document responses to interventions, and that's in both of those. And it's just they have to be able to do one, we're not…it's letting them innovate, but those are like the changes.

And then like CQM, the changes are just user-enabled features, so these are feedback we got from stakeholders that say, the developer hasn't let me, as a provider or user, be able to use these functionalities without going through some hoops. And so we've been clear about letting the user be able to enable these features.

I mean a few…and then the public health ones, as you can see, that's…if you look, that's a huge chunk is the public health, right? And they're looking for…and we've worked so closely with like CDC and then all their stakeholder groups, who've actually the ones that have contributed to the development of those standards. And those are the ones, there are what, about seven there I think, or even eight where those are all have either been revised or new and that's because it's all new standards to try to get to interoperability in a structured way of both recording and sending that information.

So, I mean I think we've focused, from an ONC perspective, on like the access as the ones we foc…ToC, data portability, API. But then like, in some respects we worked with those stakeholder groups on like the public health and they're experts in their subject matt…you know, their expertise and their stakeholders who have come to agreement on what they think the appropriate standard to be. And then the other ones, I would say we've looked at trying to improve the functionality for the provider, making sure that that…it's enabled and they can use that functionality.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
So I guess I think far be it from me to offer a critique to a presentation that's brilliantly designed visually, but not calling out the change but bolding and coloring the things that don't change, I'm not sure makes it clear enough to…just for what it's worth.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Yeah, fair critique, I mean it's tough to get everything on one piece of paper, one slide.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
No, it's a brilliant slide, I'd just change the bolding maybe in here.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
Okay.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Then the question I guess I wanted to ask a little bit more around is the intent related to the common clinical data set and the API piece on slide, I guess it's 19. I'm not sure I really understand what the

intent is behind number 3 when you talk about data; scope is limited to the data in CCDS per patient and "get" read oriented request. And I guess my question is, are you saying, I don't think you are, but are you saying that the API may only carry the CCDS data and everything else needs to go into a C-CDA? Or are you saying something different than that? And what is the intent?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Sure, so this is where it's important to think in the context of certification what a product needs to do, right? So let's keep in mind what the product needs to do. So from a scoping perspective, in order to hit the baseline, which is what certification is, we focused on the common clinical data set and we focused on read access demonstration to the application programming interface. So it's not to say that the API couldn't include write, but for the purpose of certification…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Got it.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
…all you've got to do is read.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Got it.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
And then for common clinical data set, we said everything that's in that…bundled in that phrase is…there are kind of two types of access; one is data element by data element or getting all…making a single request for all of that data in the common clinical data set, which would be where the C-CDA would fit in. So for the first one, that's where we would foresee, and as I think we said in the preamble of the rule, and I just like this phrase because it rhymes, we would allow for but not require FHIR as a way to do the data element by data element request, if someone were to choose to do that. But the scope and minimum data that would need to be supported to get certified is the data that's represented by the common clinical data set.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
And would the regulatory intent be, do you have a preference that if there are APIs that do add additional data sets, that that ought to be handled through the API as opposed to through a document based exchange or are you agnostic?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Not within the scope of certification.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Got it. And are…do you anticipate providing some guidance for what a receiver must do with optional data sent?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
So I think for the earlier point, the focus and scope of certification doesn't focus on the recipient Apps at all…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Okay.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
…in terms of their behavior.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Perfect. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So next I think we have Leslie on the phone then Arien and David and Arien, you had a follow up comment?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
I…follow up on something that was earlier, so I can wait.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, so Leslie, go ahead.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Sure, it's very much related back to the API question. So understanding this is that the APIs are really about certification for the access only and the…and I wonder how that will work in the consumer world; for instance in the patient-generated health data, the first use case that we talk about is advance directives, but we've had many listening sessions and testimony that went to the importance of patient-generated family history, patient-generated allergies and medications that they're actually taking.

And we…in the Consumer Workgroup we think that many of these new applications using APIs will come to us outside HIT. And so, if the certification is envisioned at the data holder only and by virtue of these now Apps allowing for receiving information as a data recipient, and now by virtue of functionality in that App have new things to share back into the record, like advance directives, medication history, comprehension and knowledge of education. They are now outside the domain of certification and HIPAA, but now wanting to contribute back into the record, where do you see the kinds of either certification or regulation that would help mitigate that zone?

And then…just to follow up on Dixie's comment, I also, for the consumer…the OAuth 2 or whatever authentication we need, it should be clarified. So could you first respond to the idea that data holder sends information that's certified to an App in the open API that is not, to then generate by virtue of its functionality patient-generated health data that needs to go back into the record; where do you see that playing out?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Sure, so I think there's, I guess, quite a bit of func…flexibility involved in how developers would choose to approach that. One could be building on top of what's required for certification with additional features, functionalities that wouldn't be within scope of certification in order to support that either through the API functionality or something else. And then the other is the patient health information capture certification criterion which is functionally specified in this case that a developer, depending on how forward-leaning they are, could implement that in a way that would address some of the points that you've raised, Leslie. But that's where we basically, I think similar to the API criterion itself, for the patient health information capture left that one intentionally broad to allow for people to meet that criterion in many different ways.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Okay, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Next, Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So, this is a follow-up to both my previous comments and Eric's question and comment that the Standards Committee and Policy Committee could well be useful in vetting and validating some of these activities early on. I'm very familiar with the ONC balancing act of kind of nodding and poking a little bit but not pushing so hard that people fall follow over. That's best done when there's a really clear chain of policy oriented, wants to happen in the real world mapping up to clear standards readiness. And I feel like in the cluster of standards that John previously mentioned, there's either not a clear chain of policy to activity.

So for example, in the HeD work there was originally in the Meaningful Use Workgroup a proposal to include incorporation of, you know, on-demand incorporation of checks in clinical quality measures which were then actually taken out in the final list of meaningful use recommendations. And yet HeD keeps getting…trying to get its way back. I feel like some…personally feel like somebody keeps pushing HeD back on the list and I don't believe that's appropriate when there's not a clear chain of policy to standard to certification.

In other areas, ONC hasn't actually asked the Standards Committee, but the Standards Committee has volunteered our opinion on subjects like provider directory, HPD Plus, as well as on DS4P when there were presentations on DS4P, the Standards Committee expressed a notion that we understand what the standard is, we have no idea, at least a number of us expressed the perspective, we have no idea how an EHR would actually implement the security requirements necessary to implement the standard.

So, as a meta-comment, I understand there are a lot of people who want stuff to get done and they think certification should be the lever. My request and observation is that gets done best when there's a clear chain of clear policy that wants to happen with clear public input on that policy that wants to happen. And then, clarity on standards readiness, and if you check both of those boxes, this stuff goes really, really quickly and you don't get the folks who were frankly complaining, and I think rightfully complaining about the readiness and scope and bulk of regulation. So, editorial comment, but I just wanted to make that very clear.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And I'll pile on, triggered by both Eric and Jodi's response to that. I think you gave us in this NPRM the right approach with the API, and I don't understand why you didn't extend that wisdom to these more complex and future-facing requirements. So in the API space you said, we don't think there's a standard quite ready, but we want you to meet this functional requirement and that will lead us to a standard that we can all rally around. And the vendors have responded to that clear directive with $300,000 of additional funding for HL7 to go figure out how to make this API work and aggressive and heavy engagement with lots of skin in the game by lots of vendors to figure out this very important new requirement; all appreciating that you didn't nail it down prematurely by specifying an immature standard.

But then you turned around in these future things, specified standards that are even less proven than FHIR. So why not make those functional requirements; if you believe that decision support as a service is a functional requirement, then state it as such as such, even using the use cases from the Health eDecision work; telegraph that that's your intent if it's mature enough in practice to eventually certify that. But hold us to a functional requirement to make sure we get it right. And I just…I mean, you gave us the answer, just extend it to these things in the future.

And then agree with Arien, if it is a functional requirement, there needs to be a clear reason as to why it's there and I won't repeat that thought. But it just seems like you answered the question with this approach around the API really well and I think the vendor community is reacting accordingly and it's going to go figure this out. Do the same with these future ones.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And Liz.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Just three comments; one is, I, like many others, we've already started a deep dive into these requirements in the industry and trying to assess where we are so I'm not necessarily ready, but we'll be back with additional comments for clarification primarily. I think the intent is appropriate; like Cris expressed earlier, we talked about earlier, the industry is very concerned about being able to get ready.

That concern, this is my second comment, is certainly was accelerated by the change in 2015. And I don't know how…when John and Jon we get to talk about that NPRM, but the fact that some of these requirements are now coming forward into the 2015 attestation criterion is of concern to us and it's particularly around public health, frankly. So at some point we just need an opportunity to discuss that with you, because we again, we thought that what was done around 2015 overall was very sound and gave us an opportunity to have more time to prepare for this in the future, which is very positive. But on the other hand, when we see some changes, for example, kind of as we're in motion for 2015, like public health reporting and we're already trying to collect data and you know, again, I don't want to go into the tactical component of it at this committee, but we want that opportunity to speak on it.

And then I would say looking at your table, and this is a strange question and maybe we're misreading it, but the industry has already decided that you have changed the requirement for diagnostic imaging. In the past, what we have used for the denominator is only radiology as in general radiology, because if you read the regs and the FAQs that followed, that's what it said. Here you say that it's not changed, but the industry has interpreted that Meaningful Use 3 is an expansion where you would include nuclear medicine and I'm not going into the details, but I need some clarification, as do many others. Did you intend to change it and expand that num…the denominator or help?

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
I'm not that familiar with the CMS changes; I'm sure that's what you're talking about as to what actually counts.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Correct.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
But it's a functionality certification criteria, the diagnostic imaging one so that hasn't changed. What would change from a certification perspective based on what you said to me is your certification to the automated like measure calculation criterion.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Right.

Michael Lipinski, JD – Senior Policy Analyst – Office of the National Coordinator for Health Information Technology
And that is…will be likely revised based on…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
The points you raise are, I think fair and of interest to you Liz, as we were talking in sitting down, but they're not necessarily within the scope of what ONC can respond to or from our certification rule. So if it comes…if it's related to changes to the EHR Incentive Program for the calendar 2015 year reporting, that's our colleagues at CMS. Similarly with anything to numerator denominators, it's also our colleagues at CMS.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
And I certainly understand that, so we all do Steve. I think where we get into the rug and we always will is that what you certify…what we certify for is what we also report against. And so for the David McCallie's of the world, it does matter. To you it matters, to John, to us who have proprietary applications because what we certify to does tie back. So somehow we have to tie that in a way that acknowledges the different jurisdictions, as you've said, but comes back to and again, you're right, I'm just trying to look for a place where we can get it out there, particularly if we can get any kind of certification. Because as in past years, we often used certification to guide us to interpretation of what

we attest to and what we build, frankly, right? He's shaking his head yes for those on the phone that can't see it.

So thank you. And again, gre…I mean I think again, I think the intent in the certification is very clear, we're just trying to get clarity where we need it because we're already on that path, as far away as this seems, it's not very far away at all for those of us who have to implement this in a very big way.

John Halamka, MD, MS – Chief Informatics Officer- Harvard Medical School/Beth Israel Deaconess Medical Center
Well I think the Standards Committee has been exhausted by this discussion.

M
…invigorated; I was going to say…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Looking around the room, I don't see any cards up and I believe all folks on the phone have had their comments given so let me just try to summarize. First, we applaud this remarkable presentation that you've made, your attempts to certify a 431 page, and it's double-spaced, rule in a couple of tables that make it very digestible, to show deltas rather than the absolute work ahead, so all of that I think everyone really thanks you for.

The caveats you've been given are, I reflect when I meet with all of my IT stakeholders, Jodi, and I ask them, what are your top priorities, they say, all of them. They're all valid priorities, there's no question that they're valid priorities and they're all important, it's just time, scope and resources are inexorably linked so it's not possible to do all of them. And so of course what we would say is, when we look at the collective burden in the delightful appendix from page 331 through 337, yes, I remember this stuff, that shows you the impact on the industry and you look at thousands and thousands of hours required, there are finite developer resources. There are finite opportunities. There is finite time.

It may very well be true that, you know David, Cerner may have 500 developers, I made that up, I have five, right. And so when you say, oh, well you don't need to do all 70,000 hours of work, you really only need to do 20,000 hours work, I have five guys and a bunch of coffee, right. I mean this is just alas, I'm going to have to give up, I can't do innovation, I can't self-build, it's just no longer possible because the overall scope is too big.

So I think the pushback you're hearing is, well maybe we can get around that by having functional criteria as opposed to prescriptive criteria that allows you to innovate in ways that are going to your policy goals, but maybe in ways that an individual institution can do it in something less than a thousand hours of whatever the individual criteria requires.

I think you also heard over and over that there are some standards for which we believe the future is bright, sunglass bright and others that we believe the future is dismal; that is, either they just have never been tried in the field or they're unlikely to succeed in the field so instantiate them in regulation is probably inappropriate. So I think the delicate balance here, over the comment period, is to try to figure out what scope is right and what standards are the Dixie Baker criteria for maturity, if not today, then soon enough that we can include them and what should be more functional rather than prescriptive.

And as was said, we're your friends here; we are here to help you. And if there is any way in which, as you go through this process we can help you provide objective analysis to say, ummm, fit's number 1 of the Dixie Baker criteria, but not two, three and four; we are here to please. So any other closing benediction Jon White?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Thank you for your comments.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Now Michelle, we are 10 minutes ahead of the schedule which is shocking and we do need to switch the agenda around a little bit because Jamie Ferguson needs to leave. So we have two choices; we can give everybody a bathroom break and come back in 15 minutes or we can have Jamie go now, because he promised he'd be quick; totally up to you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
I think if people want to take a quick break we can do that. I'm seeing a yes, so why don't we just do a 10 minute break, we'll come back at 11:30, we'll start with Jamie and the Content Standards group and then we still might get to Lisa and Dixie before lunch and then we might catch some time on the end so people with flights can make their flights.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
See you back in 10 minutes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
If everyone could take their seats, we're going to get started.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So Michelle, are we now transmitting in real time?

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

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, very good.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Do we have Jamie on the telephone?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Yup, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Okay Jamie, we're going to transition to you for the Semantic Standards Interoperability Roadmap comments.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Great, thank you very much. I did promise that this would be quick and I think the primary reason for that is that the recommendations were actually reviewed in the last committee meeting, we had a discussion on that and there are very few changes. And so I'm going to focus on just the changes and a little bit on the rationale for what we added and then see if there are any other areas for discussion. So if we can go on to the slide labeled, Common Themes 1 of 4, a couple more slides, I believe. There we go.

So you'll see on this slide we've added an additional focus area, number seven, on the unique device identifier. And so we do feel that the devices that are used for lab tests and has results are included in the patient's EHR, should be included. And this is for multiple purposes, so it really is for post-market surveillance, regulatory safety reporting and so forth. And I think that…so what we're talking about here is including in the patient's EHR, the UDI, remember this is for the roadmap, not for the current Certification Program, but that in the roadmap should have a view to inclusion in the EHR of the UDI of either any device that's implanted in the patient or used remotely to record data that's included in the EHR.

And so we think that including in the test result message actually and the storage in the EHR, the UDI of the device that did the test is an important roadmap component. But this couldn't be done until the UDI registry is relatively complete and so…and I think we're just close to the beta version of the registry, but there's quite a ways to go on this, so this is not at the current time ready for standards development. But I think it is important to have this in the roadmap. So that's one item that we included. We could go to the next slide, please.

And so here there are two changes that I wanted to highlight. The first one is in number 5 c), this is really a clarification of our discussion on this. We saw a need to support multiple models of data aggregation as a means to achieve the end goal of interoperability and so we wanted to clarify that, and so it's a very minor wording change on 5 c). And then we also added number 6 on here to include more of a view to device information generally in the roadmap because this really was an area that had been missing and we had talked about that, but it wasn't in our previous comments.

And so those are really the only changes that we have to our recommendations from what was presented last time. There are a couple of very…extremely minor copy editing changes, I think, but those are the only substantive changes since we presented this last time. And I'd be happy to take any discussion on these points or other parts of it.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
This is John and I just had one question for you as I ready through your presentation and that's the use of OWL and RDF. I've had a lot of experience in using those in production and have found them sometimes challenging in terms of scalability and supportability. And so, you know, we've had this discussion today in general about when is it appropriate to be prescriptive and not and so I was just curious about actually requiring those or laying those out as part of something we think should be mandatory?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well, okay. So remember again, this is not…these are comments on the roadmap not on the certification standards.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Right, right.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
So, we did talk about the use of RDF and mapping to RDF as really the best and perhaps the only way to achieve clarity of the semantics between the different model representations that exist out there. And I think probably many of you are familiar with the Yosemite Project, which I think was started by Josh Mandel that lays out a roadmap for using RDF graph mapping to compare the semantics of different models. But obviously there's a lot of work to do on that and so again, so this is not something that we're recommending as a certification standard in the near term, but we think it's something that's important to be mentioned in the long-term roadmap.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. So of course they are important concepts and so you would mention them in a roadmap, but it isn't your sense that these might find their way into mandatory requirements in certification.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well, not in the current NPRM because…remember, these are roadma…these are our comments on the roadmap, so we're switching gears from the certification discussion.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
No, I agree, it's just…I think as was said here earlier, when you mention something in a document it finds its way into suddenly regulation in the future and we of course just want to be sensitive of that.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
David McCallie.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yes, I would just echo John's concern about RDF as being promising but not yet demonstrated to practical value at large scale. The Internet community, sub-community of people that have worked on it have obviously been pushing it for years, but it has never really become a widespread approach. So, I think it's definitely worth investigation and study, but in terms of understanding the relationship…the semantic relationship amongst the various data standards, I'm guessing that something like CIMI as a model that could be linked to from existing exchange standards, may have more immediate promise for understanding the complex relationships of the various complex structures that we want to move around.

The CIMI work is accessible without understanding RDF may well be ISO semantic at some point in the future, but Jamie, I'm just curious if that was a trade-off that you considered or are you really looking at RDF as just the interchange for information models?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
I think we're looking to RDF as just the…essentially the mapping between the models to test for semantic equivalence, at least at this point. Because CIMI, and so…and by the way, so I'm on the CIMI Executive Committee and one of the founding members of CIMI. But frankly CIMI is sort of just another set of these models that need to be compared to others. And so if we look at the 13606 ISO family of standards which is currently under reversion, or if you look at the semantics, they're included in CDA or other representations, I think that…and so CIMI represents a set standards that can be compared, but how do you compare the semantics of that to the other models? And that's really what we think RDF can be used to test for.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Okay, I'll just call out that RDF is going to be very good at exposing the inconsistencies, but it doesn't help you address them. I mean, the granularity mismatch problem will be highlighted by the RDF and that's where it starts to fail because then you can't join across the mismatched granularities, so…

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well but that's…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…if the goal is to find the mistakes, sort of to find the mismatches, it's good at that, I agree.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
That's exactly right because otherwise the situation that I think we may be in on the current path is having a false sense of equivalents.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yes. I think that's a challenge and the unsolved problem of granularity mismatch whereby different clinicians need different granularity and we just can't figure out what to do about that, other than be aware of it, is…remains unaddressed and may be unaddressable.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
That's right. No, that's right and so RDF is not a comprehensive solution for that unless you map everything to it in the world.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Are there other comments on Jamie's presentation? Wow Jamie, I think you've dazzled them because people are quiet.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well, either that or they remember it from last time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well Jamie, I hope you have a peaceful afternoon and we will now move forward onto our regularly scheduled program, so let us go back to Dixie and Lisa Gallagher.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Okay. Thank you.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
That means I have to go. Okay, I think our slides are 508 compliant, but just in case. Okay, first we'd like to acknowledge the members of our workgroup who are very…we have a very active and engaged workgroup right now and we're very appreciative of their contributions. So, next slide.

We're just going over the questions that were asked us, the Transport & Security Workgroup about the roadmap. There was a question about ubiquitous secure network infrastructure in section F of the road…or E of the roadmap. Section F was ver…addressed verifiable identity and authentication. G was a question about consistent representation of permissions. And finally we addressed roadmap critical actions.

We also addressed encryption, which isn't here, but maybe…okay, the first question was, what should the federal government focus on first to move toward a uniform approach to enforcing cybersecurity in healthcare? And I would remind you that cybersecurity is not just HIPAA, cybersecurity is the full…is really protecting health information and systems, protecting data against unauthorized modification and destruction. Protecting information against unauthorized disclosure and protecting both services and data from interruption.

The…our recommendation was that the Transport & Security Standards Workgroup recommends that ONC partner with NIST and OCR and other federal agencies and industry stakeholders in several ways.

First ONC should work to advance a consistent trust framework across the health IT ecosystem. And I recall that when I last presented these to this group that David McCallie asked a question about whether this implied a uniform policy for all organizations. So to make that clear, we added that such a trust framework should allow for diversity in organizational policy while enabling foundational basis for mutual trust among the organizations.

Second, ONC should endorse a set of appropriate baseline security controls that are uniformly applied in health IT technologies that enter the ecosystem. One of the things that I think is strongest about HIPAA is that it is risk-based. So it says that every organization should perform a risk assessment and then determine for itself reasonable and appropriate security technologies and policy to implement to protect against the risk that it has identified.

But what's good about it is what's bad about it is that it's not prescriptive where a lot of organizations want more; they want more specifics to be given to them and so that's where this recommendation came from is that ONC should endorse this set of appropriate baseline security controls that everybody really needs to apply. Next slide.

The third is that ONC should work with industry to accommodate the diversity of emergency…emerging health IT technologies across the infrastructures within the health ecosystem. And the health IT infrastructure needs to be sufficiently flexible that it's able to permit any certified health IT solution to operate within this ecosystem safely.

Fourth, the ONC should provide guidance on proper governance in cybersecurity which is essential to building trust. And finally, the ONC should bring together federal, state and industry stakeholders to address the goal of reducing variation in cybersecurity enforcement. Okay, next…I think we're going to the next question.

Are there frameworks, methodologies, incentive programs that the healthcare industry has not so far, but should consider? And first there is a…when we briefed this before, we mentioned the NSTIC first and I think everybody got a…the wrong impression, they started thinking about credentialing, identity credentialing, but NSTIC is involved in more than just identity credentialing. One of the pilots that was jointly sponsored by NSTIC and NIST introduced the whole concept of a Trustmark framework where you put together a set of security protections into what they call a Trustmark.

And we wanted to encourage ONC to look at that Trustmark framework, and by the way, NIST is considering taking this Trustmark approach it's revision of its special publication 800-63. So, we thought that that would be a good framework to look at. Another one is the credit card…payment card industry PCI security standards and finally the ISO 27000 series. All are really good frameworks for establishing electronic trust.

Secondly, cybersecurity needs to be considered for both enterprises and for interconnections among enterprises. I think sometimes even when we think about EHR technology, too often we think of this as a single mainframe computer when in fact, even an EHR technology is frequently distributed. So, we really have to think about interconnections as part of systems, as well as just enterprises.

Third, the healthcare industry needs a minimum set of standards and metrics for measuring the strength of security protections. And we noted that there…they wouldn't…ONC wouldn't have to build this on their own, there are a number of these sets of minimum standards that could be…can be drawn from.

For example, OCR; we know OCR has a minimum set of standards for control areas that it uses when it goes out and reviews security in organizations. Also the CA/B Forum Baseline Requirements is a set of minimum stand…metrics that could be looked at.

And finally these insurance companies that offer cybersecurity insurance to healthcare organizations. If you've ever talked to one of these organizations, they have a set of minimum security requirements or standards that they expect all of their people that they sell their insurance…that they cover insurance to have in place. So there are sources for this minimum set of standards and metrics and we think it would be a good undertaking for ONC to put those kinds of metrics together and publish them. And finally the existing security control frameworks, such as NIST's cybersecurity framework, should be considered. Next slide, please.

Let's see, next question. Are there other gaps, aside from the lack of policies and guidance for implementing encryption, in technology and standards for encryption? Most of the recommendations we made around encryption had to do with key management. The effectiveness of encryption technology depends on several factors; the strength of the algorithm, the strength of the key, how the keys are managed and how the keys are protected and how the encryption is integrated into the system.

So it's not just…right now, our certification standard includes encryption standards to be u…encryption algorithms to be used, because it references the FIPS 140-2 Annex A, but it doesn't address key management or key length or any of these other factors I mentioned. So, we recommended that ONC work with OCR and other federal partners to address these issues.

First, to provide guidance on encryption key lifecycle management; I think any organization that distributes encryption keys knows that key management is a difficult and challenging and important process within an organization. Second, ONC should provide guidance on key escrow and key recovery. Third, ONC should publish guidance on key oversight and authorization addressing the people or entities that maintain access to the encryption keys.

And finally, ONC should also consider providing guidance on a minimum set of circumstances in which encryption should be used to secure data. Again, you know, HIPAA is risk-based and so it leaves it up to the organization to decide where encryption is needed. But, at least from our working group, is asking for more specifics on what do you think are the minimum circumstances where encryption should be used. Okay, next.

The next question had to do with identity and authentication of participants and the question was, here, legal requirements and cultural norms dictate that participants be known so that access to systems and data is appropriate? So next, let's go to the question they asked us. What ID proofing and authentication standards, policies and protocols can we borrow from other industries? Is healthcare that different from banking, social media or email? And I would remind everyone that identity proofing is the process of having an individual proving who they are before you get them an account on the system.

Authentication is measures to enable someone to prove that they are the person that the account was issued to when they log into the system or when they access resources. So our working group concluded that yes, healthcare is that different; it's not like banking and it's not like social media, although we take advantage of social media and banking. Although good cybersecurity best practices can be applied similarly, we need to acknowledge that healthcare information is different because it's highly sensitive,

both its confidentiality, it's sensitive from a privacy perspective and it's sensitive from a safety criticality perspective. So it has integrity sensitivity as well as confidentiality sensitivity. And, I wasn't finished…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Okay.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…and also there's a need in healthcare to access data and services sometimes in emergency circumstances. So in some cases in healthcare, it's necessary to break access controls in order…when safety takes precedence over privacy. So we would note that credit cards can be replaced and new email accounts can be generated, but deeply personal genetic or treatment information can't be replaced and it can't be recalled once its disclosed; some harm could be irreparable. So that said, yes, healthcare data are different; yes, healthcare services are different.

Many security protections are dependent upon user identity and for this reason, health information requires a high level of assurance in the process and mechanisms used for both identify proofing and authentication. For example, in fact when you look at most security protections, most security protections do…are directly dependent on correct user identity. Access controls depend on correct user identity. Audit depends on correct user identity. Encryption depends on correct user identity. So it is important; these are just so core to all the protections that we have in place.

ONC together with the Office of Civil Rights and other federal partners and industry stakeholders should continue to support the NSTIC Program and to draw from existing pilots, where applicable. And finally, the…ONC should support NIST's effort to update SP 800-63 and to help assure it's applicability to and utility of healthcare use cases. Special Publication 800-63 is…has to do with…it's the one that identifies the levels of assurance that you've heard us mention before here and to identity proofing and authentication. Did you want to add something?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Yeah, a couple of things I'd like to add. With regard to ONC supporting and understanding the work of NSTIC, one of the areas that NSTIC covers as a policy is the ability for an individual to have an anonymous or pseudo-anonymous identity and assert that and that's one of their principles. So one of the things we need to consider is whether that's something that will work in healthcare.

Secondly, with regard to NIST's update of 800-63 and the relationship to the Trustmark Program that NSTIC is piloting is that NIST is considering eliminating the levels of assurance for identity and going to a componentized trust methodology where the components are separated and then recombined, based on agreement between entities. And so that's the relationship there; again, a review and understanding of whether that will work for healthcare is really what we're recommending.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yes, this is Trustmark Program we mentioned earlier. Okay, next slide. ONC should provide guidance on the use of third-party identity proofing services including trusted Internet identities that are used by individuals. The NSTIC program is very dependent on the use of third-party identity proofing services and third-party issued credentials as well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
And so we had one of the healthcare pilots utilized third-party identity proofed credential from the Virginia DMV as part of the health identity. We need to understand whether that's going to work for us, it's sort of just below LOA3. Again, the theme here is, we need to consider whether these actions and these decisions are applicable and workable for healthcare going forward, and that's something NSTIC won't do, we need to do that.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Good. Let's see, such guidance should affirm that the use of third-party identity…Internet identities should be contingent on their use of high assurance methods to identity proof individuals consistent with evolving laws and regulatory requirement. Okay.

Let's see, the last question had to do with consistent representation of permissions including cons…informed consent, but not limited to; there are a number of areas where we ask for individual permissions as well as more formal informed consent. The question was, what standards should we put forward in the 2016 standards advisory for basic choice?

And the roadmap uses the term, basic choice, to refer to this whole spectrum of permissions and consent across the board. Today's standard for basic choice is a paper document that's hand signed by the patient and we appreciate ONC's recognition of the limited utility and scalability of this model in electronic exchange. I know that some people think of, when they think of electronic consent, they think of a PDF of this signed document that's emailed across organizations. And we do appreciate that ONC recognizes that we need to go beyond that kind of a PDF-type exchange.

So we share ONC's desire to identify open standards for electronically capturing permissions, representing permissions, exchanging and interpreting patient consent and patient choices. Full end-to-end electronic capture, representation, exchange and interpretation of patient consent is technologically possible and currently used in limited circumstances, such as Sharon Terry can certainly tell you how in the system that Genetic Alliance has built, that is exactly what's done. However, we don't know of any mature standards that are widely used to electronically capture or represent patient consent decisions.

There are various efforts underway, including work by OASIS and HL7 and ONC should continue to monitor these developments. There are also efforts even internationally to develop standards for electronically capturing consent.

Okay, this question is, how much work should ONC be doing on other standards while clarifying permitted uses? If standards development needs to be done, what should we be doing? They suggested, for example, DS4CDS, in addition for DS4P or something else. And our recommendation was, rather than commit resources to creating new standards; ONC should monitor and where appropriate, engage in existing efforts to capture consent electronically. And this includes the development of emerging consent…consumer consent technology. We recognize that electronic computable consent is valuable for the future of health IT. And I know that ONC already is involved in some of these efforts; our working group wanted to encourage that continued involvement.

ONC should also provide guidance that defines computable discrete data fields needed for negotiating patient consent and access to health information across organizations. Common semantics for discrete

data fields would further assist in determining whether the protected health information or personally identifiable information should be shared. And finally, ONC should consider…continue to monitor SAMHSA pilots and the application of DS4P, Data Segmentation for Privacy, for those of you who might not know that acronym, technology and derive lessons learned from those efforts.

Oh, this is when we looked…we also looked at the specific recommendations in the roadmap. One of the recommendations for critical actions; one was that ONC will coordinate with the Office of the Assistant Secretary for Preparedness and Response on priority issues related to cybersecurity for critical public health infrastructure. This is not healthcare from a HIPAA perspective; this is healthcare from a critical national infrastructure perspective.

One of the recommendations we had was that the term critical public health infrastructure should be replaced when critical health infrastructure because it's not just public health, it's also private health; it's the entire healthcare industry and its infrastructure.

In considering cybersecurity needs of the nation's healthcare infrastructure, availability and resiliency, data integrity and confidentiality should all be considered as part of the critical components for operational preparedness and response. It's…I think that the health care industry certainly seems to understand the importance of privacy, but security plays an equally important role in patient safety, with respect to the protection of data integrity and availability and the availability of critical services as well.

And then finally, in addressing issues related to preparedness and disaster recovery from cyberattacks, ONC should consider learning from and building upon the National Disaster Medical System, which is…works offline and has been tested in prior public health emergencies. That's…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Yeah, oops, two more.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
No, we have a couple more.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Three more, four more.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Okay, HHS will continue to support, promote and enhance the establishment of single health and cybersecurity Information Sharing and Analysis Center. Now the ISAC, Information Sharing and Analysis Center, that model was developed perhaps 15 years ago, some time ago, and the banking industry has used it for some time. It's basically a single infrastructure where people in the banking industry, people in the healthcare industry, can report cyberattacks or suspected events anonymously and also where they…a means by which response…recommended responses can be instantly distributed to multiple healthcare organizations. I know that probably 10 years ago, it had been proposed that the healthcare industry develop an ISAC, but I don't think it's ever really fully matured and now it's being brought to the forefront once again.

Our workgroup supports building a healthcare ISAC and for the out years, in the roadmap, ONC should provide guidance and reference implementations for enabling healthcare organizations to electronically consume the threat information to minimize the risk and impact of cyberattacks. This is a problem challenge that has come out of existing ISACs is that when they send out emails or some…information that cannot be electronically consumed, it sometimes delays organizations taking actions to prevent a potential attack. And so it's really important that as these ISACs send out information, that they be able to send it in some standardized way so that it can be electronically consumed, prioritized and routed appropriately so that actions can be timely.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
To be clear, there is an NHISAC and there are also multiple other sources of threat data. This is a challenge for the health industry one the ISAC currently has a member only model, as do some of the other threat-sharing organizations. So really what we're looking for is a single pipe of threat information that is actionable and consumable and computable, so to that end, that's the recommendation from the workgroup to HHS to continue towards that goal.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Thank you. This was just a recommendation to consider changing the timeline for the recommendation. The recommendation was the technology standards for basic choice that technology developers implement technical standards and implementation guidance for consistently capturing, communicating and processing individual choice of consents or permissions. And right now, it's in the roadmap that is for the 2018-2020 timeframe and our workgroup recommended that that be moved up to 2015-2017.

This recommendation, technology developers implement technical standards and implementation guidance, again, for capturing basic choice. And our recommendation was that due to advances in genomics, ONC should consider changing this from 2021-2024 to moving it up to 2018-2020 timeframe.

Excuse me. And then finally, the basic choice standards are used widely and electronic…to electronically capture individuals desire to have their health information included in research. And since this is happening already, we recommended that ONC should consider changing this timeframe from the 2021-2024 timeframe to the 2015-2018 timeframe.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
And this is the last one.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
And these are the reference…some references to some of the things that we cited in these recommendations.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you very much. Now I will point out that there is a very mature standard for capturing consent, the HL7 Version 2, Z-segment and for those of you of course who live in this world, that is the user definable, use it for whatever you want segment and that's what we use in Massachusetts quite successfully. It's unlike anything used anywhere else.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
And it's at least electronically unwrappable.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
That is true. We did actually do a fair amount of research on this, Wes and there is, I think you wrote it, a consent segment in HL7 Version 2 for things like surgical consent as opposed to consent to exchange information.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah for…yeah, that's…yeah.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And so we did not use that, we invented our own. So Jon White, since you put your card up, usually this is…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Early.

John Halamka, MD, MS – Chief informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…I mean, I think Arien beat you, but you, of course as the Chair, have prerogative.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
All right, all hail. Thank you. So delightful presentation, excellent presentation, very thoughtful recommendations, you know, well received. Thank you for all the work. Had…you know, as we're going through the list, many things are easily kind of actionable. There are several specific recommendations, I'll just pick on public key as an example, ONC should, ONC should, ONC should. Did you really mean ONC should or did you mean that ONC should perhaps coordinate with other people within the federal government that might be able to do that?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
I think our ONC staff advised us on the wording to use there, I was kidding.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Like, ah really?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
And it's kind of different for each one.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
It really is different, yeah, it's different for each one. In some cases it would be coordinating, but what we were…what we intended to recommend was that ONC take this action upon themselves to consider how to respond.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Okay, fair enough. So for example, if I want into Steve's office, look around OSD and say, hmm, where's my public key expert and it turns out I don't necessarily have one, you know, it would be helpful to us if there are organizations, other parts of the federal government, whatever, you did in a couple of the recommendations, but where you feel like there is other expertise that we could call on, we would value that advice as well. Thanks.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Certainly.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
And you do have, you do have encryption expert in ONC, by the way.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
No, I know, this is…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
This is an example.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…you know, kind of…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
This is very good and we appreciate his support.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yup.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well I think our order is, Arien then we have Leslie Kelly Hall, Wes and David. Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
All right, I have three questions. The first one's very simple which is, I think you pointed to the Trustmark framework and ISO 27000 and PCI, but you've got listed up there the NIST Cyber Framework and so I was surprised that you didn't include the NIST cyber framework in 800-53 and its family of standards as a…and FedRAMP, and the FedRAMP program as a framework methodology incentive program that healthcare should consider.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Well we did, we did, I don't…I can't tell you which slide, but the NIST Framework is cited, yes. Do you remember which slide that's on?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
I think…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, I don't think you…so this is more the first, ONC should consider including the, and my suggestion would be to add the NIST Cybersecurity Framework in the "including the" list. This is on slide 8, at least on the…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, NIST Cybersecurity Framework is on page 9 at the bottom…slide 9.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, so I guess my suggestion would be, include the NIST Cybersecurity Framework in the list of things that ONC should be considering or ONC or partners should be considering.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Oh, okay.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
I think we meant to, so if it's not on there, yeah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, we certainly meant to; yeah.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
More substantive to, number one is relating to identity assurance, you're focusing on individual identity assurance, individual identity assurance is important. I think one of the lessons we've had over the last few years is that organizational identity assurance is equally important if not more so and that many of the individual identity assurance issues are federated.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
I certainly agree with you.

Lisa Gallagher, BSEE, CISM, CPHIMS Vice President, Technology Solutions – Healthcare Information & Management Systems Society
And I think that's why we continue to recommend that you look at the one NSTIC pilot where they are addressing organizational identity assurance. Whether or not that's right, but we need to take a look and evaluate that.

Arien Malec – Vice President, Strategy & Product Marketing – RelayHealth Corporation
So maybe a suggestion for a friendly amendment would be to note that you're looking at organizational and individual.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Okay. Yes.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, yeah, yeah, yeah, yeah.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And the last one is maybe more involved, or maybe just as easy as the first two; with regard to computable consent. First editorial comment, I believe in this area we've had the policy folks saying "we need computable consent because they can't define what consent means and what authorizations are actually required. The standards folk came up, a container that can represent anything and they say, look, I've got a container that can represent anything and then the policy folks say, look, the standards are there.

And I would recommend that in these discussions with regard to, for example, basic choice which ONC defines as effectively individual acknowledgment of the HIPAA permitted uses as well as with regard to collection of data for research purposes and other kinds of uses that what's required here isn't so much before we have a standard, we need clear policy to standardize. In the CommonWell work that we did, we created a definition of HIPPA permitted treatment for competent adult for non-sensitive data. And we created, effectively, an identifier for that and then a framework by which patients could indicate that they had accepted that this network be used for those purposes.

I'm not saying that's the only thing to use, I'm just saying that to the extent that you can define what we you're consenting to or what you're acknowledging is going on makes the computability trivial, to the extent that you've got a compute anything, you're going to get an empty bag that you could fill in with something and then at some point you go back to the problem of, what do I fill that empty bag with.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
I completely agree. Thank you.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yes.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Was that easy?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Arien, I had actually solved that problem by creating the consent assertion markup language, CAML. It goes with HIPAA.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
No CAML to the CHPL.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, we now have Leslie Kelly Hall.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Hi, thanks. I have a comment and a question. First of all, the…I have a little bit of an alternate view on the standards importance here. I think that privacy and security issues have swirled around and been a crutch in the prevention and barrier for patients involved in health IT forever. And an opportunity that standards can bring is a key to unlock a door and then that door have policies available to…meet that need is...could be a different paradigm for us than the one that Arien just mentioned.

Another comment is, the…I think you touched on this, that the most exciting thing I saw at HIMSS was actually some work in the interoperability showcase that Debbie Bucci from ONC and Mike Smith from the VA presented on computable consent and data segmentation for privacy using the new open API standards, and I would encourage people to look at that. It's quite liberating for patients. My question is about the identity assurance for patients and if you, in your recommendations, considered patients and their family members as just another stakeholder with the same level of assurance and identity mapping, regardless of functionality or if you saw that as something entirely different in your recommendation?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yes. The patient needs…also needs to be both identified as well as authenticated, just like any other user. And I think you're talking about Mike Davis' interoperability showcase demo, which I've seen in previous years, so yeah, we're aware of that work as well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
So actually we do…

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Are you making any recommendations with regard to level of assurance for patients with use cases or functionality in mind? Or are you assuming that any participant in the ecosystem is operating at that same level of assurance?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
We're not recommending levels of assurance at all, that's policy, but the methodologies that are used to identify patients…any person is the same regardless of what their role might be, you know, and how strongly that level of assurance of their identity proofing is a policy decision. In fact, the Tiger Team took that up about a year ago, about the identity proofing for patients who were accessing a portal.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Right. I mean Leslie, this continues to come up when we work on technical and standards related work and we're trying to be clear that if there is a recommendation around whether patients should have to do two-factor authentication…that's really something on the policy side and this is really how we think we can implement identity proofed credentials and multi-factor authentication.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yes, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I think, just one more follow up, I think that that is the correct answer, but I think we need to do some briefing to the policy side of the house so that they know what if…what these things mean and what kinds of policies would revolve around them. Thank you.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Thank you.

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

Wes Rishel – Independent Consultant
I want to start by pounding the table about what Leslie just said. If there is an outcome that sounds implicit in part of this presentation, it was that this possibility that someone is going to put into regulation that every patient has to go to the post office to get identified in order to be able to use the personal health record. And I don't think either of you intend that; but the frustration comes from the tendency of security experts to say, "that's policy." And as a result, and technically that's a correct statement because the security technology is about ways to implement policy. And unfortunately, when the technology enables the implementation of fairly complex policies, it's difficult for anyone who's not a security expert to interpret what's being presented.

When the question about, and you get it down to an issue that a person can understand who is not a security expert, the answer is, that's policy. And I think, we of all, Dixie I think and I started on this committee back when the Dead Sea was just sick, and we have all learned a lot about communicating across different areas of…and I think somehow that's an area we still need to cross with regards to

security. So enough said, I was glad that Leslie Kelly Hall came before me, because I knew what she was going to say before, at the very start of this presentation and I prefer having…I was glad to have the opportunity to pound the table rather than just start from scratch.

I would like to extend Arien's observation that the Standards Committee will create an empty container and say the problem is solved. The other thing the Standards Committee will do is populate that container with a very extensive ontology and say the problem's solved without any consideration about the workflow and the cultural issues associated with working with patients about their consent.

And in fact I recall a presentation to this committee about the consent engine a few years ago, where when pressed on that issue, the presenter said, well, obviously we need a new…define a new job category in providers which is a privacy counselor, okay. And I think that as you take recommendations into account with regards to communicating privacy consent, you follow the same guidance you have authorized in terms of looking for graded adoption and feedback and the ability to change the model along the way. I think that's absolutely critical. And again, I don't criticize you as individuals, whenever you present something, you edit a large number of thoughts down to what you can present and I'm just suggesting more emphasis on that, recognizing that we have to deal with this continuous issue about not being able to…implications of the technology because of the policy issues that go along.

Finally, you recommend considerable reliance on NIST publications and I just want to relate a personal experience I had a few years ago when I was Gartner. The issue of encrypting data storage on portable devices came to the forefront through HIPAA…HIPAA experiences and a client called and said well, that's fine, will this particular Windows feature take care of that? And with the guidance of Gartner security nabobs, I went through the NIST publications and it finally got down to, there are two publications, you need to know the answer from both publications in order to answer the question.

And I couldn't figure out how to get that answer, so I called one of the staffers at ONC and they said, boy, that's a good question. And they finally got an answer that showed me where in NIST publication I needed in order to answer the question in that publication. And it…I found it took three different discussions with NIST in order to answer the question. Well, that's very much the kind of problem we've had with standards forever, it's nothing new. But it does emphasize a responsibility that kind of goes outside of NIST, which is creating the forum for interpreting NIST standards and answering those questions.

To the extent that you argue that healthcare is different, for example you say, need a different ISAC, then I think we have an obligation to make that resource available.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
And with respect to encryption, we did recommend that ONC take a look at this issue and issue guidance and that's probably one of the reasons or part of the reason.

Wes Rishel – Independent Consultant
Yeah, I'm really, as my participation in this comes to a close, I'm really thinking about the meta-issue of how do we make the communication between the security world and the business world more productive and trying to emphasize that in my discussion today?

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
I agree, I think we agree.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
David and then Andy.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I've had the privilege or duty, depending on how I feel, to serve on both the technology side and the policy side of some of these debates and I've discovered that when I go to the technology meeting I take my rubberstamp that says, that's a policy problem. And when I go to the policy meetings, I take my rubberstamp it says that's a technology problem. So we play ping pong, I think as we've all enumerated here.

And I'm wondering if maybe an approach that we should be thinking about that might be slightly different is if we recognize that there are going to be data sharing…multiple data sharing networks, and the JASON Task Force sense of arrangements where people get together and figure out how to share data, that we should assume that the more complex aspects of consent policy, as well as consent technology and security policy and security technology should be mostly handled inside those data sharing networks, because they have particular kinds of constructs and relationships to their users.

But at the same time, we could get better progress on a floor that everybody has to satisfy, sort of a minimum necessary and then if you want to go further in your data sharing network and be say more fine-grained in your consent management like say that Sharon Terry's work has done, that's fine. But you have to meet this kind of floor. If you want to have a less granular control, like say eHealth Exchange or CommonWell where it's focused on direct treatment, HIPAA exemption minus the SAMSHA restrictions and it's more operationally concerned with just being efficient, that would be fine but you still have to meet the floor.

And so maybe this isn't so much a question but just a thought is that what we ought to try to do is identify what those floor concerns are that would be fair enough for everybody to adhere to, even though you wouldn't be constrained from going further and offering more fine-grained or complex or powerful concerns and controls in your own data sharing network.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
That's generally how it's done, you know. For example, Sharon and I both are involved in this Global Alliance for Genomics and Health, which is every country which you talk about differences in policy, these are dramatic differences in policy and yet the Regulatory and Ethics Workgroup of that organization has developed exactly what you're saying; here's our floor that everybody has already agreed upon. And if you can do that at an international level, we certainly should be able to do this in healthcare across organizations that here's our floor, here's what we can assume about each other about how we will protect data. So I totally agree, that's exactly how we should go.

With respect to the policy versus technology, I wanted to clarify because I know there's a sensitivity about this. But as you'll recall, and I think Wes will recall as well, in the case of identity proofing of individual patients, the Privacy & Security Tiger Team spent considerable effort developing policy

around that. So that's what I was referring to is the policy that's already been developed. So our workgroup, especially in that area; it exists, it's out there…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
We're not going to redo it.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…we're not going to redo it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, I agree. On the technology side, your recommendation, for example, to get better guidance around key management policies and procedures, I mean, some of those come with considerable cost, right? Certification costs, infrastructure costs to implement appropriate key management that may differentiate current networks from each other. Some networks may say, we want to incur that cost; other networks may say, we don't. That to me seems to be the kind of thing that really ought to be answered at the floor level so that you don't have an expensive network arguing with a less expensive network, we'll we're expensive because you have to do this key management…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…and the other network saying, no you don't. I mean, those barriers to interoperability should go away, or at least be minimized if we could get agreement on some of these kind of must have, level playing field. If you want to add value, add services and charge more for them or incur more cost, whether you charge or not, you should be free to do so, but not to drop below the floor…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, but ONC can provide guidance…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
But…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…and I think that's a confus…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…on how to do key management so that it doesn't cost…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right, right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…you know, because you certainly can do…I do key management, you know, you can do it on the cheap and you can do it on the expensive and ONC needs to provide the kind of guidance that allows any organization to do the right things with…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
That's exactly what…that's exactly what we intended.

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

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So thank you, always interesting to listen to the work; I have two remarks. One is, yes healthcare is different; I've certainly said that to a full generation or more of CIOs who came to my organization from financial services. However, it still fits inside the larger social and technical context which is changing in regard to all of this. And in the not very distant future, which is to say, you know, next week, people will be in possession of devices that have biom…sort of biometrically certified who they are. And we'll start getting very used to waving them in front of RFID things that give them permission to do all kinds of stuff, like take every cent out of their bank account and charge things that are worth $10,000 at various luxury stores.

So, the point is, if somebody has certified who they are in a really important way, whether it's at Wes' post office or it's at their bank or some other way, is there a context in which all, of this fits that says, if you did that once someplace, and you're using appropriate tools, can we accept that…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right, right.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
…even though we haven't done it at our institution and we will never do it at our institution and so you can take your phone and stick it in front of our detector and that's good enough.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
That's right, that's our recommendation.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
That's…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Okay, because I didn't underst…I didn't get it, I don't know if I really…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…need to clarify, that's…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
And that's where the NSTIC Framework is about, using this ubiquitous multifactor, multi-level of assurance identity. And that framework is being developed, the question is, what are the requirements, limitations, restrictions or whatever for…that are special to the health sector. And those are the things that we need to continue to work on. You know, some examples are pseudo-anonymous, anonymous identity; can a patient…is it okay if patients present a different identity to different providers because they want to. Questions like that that are, no one else cares except for maybe in healthcare; those are the kinds of things we need to look at.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Trusting Swiss banks…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
But the infrastructure…right. But the infrastructure for this type of engagement is what NSTIC is and I personally believe that if we don't start looking at it, we're going to have our patients walking in with the phone saying, here's my…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
This is me.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
…form of identity, here's my form of payment, please update my PHR, I'm going to leave my phone here and I'll be back.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
No, I'm just going to wave my phone in front of your detector.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Right, wave the phone and there you are. And so we are trying to anticipate that and we're trying to…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Okay.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
…work all…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Because I didn't get that from…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
We have…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
What we have today, accept third-party identities; that means if you go get an identity at your bank, you should…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Okay.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…be able to go to your…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Right.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So I thought you were just talking about the context of healthcare because you started out by saying healthcare's different.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Well, there may be…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
We should make it…we'll make it clearer, because that's exactly what we were trying to say.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
…some special requirements or limitations; we don't know yet. I mean, in that way it is a…we have to consider whether we do have those. I think also, Andy, we've briefed some of the NSTIC concepts before and we were sort of giving our information here in that context...

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, that's true.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
…and maybe we shouldn't have. I mean, we could have been a little bit more elaborate on how we explained it, but what you said is exactly what we mean.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Okay, thanks, I have no other comment then.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Okay, no problem. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well with that, I know Michelle you actually want an approval and I recognize that for Jamie's comments we did not seek approval. But so let's just…are there any objections to forwarding these, with sounds like there are a few wordsmithing amendments you might make, as recommendations to ONC? Well, and while we're feeling positive right before lunch, on Jamie's comments, which I neglected to ask for your approval, was there any comment there?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Well again, there was some clarification…

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

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…requested for Jamie's comments and I think subject to…again, subject both of those to this clarification.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, so I think Michelle, we have endorsement with the clarifications.

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

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And, public comment?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Well, we're going to prolong lunch one more minute. Steve has a comment that he forgot to make or I forgot to remind him to make earlier.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Yeah, it's more of a public service announcement before public comment, right? So one thing to put on the Standards Committee's radar as we look to the numerous things that you've been contributing to, so you have the Interoperability Standards Advisory and that…for 2015 and the comment period for that expires May 1 at which point…so that's a public service announcement for everybody. There are a number of questions in that at which point our thinking and hope was that there'd be a task force, surprise, surprise, formed to take on the Standards Committee's own perspective and representation in

terms of response to the Advisory, as well as the distillation of the public comment. So, see timing wise, as of May 1, the ONC team will go ahead and distill and summarize the public comments that we receive and then looking for a task force on the Standards Advisory to commence it's actions beginning in June, after you get through kind of the rule related comments. And meet between June, July, say August potentially with a presentation to the Standards Committee at which point we would then take the bolus of you all's recommendations out for public comment again.

So there's a three-month period of time, now is just to get that back on your radar that this is coming up and to, I think, get in touch with Michelle if at the committee level you're interested in participating in the workgroup and/or chairing that task force for this time-limited period of time. And/or anyone on your workgroups, if you're a workgroup Chair, that you'd recommend we consider for the task force as well, that would also be appreciated. And I think that's about it in terms of time to go forward and expectations of the committee.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Just one more, for those in the public that would like to sign up to be a member, there is always the FACA application which accepts rolling applicants, so if there are people in the public that would like to join, they can apply through there as well. Okay, with that, we'll open for public comment. If there's anyone in the room with a public comment, please come up to the table; you are limited to 3 minutes for comment. And while we transition, if Alan can open the lines?

Public Comment

Alan Merritt – Interactive Specialist - Altarum Institute
If you'd like to make a comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
It looks like we have no public comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So Michelle, with regard to the schedule, do we want to give them until 1:30 and…

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

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And so the intent is that we are going to catch up a little bit of time after lunch and hopefully get people out early, because this meeting was extended until 4, and I recognize there are flights; so we will see you at 1:30. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
If everyone could take their seats, we're going to get started. Thank you. All right, well welcome back from lunch everyone. I think we're ready to get started. I think we have Rich on the phone; Rich are you there?

Richard Elmore – President, Strategic Initiatives – Allscripts
Hi, Michelle.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Rich. Hey Julie and…please sit.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So Michelle, next meeting, gavel, gavel. She who must be obeyed. Well Andy and Rich, please take it away.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Andy and Rich, please take over. So thank you very much, I'm hoping this goes as smoothly as Jamie's presentation did, meaning just to remind you all, these are the comments of the Content Standards Workgroup not on the NPRM, but on the roadmap. So, this is what's the future direction and what did we think about the nature of the future direction? So, if I can have the next slide please; is there a clicker around here or do I get to…ah, got it. Thank you.

Just…this is our notorious group, Kim is here in the room and we've had a lot of interaction actually with the Semantic Standards Workgroup as well, so, there was a lot of very intense participation, lots and lots of engagement and people being very, very helpful. We made sure to put some overarching questions to the group, as we went and reconsidered our section of the roadmap and they were these. We wanted to be sure that they had the chance to answer a very general question, is this the right direction, not just this particular set, but is this the right direction? Are there gaps that are present here? Is the timing of the actions appropriate? And are the right actors or stakeholders associated with some of the critical actions embodied in this section of the roadmap we were talking about. And just to remind everybody, we were talking about section J, consistent data format and semantics.

So, some key concepts; and again, there's not really a lot of difference between, just as there wasn't for Jamie's Semantic Standards Workgroup, between this and what you saw in our preliminary reporting. We believe there is a need for consistency in data formats and semantics. Second point I think is one that we might call out and think about as the Standards Committee as to how we would help promote ensuring, if we can, that the standards development organizations work together, collaborate with each other about what issues to attack and the timing of the release of standards.

We wanted to plead for an improvement in the consistency in the implementation of the consolidated CDA, with some guidance constraints, additional guidance constraints. The standards should be extended to promote exchange across the care continuum, we're hoping this will gladden the heart of John Derr and folks like him, because there is a continuum and the standards haven't embraced the full

continuum of care. And if we were the UK, we would be talking about social services and educational services as part of the continuum of care. And as a pediatrician, I embrace that so, these standards need to be engaged across the continuum as they can and into the other areas that we've all been talking about devices, sensors, environmental and other data and so on.

We believe there should be agreement on a core standardized common clinical data set and that that data set should or could be extensible over time and should be consistently shared during any care transition. We'd like to see agreement on the use cases that each of the standard vocabularies support. And we believe that information should be exchanged in more granular form that FHIR might promote. And finally, a comment that many of the initiatives that were listed in the section we looked at including FHIR, CIMI and DAF. And we think that there should be a limitation to these three.

We also spent a lot of time arguing and embracing the idea of focus. And you can see here some of the things that we were focused on ourselves. I would draw your attention to the fourth bullet, which is to say that this committee and ONC should use all its available influence to pursue and encourage aligned adoption of specific standards. So we've made some choices about standards, but are they in wide use? Not really, and so to the extent that they actually are important, we should use our leverage and energy to get them adopted.

And then to paraphrase the Zen Koan or other things that one can do with only one hand, we're arguing for greater specifically in the standards. How would these particular standards support some prioritized use cases as interoperability is enhanced? And hope that the standards can be refined over time, but that really key structural change to the standards be limited or constrained. And I'll move on to the next slide.

We think we need to know where we're going, what is the definition of a learning health system really? What is it that the target end state is? What are the constraints in this arena of policy and privacy and security constraints? Well, we talked a lot about APIs earlier in the day. The group believed that by themselves APIs will not open up clinical systems for learning; other things need to be done. And that we spent a lot of time talking about use cases and think that it's extremely important to select a few high-priority, high-return use cases to work on first. And that this may disappoint wide swaths of the clinical research and public health communities because they may find that the things they think are important are not on this short high-priority list at first.

And I'll digress by saying I think we need perhaps to turn around to these communities if they find that and suggest that they somehow focus on the art of the possible rather than the perfect and learn what's in the standards and what's in the data models of the existing electronic health record systems that are already deployed and see if they can get 80% or 90% of what they need from what exists rather than turfing out to the user community more and more requirements for measures that are unique to their needs. So that's my piece of editorial discussion.

Finally we believe that there are gaps that are important, but they're not the standards really, they're in the attention of policymakers to deliver clinical data from whatever the source of that data is to the end users. So, we want to refocus policy attention on that particular issue.

This is something we've shown you before, but we wanted to make sure that two concepts weren't conflated, and I think you've seen this so I don't want to re-emphasize it. We have a lot of detailed comments on the roadmap and they're here if anybody wants to look at them. They are in your

handouts, but I don't see any need to go into them now. Rich, I'm going to put your placard up so that you now get to make a statement, there you go, if you wish.

Richard Elmore – President, Strategic Initiatives – Allscripts
What Andy said, I'm good. Thank you very much, Andy.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Perfect, it's the first time and probably the last time that's ever going to happen to me. All right, so questions or comments from the other members of the committee?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Jon White has a comment.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
So, as I said with the previous presentation, thank you. As ONCs leader on the Precision Medicine Initiative, let me assure you this is getting rapidly gaining attention of policymakers, not just within ONC and HHS, but across the administration, so, the thoughts are well put. And Rich has the best comment of the day. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Other…ah, Wes.

Wes Rishel – Independent Consultant
I think Arien was first, but…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Your card is at a…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
On an angle, sorry, there we go.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, Arien, please.

Arien Malec – Vice President Strategy & Product Marketing- RelayHealth Corporation
So to…so first of all, just want to double down on endorsing Andy's comment on suggesting that the research community and public health community focus on the art of the possible and the art of the already there.

I've got a question relating to what I see are three, two overlapping and one potentially divergent workgroup comment on Consolidated CDA Version 2, where I think the…your group, which was actually turfed for content standards, endorsed that Consolidated CDA simplification has occurred between

release 1, 1.1, and 2.0. The Semantics Standards Workgroup made a comment that designated Consolidated CDA 2.0 is premature and I believe Liz and Chris have similarly suggested that Consolidated CDA has made some simplifications. So I'm wondering, this may be more appropriate when we comment on the NPRM itself, but I'm wondering whether there's a process by which we can actually, and I know that the Implementation Workgroup did some of this, can get a more consensus-oriented approach on whether Consolidated CDA 2.0, it may be both and, it may be is both an improvement over 1.1, but it doesn't solve the real world problems that we've seen in 1.1. I don't know if you have a perspective on how to answer that question.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So…what we talked about was better implementation guidance…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yup.

Andrew M. Wiesenthal, MD, SM- Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
…and maybe that's the sweet spot between what the two positions that you just…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That may actually be right on that in the testing, I'm not sure what we're testing against and it may be more of a call for implementation guidance of Consolidated CDA 2.0 where we need to provide better specificity.

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

Wes Rishel – Independent Consultant
Thanks. Andy you had a slide which you've shown before expressing a concern about the conflation of format and structure with…well, maybe I should ask it. What is the conflation that you're addressing there?

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Well, allow me to say first of all that as a colorblind person, I have a tough time reading this slide from this distance. But basically, we're worried that, let me just get it on paper so I can make sure I'm saying the right thing, that there is a difference between the format of a piece of content and the semantics of the things in the format. And that we wanted to separate those two out so that we focused on the semantic standards for the content of the content format, if you will…

Wes Rishel – Independent Consultant
And I would like to simultaneously, violently agree and violently disagree…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Okay.

Wes Rishel – Independent Consultant
…with you.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So holding two opposing concepts in your mind at one time is not a problem for you, that's good.

Wes Rishel – Independent Consultant
No. At the gross level I think that's an extremely important conflation to avoid. At the fine level of structure, however, you can't represent the same concepts necessarily interchangeably in a structure. And I think that we need to sort of simultaneously recognize that we should not be letting the structure drive our notion of what the content is or our way to conceptualizing the concept. But also notice that when we really have identified the atoms and molecules of information that we will need…we may need adjustments in the structure in order to deal with it.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Well I think…I thought you were going to say something along the lines of what Noam Chomsky would say about the structure of the form actually is content? But we'll take that conversation offline.

Wes Rishel – Independent Consultant
I haven't finished my Red Bull yet.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Okay.

M
(Indiscernible)

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
It's the only way to go…only way to go after lunch, people are tired and….a lot of blood drift down to the gut and stuff.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So I'll drag it back to the very practical and tactical from the philosophical…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Thank you.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…and that is, I think the challenge for the industry in the next couple of years is frankly to figure out whether we can use FHIR to solve these problems. I mean, it is both telegraphed in our NPRM that that's the intent in the long run for the API standard; in the near term, numerous vendors are aggressively investing in FHIR to address these standards. And for better or for worse, FHIR has taken an approach that says, we'll come up with a core structure that's called a resource, and we'll have as many of them as we need to define the domains of interest and up to 100, I think now; started with 50, up to about 100. And then for those resources we will identify the suggested vocabularies that fits in the slots and then for the rest of it, we will figure out how to combine these resources together to communicate more complex ideas. And you can do all of that in a profile without necessarily having a deeper, more complex information model.

And the profile itself becomes an implied information model; so two people who are agreeing to interchange using a common profile with FHIR have essentially solved the semantic interoperability problem to the best practical degree that's possible with the technologies that we have today. And I think our challenge to the industry is to make that work, because we've got a shot at it. I mean, this is the first time we've had a bottom-up approach that's actually tractable to solve these problems. And it doesn't solve the broader theoretical semantic computability problem, but I don't know that we need to solve that or that we are going to in the next half decade? So, I think we have a candidate to address your concerns here and we really ought to rally around and try to make it work.

Richard Elmore – President, Strategic Initiatives – Allscripts
David this is Rich Elmore. I think what the workgroup concluded was that we need both a short-term tactical program to improve and bring to national scale the work that's already been done with Consolidated CDA and Direct; that that's our shortest path to having some measure of interoperability that's going to work nationally, across all settings…EHR-related settings of care. And beyond that, the workgroup was very supportive of FHIR as being able to play a significant role in the way in which you described. But we didn't see that, because of the maturity level today, of being able to fit into the timeframe really required by patients and also by macro the SGR affects.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah Rich, thank you for that. And I should qualify that I'm fully in agreement that we need the CDA to get to release 2 and to have that become a usable tool. That's a model of refinement rather than changing any fundamentals. The opportunity with FHIR is we have…it's not baked in…it's not set in concrete yet so we can, in fact, go out and fix it if it's missing something.

So my call to arms if you would, is to go work really hard on making that work without trying to do too much. So, for example, some of Jamie's concerns in the previous presentation around proving the RDF that we are talking about the same semantics in any particular message is a worthy goal, but we don't need to solve that problem to start sending really important messages back and forth. So I'm just urging us not to get hung up on the perfect being enemy of the next good enough.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Yeah, I think we're all in violent agreement. On my run this morning I tried to think a little bit and I was thinking what would have happened if Tim Berners-Lee had reported to a committee? Would we even have, you know, hypertext transfer protocol and anything that he had created?

M
(Indiscernible)

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standard Development (SNOMED)
You know, it's horrifying, isn't it? So thank you.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Sounds like a call for somebody to create the RDF and SNOMED composition of colorless green ideas sleep furiously. That's a Noam Chomsky joke, okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
God we're getting deep. Leslie, take us back to reality.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
What did you all eat for lunch?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I'm not sure it's real…that it's reality, I just would like to know if there is any discussion or comments about how a patient vocabulary or patient synonym based vocabulary to an existing vocabulary, like SNOMED was discussed in this group or how, as we advance the patient's integration, we advance both a process as well as a vocabulary that enhances integration rather than further disintermediates patients.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So it wasn't discussed Leslie…this is Andy answering the question, but putting on a different hat, because I'm about to go off next week, or on Saturday, to the IHTSDO Board meeting, KP donated the conversion medical terminology to the National Library of Medicine and to the IHTSDO through the NLM, that includes patient-friendly terms that have been vetted and tested with patient focus groups. So…and they are attached one-to-one to SNOMED concepts.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Was there further discussion about how this could be enhanced as we go forward…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
I don't know how much enhancement it requires, I think people actually need to look at it and use it first and then they can decide what's missing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Okay.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
But certainly it's been in use in Kaiser for more than a decade.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Okay, thank you very much Andy.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
You're welcome.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments? Okay, well I think each of these presentations is incredibly non-controversial and Michelle, we're going to be breaking early, right when the rainstorm hits, I think. So again, as I've asked for previous approvals, are there any objections to forwarding these recommendations to ONC as written?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
With some of the comments…right…some wordsmithing or not.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay…any suggested language for that?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
Well I agreed with David's point to the practicality of the short-term.

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

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
And so I'd like to see that Incorporated to some degree.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. So Andy, just to the notion that you take into account some of the recommendations about the short-term wins versus the long-term strategy.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
It may be clarification to what Andy's got, I mean, I don't think it was substantial…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Sorry, sorry.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
…to directional change.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Well with no other amendments offered, Michelle, you have that approval. So next we go to the Interoperability Roadmap comments of the Implementation, Certification and Testing Workgroup.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Do you want to start?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I think I'm going to start and then Liz is going to improve on whatever I say and go forward. I want to start first by noting our committee. There may be other workgroups that have smarter and much better looking Chair people, not speaking of course about my esteemed beautiful Co-Chair, but we have the hardest working and the smartest team. And these folks worked incredibly heard. I think the workgroups oftentimes don't get the credit and the recognition they…but we have some real experts in that group who put in an awful lot of time, and I want to make sure we note them.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Yeah, I think the other person that we'd like to note is Brett and he's sitting right over there and he has been instrumental in us being able to get together our comments and keeping us organized and so, also thank you to you, Brett, for all of your hard work.

Brett Andriesen – Project Officer Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
Absolutely.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
So our comments, I think, we have kept in mind two issues, one of which is the actual essence of what is required for certification and testing activities so that they move smoothly? The second sort of meta-category is, how much is enough and how much is too much? So we're trying to keep a lookout for where are implementation issues going to be problematic, simply because of the load of too much activity.

I'm going to skip to our recommendations, some of which I think are well aligned with what we heard this morning from Steve and Mike around the 2015 edition. Recommendation number one was about the presence of testing tools to be used for precertification testing, provided with adequate lead time. We heard from vendors, who were represented on the workgroup, who indicated that this was problematic for them, that they needed two things; one of which was tools in advance and second, that they needed to be relevant for the work ahead.

A parallel observation with that is that it was not clear to us that the combination of vendors and SDOs are appropriately resourced or are incented to create these kinds of tools for certification requirements, except for the ones that they're working on today. So unless it is focused on getting certified today to get a product to market and keep it in market, may not be developed on a timely enough basis. So we had some musings about are there ways in which some kind of funding could be located across the industry in a collaborative way to support development and maintenance of those tools? And we'll talk about some additional context in the next one.

We've talked about C-CDA simplification; there are number of specific comments that are attached to this report. Again we have some folks on the workgroup who have been very close to this work in detail and gave us a bunch of practical recommendations. I think we would note that the CCDS and API work that are recommended in the 2015 certification and Meaningful Use 3 may, in fact, supersede some of this, but I think we also had some recognition that there are cases in which a data service via API is appropriate and there are some other instances where a document-centric view is appropriate. And I think that viewpoint is represented in places like HL7 as their generating standards.

Then we had two recommendations that related to essentially post-certification testing. So, as you'll in the sub-bullet, we used the example of HIPAA X12 experience around post-certification testing. Many of you have had some involvement in that in the past when we moved to claims management, eligibility management, circa 12 years ago as the first wave of HIPAA requirements was put in place. There was a robust set of X12 base tools that vendors and participants could use to continue to manage their conformance as the definitions changed, as vocabulary improved and so on.

The emphasis here would be on testing on a voluntary conformance basis, rather than something that's mandatory or compliance driven. There was a lot of concern, especially from the vendor representatives on the workgroup of, don't make us continue to certify for certification sake. Instead, this gets to the asynchronous bidirectional issues that Wes has raised for us many times before.

And then a little bit of concern about the phrase, "regular use of testing tools," what exactly does that mean; again, not testing for testing sake, but testing for outcomes. Those are our comments on I1, Liz is going to comment on I2.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation

So for those of you who are joining us on the phone, we're now going to slide 7, of course slide 6 just re-emphasizes what our tour at hand was; so further comments, building on what Cris has begun as a foundation is, we'd like to see the concept of deeming be put in place. And, thank you, the concept being there is that in many instances we already are u…the vendors are already using applications that have been deemed and certified, but we're having to ask them to recertify again during this process, which seems non-productive to us. So we would like to see that happen in a real way, and obviously Surescripts and Cris can certainly speak to that one, is a very good example of one that is subject to this today.

I think we need to really look for…and the next comment really has probably more to do with, and so we forgive…you'll have to forgive us, we were talking earlier at lunch about this next comment; probably really belongs to CMS rather than ONC, but it's here and our group thought it was important so we're bringing it forward. And that is, when you tie the certifications to Medicare reimbursement or conditions of participation, it creates many, many problems for the providers and frankly the vendors are not in a position to be held to that kind of accountability. So we want to be careful, and again, we will make sure this gets routed in the right direction, recognizing, particularly given our comments this morning, probably belongs with CMS.

I think we've said this from the day…the very first day almost that we met; we need mature standards. When we use, particularly as we go toward a single stage of Meaningful Use, a final stage of Meaningful Use, whatever that may mean in context, we want to be sure that we somehow come up with a balance between developed standards and our ability to innovate. So again, leeway and innovation are going to

have to take a role in this, but where you call out very specifically for a standard that's not well developed and then we feel very much drawn into that very closed box and the vendors feel that we are closing out our opportunities very quickly.

And then I think on the…and Cris talked about this a little bit, was rather than setting criteria that's specific to a setting, it might be more appropriate just to look at all settings or other settings and try to make it, I suspect the word generic will make people crazy but, I think we need to keep in consideration that there are many settings in which we use Meaningful Use in which we provide care, right? And which the vendors support us, but we need to be careful about how we use test data to do that. And you know John, wherever you are, certainly has been one of our strongest advocates for recognizing that long-term care is part of what we do. And yet to ask a vendor to test for an acute care setting product with long care setting kind of criteria makes little to no sense. So, we just need to be pragmatic in our process there.

Moving on to slide 8, we want to complement and continue to support the Kaizen meetings that have been going on. Those, I feel…we feel confident that you've gotten some very positive feedback, we certainly have heard it in the industry. The fact that you're going out and getting end-users and persons that are using this both from the vendor setting as well as in the provider setting, is going to enhance our ability to be more productive and appropriate in the future. So we would encourage you strongly to continue to do that; it's very, very well received and we think very productive.

We…Cris and I both have the battle scars from scenario-based testing; it's something that we believe in and we know a lot of people on this committee really believe in. But it is very, very difficult to do; it is very time-consuming so we're going to suggest to you, and Cris you may want to build on this, but we don't want to give this up. We really do think that by doing scenario-based testing you're going to get better product in the end.

But we may need to build in the time and certainly involve providers and hospitals to really document their workflows so that we can test against real workflows not against our proposed workflows. We really need to understand how the EHR responds in that setting because we assume, all of us assume a great deal about how EHRs work in various settings and then we discover how they actually work when we implement them. And we can only take…the vendors can only take this so far, yet it's critical to really using this for the intent for which we got here, which was, we would take the power of an EHR and improve care. So, we're all back to that same place, it's just really critical that we go and then really figure out, what are the big things that matter? What are the key elements that really have to work right to be effective? I don't know if you want to build on that?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Well, we took a look at clinical scenario-based testing as a part of Meaningful Use Stage 2. And Liz will remember it, Wes will remember our work through that and the intent was to accomplish two things; one was clinical reality and the second was to develop some preset components that could make testing go more quickly, specifically data sets that could be moved from test case to test case. And I think we had laid out something like two dozen scenarios that were relevant in an inpatient outpatient setting on a large granular scale.

And we slugged our way through I think three and then the work was abandoned, which may or may not have been a good idea. But if we were to do this work again, it would require some commitment of resources and some real clinical knowledge, to make sure that we're testing against realistic kinds of

things. In some ways the certification bodies have lessened this problem, but we believe there's still an opportunity for ONC to convene some work to advance this.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I'm going to continue on because I know there will be comments that will be wanted to be made. This is a real dichotomy that we ran into and that is, we really think there needs to be a place to take problems post-implementation with products. And yet our vendors, and understandably, felt like the expansion that was going to be required for post-implementation surveillance and testing was onerous. So somehow we have got to make some recommendations or help ONC make the right decisions around how do you ensure that when we discover a real issue that we have a place to go with it and something to do, so that we can ensure we're moving forward without overburdening the vendor community.

It's a tough problem, but it's real and there is no question that regardless of the amount of diligence that we use between now and when we get to the next stage, or any stage, there are going to be problems that occur that we did not anticipate and we rely on FAQs, we rely on all kinds of guidance, but we don't necessarily have a way to go back on the product side of it and it's very important.

We're always going to ask for a consideration of the amount of time that it takes to develop. We've been round and round on this one, as you guys know. We face an issue of the ability to get a final rule in place, to get the building done that takes that to test and then to certifies; then to implement and then any time post implementation to actually ensure that it's working in a safe and efficient manner. And we're, again, up against that timeline.

So we're always going to bring it back and say, we very much appreciate the fact that given the latest developments that there has been a clear understanding given to longer periods of time between potential final rule and actual implementation, and that's very positive. But their timelines are still short and we can never let that off our plate because, at the end of the day, if the EHRs that we are putting in place are not safe, and we're not providing the kind of care that we anticipated, we're not achieving the goals that we all have in mind. So it's really, really critical.

I think that, it's interesting, one of the suggestions was that we conduct a thorough environment to ensure that the requirements are not outpacing our vendor's capabilities. We haven't talked about it in a little while, ICD-10; I don't think any of us have forgotten about it. But we have, ICD-10 upon us and frankly, a number of us are going through a process of changing out vendors and doing work around changing out vendors, but a lot of our specificity and requirements have not changed.

And so we are, as we call it where I come from, we're watching the train go down the track as we're trying to jump on the car. And that hasn't changed, it's not going to change, so we're…the implementation group has strived, and will always strive to be the consciousness in the voice of the people. And we're telling you as the voice of the people, and we are the people, as are me or you, this is tough guys and we need to really pay attention to the environment and what can it withstand?

And then finally moving to slide 9, we really need to be really clear about what is it that you have to do to need recertification. Because one of the things that we go through, and Cris and I both have experienced real life experiences in the relative near past where a vendor makes a change in a product, recertifies, so that's good, but in the meantime we're back at the ranch without the new version and

they've recertified and updated the CHPL, all appropriate actions guys, but did they really need to recertify, was it substantial enough for recertification? Was it a functionality change or an MU change?

I mean…and we won't go into the minute details of that, but I think you can understand, the vendors want to know, the providers want to know, when do you have to retest? And not talking about, we always test after implementation, I'm talking about a product retest and a recertification. And then we're always going to bring back, always better to do more right, I mean, less right, excuse me than more and just bigger, always going to tell you that. And use leverage-proven test cases for certification so that we can be sure that what we get on the…as an end product is effective. And Cris, I'll turn it back to you for further comment.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
What Liz said.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Arien?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well we have Arien and then Wes.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So first of all, this is a fabulous presentation. I think two comments; number one, just want to double down and this is relative to our earlier discussion on the overall NPRM, but double down on the notion that doing less really well with adequate timelines is going to mean that the level of provider dissatisfaction that gets expressed in multiple settings, sometimes is not because of the Meaningful Use Program itself, but because of the timelines under which we have rushed to implement and the pain that we've experienced in that rush to implement.

Wanted to ask about testing tools; my observation is that in areas such as Consolidated CDA, we have done testing to standards conformance, but not always testing to end-to-end clinical correctness. And I wonder whether that's the intent of your comment is that we should be able to go from a patient with an allergy…a medication allergy but no environmental allergies, to a Consolidated CDA that looks like this? Or a patient that has a mix of active and inactive meds and a Consolidated CDA that looks like this? So, I didn't see that, but I thought it was implied in the comments.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
No, I think it's a great comment and I am sure…usability and applicability in the true clinical setting is sort of where we touch on the scenarios, but I think your point being extracted from there, Arien, is exactly right, because it is critical and we're not accomplishing it consistently.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And then as a potential idea just thrown out there for comment is that if the testing tools were user enablable, if…Liz, if you could use it in Tenet, you know in a Tenet facility to self-test your EHR in the same way that the EHR developer uses it, boy, wouldn't that solve a bunch of problems? Because we've

seen in practice that a certified EHR in the field is not capable of some of the functions for which they have been certified and…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
You're absolutely right.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…there may be improper configuration, it may be all kinds of things, but nobody can test it prior to going…interoperability.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
No we…unfortunately, despite all the testing that we do, I know everybody does, we often learn things in production, meaning we're live, which is not where we want to learn them, but…and then of course we are ready, set, go to immediately start either pulling code back or doing whatever is necessary to protect; not ideal. You're right.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
So I would strongly agree. I was with a payer organization during the X12 certification days and I don't know what the clearinghouses worked on, I'm sure they did important work, but the amount of volume between trading partners in those days was enormous and I think we have had the experience as providers, maybe I'll speak a little bit from my organization, but I think we've seen it elsewhere. I don't think our clinicians really knew what they were getting into when they started receiving C-CDAs.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
No.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
And if we had started running that through some test frames and people had had a chance to say, my goodness, is this what I can expect? We might have had a chance to do some of the conformance work before we were in heavy duty production. Because I don't think it was ideal.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Yup.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…capture, which is, I think we've all experienced the reality of such things as organization to organizational transition of care summaries; it may very well be that the product passed the test, but then the reality of implementation seems to be a bit different.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Right. And there's maybe a theme here that we've sort of circled around and I don't think we've really landed on it fully which was the idea of, how do you really do clinical reality certification? It's embedded in here in various places, but is anyone really keeping their eye out for the fact of, is this good medicine?

You know, it's sort of embarrassing to say it, but I think that's an artifact of where we've been and in large part because of the speed at which we've been attempting to move.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
I think this is true. So one of the things that we've had to do is do ACO advanced payment model kind of things and we've had to create warehouses that are based on C-CDA data extraction. And now we have to go back and look at end-to-end integrity between what was entered by the clinician, what ended up in the warehouse and what we're discovering is all kinds of mapping problems. And a lot of that had nothing to do with intent, it was haste; you know, just short timeframes.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
That's right, and I think also…this is Liz; I think we also have expanded beyond the C-CDA because we're not asking anybody to add to it so don't, folks from ONC, I'm not asking for that. I am telling you though that in order to make it relevant information for those who are receiving it, and we've been…we've heard lots of information from our specialists, who the information that we're sending over is not what they need. So we send over the information that's required and then we send over more. It is what it is; I think everybody's doing it.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…discovering things that the workflow of delivering to a patient a summary as they walk out the door means that you don't have the note and you don't have the labs, you're giving them a summary that says you were the doctor today. Really, oh my God, is that how I spent the last hour?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
But you checked the box.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Really.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So this is all things that as we as society develop and we find we're close, have the luxury of time, we'll figure this out.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
We will.

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

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
I was intrigued by your comment about, and by the way, excellent presentation. And I was intri…and it certainly was thought provoking about how reality in testing line up. You had a comment about exploring a potential of deeming rather than certification. What's the difference between, in your mind, between deeming and attestation?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
That's a good question.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I think it was, in this context, it was maybe the difference between vendor certification and provider attestation.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Provider…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
So this is like vendor attestation.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yes.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Yes.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Okay.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yes, so a vendor gets their certificate from Surescripts or a lab organization…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Does the same thing, in other words, it's just…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
…or public health and they…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
But I think the…that's a good caveat that Cris just brought up though because in the early days, what we discovered about certification was that vendors were not demonstrating, they were simply saying they did it.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right, right.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
And so we reacted strongly to the fact that there should be something that is more than just, I did it. And so what we were suggesting was that where you were already certified with someone else that you would provide that as part of your information to the accrediting body. And then therefore isn't just a checkbox, it's truly a certification-like, I'm certified for Surescripts, therefore I can show you that certification, not just check the box.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Which is similar to what…something that David has proposed a number of times about certifying within the community, for the capability within the community…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Exactly, Exactly.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Just to offer friendly amendments on both those suggestions. I think it's totally feasible technically to say that anything that is a certification test that essentially is a message or data that passes back and forth in and out of your institutions, there ought to be a test bed server out there…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Yeah.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…that at any point in time, you could send to, which would validate that it passes the test. And ideally, it would decompose it, recompose it correctly, send it back and you'd have to verify that you could decompose it correctly. And if you could do that roundtrip, then we could eliminate most of these problems, or at least find out where they are. And that ought to just be out there. I fiddle around with telephone stuff and set up VoIP servers and routers and just have fun with it. And when you all get it configured, there's a service out there that will call you, you know, and validate that in fact it works.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Works, right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And it's, you know, you can call it and it'll take your message, record it and then it'll call you back. And you never know that you've got your system configured until you do that test at the end. And we ought to have that for Direct messages, for XDM embedded Direct messages, for C-CDA, query and generate and receive. I don't know who runs it, but it ought be somebody.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
So that's the issue that gets to the, where will the test frame be and how do we fund it and all that. And if we're observing the advance of the API world, it sure seems like I don't want to put too much weight on it but, and I don't know the duration of it, but Argonaut has been a very effective vehicle for doing definition of what the content could be around FHIR. Is there a similar kind of consortia that would

continue that work, exactly along the lines that David's talking about, something in the neutral center. It feels to us as though there are a lot of opportunities for industry players, in some way, to fulfill that role and I think as long as there was a sufficiently neutral party, I think from a policy and a kind of industry consensus standpoint, we ought to cheer for the emergence of such a thing.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
And the value proposition should be pretty straightforward if you can actually could count it towards…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Absolutely.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…point out that DirectTrust does a lot of direct certification testing that's far more extensive than the…direct testing that's far more extensive than certification. I'd much rather go through the DirectTrust process than go through the ONC certification body process. But I have to go through one, don't have to go through the other until later on. It would be great if I could get, as you say deemed, for being certified by going through DirectTrust.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
So if I can present my certificates that have been issued to me via DirectTrust when I go to a certification body or I do my attestation as a provider, hurray; and behind DirectTrust is EHNAC and some pretty industrial strength capability. It sure feels like, you know, if we can sort of step away from the formalism of the regulatory world, I get it, but it's a little bit of a call to action here of how can we as like-minded smart enough, good willed folk find a way to make this happen; shame on us if we don't.

Forgive me for getting on my soapbox, but it feels like there's a sense in which we have to step away from ONC and CMS have this duty around statutory and regulatory authority and an amount of formalism that's required. I don't think we're limited to that so, I think we're hearing it every time we meet around, gosh, wouldn't it be great if and it would be a mistake if we didn't represent that strong feeling from the workgroup.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Well and if we don't, like Cris just it with this group and with every group that we meet with, call…it's a call to action and it's everybody's job, it's not just to talk about it and do nothing.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…call the group's attention to the cover story of Modern Healthcare's HIT Strategy newsletter that just came out two minutes ago saying all the senders are very happy with C-CDA and all the recipients are miserable. And the mismatch between what we send versus what we need is very significant and there are some really great interviews so, worth reading.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Only John Halamka gives you news that happened two minutes ago, right; constantly plugged in. So just in response to that excellent discussion and exchange, I just want to say, you know, we…HHS has been…supportive of Argonauts. We would love to be supportive of additional initiatives. As I said with my previous comments, please also tell us how we can trust you but verify because we're going…we do have ultimate culpability, right, to the American public. We love working with you guys, but that's who…ultimately who we work for so, thanks.

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

Wes Rishel – Independent Consultant
I just want to say Jon, that…

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
(Indiscernible)

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, you can both make comments, but Wes has the floor at the moment. Wes is not Les.

Wes Rishel – Independent Consultant
Yeah, I just want to say, every time there's an upgrade to the security protocols for the Internet, it must be painful to you to have a chip in your brain updated to get the two-minute news?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…headache for…

Wes Rishel – Independent Consultant
The… since I put my card up, this discussion has come a little bit back towards what I would call reality. A couple of points; one certification is a regulatory requirement which imposes costs on the regulated. And we have…ONC has clearly, over the years made decisions to limit that impact at the cost of less than the most thorough certification. And I wouldn't have made the decisions any different, I might have managed expectations differently with regards to certification. And I don't think they did a bad job of that even, it's just that expectations have a way to grow.

We will not find the solution to the problem we're looking for in a government program. We won't find it in a vendor-funded program unless the vendors have such an economic stake in what's being tested that they're willing to overcome a) to put funds out and b) to overcome short-term needs for this. And we will never get universal vendor concurrence or even user concurrence on what should be tested because whether you're talking about a vendor or whether you're talking about an org…a healthcare delivery organization, there is a range of capabilities in that organization and no organization is going to argue for something they can't do.

So if we are going to find…if we're going to actually answer this call to action, we are going to need to find a, and I can't even come up with a good acronym here, we need to find a semi-official, semi-czar some way of calling shots for the industry that are backed up by the resources in order to actually be able to test or certify, with some assistance and policy guidance from government. But it's just not practical that it comes out of the government or that it comes out of a universal laying on the hands of all the vendors holding hands together around the circle. So, it's a tough problem, but boy do we need a solution.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Wes, I wouldn't want to add anything to your comment except to say, we talked about that within the workgroup and sort of likely candidates were raised and, you know, SDOs were raised…but SDOs don't…aren't in this business for example. We're missing a key player in this part of the industry which is a sixth of our economy. It's rather remarkable.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Leslie Kelly Hall.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So aren't we looking at some sort of equivalency process? Could the government be prescriptive in saying, here's how we determine equivalency, but then say, if you've met that, we have a deeming process. So is there a way that we can have process-based equivalency without having to get into the details and mandate a testing, so that's one question. And I think this gap is sort of like the…it's almost like the joint commission for data standards, and I wonder if there is a possibility to fill the void in a new way.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
You know, I think, Leslie this is Liz, I think there's no question that we need to be inventive in our way of looking at it, and I guess I get the, forgive me, hebejebes when say the joint commission of deeming, you know, I don't know how everybody else feels about that…

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
That was tongue in cheek, sorry.

Elizabeth Johnson, MS, FHIMSS, CHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I understand. I think your concept is exactly right…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I love the joint commission…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Oh and Cris, of course, loves the joint commission. But anyway, we all love the joint commission, Cris, it's our job to…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
We sure do. All day long.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
…it's our job to love the joint commission all day long. Anyway, I think your point is very well taken and I think that the concept, just as Cris has started and built on what Wes has said, we've got to figure out how to do this and it's our job, and I think Jon, you said it; it's our job to pay attention to this and come forward with an idea not just simply to continue to acknowledge that we've got a…if people buy the deeming concept, and we think they do, we do; then we ought to be coming forward with, and how could we take that idea and actually make it an executable kind of a concept. And I think that's where you're going, Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yes, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Arien do you have another…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
One more nuance I think to Wes' and to Leslie's comment. I don't see this deeming concept as being a substitute, an uber substitute for all of certification; rather I would see it that data sharing networks who have themselves strict certification and testing criteria and strict oversight to some well-defined standard, could then deem.

So the two examples I think we've heard are for ePrescribing there's already adequate and ample certification testing for directed exchange. There's already adequate and ample certification testing. If we had the appropriate policy framework, it would be easy to allow people to go to one of those networks, get their cert…you know, get their mark and come back to the certifying body and exchange that for a certification. I think that's the concept that we're looking for and to Wes' comment, it's not a laying on hands of the vendors, it's actually an organization that's held to some level of strict standards.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Right and then we figure out the logistics for when I go to CHPL or Cris or whomever goes and does the actual check-off, it would be there because, you know, that part of it needs to happen. It's just that it wouldn't be a testing procedure that took place at one of the accrediting bodies.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
But just to be clear, too, totally agree. There are two concepts, right, one is deeming and the second is the idea of this ongoing test frame. I think those are entirely separate and could happen in different venues. We need to keep our eye on the ball, on both balls, excuse me.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And…to your point, I do 4000 transactions a day with the CDC, but I also spend 17 hours with a testing body telling them that I can exchange public health transactions. So, huh? I trust the CDC, I mean, they give me…

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I love the CDC, too.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
But they're not as good as the joint commission.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
That's right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well, with that, do…as with previous presentations, we need to approve these recommendations be forwarded to ONC. Do we have any objections or amendments? Okay.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Ah, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well Michelle, you had scheduled us for 2:30 break, but we have one small presentation left and then we're done for the day, I think. So, it's up to you, what do you want to do?

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

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

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
A substantive…

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Lots of work went into this.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
A meaningful presentation.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, I didn't imply anything about quality, of course. Should we go forward and finish up?

M
Yes.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. I said small only because it's information richness.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Highly dense. We've ascribed to the notions of parsimony, so we say a lot in a few words.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Or we'll say a lot of words in a small amount of time, how's that? Okay, so I'm going to lead off and then Arien's going to follow and we'll probably ping back and forth. We had the benefit of starting our work in the API Workgroup slightly before the roadmap came out and we started working on what we called a framework for rethinking the approach to interfacing standards and the use of APIs to facilitate a broader repertoire of capabilities than the bespoke interface approaches of the past. So we were well on our way towards thinking through this roadma…through this framework when the roadmap came out. And when we went through the questions of the roadmap we discovered that almost all of the questions could be answered with short, see framework footnote.

So most of our work is in fact pointing back to our framework, but that led us to realize that we really needed to formalize what was in the framework. So with Arien taking the lead and with all of the workgroup members contributing heavy edits, we have actually produced a transmittal letter which captures the recommendations for our framework in thinking about the APIs. And I believe we'd like to…Michelle, you can help me with this, get approval at this meeting of the transmittal letter.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yes, so you'll actually need two approvals; one on the transmittal and one for the comments on the roadmap.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Okay, so what we're going to do is, I'm going to walk us quickly through the core ideas that are captured in the transmittal. You have the document, but you probably won't have read it but I can walk you through what it says, the meat of it. And then Arien's going to walk us through the specific framework recommendations and then we can either do two votes or one vote…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And just to level set, the intent of the written transmittal is the first part is effectively the…covers the narrative we did at the last meeting and the second part is actually word identical in terms of the

recommendations. So we haven't altered it from a recommendations perspective, we've just written up all of the words that we spoke last time in 10 pages.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Ten really concise pages.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Dense pages. So, first slide please. Okay, so at first a little bit of backdrop. As we were preparing the framework transmittal letter, and I circulated it to our colleagues for their feedback and edits, one of the members of the workgroup commented that it seemed a little preachy...thank you. And I thought to myself, at first I was sort of hurt by that and then I thought no, in fact it is a little preachy because we are, in fact preaching what we think is a really important set of concepts that do need to be attended to with a sense of urgency, because they really can change the way we think about things. So, all preachiness apologized for in advance.

What we started with was a fairly thorough review of a number of successful large scale systems where APIs and core services led to the success and obviously the Internet is the ER example of that. So we reviewed sort of the notion of what makes the Internet work and this concept that was elucidated early on in the discussions around the Internet I've called the narrow waist of the hourglass. And it's a metaphorical way of stressing that what makes the Internet work is that there's tight agreement on a few small core things, in particular the Internet Protocol, IP, that then branches out and allows progressive diversity and heterogeneity as you get further away from the core. But the stuff at the top, where there's a lot of diversity is always layered over things underneath it that have less diversity and that's layered over things that get back to the core, which has essentially no diversity.

So the trick in healthcare was to come up with an equivalent layering that we felt could capture the things that need to make healthcare interoperability more scalable in a way that the Internet has proven scalable. So this is our healthcare or health IT hourglass proposal. And you can see at the core we've just kind of rolled up the notion of the Internet, so those things that are reusable from the principles that make the Internet work are our starting points. And that's a big deal because healthcare standards have not always started with that as their principles.

And then on top of that there's a layer that we call the core composables. These are the building blocks that we expect to be reused over and over again to achieve higher level functions. And I'll drill into the details of that in a second but you could consider FHIR, for example, to be a core composable; we're going to reuse the FHIR API in a lot of different ways. We're going to reuse HTML in a lot of different ways. That reuse pattern for these core composables is captured in the next layer we called orchestration patterns. An orchestration pattern is a specific recipe or blueprint as to how to take the core composables and weave them together to solve some particular problem.

So, I was explaining this to someone the other day and I used the metaphor of a hardware store. When you go into the hardware store you expect to find core building blocks, there are 2x4s that are uniform and the same at every hardware store in the country. There are cinder blocks that are the same in every store in the country. And if you want to go build a swing set or a tool shed or an addition to your house,

you need a blueprint, that's the orchestration pattern; but you can get the building materials from any store because they all carry the same core composables.

So core composable is the lumber, orchestration patterns are the blueprints and then the use cases take a particular orchestration pattern and flesh it out with specific details on how to constrain and use the core composables. And we'll illustrate very briefly one or two of those. And then at the top, we just remind ourselves and everyone else that these things don't exist in a vacuum and not everybody has to do it exactly the same way. They exist in the space of governed…self-governed data sharing arrangements. So we may have a data sharing arrangement that works extremely well with one particular orchestration that no one else in the world uses, but since it's layered over the core composables, the effort by the vendor community and by the folks who build our systems is minimized.

So this is a very tentative, early population of some of the things that might slot into these layers. We start with the Internet at the bottom and then the core composables, probably the most important layer for us to think about at this point, we've populated that just for example with profiled FHIR. And by profiled FHIR we mean something like what the Argonaut group is going to produce which is a set of FHIR resources and an appropriate set of profiles to constrain them sufficiently for people to actually implement and interchange them successfully.

TLS, you could argue that that should be down at the Internet layer. OAuth 2, which is a handshake protocol for security, one of several that would probably be needed in the long run. OpenID Connect and then HTML 5. We put HTML 5 as a core composable because we wanted to have the notion that there's sort of a universal user experience language that could be deployed if you need universality. You certainly can go and specialize and customize for devices like and IOS iPhone or Android APIs. But HTML 5 is guaranteed to be near universal.

And then on top of that we have these orchestration patterns. The one that we have had most experience with is SMART on FHIR, which is more generically called pluggable App orchestration pattern. Decision support is a service, it's something we discussed a couple of times this morning already and we talked about it in depth at the last meeting. Peer-to-peer trust, brokered trust, pub-sub and so forth; there will be more than these small number of them, and these all need to be further fleshed out, but we think this is where the creativity of the industry needs to occur is at this level, in figuring out what these orchestration patterns look like.

Then on top of that you put those patterns to use in interoperability opportunities; so SMART on FHIR would be an interoperability use case layered over the pluggable App pattern, which itself, of course, is layered over FHIR, OAuth 2 and HTML 5. And then at the top you have data sharing arrangements that take advantage of these. So for example, you might have a vendor-run App store where they have a vetting process for SMART on FHIR Apps that they have certified to be safe and secure on their platforms and they have a licensing agreement and appropriate constraints to govern who gets to use the Apps. That would be an ecosystem, a data sharing arrangement on top of an orch…on top of a use case, SMART on FHIR on top of an orchestration pattern, pluggable Apps, which is layered on top of the core composables.

And just to illustrate how this might play out and where there are synergy and gain. At HIMSS this year there were quite a few vendors demonstrating FHIR-based activities. So one set of those demonstrations was about a dozen SMART on FHIR Apps running in at least three vendors, maybe more. I know of at least three vendors who are running it. Those Apps ranged in capabilities from very

sophisticated automation workflow, decision support for a rheumatology clinic on the one extreme, all the way to an App useful for the first 36 hours of a neonates life to make sure that they don't have excessively high bilirubin.

So there's a tremendous range of functionality that is available by leveraging exactly the same core composables. So that dozen different Apps that were demonstrated across the vendor community from a single vendor's perspective, didn't require any changes to enable the new Apps; they just plugged in because they used the core composables.

And then for a completely different use case, some of the CommonWell vendors demonstrated early work in using FHIR to create faster, more granular interchange. So we had four different vendors shipping data back and forth in under 2 seconds to go data entered in one vendor's EHR, it was visible 2 seconds later in the other vendor's EHR. It used exactly the same FHIR services as the SMART Apps use, without any changes on the vendor's part. So that's the kind of leverage that you get with this approach.

This is an example of what we mean by an orchestration. This orchestration is the layer that people have the hardest time grasping. And so this is my notion of sort of what the recipe for how you use core composables to build SMART Apps. You have to follow this recipe to weave things together; once you do this, then you can plug in any kind of functionality in the SMART App itself. So, I put this in not because you need to know the details, but just because to understand these recipes for these orchestration patterns can be non-trivial, but they can be agreed upon, as this one was, through a community process and then deployed quickly by the vendor community. Arien, I think you get…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right. So I think if you look at the transmittal, that's the first 10 pages of the transmittal and the second 4 pages of the transmittal are the actual recommendations. We wanted to explain the concept of a core compatible and orchestration patterns, give the reference to the work of the Internet, provide a framework for thinking about why that's been such a successful pattern. But then this is where we actually get into the meat.

So our highest level requirements are to move towards parsimony of composables for security transport and data and extend with common orchestration patterns such as pluggable Apps and others including clinical decision support as a service. The second, there should be a bullet here, is to adopt and deliver policy of rebalancing the standards portfolio towards the HIT hourglass model. And what rebalance means is not, and this is actually relevant to Andy and Rich's discussion previously, what rebalance means is not the same as throw away all of the old stuff and do all the new stuff. It means take the stuff that works, make sure that it continues to work and that we continue to refine it, but minimize the changes to it as we move over to the HIT hourglass-based framework model.

Allow sufficient time to develop, adopt and use the core composables and orchestration patterns. And again, the certification framework that was proposed for edition 2015, associated with Stage 3, is a useful way of providing flexibility to industry through Argonaut and others, to give us time to figure out how to do this rather than prematurely standardize; that's a very useful policy framework for ONC to have adopted.

And then, as recommend…as already recommended in the joint HIT Policy and Standards Committee, use specific detailed governance of specific use cases through data sharing arrangements. And that's

actually relevant to the discussion we were just having about how do you test? A lot of times you test in the context of real-world data sharing arrangements.

This is a summarized view of our recommendations; we have more detailed recommendations in the transmittal, and as I said, they're word identical to the same recommendations that we presented last time. But at a very high level, create a glide path, as just discussed, toward core composables and orchestrations in the 2015-2017 timeframe; in the same timeframe to adopt a deliberate stance of reducing frication and distraction to adopters and implementers. And again that doubles down on Cris and Liz's notion that we should do a few things really well. And minimize overall changes in certification so that we can concentrate on this transitional path.

2018 to 2020, we start to refine and extend core composables. So, we made a lot of progress with a pluggable App compo…orchestration. We've made a lot of progress in Argonaut with constraining and profiling FHIR. We would expect to do the same thing for other kinds of orchestration patterns like pub-sub or clinical decision support as a service or other kinds of approaches. And we're going to be discovering those through learning in this timeframe.

As we do that, we can expand the number of pilot or use cases and certified use cases based on the core composable and orchestration. We need to start thinking about putting in national scale services that make the orchestration patterns work better. As data sharing networks emerge, let's think about network bridging; again, there's no reason to wait until 2017 as we actually have, in production, data sharing networks. I think the thought process is, we're going to be building the hourglass-based data sharing networks in the 2015-2017 timeframe and proving that they work and getting into production and then we can bridge them.

And as we have mature standards, think about adding those to certified health information technology. And then start the work of transitioning from non-core orchestration standards and APIs in this timeframe. And we presented examples last time of what a transition path might look like. And how…what kinds of deliberate policies might be put in place to affect that transition.

By 2021, we start to think about addressing more complex data profiles for precision medicine and learning health system, although I think a lot of that work will actually get done earlier in the timeframe…we're successful at creating an ecosystem. And then there's always the notion that we're talking about a 10-year roadmap. Ten years ago was 2005 and in 2005, we thought that iPhones were this pretty cool new thing.

M
2007…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right, so 2007 we thought that iPhones were pretty cool new things…

M
(Indiscernible)

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's exactly right. So, this is a reflection that the technology world in 2024 will be nothing like the technology world…the technology world in 2025 will be nothing like the technology world that we have

right now and we should have a deliberate strategy of doing all this work all over again 10 years from now when we have quantum-based data interchange protocols, for example.

There are a bunch of details, comments, as David said, a lot of the detailed comments say, "see framework." I want note a couple of them for particular call outs. There was a comment here on going through a testing process as opposed to a certification process as our primary lever for ensuring interoperability, which highly overlaps with the Implementation Workgroup's comment.

There is a comment on…there was a specific request that we had for how health IT developers should work with SDOs to develop standards for interoperable electronic health devices. I think there's a comment that we had or a recommendation that we had that it is highly useful to be working on electronic device interoperability, we probably should include health device manufacturers in that process, but that this is a rapidly emerging space and it's probably premature to…we need to establish practice before standards and certification in that process. And, there was one more, David, we wanted to call out, do you remember what that was?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
(Indiscernible)

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Not remembering it, so I think that's…I think pretty much all the rest of our comments focus back on the general comments that we laid out in the framework. So with that I think Michelle, we need to call for…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
But we have probably some questions.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, we probably have some questions, right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…less is more. So we have Wes...

Wes Rishel – Independent Consultant
I…could you go back to the hourglass model, your starting slide?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Ooh, all the way back.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
The Internet one or the health IT one?

Wes Rishel – Independent Consultant
This one.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
That one, okay.

Wes Rishel – Independent Consultant
I just want to point out, first of all, I think most everybody looks at all your detailed charts and says, well, yeah, that's what techie guy needs to prove it to another techie guy, that's fine, but, it's all much more complex and Greek to me. But I think we all can basically understand these notions. And I just want to point out one thing, Interoperability use case is way out of the center and that's anathema to every approach we've used in terms of HIT standardization that I can remember, where we start with a use case. That represents, if you will, a fresh approach in that it's only been used in the Internet for the last 30 years, that wasn't there when we started HL7 and we were worried about variable length fields because we were communicating over these RS232 25 pin plugs, okay?

This is so fundamental that I think we simply…I simply need to acknowledge and beyond, pardon the expression, the recognition and the formula for building on it here. I would propose an acronym, the HHM, the Health IT Hourglass model, because without…if you ain't got an acronym, you just ain't. And this would have the advantage of being a higher order model in that it's composed of another acronym inside. That's my comment, thank you.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So if you go HITHM, it's "hit em" which is you're pounding the table. So you can pound the table.

Wes Rishel – Independent Consultant
But we lose the higher order acronym.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
HITHM.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Actually one of the early deliberations that we had looked at the success that HL7 V2 has had. And I would argue that V2 got this right for the class of service that it intended to, although it's been hard to extend and modify over time. But in V2 you've got fields that have reasonably rigorous definition, some might argue about that, you've got segments that have some common definition and if you've seen one PD1 segment, you can kind of parse one PD1 segment. But you recompose those into an ADT or an ORU which represent very different things and then you specialize the ADTs in all of the alphabet soup of ADTs and you specialize the ORUs in things like the LRI that may be different from a clinical trial's use case and may be different from other kinds of reporting use cases. And so you see that pattern actually up and down the stack at V2 and V2 has been in use for, let's remind us, but a long time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…Jon, I know you have a comment, but very quick, Wes said so right that…and Jon reminded me that it was Dr. Loonsk in the HITSP days that had, you know, a layered framework like this, but all of the technology wasn't quite ready to put it together into this solid description that you've presented today. I mean, it's so clear. Yeah of course, you know, you start with TCP/IP and layer up past all of these things that you've done and it's wow, that's how interoperability in the future is going to work. We don't even need to wait for the quantum thing. So, Jon.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yeah, no, that's exactly right. As…was explained, I was actually looking at the slide and thinking my hippocampus started itching and I'm like, what's going on and I'm like oh. There are elements here that came from the AHIC days, however, John just exactly said it right, the technology has evolved around this, both on the top and the bottom and the context is different so it makes a lot more sense.

So number one, I was also reflecting this past month that it was a year ago that I was talking to you guys about the first JASON Report, so I hope you feel like the time you spent on the JASON Task Force kind of wrestling with all the rest of us about these issues has come to good fruition.

The one additional comment I'd add in terms of the timeline, and Arien called this out, but I just want to put a point on it, there are bits and pieces of that that are going to fit that timeframe and there are some that may be slower and some may be faster. But take us back to the first comment I made today, the sustainable growth rate repeal, the first year that those programs come into effect is 2019. So I look at 2017, 2018…right, so there are some things that we're going to need to look at in terms…that are going to need to move faster, but all in all, very excellent. Thank you very much.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Thank you.

John Halamka, MD, MS – Chief Informatics Office – Harvard Medical School/Beth Israel Deaconess Medical Center
Other comments? Michelle, any…so, I guess then if there are no comments from the phone, we will seek the approval to forward these recommendations to ONC. Any objections? Okay, well, Michelle, I think we are actually done with our agenda.

You know one comment I would want to highlight is that I know several members of this committee do have their terms end in June, my term I think ends in January, so there are going to be a lot of changes in faces and Wes, you told us so wisely, I think, that when you change the constituents of a committee you change the consensus. So I just want to reflect and today's meeting has gone through an immense amount of material, and I think we've all had, with a few polishing remarks here, general consensus as to where we're headed. And you will have a lot of fresh ideas fairly soon.

And I hope, Michelle, you are planning to the extent that the federal government can fund anything, a massive celebration of all the people who have served for so long.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
No muffins.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
A cup of coffee and a certificate? But I only mention this because that implies we will have an in-person meeting in May and an in-person meeting in June and for many folks, those will be our two final meetings together.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yes, and that's exactly why the June meeting is in-person, because we want to make sure that we have the opportunity to thank those members who…those 10 members who have been here for 6 years, so they've dedicated a lot of time and effort and so, it will be very sad to see them go.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well with that Michelle, do you have, I guess, public comment and any other administrative items?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yup, so if there is anyone in the room who has a public comment, please come up to the table. And Alan, if you could please open the lines.

Public Comment

Alan Merritt – Interactive Specialist – Altarum Institute
If you'd like to make a comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
While we wait for public comment, I just want to thank everyone; a tremendous amount of work went into these comments and all of the work over the coming months on the NPRM. So unfortunately, there's no break for you, but we really do appreciate all of the time and effort that has been put forth and continues to be put forth. And we have no public comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, with that, Jon, another successful meeting, I hope those recommendations are helpful to you, of course we'll get them all transmitted. And have we missed a thunderstorm or is…are the heavens about to open up around us?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hopefully we've missed it and everyone who is on a plane will get out and there will be no problems.

John Halamka, MD, MS Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Closing comments? The floor is yours.

P. Jonathan White, MD – Acting Deputy National Coordinator Office of the National Coordinator for Health Information Technology
No, what John said. Thank you very much.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Safe travels everybody.
Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you everyone.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Bye.

Public Comment Received During the Meeting

1. I think it is important that the committee think deeply about the amount of development work that this NPRM might be for some HIT vendors. As the bar has been raised on the design and development standards and processes, which is good to increase the patient safety and usability of the products, the time needed to get a module designed, developed and certified to be ready for our clients would be longer than the currently proposed timeline. CMS has proposed that all providers (EPs and EH/CAHs) be on 2015 Edition software by Jan. 1, 2018. Think about the log jam with the ATL/ACBs to certify products by April-July 2017. Their bandwidth will not support the need. Also, the development time for the huge number of projects in the ONC NPRM will not permit vendors to do this well, i.e. in a way the clinicians' workflow is supported. That takes a lot of back and forth with the clinician base. This timeline does not support that.

2. The slide said that Vital signs is NOT in MU3. However, this criterion is in the CCDS which must be available and thus developed for the API & the CCDA. Thus, HIT vendors must do the development of vital sign with the standards. This is not an insignificant volume of work.

3. The work on 55% of new criteria in the 2015 Edition is a huge amount of work. It appears that the lessons of the 2014 Edition and the availability of certified software is going to happen again. Also, this development does not include the criteria for the other settings of care. My guess is that the majority of vendors will not address these criteria until the work to get the MU3 certified EHR is done and certified. This will cause a confusion and dissatisfaction in the provider workplace, especially LTPAC & Behavioral Health.

4. Maybe there needs to be a regulation for alternative settings of care separate from the EHR Incentive Program. That could signal more clearly to the provider industry what is needed in CEHRT for Stage 3 of the Incentive Program and proving meaningful use. Other needs for other settings of care could have their regulation that specifies the criteria for their needs of interoperability, care coordination, patient engagement and Privacy & Security above and beyond the Base EHR & CEHRT.

5. How will we deal with the operational need to know if the provider's implementation of the certified system meets testing in the field? NIST testing for the masses, or seeking/supporting commercial success in this area?

6. Significant market influencer is what he is seeking.

7. Thank you. PCI is a great model for this and has solved a similar problem without the government regulation and was able to self-regulate and certify their products and standards. There is not a single company but the collection of the top is over their

Meeting Attendance								
Name	**04/22/15**	**03/18/15**	**01/27/15**	**12/10/14**	**11/18/14**	**10/15/14**	**09/10/14**	**08/20/14**
Andrew Wiesenthal	X	X	X	X				X
Anne Castro		X	X	X	X		X	
Anne LeMaistre	X	X	X	X	X			X
Arien Malec	X	X	X	X	X		X	X
C. Martin Harris	X	X	X	X	X		X	
Charles H. Romine	X	X	X					
Christopher Ross	X	X	X				X	X
David McCallie, Jr.	X	X	X	X	X		X	X
Dixie B. Baker	X	X	X	X	X		X	X
Elizabeth Johnson	X	X	X	X	X		X	X
Eric Rose	X	X	X	X	X		X	X
Floyd Eisenberg		X	X	X	X			
James Ferguson	X	X	X	X			X	X
Jeremy Delinsky		X	X		X			
John Halamka	X	X	X	X	X		X	X
John F. Derr	X	X	X	X	X		X	X
Jon White	X	X	X	X				
Jonathan B. Perlin		X						X
Keith J. Figlioli		X		X			X	
Kim Nolen	X	X	X	X	X		X	X
Leslie Kelly Hall	X	X	X	X	X		X	X

Lisa Gallagher	X	X	X	X	X		X	X
Lorraine Doo	X	X	X	X	X		X	X
Nancy J. Orvis	X	X	X				X	
Rebecca D. Kush			X		X		X	X
Sharon F. Terry	X						X	X
Stanley M. Huff		X	X	X	X		X	X
Steve Brown	X			X			X	
Wes Rishel	X	X	X	X	X			X
Total Attendees	**22**	**26**	**25**	**22**	**20**	**1**	**22**	**21**